TO: Consensus Standards Approval Committee (CSAC)

FR: Margaret Terry, Wunmi Isijola, Christy Skipper, Yetunde Ogungbemi

RE: Neurology

DA: August 9, 2016

The CSAC will review recommendations from the Neurology project at its August 9, 2016 meeting.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Accompanying this memo are the following documents:

1. **Neurology Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment Table.** Staff has identified themes within the comments received. This table lists 16 comments received during the post meeting comment period and the NQF/Standing Committee responses.

BACKGROUND

Neurological conditions and injuries affect millions of Americans each year and take a tremendous toll on patients, families, and caregivers. Additionally, billions of dollars are spent on treatment, rehabilitation, and lost or reduced earnings. Strokes are the fifth leading cause of death in the United States as well as a leading cause of disability. Each year, approximately 795,000 people suffer a stroke. Healthcare costs of stroke, including medications and missed days of work, are estimated at $34 billion annually.[i]

Alzheimer's disease is the most common form of dementia with an estimated five million Americans living with the disease. An estimated 14 million people will have Alzheimer's by 2050. In 2009, Alzheimer's disease was the fifth leading cause of death for adults ages 65 and older. In 2010, cost for Alzheimer's disease reached nearly $215 billion, and is projected to rise to more than $500 billion annually by 2040[ii]. Epilepsy affects over five million Americans and is estimated to cost $15.5 billion each year in medical costs and lost or reduced earnings and production[iii].

DRAFT REPORT

The Neurological Conditions Draft Report presents the results of the evaluation of 26 measures considered under the Consensus Development Process (CDP). Nine are recommended for endorsement, one is recommended for approval for trial use, six measures are recommended for inactive endorsement with reserve status and 10 were not recommended.

The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	12	14	26
Measures recommended for endorsement	5	4	9
Measures recommended for inactive endorsement with reserve status	6	--	6
Measures approved for trial use	--	1	1
Measures not recommended for endorsement or trial use	1	9	10
Measures withdrawn from consideration	5	--	5
Reasons for not recommending	Importance – 0 Scientific Acceptability – 1 Overall – 0	Importance –7 Scientific Acceptability – 2 Overall – 9	

Pursuant to the CDP, the CSAC may consider approval of nine candidate consensus measures and one measure recommended for approval for trial use.

Neurological Conditions Measures Recommended for Endorsement:

- #0437 STK 04: Thrombolytic Therapy
  Overall Suitability for Endorsement: Y-23; N-0
- #0507 Diagnostic Imaging Stenosis Measurement in Carotid Imaging Reports
  Overall Suitability for Endorsement: Y-19; N-0
- #0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival
  Overall Suitability for Endorsement: Y-19; N-4
- #1952 Time to Intravenous Thrombolytic Therapy
  Overall Suitability for Endorsement: Y-21; N-0
- #2111 Antipsychotic Use in Persons with Dementia
  Overall Suitability for Endorsement: Y-16; N-0
- #2863 CSTK 06: Nimodipine Treatment Administered
  Overall Suitability for Endorsement: Y-22; N-1
- #2864 CSTK 01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients
  Overall Suitability for Endorsement: Y-19; N-3
- #2866 CSTK 03: Severity Measurement Performed for Subarachnoid Hemorrhage and Intracerebral Hemorrhage Patients
  Overall Suitability for Endorsement: Y-21; N-1
- #2877 Hybrid, Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity
  Overall Suitability for Endorsement: Y-19; N-2

Neurological Conditions Measures Recommended for Approval for Trial Use:

- #2872 Dementia-Cognitive Assessment
  Overall Recommendation for eMeasure Approval for Trial Use: Y-17; N-0

Neurological Conditions Measures Recommended for Inactive Endorsement with Reserve Status:

- #0434 STK 01: Venous Thromboembolism (VTE) Prophylaxis
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-15; N-2
- #0435 STK 02: Discharged on Antithrombotic Therapy
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-20; N-3
- #0436 STK 03: Anticoagulation Therapy for Atrial Fibrillation/Flutter
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-22; N-1
- #0438 STK 05: Antithrombotic Therapy By End of Hospital Day Two
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-21; N-2
- #0439 STK 06: Discharged on Statin Medication
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-17; N-0
- #0441 STK 10: Assessed for Rehabilitation
  Overall Recommendation for Inactive Endorsement with Reserve Status: Y-22; N-1

Neurological Conditions Measures Not Recommended (See Appendix A for the Committee's votes and rationale)

- #1814 Counseling for Women of Childbearing Potential with Epilepsy
- #2832 STK 02: Discharged on Antithrombotic Therapy (eMeasure)
- #2833 STK 03: Anticoagulation Therapy for Atrial Fibrillation/Flutter (eMeasure)
- #2834 STK 04: Thrombolytic Therapy (eMeasure)
- #2835 STK 05: Antithrombotic Therapy by End of Hospital Day Two (eMeasure)
- #2836 STK 06: Discharged on Statin Medication (eMeasure)
- #2837 STK 10: Assessed for Rehabilitation (eMeasure)
- #2865 CSTK 01: Modified Rankin Score (mRS) at 90 Days
- #2870 Overuse of Opioid Containing Medications for Primary Headache Disorders (trial use)
- #2876 Hospital 30-day, all-cause, risk standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity

COMMENTS AND THEIR DISPOSITION

NQF received 16 comments from six organizations (including five member organizations) and individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Neurology project page under the Public and Member Comment section.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developers, who were invited to respond.

The Standing Committee reviewed all of the submitted comments and developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Theme 1 – Lack of Opportunity for Improvement and related new eMeasures

One comment focused on the lack of stroke measures as several long-standing stroke measures were recommended for Inactive Endorsement with Reserve Status. Additionally, the electronic versions of these measures were not recommended for endorsement by the Committee.

Committee Response: Thank you for your comment. The Committee follows the NQF's measure evaluation criteria and evaluates each proposed measure against those standards. Although measures have been moved to Inactive Endorsement with Reserve Status due to little additional performance opportunity, these measures will still remain within the Neurology portfolio. The purpose of an Inactive Endorsement with Reserve Status is to retain endorsement of reliable and valid quality performance measures that have overall high levels of performance with little variability so that performance can be monitored as necessary to ensure that performance does not decline. This status would apply only to highly credible, reliable, and valid measures that have high levels of performance due to incorporation into standardized patient care processes and quality improvement actions. Inactive Endorsement with reserve status retains these measures in the NQF portfolio for periodic monitoring, while also communicating to potential users that the measures no longer address high-leverage areas for accountability purposes. The Committee recommends to the developer that, if additional data indicating a performance gap is available for these measures, they should re-submit the measure for future consideration.

Theme 2 – Insufficient Evidence

#2865 CSTK-02 Modified Rankin Score (mRS) at 90 days

A comment was received on *#2865 CSTK-02 Modified Rankin Score (mRS) at 90 days* recommending that the "measure be implemented for patient outcomes," noting that, while the measure is difficult to implement, it is the only outcome measure for stroke care within the portfolio.

Committee Response: The Committee debated the appropriateness of holding providers accountable for this measure since it did not demonstrate how completing the Modified Rankin Score within 90 days would improve health outcomes. NQF evaluation criteria allows for measures that fail on Evidence to be voted upon as an exception to evidence. The Committee moved to vote for exception to the empirical evidence criterion but failed to reach consensus. Therefore, the measure failed on Evidence and was not recommended for endorsement.

#2870 Overuse of Opioid Containing Medications for Primary Headache Disorders

Two comments on the Committee's decision not to recommend #*2870 Overuse of Opioid Containing Medications for Primary Headache Disorders* stated that the measure should have been implemented on a trial basis, given the prevalence of opioid overuse and their use as a first line of treatment despite availability of other medications.

Committee Response: Thank you for your comments. The Committee evaluated the measure against the NQF measure evaluation criteria, looking at evidence submitted by the developer that stated rates of rebound headaches and healthcare resource utilization were greater for opioid users than non-users. The Committee countered the evidence by stating that more intractable patients could have been prescribed opioids resulting in more rebound headaches and greater healthcare resource utilization. Further, the evidence submitted substantiates the harms and clinical guideline recommendations against opioid use, but does not support the processes of referral and treatment outlined in the measure. Therefore, the Committee did not believe there was sufficient evidence to recommend this measure for endorsement.

Theme 3 – Discussion of Measure Specifications

0661: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival

One comment expressed overall agreement with mandating a time limit for head CT and MRI scan, emphasizing the importance of interpreting CT and MRI scan reads as soon as possible as timely interpretation is directly related to patient morbidity and mortality.

Developer Response: Thank you for the comment. CMS agrees performing prompt brain imaging for patients suspected of acute stroke is a critical component of emergency care for accurate diagnosis and treatment. As you noted in your comment, use of a head CT or MRI allows clinicians to differentiate ischemic stroke, hemorrhagic stroke, and mini strokes; these scans also help identify candidates for tPA, which is used to treat ischemic stroke patients (and is contraindicated for treatment of hemorrhagic stroke). The specifications for NQF #0661 align with recommendations made by the American Heart Association/American Stroke Association, which recommend that imaging studies be interpreted within 45 minutes of patient arrival; CMS encourages imaging studies be interpreted as rapidly as possible to ensure timely, appropriate treatment.

Committee Response: The Committee suggests that the developer include supporting information within the measure description to emphasize that scans should be interpreted as soon as possible.

2111: Antipsychotic Use in Persons with Dementia

One comment indicated support for efforts to ensure that antipsychotics are appropriately prescribed and monitored, but expressed concern with unintended consequences of prescription of antipsychotics for patients without psychotic disorders, such as those with agitation as a result of dementia and Parkinson's disease.

Developer Response: When constructing the measure specifications for the Antipsychotic Use in Persons with Dementia measure, the goal was to identify the population of patients that are at high-risk of adverse events from the use of antipsychotic medications (i.e., persons with dementia) and to further focus on the sub-population of dementia patients who do NOT have a documented diagnosis for which an antipsychotic is clearly indicated (i.e., we exclude persons who have a diagnosis that identifies them as having psychoses or behavioral disturbances). Thus, the measure identifies the proportion of patients at high risk of antipsychotic-associated adverse events but without a diagnosis code to indicate that an antipsychotic drug is beneficial. Since this is a claims based measure, it is impossible to identify every patient with dementia where antipsychotic medication use is appropriate. Therefore, the intended rate of the measure is not expected to approach zero.

A review of the measure is performed annually to determine if there is new information that supports changes to the measure. This review includes consideration of expanding the list of numerator

exclusions using specific ICD codes. The comment to consider excluding persons with dementia who also have severe agitation will be considered during our annual review.

NQF MEMBER VOTING RESULTS

Twenty-three of the recommended measures were approved with 67% approval or higher. Representatives of 13 member organizations voted; no votes were received from Consumer, Health Plan, Provider Organization, or Public/Community Health Agency Councils. Results for each measure are provided in Appendix B.

REMOVAL OF ENDORSEMENT

Five measures previously endorsed by NQF have not been re-submitted and are withdrawn from maintenance of endorsement:

Measure	Reason for Withdrawal
0240 Stroke and Stroke Rehabilitation: Venous Thromboembolism (VTE) Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage (American Academy of Neurology)	The developer is currently reviewing the measure set for updates.
0241 Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge (American Academy of Neurology	The developer is currently reviewing the measure set for updates.
0243 Stroke and Stroke Rehabilitation: Screening for Dysphagia (American Academy of Neurology)	The developer is currently reviewing the measure set for updates.
0244 Stroke and Stroke Rehabilitation: Rehabilitation Services Ordered (American Academy of Neurology)	The developer is currently reviewing the measure set for updates.
0325 Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy (American Academy of Neurology)	The developer is currently reviewing the measure set for updates.

Appendix A – Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

Measure	Voting Results	**Rationale:**
#1814 Counseling for Women of Childbearing Potential with Epilepsy	**Initial Vote:** **Evidence** H-0; M-2; L-3; I-15 **Insufficient Evidence with Exception** Y-18; N-2 **Gap** H-17; M-2; L-1; I-0 **Reliability** H-0; M-8; L-6; I-6; Second Vote: H-0; M-11; L-3; I-6 **Validity** H-0; M-13; L-2; I-4 **Feasibility** H-0; M-17; L-1; I-1 **Usability and Use** H-2; M-16; L-0; I-0 **Post Comment Call Vote:** **Reliability** H-0; M-7; L-11; I-1	Reliability testing was conducted using data element validity testing at three neurology practices. The Committee questioned why the developer had not re-tested the measure in one of the practices to determine if a problem identified with exclusion criteria (i.e., patients with intellectual disability) had been resolved. Additional testing data on the new exclusions was not provided for the Committee's review. During the in-person meeting, the Committee could not reach consensus on Reliability. At the time of the Post Comment Call, the Committee again discussed that new exclusions data had not been provided for review and the Committee did not vote to pass this measure on Reliability.
#2832 STK 02: Discharged on Antithrombotic Therapy (eMeasure)	**Evidence** H-21; M-2; L-0; I-0 **Gap** H-0; M-0; L-18; I-5	This measure has been re-specified from a legacy, paper-based measure (#0435) into an eMeasure. The paper-based measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also believed this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.
#2833 STK 03: Anticoagulation Therapy for Atrial Fibrillation/Flutter (eMeasure)	**Evidence** Accepted Prior Evaluation **Gap** H-0; M-6; L-17; I-0	This measure has been re-specified from a legacy, paper-based measure (#0436) into an eMeasure. The paper-based measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also believed this

		measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.
#2834 STK 04: Thrombolytic Therapy (eMeasure)	**Initial Vote:** **Evidence** Accepted Prior Evaluation **Gap** Accepted Prior Evaluation **Reliability** H-0; M-10; L-8; I-5 **Validity** H-4; M-14; L-2; I-3 **Feasibility** H-0; M-6; L-1; I-16 **Usability and Use** H-2; M-11; L-4; I-6 **Post Comment Call Vote:** **Reliability** **H-0; M-2; L-12; I-3**	This measure has been re-specified from a legacy, paper-based measure (#0437) into an eMeasure. This measure is based on the same Evidence and Gap data as the paper measure and therefore the Committee accepted the vote on #0437 for this measure. The Committee reviewed the reliability of this measure but did not believe that BONNIE testing was sufficient for reliability testing. Therefore, the Committee did not reach consensus on this measure during the in person meeting. At the Post Comment Call, the Committee again stated that BONNIE testing was not sufficient for reliability testing and did not pass the measure on this criterion. Therefore, the measure was not recommended for endorsement.
#2835 STK 05: Antithrombotic Therapy by End of Hospital Day Two (eMeasure)	**Evidence** Accepted Prior Evaluation **Gap** H-0; M-3; L-20; I-0	This measure has been re-specified from a legacy, paper-based measure (#0438) into an eMeasure. The paper-based measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also felt this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.
#2836 STK 06: Discharged on Statin Medication (eMeasure)	**Evidence** H-5; M-11; L-1; I-0 **Gap** H-0; M-2; L-14; I-1	The Committee discussed that the measure did have sufficient evidence to support the use of statins at discharge. However, after reviewing performance gap and disparities data, the Committee did not believe the data showed an opportunity for improvement as the performance gap had decreased over time. The Committee also noted that the disparities were most notable in older data cohorts, but less so in the more recent cohorts. Therefore, this measure did not pass on these criteria and was not recommended for endorsement.
#2837 STK 10: Assessed	**Evidence** Accepted Prior	This measure has been re-specified from a legacy, paper-based measure (#0441) into an eMeasure.

for Rehabilitation (eMeasure)	Evaluation **Gap** H-0; M-2; L-21; I-0	The paper-based measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also felt this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.
#2865 CSTK 01: Modified Rankin Score (mRS) at 90 Days	**Evidence** H-0; M-2; L-3; I-17 **Insufficient Evidence with Exception** Y-11; N-11	The Committee noted the measure cited expert opinion and not systematic review of the evidence in support of the 90 day time period for follow up. The developer noted that the 90 day timeframe was chosen based on the NINDS-tPA trial in 1996. The Committee debated the appropriateness of holding providers accountable for this measure in the absence of evidence that is linked to the outcome. After failing on evidence, the Committee moved to vote for exception to the empirical evidence criterion but failed to reach consensus. Therefore, the measure failed on Evidence and was not recommended for endorsement.
#2870 Overuse of Opioid Containing Medications for Primary Headache Disorders (trial use)	**Evidence** H-0; M-0; L-2; I-17 **Gap** No Votes Taken	This process measure was newly presented to the Committee and was submitted for the NQF Approval for Trial Use program. The developer provided a study of nearly 6,000 patients of which 15.9% were current users of opioids. This measure focuses on the interventions of 1) assessing for overuse of opioid medications in a typical headache patient and 2) for those patients identified as being over-users of opioid medications, treatment for that overuse or a documentation of referral for treatment. The evidence submitted substantiates the harms and clinical guideline recommendations against opioid use, but does not support the processes (interventions) of referral and treatment. Overall, the Committee voted that there was not sufficient evidence to support this measure and did not recommend it for endorsement.
#2876 Hospital 30-day, all-cause, risk standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk	**Initial Vote:** **Evidence** Y-19; N-0 **Gap** H-7; M-12; L-3; I-0 **Reliability** H-1; M-17; L-1; I-3 **Validity**	The Committee did not believe the measure met the Validity criterion due to the frequency of missing data and whether the method to assess validity was adequate. The Committee discussed that it is unlikely that reduced mortality reflects much better care for African Americans and seems more likely that reduced mortality reflects different preferences for care by race. During the in-person

adjustment for stroke severity	H-0; M-5; L-9; I-2 **Feasibility** H-8; M-11; L-2; I-1 **Usability and Use** H-0; M-18; L-3; I-1 **Post Comment Call Vote:** Validity H-0; M-5; L-9; I-2	meeting, the Committee did not reach consensus on Validity. At the time of the Post Comment Call, the Committee again discussed the issues with validity described above. The Committee did not pass the measure on the Validity criterion and it was not recommended for endorsement.

Appendix B – NQF Member Voting Results

NQF MEMBER VOTING RESULTS

Twenty-three of the recommended measures were approved with 67% approval or higher. Representatives of 13 member organizations voted; no votes were received from Consumer, Health Plan, Provider Organization, or Public/Community Health Agency Councils. Results for each measure are provided below.

Measure #0437 STK 04: Thrombolytic Therapy

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	2	0	0	2	100%
All Councils	**10**	**0**	**3**	**13**	**100%**
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #0507 Diagnostic Imaging Stenosis Measurement in Carotid Imaging Reports

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	2	0	0	2	100%
All Councils	**9**	**0**	**4**	**13**	**100%**
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	2	0	0	2	100%
All Councils	**9**	**0**	**4**	**13**	**100%**
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #1952 Time to Intravenous Thrombolytic Therapy

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	2	0	0	2	100%
All Councils	**10**	**0**	**3**	**13**	**100%**
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #2111 Antipsychotic Use in Persons with Dementia

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	

Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	2	2	5	33%
Supplier/Industry	1	0	1	2	100%
All Councils	**7**	**2**	**4**	**13**	**78%**
Percentage of councils approving (>60%)			**75%**		
Average council percentage approval			**83%**		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Psychiatric Foundation: The APA sees the value and applauds the inclusion of mental health focused measures; however, we have concerns over the recommended "Antipsychotic Use in Persons with Dementia." There are several reasons for concern, including this measure's implicit assumption that any use of these medications in individuals with dementia is "inappropriate". In writing the recent APA Antipsychotics in Dementia guideline, great lengths went to emphasizing that other approaches should be tried first, that antipsychotics (if used at all) should be used in the minimal necessary dose and for a limited duration of time, whenever that is possible. The overall focus is on using antipsychotic medications judiciously, which is not the same as never using them at all. It was surprising (4c.1.) that no unintended negative consequences were identified. This is in stark contrast to the concerns and experiences that the guideline writing group heard expressed by psychiatrists and also by advocates such as the Alzheimer's Association during the comment process. There was a considerable sense that there are clearly individuals for whom the use of these drugs has produced a significant benefit, despite the lack of a statistical benefit in clinical trials (which tend to have less severely ill patients). The fact that a sizeable proportion of individuals in discontinuation studies had a return of symptoms with tapering also suggests that a subset of individuals do experience benefit. In terms of unintended negative consequences, there were clearly reports that the forced review and the use of draconian benefits management (by CMS, insurers and others) via metrics such as this created significant worsening (sometimes dangerously so) for some patients. We advocate that the integration of this measure be reconsidered.

Measure #2863 CSTK 06: Nimodipine Treatment Administered

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%

QMRI	1	1	3	5	50%
Supplier/Industry	2	0	0	2	100%
All Councils	9	1	3	13	90%
Percentage of councils approving (>60%)			75%		
Average council percentage approval			88%		

*equation: Yes/ (Total - Abstain)

Measure #2864 CSTK 01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	2	0	0	2	100%
All Councils	10	0	3	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #2866 CSTK 03: Severity Measurement Performed for Subarachnoid Hemorrhage and Intracerebral Hemorrhage Patients

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	1	3	5	50%
Supplier/Industry	2	0	0	2	100%
All Councils	9	1	3	13	90%
Percentage of councils approving (>60%)			75%		
Average council percentage approval			88%		

*equation: Yes/ (Total - Abstain)

Measure #2877 Hybrid, Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	5	0	0	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	4	1	5	0%
Supplier/Industry	2	0	0	2	100%
All Councils	8	4	1	13	67%
Percentage of councils approving (>60%)			75%		
Average council percentage approval			75%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Heart Association/American Stroke Association: The AHA/ASA strongly supports endorsement of this measure, which incorporates the NIHSS in the risk adjustment model as a measure of stroke severity. Including this critical information will allow more robust risk adjustment and enhance the accuracy of quality of care reporting.

Measure #2872 Dementia-Cognitive Assessment (recommended for approval for trial use)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	3	0	2	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	3	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	7	0	6	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Measure #0434 STK 01: Venous Thromboembolism (VTE) Prophylaxis (recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	0	5	5	
Supplier/Industry	1	0	1	2	100%
All Councils	6	0	7	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #0435 STK 02: Discharged on Antithrombotic Therapy (recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	7	0	6	13	100%

Percentage of councils approving (>60%)	100%
Average council percentage approval	100%

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #0436 STK 03: Anticoagulation Therapy for Atrial Fibrillation/Flutter (recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	7	0	6	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #0438 STK 05: Antithrombotic Therapy By End of Hospital Day Two(recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	**7**	**0**	**6**	**13**	**100%**
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #0439 STK 06: Discharged on Statin Medication (recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	7	0	6	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #0441 STK 10: Assessed for Rehabilitation (recommended for Inactive Endorsement w/Reserve Status)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	4	0	1	5	100%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	7	0	6	13	100%
Percentage of councils approving (>60%)			100%		
Average council percentage approval			100%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA recognizes that performance is high on these process measures, however, they remain critical to good outcomes for patients. Given the small number of stroke measures that the committee has recommended, and until better measures are available to replace them, we strongly urge the committee to maintain active endorsement of these measures.

Measure #1814 Counseling for Women of Childbearing Potential with Epilepsy (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	

Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	0	0	5	5	
Supplier/Industry	1	0	1	2	100%
All Councils	3	2	8	13	60%
Percentage of councils approving (>60%)			50%		
Average council percentage approval			75%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

Measure #2832 STK 02: Discharged on Antithrombotic Therapy (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	4	2	7	13	67%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

Measure #2833 STK 03: Anticoagulation Therapy for Atrial Fibrillation/Flutter (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	

Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	4	2	7	13	67%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

Measure #2834 STK 04: Thrombolytic Therapy (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	4	2	7	13	67%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA urges the committee to reconsider its decision not to recommend the electronic version of this measure. The committee's judgment that BONNIE testing is inadequate in this instance seems inconsistent with the NQF measure evaluation criteria, which specifies that for legacy* measures such as this, BONNIE** testing suffices. We urge the committee to recommend endorsement of this measure.

Measure #2835 STK 05: Antithrombotic Therapy by End of Hospital Day Two (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	4	2	7	13	67%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: As noted above, we recommend the committee reconsider active endorsement for the chart-based corresponding measure and would strongly urge the committee to consider for this electronic version as well.

Measure #2836 STK 06: Discharged on Statin Medication (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	4	2	7	13	67%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: As noted above, we recommend the committee reconsider active endorsement for the chart-based corresponding measure and would strongly urge the committee to consider for this electronic version as well.

Measure #2837 STK 10: Assessed for Rehabilitation (eMeasure) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	0	0	0	0	
Percentage of councils approving (>60%)			67%		
Average council percentage approval			83%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: As noted above, we recommend the committee reconsider active endorsement for the chart-based corresponding measure and would strongly urge the committee to consider for this electronic version as well.

Association of Rehabilitation Nurses: Given the release of the American Heart Association/American Stroke Association Guidelines for Adult Stroke Rehabilitation and Recovery we believe that there needs to be a measure to assess the need for rehabilitation in acute care to determine if the patient can benefit from therapy in acute care and possibly be discharged home or to require the appropriate setting for continued therapy services. The guideline states that stroke patients in acute care should have a screening for the appropriate rehabilitation setting, considering the following elements: severity of residual neurological deficits, resulting activity limitations, cognitive and communicative ability, psychological status, swallowing ability, premorbid functional ability, medical comorbidities, level of family/caregiver support, likelihood of returning to community living, and ability to participate in a rehabilitation program.

Additionally, Conditions of Participation for Inpatient Rehabilitation Facilities are indicating the need to determine if a patient can benefit from therapy. The standard of practice is such that the results / participation from acute care helps to determine if the patient can participate in and tolerate therapy.

Measure #2865 CSTK 01: Modified Rankin Score (mRS) at 90 Days (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	3	2	0	5	60%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	1	0	4	5	100%
Supplier/Industry	1	0	1	2	100%
All Councils	5	2	6	13	71%
Percentage of councils approving (>60%)			67%		
Average council percentage approval			87%		

*equation: Yes/ (Total - Abstain)

Voting Comments

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

Association of Rehabilitation Nurses: The Modified Rankin Score at 90 days should be required to determine the durability and results from a patient outcomes perspective. This could apply to acute care hospitals and post-acute settings and provide insight into the effect of rehab as well as to help distinguish any possible differences in PAC settings. This indicator would be meaningful and useful to patients to get a sense of what to expect in terms of outcomes at 90 days.

Measure #2870 Overuse of Opioid Containing Medications for Primary Headache Disorders (trial use) (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	0	0	5	5	
Supplier/Industry	1	0	1	2	100%

All Councils	3	2	8	13	60%
Percentage of councils approving (>60%)			50%		
Average council percentage approval			75%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

Measure #2876 Hospital 30-day, all-cause, risk standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity (Not Recommended)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	2	2	1	5	50%
Provider Organizations	0	0	0	0	
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	1	1	
QMRI	0	0	5	5	
Supplier/Industry	1	0	1	2	100%
All Councils	3	2	8	13	60%
Percentage of councils approving (>60%)			50%		
Average council percentage approval			75%		

*equation: Yes/ (Total - Abstain)

Voting Comments:

American Academy of Neurology: The AAN disagrees with the Neurology Standing Committee decision.

American Heart Association/American Stroke Association: The AHA/ASA strongly urges the committee to reconsider its decision not to endorse this measure. The developer has documented that the discrimination of the risk model and the patient preference aspects of this measure are similar to the corresponding hybrid measure (2877) that was recommended by the committee. The availability of the new ICD-10 code for NIHSS beginning this October will greatly enhance the feasibility of this measure by enabling claims-based reporting of this information. We urge the committee to recommend endorsement of both 2877 and 2876.

Appendix C – Measure Evaluation Summary Tables

0437 STK-04 Thrombolytic Therapy
Submission | Specifications
Description: This measure captures the proportion of acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well for whom IV t-PA was initiated at this hospital within 3 hours of time last known well. **Numerator Statement**: Acute ischemic stroke patients for whom IV thrombolytic therapy was initiated at this hospital within 3 hours (less than or equal to 180 minutes) of time last known well. **Denominator Statement**: Acute ischemic stroke patients whose time of arrival is within 2 hours (less than or equal to 120 minutes) of time last known well. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility, Population : National **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process

0437 STK-04 Thrombolytic Therapy

Data Source: Electronic Clinical Data, Paper Medical Records Each data element in the data dictionary includes suggested data sources. The data are collected using contracted Performance Measurement Systems (vendors) that develop data collection tools based on the measure specifications. The tools are verified and tested by Joint Commission staff to confirm the accuracy and conformance of the data collection tool with the measure specifications. The vendor may not offer the measure set to hospitals until verification has been passed.

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-6**; **M-16**; **L-1**; **I-0**

<u>Rationale</u>:

- The Committee summarized the evidence presented by the developer during the previous endorsement, citing a study that early administration of thrombolytic therapy to eligible ischemic stroke patients within the three hour time frame improves patient outcomes. The developer presented recent guidelines from the European Cooperative Acute Stroke Study III showing that thrombolytic therapy can be administrated effectively up to 4.5 hours after time last known well. The Committee did not consider the European Cooperative Acute Stroke Study a fundamental change to the evidence and accepted the prior evaluation of this measure without further discussion.
- The Committee reviewed data on the opportunity for improvement and determined that although median hospital performance had improved overtime, from 57% to 75%, there was still room for improvement.
- Disparities data were not provided for this measure. The Committee mentioned that disparities data would be important to assess whether there are gaps among subpopulations.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Accepted Prior Evaluation** 2b. Validity: **H-1**; **M-15**; **L-4**; **I-3**

<u>Rationale</u>:

- Several of the tested data elements showed strong inter-rater reliability, ranging from 80% to greater than 90%; inter-rater reliability for the element 'reason for not initiating IV thrombolytic therapy' was lowest at 77%. These data were presented during the last review; therefore the Committee agreed to accept the prior evaluation on reliability.
- A Committee member questioned the exclusion 'reason for extending the initiation of IV thrombolytic therapy' and its relationship to the European Cooperative Acute Stroke Study III. The Committee accepted the developer's response that the exclusion had been included in the previous submission as an open text field in the abstraction guidelines. The developer further clarified that the computer based measure logic algorithm had been updated with a data element to capture extended IV thrombolytic therapy.
- The developer clarified that patients could also be excluded for other medical reasons through the 'extended IV thrombolytic therapy' data element.
- The developer also acknowledged that exclusions may be applied differently across hospitals.

3. Feasibility: H-10; M-13; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Some of the data elements are captured in an electronic health record and can be collected via chart abstraction at facilities without an electronic health records.
- The Committee reviewed the feasibility of capturing data without undue burden and whether the measure could be implemented for performance measurement.

0437 STK-04 Thrombolytic Therapy

4. Usability and Use: H-7; M-15; L-0; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee discussed the unintended consequences of hospitals working to improve stroke treatment and the impact this could have on stroke mimics, particularly in pediatric patients.
- A Committee member questioned whether the denominator includes patients aged 18 and older; the American Academy of Pediatrics defines pediatric up to age 21.
- The developer noted that all of their in-patient hospital measures are specified for adults and that the measure is not intended to address the pediatric population.

5. Related and Competing Measures

- Measure # 0437 competes with #1952 Time to Intravenous Thrombolytic Therapy. Measure #0437 and #1952 focus on acute ischemic stroke patients for whom IV tPA was initiated at the hospital. They also share the same patient population, ischemic stroke patients.
- Measure #0437 is related to Measure #0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival. These measures share some key data elements (i.e., Last Known Well, Date Last Known Well, Time Last Known Well, and Arrival Time) but focus on different target populations and purposes: #0661 focuses on imaging in the ED setting, while #0437 focuses on administration of thrombolytic therapy in an inpatient setting.
- To address harmonization concerns, the developer stated that the measure maintenance teams for #0661 and #0437 work closely together and coordinate updates to the measures' specifications (e.g., updates to the appropriate ICD-10 codes to determine measure inclusion).
- Measure #0437 is related to measure #0288 Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival, however, #0288 focuses on patients with acute myocardial infarction receiving fibrinolytic therapy.

Standing Committee Recommendation for Endorsement: Y-23; N-0

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports

Submission | Specifications

Description: Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography (MRA), neck computerized tomographic angiography (CTA), neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.

Numerator Statement: Final reports for carotid imaging studies that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement

Denominator Statement: All final reports for carotid imaging studies (neck MRA, neck CTA, neck duplex ultrasound, carotid angiogram) performed.

0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports

Exclusions: No Denominator Exclusions or Denominator Exceptions

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Clinician : Individual

Setting of Care: Hospital/Acute Care Facility, Imaging Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American College of Radiology (ACR)

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-1; M-16; L-1; I-1**; 1b. Performance Gap: **H-9; M-10; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed that there was strong evidence to support compliance with a standardized reporting criterion for carotid stenosis.
- The developer provided performance scores based on data from 2010 – 2013. While these rates do show a steady increase in performance, the Committee agreed there is still opportunity for improvement with average performance rates at 76% (in 2013).

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-15; M-4; L-0; I-0;** 2b. Validity: **H-11; M-8; L-0; I-0**

<u>Rationale</u>:

- The testing sample included 2012-2014 data from 133,717 physicians and 2,268,250 patients; data from both claims and registry were used. The Committee noted concerns with the denominator, which includes a vast target population and potential exclusions challenges.
- Developers conducted inter-rater reliability testing by comparing data gathered by two trained clinical abstractors and evaluating the rate of agreement among the abstractors. The developer assessed data from three radiology sites during calendar year 2010; 109 records were included in the testing sample. Despite the updated testing, the Committee agreed there were no major changes to reliability since the last submission and that the new testing data continued to support reliability of the measure.
- New face validity was assessed by an expert panel of 14 members. The result of the expert panel rating was that 85.71% of respondents either agreed or strongly agreed that this measure could accurately distinguish good and poor quality.

3. Feasibility: H-18; M-1; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed the measure is feasible. All data elements are in defined fields in electronic claims and are generated by or collected by healthcare personnel during the provision of care.

4. Usability and Use: H-15; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The measure met the usability and use criterion and is currently included in the CMS Physician Quality Reporting System.

0507 Diagnostic Imaging: Stenosis Measurement in Carotid Imaging Reports
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-19; N-0**
6. Public and Member Comment • No comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
Submission | Specifications
Description: This measure calculates the percentage of acute ischemic stroke or hemorrhagic stroke patients who arrive at the emergency department (ED) within two hours of the onset of symptoms and have a head computed tomography (CT) or magnetic resonance imaging (MRI) scan interpreted within 45 minutes of ED arrival. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year. The measure has been publicly reported, annually, by CMS as a component of its Hospital Outpatient Quality Reporting (HOQR) Program since 2012. **Numerator Statement**: The number of acute ischemic stroke or hemorrhagic stroke patients who arrive at the ED within two hours of the onset of symptoms and have a head CT or MRI scan interpreted within 45 minutes of ED arrival. **Denominator Statement**: The number of acute ischemic stroke or hemorrhagic stroke patients who arrive at the ED within two hours of the onset of symptoms and have a head CT or MRI scan ordered. **Exclusions**: Studies are excluded for any patients under 18 years of age, patients who expired in the ED, or patients who left the ED against medical advice or discontinued care. Additionally, patients who do not arrive to the ED within two hours of symptom onset or who do not have a head CT or MRI scan ordered are excluded from the target population. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility, Population: National **Setting of Care:** Emergency Medical Services/Ambulance, Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records An electronic data collection tool is made available from vendors or facilities can download the free CMS Abstraction & Reporting Tool (CART). Paper tools for manual abstraction, which are posted on www.QualityNet.org, are also available for the CART tool. These tools are posted on www.QualityNet.org. **Measure Steward**: Centers for Medicare & Medicaid Services
STANDING COMMITTEE MEETING [04/04/2016-04/05/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-1**; **M-14**; **L-5**; **I-2**; 1b. Performance Gap: **H-21**; **M-2**; **L-0**; **I-0** <u>Rationale</u>: • The Committee agreed that new evidence submitted by the developer supported the need for urgent

imaging to treat acute ischemic stroke. However, the Committee noted that there was no empirical evidence to support the 45 minute time interval defined in the measure.
- Additional Committee discussion centered on the difficulty of properly tracking time of patient arrival in an electronic health record and whether the 45 minute timeframe was realistic in clinical practice.
- One Committee member noted that other factors could lead to potential delays in interpreting CT or MRI scans. Another Committee raised an unintended consequence where the time interval may result in a 45 minute delay in interpreting the scan.
- A Committee member suggested that the developer capture both the time that the scan is completed and the time the scan is interpreted.
- The Committee acknowledged there is an opportunity for improvement in treating ischemic stroke, with disparities existing for certain subpopulations including African Americans, Hispanics, and women.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-5**; **M-15**; **L-3**; **I-0** 2b. Validity: **H-0**; **M-17**; **L-3**; **I-3**

<u>Rationale</u>:

- Reliability testing was conducted at the measure score level. The data used for testing included 92,633 cases from 2,985 hospital associated outpatient services nationwide. Results of reliability testing ranged from .62 to 1.0 with a median of .77.
- The Committee accepted the empirical validity testing that assessed the agreement between facility abstraction and auditor abstraction of eight data elements from 774 cases. The Kappa statistic was .52 and 1.00 for numerator and denominator cases, respectively.

3. Feasibility: H-2; M-16; L-5; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- Data are available through administrative claims, electronic clinical data, and electronic health records, paper records and the Centers for Medicare & Medicaid Services abstraction and reporting tool.
- A Committee member raised concern about the capability of data collection systems at smaller hospitals. The developer responded that manual chart abstraction is required for this measure regardless of where the data are stored.

4. Usability and Use: H-15; M-7; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The Committee acknowledged that the measure is publicly reported through the CMS HOQR program and that performance has increased from 14.5% in 2012 to 71% in 2014.
- Unexpected findings showed wide variation in facility performance, suggesting that clearer abstraction guidance could improve measure validity. Additionally, many facilities had not met the minimum case count due to the small sampling requirement and variability in application of exclusion criteria. Ultimately, the Committee agreed the measure met the usability and use criterion.

5. Related and Competing Measures

- Measure #0661 and #0437 STK 04 Thrombolytic Therapy share some key data elements (i.e., Last Known Well, Date Last Known Well, Time Last Known Well, and Arrival Time). The two measures focus on different target populations and purposes: #0661 focuses on imaging in the ED setting, while #0437

0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival

focuses on administration of thrombolytic therapy in an inpatient setting.

- To address harmonization concerns, the developer stated that the measure maintenance teams for #0661 and #0437 work closely and coordinate updates to the measures' specifications (e.g., updates to the appropriate ICD-10 codes to determine measure inclusion).

Standing Committee Recommendation for Endorsement: Y-19; N-4

6. Public and Member Comment

One comment was received:

- The American Association of Neurological Surgeons (AANS) agrees with mandating a time limit for head CT and MRI scan interpretations for patients in whom there is concern regarding acute ischemic stroke or hemorrhagic stroke. While we recognize that there is evidence to support the 45 minute time limit, we would like to emphasize the importance of finalizing reads as soon as possible. The treatment paradigm for acute ischemic stroke and hemorrhagic stroke is at the opposite ends of the spectrum. For both, real time, immediate interpretation of the radiographic study is critical. In one situation tPA would be given and mobilization of the interventional team based on at least five level one studies that show favorable outcome with large vessel occlusion recanalization for ischemic stroke. Higher blood pressures are needed to promote collateral blood flow. For hemorrhagic stroke, any antithrombotic agent is contraindicated and the medical management among other things consists of lowering blood pressure. It is impossible to distinguish between the two entities based on clinical exam. Patient morbidity and mortality is directly related to the institution of the current treatment algorithm in a timely fashion. This cannot be done without intracranial imaging. Intracranial imaging should be interpreted in real time. The time parameters proposed are necessary to ensure that the appropriate treatment algorithm is instituted. This is very time sensitive with a direct correlation to clinical outcome

Developer Response: Thank you for the comment. CMS agrees performing prompt brain imaging for patients suspected of acute stroke is a critical component of emergency care for accurate diagnosis and treatment. As you noted in your comment, use of a head CT or MRI allows clinicians to differentiate ischemic stroke, hemorrhagic stroke, and mini strokes; these scans also help identify candidates for tPA, which is used to treat ischemic stroke patients (and is contraindicated for treatment of hemorrhagic stroke). The specifications for NQF #0661 align with recommendations made by the American Heart Association/American Stroke Association, which recommend that imaging studies be interpreted within 45 minutes of patient arrival; CMS encourages imaging studies be interpreted as rapidly as possible to ensure timely, appropriate treatment.

Committee Response: After a review of the comments, the Committee recommended that in the future that the developer include supporting information within the measure to emphasize that scans should be interpreted as soon as possible.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

1952 Time to Intravenous Thrombolytic Therapy

Submission | Specifications

Description: Acute ischemic stroke patients aged 18 years and older receiving intravenous tissue plasminogen activator (tPA) therapy during the hospital stay and having a time from hospital arrival to initiation of thrombolytic therapy administration (door-to-needle time) of 60 minutes or less.

Numerator Statement: Acute ischemic stroke patients aged 18 years and older receiving intravenous tissue

1952 Time to Intravenous Thrombolytic Therapy

plasminogen activator (tPA) therapy during the hospital stay and having a time from hospital arrival to initiation of thrombolytic administration (door-to-needle time) of 60 minutes or less.

Denominator Statement: All acute ischemic stroke patients who received intravenous thrombolytic therapy during the hospital stay.

Exclusions: Denominator Exclusions:

•Patients less than 18 years of age

•Patient stroke occurred while in hospital

•Patients received in transfer from the inpatient, or outpatient of another facility

•Patients that receive tPA greater than 4.5 hours after Last Known Well

•Clinical trial

Denominator Exceptions:

Patients with documented Eligibility or Medical reason for delay in treatment [eg, social, religious, initial refusal, hypertension requiring aggressive control with intravenous medications, inability to confirm patients eligibility, or further diagnostic evaluation to confirm stroke for patients with hypoglycemia (blood glucose < 50); seizures, or major metabolic disorders, or management of concomitant emergent/acute conditions such as cardiopulmonary arrest, respiratory failure requiring intubation), or investigational or experimental protocol for thrombolysis.]

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Heart Association/American Stroke Association

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-18; M-3; L-0; I-0**; 1b. Performance Gap: **H-15; M-6; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed the developer provided sufficient data to support the evidence criterion. Data for this process measure included the AHA/ASA Guidelines from 2007, which demonstrate that when acute ischemic stroke patients receive intravenous tissue plasminogen activator (tPA) therapy during the hospital stay and have a time from hospital arrival to initiation of thrombolytic therapy administration (door-to-needle time) of 60 minutes or less, will have lower in-hospital mortality and intracranial hemorrhage, better clinical and functional outcomes. Guidelines were based on 16 randomized control trials, 1 open trial, 32 observational studies, and 4 meta-analyses.
- Submitted Get with the Guidelines Registry data demonstrated the average performance increased from 53% to 70% (2012 to 2015). The Committee agreed there is still an opportunity for improvement.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1; M-20; L-0; I-0;** 2b. Validity: **H-1; M-19; L-1; I-0**

<u>Rationale</u>:

- For measure score reliability, the developer conducted beta-binomial analysis at the measure score level. This measure had a score of 0.63 for reliability when evaluated at the minimum level of quality reporting events, and 0.81 for reliability at the average number of quality events.
- Face validity was assessed by an expert panel of 20 members. The mean rating was 4.2 out of 5.

1952 Time to Intravenous Thrombolytic Therapy
• The Committee noted the lack of exclusion criteria for hospitals with smaller case volumes and believed this could lead to measurement burden. The developer acknowledged the Committee's concern and noted the importance of appropriate care coordination especially for hospitals with smaller case volumes.
3. Feasibility: H-2; M-19; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee agreed the measure is feasible. All data elements are in defined fields in electronic claims and are generated by or collected by healthcare personnel during the provision of care.
4. Usability and Use: H-4; M-15; L-2; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is included in various accountability programs including Get with the Guidelines – Stroke Hospital Recognition Program.
5. Related and Competing Measures • Measure #1952 competes with #0437 STK04 Thrombolytic Therapy. These measures have similar measure foci and populations, but #1952 focuses on the timely administration of tPA rather than whether tPA should be administered for eligible patients (i.e., there could be varying reasons that a client is not treated within 60 minutes). During the Post-meeting Call, the developer stated that measure #0437 and #1952 have been harmonized to the extent possible.
Standing Committee Recommendation for Endorsement: **Y-21; N-0**
6. Public and Member Comment • No comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2111 Antipsychotic Use in Persons with Dementia
Submission | Specifications
Description: The percentage of individuals 65 years of age and older with dementia who are receiving an antipsychotic medication without evidence of a psychotic disorder or related condition. **Numerator Statement**: The number of patients in the denominator who had at least one prescription and > 30 days supply for any antipsychotic medication during the measurement period and do not have a diagnosis of schizophrenia, bipolar disorder, Huntington's disease or Tourette's. **Denominator Statement**: All patients 65 years of age and older continuously enrolled during the measurement period with a diagnosis of dementia and/or two or more prescription claims within the measurement year for a cholinesterase inhibitor or an NMDA receptor antagonist within the measurement year where the sum of days supply is >60. **Exclusions**: N/A **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Health Plan, Population : National

2111 Antipsychotic Use in Persons with Dementia

Setting of Care: Other, Pharmacy

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-5; M-10; L-1; I-0**; 1b. Performance Gap: **H-2; M-14; L-0; I-0**

<u>Rationale</u>:

- No new evidence was submitted by the developer, however the Committee pointed out that the American Geriatric Society updated the Beers criteria for potentially inappropriate medication use in older adults to include antipsychotics.
- The Committee agreed that the gap in performance (7.7% to 19.4%) across 731 Medicare contracts and the disparity of antipsychotic prescription among those patients living in nursing homes (23.9%) compared to those living in the community (10.8%), highlighted an opportunity for improvement.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0; M-16; L-0; I-0;** 2b. Validity: **H-0; M-13; L-3; I-0**

<u>Rationale</u>:

- The Committee discussed the breadth of the denominator which was specified to use medications rather than ICD codes to identify patients with dementia. The Committee was concerned that the denominator would capture patients without dementia (e.g., mild cognitive impairment, Parkinson's disease), who are prescribed cholinesterase inhibitors and N-Methyl-D-aspartate antagonists (NMDA). A Committee member mentioned the Food and Drug Administration's (FDA) 2005 advisory requiring that manufacturers of atypical psychotics to include a black box warning to indicate that use increases risk of mortality in patients with dementia.
- Committee members highlighted the importance of this measure, but also acknowledged the challenge in specifying the denominator. The Committee also discussed whether a diagnosis of Parkinson's disease should be an inclusion or exclusion for this measure.
- The developer noted that the medications included in the measure are FDA approved for dementia related to Alzheimer's. The developer noted that by including cholinesterase inhibitors and NDMA antagonist, they may be able to detect more clients with dementia who were prescribed antipsychotics.
- The developer submitted updated reliability testing. Testing was conducted using 720 Medicare Part D contracts, including 35 million beneficiaries. With measurement at the health plan level, testing results showed the contract reliability mean score of 0.76 and the median score of 0.87.
- An expert panel was convened to assess face validity with 67% of the panel in favor of endorsement. The Committee accepted the expert panel's results.

3. Feasibility: H-11; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed that the measure is feasible and that the data are easily collected through electronic claims.

4. Usability and Use: H-3; M-12; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

2111 Antipsychotic Use in Persons with Dementia

Rationale:

- A Committee member questioned why the measure has not been publicly reported or used in accountability programs. The developer clarified that the measure was designed for Medicare Part D patient safety reports.
- The Committee discussed the unintended consequence of approving a measure that would recommend against on-label use when some antipsychotics are indicated for particular conditions. The Committee was concerned that the measure only excluded four conditions (i.e., schizophrenia, Tourette's Huntington's and bipolar disorder) when other conditions (i.e., Parkinson's) are also indicated for antipsychotic treatment.
- The developer noted that the measure is used for quality improvement purposes only. The measure is reported by providers, but is no longer considered a star rating performance measure and would not be used as a performance-based measure for payment.

5. Related and Competing Measures

There were no related measures.

Standing Committee Recommendation for Endorsement: **Y-16; N-0**

6. Public and Member Comment

One comment was received:

- Otsuka America Pharmaceutical, Inc., part of the Otsuka Group, is focused on bringing novel medicines and new healthcare products to the U.S. Otsuka is invested in efforts to advance the quality of life for patients with Alzheimer's disease and their families. We appreciate the opportunity to comment on the NQF Neurology Project measures currently under review and encourage NQF to expand the list of excluded patient diagnoses in the numerator statement of measure 2111 Antipsychotic Use in Persons with Dementia. Otsuka supports efforts to ensure that antipsychotics are appropriately prescribed and monitored. Toward that end, Otsuka echoes the concern expressed by the Committee that this measure, as written, may result in unintended consequences. The Committee pointed to the potential impact on patients with conditions other than psychotic disorders for which antipsychotics are routinely prescribed. One such condition is agitation in patients with dementia. Agitation is separate and distinct from psychosis and was recently defined by the International Psychogeriatric Association as, "(1) occurring in patients with a cognitive impairment or dementia syndrome; (2) exhibiting behavior consistent with emotional distress; (3) manifesting excessive motor activity, verbal aggression, or physical aggression; and (4) evidencing behaviors that cause excess disability and are not solely attributable to another disorder (psychiatric, medical, or substance-related)" (Cummings, 2015). APA Practice Guidelines state that, "nonemergency antipsychotic medication should only be used for the treatment of agitation or psychosis in patients with dementia when symptoms are severe, are dangerous, and/or cause significant distress to the patient" (2016), indicating that there are specific circumstances under which older adults can benefit from the use of antipsychotics. Otsuka encourages NQF to expand the list of excluded patient diagnoses in the numerator statement of measure 2111 Antipsychotic Use in Persons with Dementia to incorporate patients with agitation as a result of dementia and Parkinson's in order to more accurately capture inappropriate prescribing of antipsychotic medications. Failing to exclude additional diagnoses for which antipsychotics are indicated could skew measurements that will have broad consequence for accountability programs. References 1. American Psychiatric Association. Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia. 2016. 2. Cummings, Jeffrey, et al. "Agitation in cognitive disorders: International Psychogeriatric Association provisional consensus clinical and research definition." International Psychogeriatric 27.1 (2015): 7–17.

Developer Response: When constructing the measure specifications for the Antipsychotic Use in Persons with Dementia measure, the goal was to identify the population of patients that are at high-risk of adverse events from the use of antipsychotic medications (i.e., persons with dementia) and to further focus on the sub-population of dementia patients who do NOT have a documented diagnosis for which an antipsychotic is

2111 Antipsychotic Use in Persons with Dementia
clearly indicated (i.e., we exclude persons who have a diagnosis that identifies them as having psychoses or behavioral disturbances). Thus, the measure identifies the proportion of patients at high risk of antipsychotic-associated adverse events but without a diagnosis code to indicate that an antipsychotic drug is beneficial. Since this is a claims based measure, it is impossible to identify every patient with dementia where antipsychotic medication use is appropriate. Therefore, the intended rate of the measure is not expected to approach zero. **Committee Response:** After a review of the comment, the Committee clarified that the larger issue pertained to the denominator specifications, which did not use ICD codes for dementia and instead used antipsychotic medications, which could inappropriately include clients without dementia in the denominator.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2863 CSTK-06: Nimodipine Treatment Administered
Submission | Specifications
Description: Proportion of subarachnoid hemorrhage (SAH) patients age 18 years and older for whom nimodipine treatment was administered within 24 hours of arrival at this hospital. This is the sixth measure in a set of measures developed for Joint Commission Comprehensive Stroke Certification. The other measures in the set include CSTK-01 National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients; CSTK-02 Modified Rankin Score (mRS) at 90 Days; CSTK-03 Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate). Although it is not required that these measures are reported in conjunction with each other, The Joint Commission develops measures in sets in order to provide as comprehensive a view of quality for a particular clinical topic as possible. **Numerator Statement**: SAH patients for whom nimodipine treatment was administered within 24 hours of arrival at this hospital. **Denominator Statement**: SAH patients **Exclusions**: • Patients less than 18 years of age • Patients who have a Length of Stay greater than 120 days • Patients with Comfort Measures Only documented on the day of or day after hospital arrival • Patients enrolled in Clinical Trials • Patients discharged within 24 hours of arrival at this hospital **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility, Population : National **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Paper Medical Records **Measure Steward**: The Joint Commission
STANDING COMMITTEE MEETING [04/04/2016-04/05/2016] **1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>** (1a. Evidence, 1b. Performance Gap) 1a. Evidence: **H-14; M-9; L-0; I-0**; 1b. Performance Gap: **H-3; M-20; L-0; I-0**

2863 CSTK-06: Nimodipine Treatment Administered

Rationale:

- The Committee acknowledged the importance of administering nimodipine to patients with aneurysmal subarachnoid hemorrhage and its correlation to increased independence and decreased mortality.
- The developer presented data that show variability across hospitals, with the top hospitals performing at the 10th percentile (0.75) and the low performing hospitals at the 90th percentile (0.92). Committee members concluded there is a performance gap and opportunity for improvement.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2; M-21; L-0; I-0;** 2b. Validity: **H-1; M-21; L-1; I-0**

Rationale:

- The Committee agreed that the reliability and validity testing met the evaluation criterion.
- Inter-rater reliability testing was conducted at 12 sites with 281 records showing a percent agreement greater than 95% and a Kappa score of 0.93.
- Empirical validity testing was conducted at the measure score level with two hypotheses: 1- Hospital results for two process measures for hemorrhagic stroke CSTK 03: Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate) and CSTK 06: Nimodipine Treatment Administered. A Pearson Correlation Coefficient was calculated to compare the results of the two measures and hypotheses 2- Hospitals that do well on one stroke measure are likely to do well on other stroke measures. Pearson Correlation coefficients were calculated to compare results of several stroke measures (p-value = 0.85).

3. Feasibility: H-3; M-19; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee acknowledged that the measure is currently in use and the data are routinely generated through clinical care delivery.
- Although data can be abstracted, the Committee expressed concern that not all hospitals are able to generate the data electronically; manual paper abstraction may add to data collection burden (averaging $3.50 per abstraction and 45 minutes per record).

4. Usability and Use: H-3; M-19; L-1; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is currently being used for The Joint Commission Care Certification for Comprehensive Stroke Centers.
- The developer plans to include this measure in public reporting and external benchmarking programs.

5. Related and Competing Measures

- Measure #2863 is related to #2866 CSTK-03 Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate). These measures assess similar populations, however, #2863 focuses on SAH clients that received treatment whereas #2866 focuses on whether an assessment was done prior to medical intervention.

Standing Committee Recommendation for Endorsement: **Y-22; N-1**

6. Public and Member Comment

One Comment was received:

- The American Association of Neurological Surgeons (AANS) agrees with the administration of

2863 CSTK-06: Nimodipine Treatment Administered

nimodipine for patients with aneurysmal subarachnoid hemorrhage. These patients are monitored in the hospital during the period of concern for vasospasm. It is accepted that there are radiographic findings that can predict which patients are at higher risk for vasospasm. Nimodipine is continued during patient hospitalization. There is no clinical or scientific rationale to continue nimodipine for 21 days in all patients with subarachnoid hemorrhage once they are discharged from the hospital. The fact that they are discharged from the hospital implies that they have been monitored closely and are out of the window for vasospasm. Mandating the use of nimodipine for 21 days places undue hardships on patients. These include expense, lack of availability of the drug in many outpatient pharmacies, and risks of unintended hypotension all with no appreciable clinical benefit. Our position is supported by the following study: Toyota BD The efficacy of an abbreviated course of nimodipine in patients with good-grade aneurysmal subarachnoid hemorrhage. J Neurosurg. 1999 Feb;90(2):203-6.

Developer Response: Thank you for commenting on The Joint Commission CSTK-06 Nimodipine Treatment Administered measure. Clinical trials have demonstrated the benefit of nimodipine to prevent or limit the severity of cerebral vasospasm for patients with aneurysmal subarachnoid hemorrhage (The American Nimodipine Studies Group, 1992). The recommended course of treatment is 21 days; however, the CSTK-06 Nimodipine Treatment Administered measure captures in the numerator population subarachnoid hemorrhage patients who receive an initial dose of nimodipine within 24 hours of hospital arrival. If nimodipine is discontinued prior to 21 days, there is no impact on the measure rate.

Committee Response: After a review of the comment, the Committee suggest the developer provide additional wording in the measure to clarify that there is no penalty for hospitals if Nimodipine is discontinued prior to the recommended 21 days course of treatment 21 days. The Committee also recommended that the developer review other studies related to Nimodipine treatment to support the measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2864 CSTK-01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients

Submission | Specifications

Description: Proportion of ischemic stroke patients age 18 years or older for whom an initial NIHSS score is performed prior to any acute recanalization therapy (i.e., intra-venous (IV) thrombolytic (t-PA) therapy, or intra-arterial (IA) thrombolytic (t-PA) therapy, or mechanical endovascular reperfusion (MER) therapy) in patients undergoing recanalization therapy and documented in the medical record, or documented within 12 hours of arrival at the hospital emergency department in patients who do not undergo recanalization therapy.

This is the first in a set of measures developed for Joint Commission Comprehensive Stroke Certification. The other measures in the set include CSTK-02 Modified Rankin Score (mRS) at 90 Days; CSTK-03 Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate); CSTK-06 Nimodipine Treatment Administered. Although it is not required that these measures are reported in conjunction with each other, The Joint Commission develops measures in sets in order to provide as comprehensive a view of quality for a particular clinical topic as possible.

Numerator Statement: Ischemic stroke patients for whom an initial NIHSS score is performed prior to any acute recanalization therapy in patients undergoing recanalization therapy and documented in the medical record, OR documented within 12 hours of arrival at the hospital emergency department in patients who do not undergo

2864 CSTK-01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients

recanalization therapy.

Denominator Statement: Ischemic stroke patients who arrive at this hospital emergency department (ED).

Exclusions: • Patients less than 18 years of age

• Patients who have a Length of Stay greater than 120 days

• Patients with Comfort Measures Only documented on the day of or day after hospital arrival

• Patients admitted for Elective Carotid Intervention

• Patients who do not undergo recanalization therapy and are discharged within 12 hours of arrival at this hospital

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-16; L-5; I-0**; 1b. Performance Gap: **H-6; M-16; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed the developer provided sufficient data to support the evidence criterion. The developer provided evidence from the American Heart Association/American Stroke Association with two guideline statements for the emergency evaluation and diagnosis of acute ischemic stroke. However, the Committee believed the evidence did not support the 12-hour time frame for documenting that the NIH Score Scale was performed on patients who did not undergo recanalization.
- Additionally, the Committee noted minimal performance improvement but agreed there was an opportunity for improvement, with a mean hospital rate of 85% in Q2 in 2015.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2; M-20; L-0; I-0;** 2b. Validity: **H-1; M-15; L-6; I-0**

<u>Rationale</u>:

- Inter-rater reliability testing of 14 data elements was conducted at 12 sites with 281 total records (from 2013). Percent agreement for the 14 data elements ranged from 71.5% (Discharge Time) to 99.3% (ED Patient).
- Empirical validity testing was conducted at the measure score level. The developer conducted several construct validation analyses, first hypothesizing a relationship between this measure and three other TJC stroke measures (specifically testing the hypothesis that hospitals that perform well on this measure will likely perform well on the other measures). The developer examined the degree of association between the measure results using the Pearson Correlation Coefficient, with a p- value of 0.038. The Committee deemed this to be a statistically significant positive correlation between the two measures.

3. Feasibility: H-9; M-11; L-2; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed the measure is feasible. All data elements are in defined fields in electronic claims

2864 CSTK-01: National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients

and generated or collected by and used by healthcare personnel during the provision of care

4. Usability and Use: H-15; M-7; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is included in the Joint Commission Disease-Specific Care Certification for Comprehensive Stroke Centers. The developer plans to include the measure in public reporting programs and for external benchmarking; a timeframe was provided.
- There were no unintended negative consequences reported or detected during testing or since implementation of the measure specifications.

5. Related and Competing Measures

- Measure #2864 and Measure #2866 CSTK 03 Severity Measurement Performed for Subarachnoid Hemorrhage and Intracerebral Hemorrhage Patients (Overall Rate) are related. The measure focus is the same as both assess (through a score or measurement) the patient prior to a medical intervention. However, the patient populations are different as measure #2864 focuses on ischemic patients and #2866 on hemorrhagic stroke patients.

Standing Committee Recommendation for Endorsement: **Y-19; N-3**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2866 CSTK-03: Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate)

Submission | Specifications

Description: Proportion of SAH and ICH stroke patients age 18 years or older for whom a severity measurement (i.e., Hunt and Hess Scale for SAH patients or ICH Score for ICH patients) is performed prior to surgical intervention (e.g., clipping, coiling, or any surgical intervention) in patients undergoing surgical intervention and documented in the medical record; OR, documented within 6 hours of arrival at the hospital emergency department in patients who do not undergo surgical intervention.

This is the third measure in a set of measures developed for Joint Commission Comprehensive Stroke Certification. The other measures in the set include CSTK-01 National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients; CSTK-02 Modified Rankin Score (mRS) at 90 Days; CSTK-06 Nimodipine Treatment Administered. Although it is not required that these measures are reported in conjunction with each other, The Joint Commission develops measures in sets in order to provide as comprehensive a view of quality for a particular clinical topic as possible.

Numerator Statement: CSTK-03 The number of SAH and ICH stroke patients for whom a severity measurement is performed prior to surgical intervention in patients undergoing surgical intervention and documented in the medical record; OR documented within 6 hours of arrival at the hospital emergency department in patients who do not undergo surgical intervention.

CSTK-03a The number of SAH stroke patients for whom a Hunt and Hess Scale is performed prior to surgical

2866 CSTK-03: Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate)

intervention in patients undergoing surgical intervention and documented in the medical record; OR documented within 6 hours of arrival at the hospital emergency department in patients who do not undergo surgical intervention.

CSTK-03b The number of ICH stroke patients for whom an ICH Score is performed prior to surgical intervention in patients undergoing surgical intervention and documented in the medical record; OR documented within 6 hours of arrival at the hospital emergency department in patients who do not undergo surgical intervention.

Denominator Statement: SAH and ICH stroke patients who arrive at this hospital emergency department (ED).

Exclusions: • Patients less than 18 years of age

• Patients who have a Length of Stay greater than 120 days

• Patients with Comfort Measures Only documented on the day of or day after hospital arrival

• Non-surgical patients discharged within 6 hours of arrival at this hospital

• Patients with admitting diagnosis of traumatic brain injury (TBI), unruptured arteriovenous malformation (AVM), and non-traumatic subdural hematoma (ICD-9-CM Other Diagnosis Codes as defined in Appendix A, Table 8.2f)

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-17; L-4; I-1**; 1b. Performance Gap: **H-18; M-3; L-0; I-0; ;** Evidence Exception: **Y-X; N-X**

<u>Rationale</u>:

- Evidence provided by the developer included three clinical guidelines indicating severity measurement for all SAH and ICH patients, increases early detection and diagnosis of stroke and increases the identification of patients eligible for surgical intervention.
- Data on performance gap and opportunity for improvement were provided from both the pilot test (66 sites and 2471 cases) and data collected in early 2015. Assuming a target performance of 100%, the developer indicated there is a possible gap of 80%; the Committee concluded that an opportunity for improvement still remains.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-5; M-16; L-0; I-0;** 2b. Validity: **H-7; M-14; L-1; I-0**

<u>Rationale</u>:

- The developer conducted reliability testing at the data element level within 12 participating sites, using 281 medical records. Percent agreement of the data elements between the abstractors ranged from 71.5% for discharge time and 99.3% for confirmation of emergency department patient. Kappa scores were calculated on three data elements: Initial Hunt and Hess performed (K=0.91), Initial ICH Score performed (K=0.86) and Emergency Department patient (K=0.96).
- Empirical validity testing was conducted at the performance score level. The developer examined the Pearson Correlation Coefficient in comparison to three distinct subpopulations (ischemic stroke without procedure, ischemic stroke with IV t-PA, IA t-PA, or MER; and hemorrhagic stroke); these data show a p-value of 0.85.

2866 CSTK-03: Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate)

- Face validity of data elements was assessed via hospital survey and focus groups but did not address validity of the measure score as a representation of quality.

3. Feasibility: H-9; M-13; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- While the Committee agreed that data collection for this measure should be simple and feasible, the value of the data relative to the cost of collection is unclear.

4. Usability and Use: H-1; M-19; L-1; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The Committee discussed measure user feedback that indicated some users may have had difficulty calculating the ICH score.

5. Related and Competing Measures

- Measure #2866 and Measure #2864 CSTK01 National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients are related. The measure foci are the same; both assess (through a score or measurement) the patient prior to a medical intervention. However, the patient populations are different as measure #2866 focuses on both hemorrhagic and intracerebral patients, and #2864 focuses on ischemic stroke patients.

Standing Committee Recommendation for Endorsement: **Y-21; N-1**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2877 Hybrid hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity

Submission | Specifications

Description: This hybrid stroke mortality measure estimates the hospital-level, risk-standardized mortality rate (RSMR) for patients discharged from the hospital with a principal discharge diagnosis of acute ischemic stroke. The outcome is all-cause 30-day mortality, defined as death from any cause within 30 days of the index admission date, including in-hospital death, for stroke patients. This measure is a newly developed measure with a cohort and outcome that is harmonized with the CMS's current publicly reported claims-based stroke mortality measure, and includes the National Institutes of Health (NIH) Stroke Scale as an assessment of stroke severity in the risk-adjustment model. The measure is referred to as a hybrid because it is CMS's intention to calculate the measure using two data sources: Medicare fee-for-service (FFS) administrative claims and clinical electronic health record (EHR) data.

Numerator Statement: The outcome for this measure is 30-day, all-cause mortality. We define mortality as death from any cause within 30 days of the index admission for patients with a principal discharge diagnosis of acute

2877 Hybrid hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity

ischemic stroke.

Denominator Statement: The cohort includes inpatient admissions for Medicare FFS patients, age 65 years and older, who were discharged from non-federal, short-term, acute care hospitals with a principal discharge diagnosis of acute ischemic stroke.

Additional details are provided in S.9 Denominator Details.

Exclusions: The measure excludes admissions for patients:

1. With inconsistent or unknown vital status or other unreliable data;

2. Enrolled in the Medicare hospice program at any time in the 12 months prior to the index admission, including the first day of the index admission; and

3. Discharged against medical advice (AMA).

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

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Other, Electronic Clinical Data : Registry

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

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-20; N-1**; 1b. Performance Gap: **H-8; M-14; L-0; I-0**

<u>Rationale</u>:

- The developer cited studies demonstrating that appropriate guideline-recommended care and timely treatment for stroke patients can reduce the risk of mortality within 30 days of hospital admission.
- The developer provided risk-standardized mortality rates using two data sources: July 2011 – June 2014 Medicare Administrative claims and 2013 AHA/ASA GWTG-Stroke Registry. Both values for the NIHSS were obtained from the Registry as a surrogate for NIHSS scores that will be obtained from ICD-10 codes beginning in October 2016. With the mean risk-standardized mortality rate at 14.5%, the Committee agreed that the data reflect opportunity for improvement.
- The developer also presented disparities data using three subpopulations (Dual Eligibles, African Americans and AHRQ SES Index); these data show minimal differences in the mortality rates across hospitals.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2; M-18; L-1; I-1;** 2b. Validity: **H-0; M-16; L-6; I-0**

<u>Rationale</u>:

- The measure is specified at the facility-level for the hospital/acute care setting. The denominator includes all Medicare FFS beneficiaries, age 65 and over, with a principal discharge diagnosis of acute ischemic stroke.
- The developer used a split-sample methodology to test the measure score reliability, assigning half of the patients in each hospital to two separate groups. Then the developer calculated the performance measure score for each hospital in each of the two groups, and compared the agreement between each

2877 Hybrid hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity

hospital's paired scores using the intra-class-correlation coefficient (ICC). A correction factor to account for the overall sample size was also applied. The ICC values from the split-sample analysis was 0.56, indicating 56% of the variance in scores was due to differences between hospitals. According to the Landis and Koch classification, this is interpreted as moderate agreement.

- Data element validity of electronic clinical data elements: The developer validated all three electronically abstracted critical EHR data elements (heart rate, diastolic blood pressure, and glucose) against manual chart abstraction.
- Empirical validity testing was conducted at the measure score level by comparing this measure to two similar stroke mortality measures. All three models include a total of 188,975 hospital admissions derived from registry and claims data.
- The developer noted that each of the three cohorts for the three risk models used the same inclusion/exclusion criteria and a risk-adjustment (statistical modeling) strategy and only differed with respect to the risk variables used.

3. Feasibility: H-3; M-16; L-2; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- All data elements are in defined fields in a combination of electronic sources. Data elements are also generated or collected and used by healthcare personnel during the provision of care.
- Data availability was tested in three separate health systems and three EHRs (Epic, Cerner, and GE Centricity). Data accuracy was tested in two hospitals and two EHRs (Cerner and GE Centricity).
- The data element feasibility assessment scorecard submitted by the developer demonstrated a feasibility score of "3" (highest rating) on all four components (i.e., data availability, data accuracy, data standards, and workflow) for the required clinical data elements (heart rate, diastolic blood pressure, and glucose).

4. Usability and Use: H-2; M-16; L-3; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- This measure is not currently in use in any publicly reported or accountability programs. However, CMS intends to implement this measure in the Hospital IQR program once the new NIH Stroke Scale ICD-10 codes and the core clinical data elements (CCDE) have been in use for three years. Once implemented, this measure could replace the currently reported Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure.
- The developer did not identify any unintended consequences related to this measure; however the Committee did raise concerns with variations in electronic health record systems.

5. Related and Competing Measures

- Measure #2877 and #2876 Hospital 30-day, all-cause, risk standardized mortality rate following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity are competing measures as they have the same patient populations and the same focus (ischemic stroke patients and 30-day mortality).
- Measure #2876 uses administrative claims data for risk adjustment. The developer noted that #2876 is otherwise harmonized with measure #2877.
- Measure #2877 is related to #0467 Acute Stroke Mortality rate because the focus is on mortality in acute stroke patients. However, measure #0467 captures in hospital deaths per 1,000 discharges with acute stroke as the principal diagnosis for individuals aged 18 and older. Measure #2877 is a 30-day, all cause

2877 Hybrid hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke with risk adjustment for stroke severity
RSMR including Medicare patients aged 65 and older in the denominator
Standing Committee Recommendation for Endorsement: **Y-19; N-2**
6. Public and Member Comment Two comments were received: • The American Association of Neuroscience Nurses is in support of this measure with CMS adding NIHSS risk adjustment. • Another comment that some mention should be made that the limitations that were cited for 2876 were mentioned as also being relevant for 2877, in particular concerns about the validity issues raised by end of life preferences and intensity of care. **Committee Response:** After review of the comments, the Committee did not reconsider their vote to recommend this measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Recommended for Inactive Endorsement with Reserve Status

0434 STK-01: Venous Thromboembolism (VTE) Prophylaxis
Submission | Specifications
Description: This measure captures the proportion of ischemic or hemorrhagic stroke patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given on the day of or the day after hospital admission. This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. **Numerator Statement**: Ischemic or hemorrhagic stroke patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given on the day of or the day after hospital admission. **Denominator Statement**: Ischemic or hemorrhagic stroke patients **Exclusions**: • Less than 18 years of age • Length of Stay < 2 days • Length of Stay > 120 days • Comfort measures only documented on day of or day after hospital arrival • Enrolled in clinical trials related to stroke • Admitted for elective carotid intervention **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility, Population : National **Setting of Care:** Hospital/Acute Care Facility

0434 STK-01: Venous Thromboembolism (VTE) Prophylaxis

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-18; M-5; L-0; I-0**; 1b. Performance Gap: **H-0; M-1; L-16; I-0**

<u>Rationale</u>:

- The Committee reviewed the evidence submitted from the prior review and noted that mobile patients are not listed in the exclusions, although the measure applies to immobilized patients. The developer confirmed that mobile patients would be excluded from this measure.
- During the discussion of gaps in care, the Committee agreed there was little room for improvement with 23% of hospitals conforming to the measure specification at a mean performance of 96% in 2014.
- Disparities data were not submitted, although there are known disparities among ethnic minorities. The developer collects race and ethnicity data but does not report that information. During the meeting, the developer was able to verbally confirm that there were no statistically significant differences with regard to race among individual hospitals.
- The Committee requested additional disparities data before considering this measure for *Inactive Endorsement with Reserve Status.*
- During the Post Comment Call on June 23, the Committee reviewed additional disparities data submitted by the developer. The Committee noted that the additional data submitted for review did not indicate there an opportunity for improvement. Therefore, the Committee did not pass this measure on performance gap.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-6; M-16; L-1; I-0;** 2b. Validity: **H-15; M-5; L-0; I-0**

<u>Rationale</u>:

- In reviewing reliability of this measure, Committee members noted that reliability testing had not been done on patients who were in the numerator but did not receive the medication. The developer responded that reliability testing could not be completed for these patients because of data collection challenges.
- Another Committee member asked for clarification on the 120 day and stroke trial exclusions. The developer responded that the 120 day time frame is based on CMS regulations; this ensures that patients are not double billed for extended stays. The clinical trial exclusion was included because the developer assumed that patients enrolled in clinical trials may not follow the recommended therapy.

3. Feasibility: H-17; M-6; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed all data elements are in defined fields and generated or collected and used by healthcare personnel during the provision of care.

4. Usability and Use: H-21; M-2; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- This measure is publicly reported on The Joint Commission's Quality Check and in CMS Hospital Compare.

0434 STK-01: Venous Thromboembolism (VTE) Prophylaxis

5. Related and Competing Measures

Measure #0434 is related to #0239 Venous Thromboembolism (VTE) Prophylaxis and #0371 Venous Thromboembolism Prophylaxis; both focus on the administration of VTE. However, #0239 and #0371 both target patients who have undergone or are undergoing surgical procedures, while this measure focuses only on hemorrhagic and ischemic stroke patients.

Standing Committee Recommendation for Inactive Endorsement with Reserve Status: **Y-15; N-2**

6. Public and Member Comment

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0435 STK 02: Discharged on Antithrombotic Therapy

Submission | Specifications

Description: This measure captures the proportion of ischemic stroke patients prescribed antithrombotic therapy at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy,STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic stroke patients prescribed antithrombotic therapy at hospital Discharge.

Denominator Statement: Ischemic stroke patients

Exclusions: • Less than 18 years of age
• Length of Stay > 120 days
• Comfort measures only documented
• Enrolled in clinical trials related to stroke
• Admitted for elective carotid intervention
• Discharged to another hospital
• Left against medical advice
• Expired
• Discharged to home for hospice care
• Discharged to a health care facility for hospice care
• Documented reason for not prescribing antithrombotic therapy at discharge

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

0435 STK 02: Discharged on Antithrombotic Therapy

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-21; M-2; L-0; I-0;** 1b. Performance Gap: **H-0; M-0; L-18; I-5**

<u>Rationale</u>:

- The developer's presentation of evidence demonstrating that discharging the appropriate patients on antithrombotic therapy reduces subsequent stroke mortality and morbidity remained strong and unchanged from the previous endorsement. The Committee accepted the prior evaluation without further discussion on evidence.
- The Committee agreed that there was very little room for improvement, with a 98% rate of compliance for the 10th percentile. Because the measure did not meet the performance gap criterion, the Committee recommended the measure for inactive endorsement with reserve status.
- The Committee expressed concern with the lack of disparities data because there are known disparities in stroke risk.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-12; M-10; L-0; I-0;** 2b. Validity: **H-16; M-7; L-0; I-0**

<u>Rationale</u>:

- The Committee reviewed previous reliability testing results; the inter-rater reliability of data elements in 77 hospitals and 739 patient records showed an overall agreement rate of 97.61%. Kappa scores were not presented.
- One Committee member expressed concern with the data element 'Reason for Not Prescribing Antithrombotic Therapy at Discharge'. Some measure users have cautioned that the data element may not capture all the appropriate patients. A Committee member raised concern with the frequency with which the listing of acceptable drugs was updated (e.g., new drugs approved or not approved) by the Food and Drug Administration. The Committee noted it would be difficult to assess validity.
- During workgroup discussions of this measure, the Committee questioned the large percentage of clients excluded due to hospice. At the in-person meeting, the developer presented corrected exclusion data showing that 1.29% of patients had been discharged to hospice; the Committee accepted the new data.

3. Feasibility: H-11; M-12; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee agreed the measure was feasible using medical record abstraction as the data source but noted that some data elements are in electronic form.

4. Usability and Use: H-19; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The Committee agreed that the measure met the usability and use criterion. A Committee member also noted that improved performance on this measure could be attributed to Get with the Guidelines reporting requirements.

5. Related and Competing Measures

- Measure #0435 and #0438 STK05 Antithrombotic Therapy by End of Hospital Day Two are related measures; they assess the same patient populations and similar measure focus. However, the timeframe for antithrombotic administration is specified differently in the two measures. Measure #0435 focuses on the prescription of antithrombotic medications at the time of hospital discharge, while #0438 focuses on

0435 STK 02: Discharged on Antithrombotic Therapy

the delivery of antithrombotic therapy administered by the end of hospital day two for ischemic stroke patients.

- In 2012, the Committee suggested that the developer develop a composite measure that included #0435 and #0438; this composite measure would assess the percentage of patients who receive appropriate care at both time points, and therefore provide more opportunity for improvement.
- During the post in-person meeting call, the Committee again stated its earlier suggestion to combine the measures. However, both #0435 and #0438 have been recommended for inactive endorsement with reserve status. A combined measure would have to be submitted as a new measure.

Standing Committee Recommendation for Inactive Endorsement with Reserve Status: **Y-20; N-3**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0436 STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter

Submission | Specifications

Description: This measure captures the proportion of ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic stroke patients prescribed anticoagulation therapy at hospital discharge.

Denominator Statement: Ischemic stroke patients with documented atrial fibrillation/flutter.

Exclusions: • Less than 18 years of age

• Length of Stay > 120 days

• Comfort measures only documented

• Enrolled in clinical trials related to stroke

• Admitted for elective carotid intervention

• Discharged to another hospital

• Left against medical advice

• Expired

• Discharged to home for hospice care

• Discharged to a health care facility for hospice care

• Documented reason for not prescribing anticoagulation therapy at discharge

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

0436 STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation;** 1b. Performance Gap: **H-0; M-6; L-17; I-0**

<u>Rationale</u>:

- The developer submitted evidence during the prior endorsement review, citing the recommendation for anti-coagulation therapy at discharge. The developer also noted that in addition to warfarin, direct oral anti-coagulants have been approved by the FDA and have been included on the list of acceptable drugs for inclusion in the numerator. The Committee agreed that the data that demonstrates the effect of anti-coagulants on the reduction of stroke risk is well established. Without further discussion, the Committee accepted the prior evaluation on evidence.
- While the Committee noted the importance of this measure, they also recognized that there is minimal opportunity for improvement; performance rates in CY 2015 were 97%. Because the measure did not meet the performance gap criterion, the Committee considered the measure for inactive endorsement with reserve status.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3; M-20; L-0; I-0;** 2b. Validity: **H-6; M-17; L-0; I-0**

<u>Rationale</u>:

- Committee members noted that the numerator had changed with the addition of new anticoagulant therapies and questioned how many more clients had been captured in the numerator. The Committee also questioned how long it took for patients to be added to the numerator from when new anticoagulants were approved. The developer responded that once anticoagulants become FDA approved, they are added to the VTE prophylaxis data element during the next update of the tool.
- During workgroup discussions of this measure, the Committee questioned the large percentage of clients excluded due to discharges to hospice. At the in-person meeting, the developer presented corrected exclusion data showing that 1.26% of patients had been discharged to hospice. A Committee member also questioned why discharge to another hospital was included as an exclusion for this measure.

3. Feasibility: H-8; M-15; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- While chart reivew is required to populate the measure, overall the Committee believed the measure met the feasibility criterion.

4. Usability and Use: H-17; M-6; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- This measure is currently publicly reported in the CMS Hospital IQR program and Hospital Compare.

5. Related and Competing Measures

- Measure #0436 has been recommended for inactive endorsement with reserve status; however, it is related to #1525: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy. The target population in measure #1525 differs from #0436 in that the denominator includes all patients aged 18 and older with a diagnosis of non-valvular atrial fibrillation or atrial flutter. Measure #1525 is not only specified for ischemic stroke patients with atrial fibrillation/flutter.

0436 STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter

Standing Committee Recommendation for Endorsement with Reserve Status: **Y-22; N-1**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0438 STK 05: Antithrombotic Therapy By End of Hospital Day Two

Submission | Specifications

Description: This measure captures the proportion of ischemic stroke patients who had antithrombotic therapy administered by end of hospital day two (with the day of arrival being day 1).

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-6: Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic stroke patients who had antithrombotic therapy administered by end of hospital day two.

Denominator Statement: Ischemic stroke patients

Exclusions: • Less than 18 years of age

• Duration of Stay < 2 days

• Length of Stay > 120 days

• Comfort measures only documented on the day of or day after hospital arrival

• Enrolled in clinical trials related to stroke

• Admitted for elective carotid intervention

• IV OR IA thrombolytic therapy administered at this hospital or within 24 hours prior to arrival

• Documented reason for not administering antithrombotic therapy by end of hospital day 2

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation;** 1b. Performance Gap: **H-0; M-3; L-20; I-0**

<u>Rationale</u>:

- The developer reviewed evidence submitted at the last endorsement review, citing numerous clinical studies, which highlight the benefit of early antithrombotic therapy in reducing stroke mortality and morbidity. The Committee agreed to accept the prior evaluation on evidence without further discussion.

0438 STK 05: Antithrombotic Therapy By End of Hospital Day Two

- In discussing opportunity for improvement, a Committee member noted that the mean hospital performance on this measure has remained at 98% since 2012. The developer did not submit disparities data; the Committee believed those data might yield opportunities for improvement across and within subpopulations. Because the measure did not pass performance gap, the Committee considered inactive endorsement with reserve status.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **Accepted Prior Evaluation;** 2b. Validity: **H-13; M-10; L-0; I-0**

<u>Rationale</u>:

- The Committee reviewed the prior reliability data showing a 97% agreement rate of tested data elements in 77 hospitals and 739 patient records. The Committee accepted the prior evaluation on reliability.
- The developer presented new validity data showing a positive correlation with six other stroke measures, in over two million patient records at 1,300 hospitals. Two new exclusions were added to this measure: the first, 'Patients with IV or IA Thrombolytic Therapy Administered at This Hospital or Within 24 Hours Prior to Arrival.' The developer noted that this element would account for patients transferred in from other centers; and the second, 'Patients with a documented Reason for Not Administering Antithrombotic Therapy by End of Hospital Day 2.'

3. Feasibility: H-5; M-18; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee acknowledged that the measure had been in place for several years; however, one member noted that the timing of the measure at 'hospital day two' was not a standard time frame for similar measures. The developer referenced the CAST trial that demonstrated the benefit of antithrombotic therapy within the first 48 hours. The developer further clarified that feedback from initial implementation of the measure found the time frame too difficult to capture; therefore the measure was then changed to 'hospital day two.'

4. Usability and Use: H-19; M-4; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The Committee believed the measure met the usability and use criterion since it is currently publicly reported in the CMS IQR and Hospital Compare.

5. Related and Competing Measures

- Measure #0438 and measure #0435 Discharged on Antithrombotic Therapy are related measures. They have a similar measure focus and patient population. However, the timeframe for antithrombotic administration is different in both measures. Measure #0435 focuses on the prescription of antithrombotic medications at the time of hospital discharge, while #0438 focuses on the delivery of antithrombotic therapy administered by end of hospital day two for ischemic stroke patients.
- In 2012 the Committee suggested that the developer develop a composite measure that includes #0435 and #0438; this composite measure would assess the percentage of patients who receive appropriate care at both time points and therefore provide more opportunity for improvement.
- During the post in-person meeting call, the Committee restated their suggestion to develop a composite measure. However, both #0435 and #0438 have been recommended for inactive endorsement with reserve status. A combined measure would have to be submitted as a new measure.

Standing Committee Recommendation for Endorsement with Reserve Status: **Y-21; N-2**

0438 STK 05: Antithrombotic Therapy By End of Hospital Day Two

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0439 STK-06: Discharged on Statin Medication

Submission | Specifications

Description: This measure captures the proportion of ischemic stroke patients who are prescribed a statin medication at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic stroke patients prescribed statin medication at hospital discharge

Denominator Statement: Ischemic stroke patients

Exclusions: • Less than 18 years of age

- Length of Stay > 120 days
- Comfort measures only documented
- Enrolled in clinical trials related to stroke
- Admitted for elective carotid intervention
- Discharged to another hospital
- Left against medical advice
- Expired
- Discharged to home for hospice care
- Discharged to a health care facility for hospice care
- Documented reason for not prescribing statin medication at discharge

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-17**; **M-1**; **L-0**; **I-0**; 1b. Performance Gap: **H-0**; **M-5**; **L-12**; **I-0**

<u>Rationale</u>:

- The Committee accepted the prior evaluation of this measure because they believed there was strong evidence that statin therapy prescribed at discharge improved outcomes for stroke patients.

0439 STK-06: Discharged on Statin Medication

- The developer stated that the performance gap data presented were based on the previous denominator, where all patients with an LDL greater than 100 mg/dL were included. The current measure includes all patients with an LDL greater than 70 mg/dL. The developer was unable to update the measure submission with the revised guidelines because the release of this new information did not coincide with NQF's measure submission deadline. The developer stated they could provide one quarter's worth of performance data for the Committee's consideration. The Committee agreed to defer voting on this measure until performance data were submitted. During the Post Comment Call on June 23, 2016, the Committee agreed that there was sufficient evidence to support this measure but did not believe the measure met the criteria for opportunity for improvement. After reviewing additional performance gap data submitted by the developer, the Committee noted that the performance gap of 12 to 13% was among the lowest 10 percent of hospitals.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-15**; **M-1**; **L-0**; **I-0;** 2b. Validity: **H-16**; **M-0**; **L-0**; **I-0**

<u>Rationale</u>:

- The developer did not provide any new reliability testing for the Committee's consideration. Reliability testing consisted of inter rater-reliability of the data elements across one year in 77 hospitals and 739 patients. The overall agreement rate was 96.7%.
- The Committee reviewed updated validity testing which consisted of an analysis of 1,318 hospitals and 2,206,379 patient records. The Pearson Correlation Coefficient results showed a statistically significant, positive correlation of this measure with six other stroke performance measures.
- Overall, the Committee believed this measure met the scientific acceptability criteria.

3. Feasibility: H-15; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee noted that the measure had been in use for several years and therefore passed the measure on feasibility.

4. Usability and Use: H-17; M-0; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- The Committee agreed that the measure met criteria for usability and use since it has been publicly reported and used in several accountability programs.

5. Related and Competing Measures

Measure #0439 is related to the following measures:

- #0118 Anti-Lipid Treatment Discharge
- #0074 Chronic Stable Coronary Artery Disease: Lipid Control
- #1519 Statin Therapy at Discharge after Lower Extremity Bypass
- #0545 Adherence to Statins for Individuals with Diabetes Mellitus

These measures are related to #0439 but they address other diseases or specific surgical procedures. Specifically, measure #0118 is at the provider level and targets patients undergoing coronary artery bypass graft (CABG) in an ambulatory care setting; measure #0074 is also at the provider level and targets patients with a diagnosis of coronary artery disease in an ambulatory care setting; and #1519 focuses on clients undergoing lower extremity bypass surgery. Measure #0545 addresses adherence to statins for eligible patients with diabetes mellitus.

Standing Committee Recommendation for Inactive Endorsement with Reserve Status: **Y-17**; **N-0**

0439 STK-06: Discharged on Statin Medication

6. Public and Member Comment

One comment was received:

- The American Association of Neuroscience Nurses strongly urges the committee to vote on this measure. Even with lowering of the LDL level to 70, hospitals will continue to show room for improvement.

Committee Response: After a review of the comment, the Committee voted on this measure but did not pass it on opportunity for improvement. The Committee did not believe the measure demonstrated a performance gap, noting that the gap had decreased over time. The measure met the remaining NQF criteria and was therefore recommended for inactive endorsement with reserve status.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0441 STK-10: Assessed for Rehabilitation

Submission | Specifications

Description: This measure captures the proportion of ischemic or hemorrhagic stroke patients assessed for or who received rehabilitation services during the hospital stay.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, and STK-8: Stroke Education) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic or hemorrhagic stroke patients assessed for or who received rehabilitation services.

Denominator Statement: Ischemic or hemorrhagic stroke patients.

Exclusions: • Less than 18 years of age

• Length of Stay > 120 days

• Comfort measures only documented

• Enrolled in clinical trials related to stroke

• Admitted for elective carotid intervention

• Discharged to another hospital

• Left against medical advice

• Expired

• Discharged to home for hospice care

• Discharged to a health care facility for hospice care

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

0441 STK-10: Assessed for Rehabilitation

1. Importance to Measure and Report: <u>The measure did not meet the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation;** 1b. Performance Gap: **H-0; M-2; L-21; I-0**

<u>Rationale</u>:

- The Committee agreed that the underlying rationale for the measure appears to be the same since the last NQF endorsement review. The Committee accepted the prior evaluation on evidence without further discussion.
- The developer provided performance scores based on data from 2010-2014. National hospital performance rates have been consistent at 98%, showing minimal opportunity for improvement.
- Because the measure failed on performance gap, the measure was eligible for consideration for inactive endorsement with reserve status.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2; M-20; L-1; I-0;** 2b. Validity: **H-20; M-3; L-0; I-0**

<u>Rationale</u>:

- Inter rater-reliability of the data elements for one year (4Q2010-3Q2011) in 77 hospitals and 739 patient records showed an overall agreement rate of 98.3%.
- The Committee agreed there were no major changes in reliability since the last submission and that the new testing data continued to support reliability of the measure.
- Empirical validity testing, conducted at the measure score level with 1,318 hospitals and 2,206,379 patients records, generated p-values that show a statistically significant (P<.0001), positive correlation of this measure with six other stroke performance measures. These results support the hypothesis that hospitals with high quality on one stroke measure tend to have high performance on the other stroke measures.

3. Feasibility: H-20; M-3; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The required data elements are routinely generated and used during care delivery. The required data elements are available in electronic form and should be ready for operational use.

4. Usability and Use: H-20; M-3; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

<u>Rationale</u>:

- This measure is currently in used in the CMS Hospital Compare and IQR program. No concerns regarding usability and use were noted.

5. Related and Competing Measures

No related or competing measures noted.

Standing Committee Recommendation for Inactive Reserve Status: Y-22; N-1

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

Measure Recommended for Approval for Trial Use

2872 Dementia – Cognitive Assessment

Submission | Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period.

Numerator Statement: Patients for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period

Definition: Cognition can be assessed by the clinician during the patient´s clinical history. Cognition can also be assessed by direct examination of the patient using one of a number of instruments, including several originally developed and validated for screening purposes. This can also include, where appropriate, administration to a knowledgeable informant. Examples include, but are not limited to:

-Blessed Orientation-Memory-Concentration Test (BOMC)

-Montreal Cognitive Assessment (MoCA)

-St. Louis University Mental Status Examination (SLUMS)

-Mini-Mental State Examination (MMSE) [Note: The MMSE has not been well validated for non-Alzheimer´s dementias]

-Short Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)

-Ascertain Dementia 8 (AD8) Questionnaire

-Minimum Data Set (MDS) Brief Interview of Mental Status (BIMS) [Note: Validated for use with nursing home patients only]

-Formal neuropsychological evaluation

-Mini-Cog

Denominator Statement: All patients, regardless of age, with a diagnosis of dementia

Exclusions: Exceptions: Documentation of medical reason(s) for not assessing cognition (eg, patient with very advanced stage dementia, other medical reason)

Documentation of patient reason(s) for not assessing cognition

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Behavioral Health/Psychiatric : Inpatient, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other, Ambulatory Care : Urgent Care

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: Physician Consortium for Performance Improvement (PCPI)

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-6; M-11; L-0; I-1**; 1b. Performance Gap: **H-14; M-4; L-0; I-0;**

Rationale:

- The intent of the measure is to encourage initial and ongoing cognitive assessments in patients with any type of dementia across care settings. A Committee member questioned how the information was used to influence decisions about patient care.
- Another Committee member noted that cognitive assessment for patients with dementia is already in place through annual Medicare wellness visits.
- The Committee acknowledged that the 63.93% performance rate indicated a strong gap in performance.

2872 Dementia – Cognitive Assessment

They also requested that the developer collect disparities data during trial use of the measure.

2. Scientific Acceptability of Measure Properties: This e-measure is a candidate for eMeasure Approval for Trial Use; therefore, testing for the measure will be submitted at a later time**.** (2b1. Specifications consistent with evidence)

eMeasure Trial Measure Specifications: H-6; M-11, L-0; I-0

This measure may be considered for endorsement after sufficient data to assess reliability and validity have been submitted to NQF, within three years of approval.

Rationale:

- The Committee discussed whether the measure specifications were consistent with the evidence. A Committee member questioned the wording of the numerator that indicated the assessment had to be performed and reviewed. The developer responded that they are particularly interested in whether or not the assessment was performed. Overall, the Committee agreed that the measure specifications were adequate and that the measure could be recommended for Approval for Trial Use.

3. Feasibility: H-8; M-8; L-1; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee accepted that the measure was feasible since it was tested with an electronic health record (EHR) vendor and a national network of post-acute care facilities, both providing favorable reports on feasibility.
- A Committee member questioned whether the measure would be feasible in acute care and primary care settings. The developer assumes the measure would be feasible in those environments since the two EHR vendors that tested feasibility also allow the EHR system to be used in ambulatory care settings and physicians' offices.

4. Usability and Use: H-10; M-7; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently used in the CMS PQRS and Meaningful Use Stage 2 programs. Without further discussion, the Committee agreed that the measure met the *Usability and Use* criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for eMeasure Approval for Trial Use: **Y-17; N-0**

6. Public and Member Comment

Two comments were received:

- The American Association of Neuroscience nurses feels that it is reasonable that a person diagnosed with dementia would have a cognitive assessment/reassessment annually.
- Otsuka America Pharmaceutical, Inc., part of the Otsuka Group, is focused on bringing novel medicines and new healthcare products to the U.S., and is invested in efforts to advance the quality of life for patients with Alzheimer's disease and their families. We appreciate the opportunity to comment on the NQF Neurology Project measures currently under review. Otsuka supports NQF's efforts to capture the percentage of patients with a diagnosis of dementia who receive a cognitive assessment and subsequent annual reviews of the results through measure 2872 Dementia-Cognitive Assessment.

Developer Response: A review of the measure is performed annually to determine if there is new information that supports changes to the measure. This review includes consideration of expanding the list of numerator exclusions using specific ICD codes. The comment to consider excluding persons with dementia who also have

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severe agitation will be considered during our annual review. • After a review of the comments, the Committee did not reconsider their vote to recommend this measure for trial use.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Not Recommended

1814 Counseling for Women of Childbearing Potential with Epilepsy

Submission | Specifications

Description: All female patients of childbearing potential (12–44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year

Numerator Statement: Female patients or caregivers counseled* at least once a year about how epilepsy and its treatment may affect contraception OR pregnancy.

*Counseling should include a discussion about folic acid supplementation, contraception, potential anti-seizure medications effect(s) on pregnancy, safe pregnancies, and breastfeeding.

Denominator Statement: All females of childbearing potential (12-44 years old) with a diagnosis of epilepsy.

Exclusions: Excluded: patients diagnosed with menopause or surgically sterile.

Exceptions:

Patient has a diagnosis of neurodevelopmental disorder, encephalopathy, hydrocephalus, brain injury, or cerebral palsy.

Patient has a diagnosis of severe cognitive impairment or severe intellectual disability.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: American Academy of Neurology

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0; M-2; L-3; I-15**; 1b. Performance Gap: **H-17; M-2; L-1; I-0;** Evidence Exception: **Y-18; N-2**

Rationale:

- The Committee reviewed updated evidence for this measure but questioned whether there was direct evidence that counseling leads to improved outcomes in women with epilepsy. A Committee member questioned the absence of data for this maintenance measure.
- A Committee member also questioned the difference between counseling women with epilepsy and counseling women in general, and whether the measure could be used to influence providers' behaviors. Another Committee member stated that counseling did not have an impact on pregnancy.
- The measure did not pass on the evidence criterion but the Committee did vote on the exception to the lack of empirical evidence.
- The Committee reviewed data that show less than 40% of women received counseling about epilepsy and epilepsy treatment. The Committee agreed this measure showed sufficient opportunity for improvement.

2. Scientific Acceptability of Measure Properties: This measure does not meet the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0; M-7; L-11; I-2; I-1;** 2b. Validity: **H-0; M-13; L-2; I-4**

Rationale:

- Reliability testing was conducted using data element validity testing at three neurology practices. The Committee questioned whether testing in three practices was sufficient. The Committee questioned why the developer had not re-tested the measure in three new practices to determine if a problem identified

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with exclusion criteria (i.e., patients with intellectual disability) had been resolved. The Committee could not reach consensus on the reliability criterion.

- In discussing validity, the Committee voiced concern over the exclusion for patients with intellectual disability, which they believed was open to interpretation. The developer revised the measure to clarify which patients would meet the intellectual disability exclusion criteria.
- A Committee questioned how the various modes of counseling outlined in the measure are distinguished from one another. Ultimately, the Committee believed the measure met the validity criterion.
- During the Post Comment Call, the Committee again discussed the reliability of the measure and the specification of the denominator exclusions. Because additional testing data on the new exclusions was not provided for the Committee's review, the Committee believed this measure did not meet the *Reliability* criterion.

3. Feasibility: H-0; M-17; L-1; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee questioned how data are pulled from the electronic health record without additional burden of completing a chart review. The developer explained that a data dictionary was created to capture the variations of words that could be used for each data element rather than those explicitly listed in the measure.
- The Committee noted that participating sites could generate the required data elements; one facility, however, reported difficulty with this.

4. Usability and Use: H-2; M-16; L-0; I-0

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- The measure is currently in use within the CMS PQRS.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-12; N-6**

Rationale:

- The measure did not pass the evidence criterion; however, it passed on the exception to empirical evidence criterion.
- The Committee could not reach consensus on reliability, a must pass criterion. The Committee will revote on the measure during the Post Comment call on June 23, 2016

6. Public and Member Comment

One Comment was received from the developer:

- The AAN encourages the Committee to make a decision to re-endorse this measure. The AAN notes the report highlights the Committee's concerns with validity, specifically that testing was conducted at three practices and feasibility of extracting data elements based on exclusions, which may all be documented differently. The AAN worked with Minnesota Community Measurement to test the measure using the NCQA process for validation. The testing report indicated, "The validation process was successful in identifying errors (with subsequent corrections) and verifying the accuracy of the data submitted by medical groups A, B, and C. Finding no significant flaws or errors with the data MNCM is confident the rate calculation and any additional data analysis can be completed using validated and reliable data." The AAN believes this testing is sufficient to represent the variety of providers whose performance will be measured. The AAN previously submitted this same testing data to CSAC who recommended the measure

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for continued endorsement noting denominator exceptions should be further specified. The AAN convened a measure work group to update the measure. The work group agreed to further specification and clarification of denominator exclusions. Denominator exclusions are now clearly defined with greater specificity reducing documentation concerns given discreet diagnoses required to meet exclusion requirements. This measure has the opportunity to improve outcomes for women with epilepsy and future potential offspring.

Committee response: After a review of the comment, the Committee again discussed the reliability of the measure and the further specification of the denominator exclusions. Without having new testing data on the new exclusions to review, the Committee believed this measure did not meet the reliability criterion.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2832 STK 02: Discharged on Antithrombotic Therapy

Submission

Description: This measure captures the proportion of ischemic stroke patients prescribed antithrombotic therapy at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. STK-2, Discharged on Antithrombotic Therapy, is one of six of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Patients prescribed antithrombotic therapy at hospital discharge.

Denominator Statement: Patients with a principal diagnosis of ischemic stroke.

Exclusions: Denominator Exclusions:

Patients with comfort measures documented.

Patients admitted for elective carotid intervention. This exclusion is implicitly modeled by only including non-elective hospitalizations.

Patients discharged to another hospital

Patients who left against medical advice

Patients who expired

Patients discharged to home for hospice care

Patients discharged to a health care facility for hospice care

Denominator Exceptions:

Patients with a documented reason for not prescribing antithrombotic therapy at discharge.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data :

2832 STK 02: Discharged on Antithrombotic Therapy

Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-21; M-2; L-0; I-0**; 1b. Performance Gap: **H-0; M-0; L-18; I-5**

<u>Rationale</u>:

- This measure has been re-specified from a legacy, paper-based measure (#0435) into an eMeasure. The legacy registry measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also believed this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.

Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2833 STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter

<u>Submission</u>

Description: This measure captures the proportion of ischemic stroke patients with atrial fibrillation/flutter who are prescribed anticoagulation therapy at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. STK-3, Anticoagulation Therapy for Atrial Fibrillation/Flutter, is one of six of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Patients prescribed anticoagulation therapy at hospital discharge.

Denominator Statement: Patients with a principal diagnosis of ischemic stroke, history of atrial ablation, and current or history of atrial fibrillation/flutter.

Exclusions: Denominator Exclusions:

Patients with comfort measures documented.

Patients admitted for elective carotid intervention. This exclusion is implicitly modeled by only including non-elective hospitalizations.

Patients discharged to another hospital.

Patients who left against medical advice.

Patients who expired.

Patients discharged to home for hospice care.

Patients discharged to a health care facility for hospice care.

Denominator Exceptions:

2833 STK-03: Anticoagulation Therapy for Atrial Fibrillation/Flutter

Patients with a documented reason for not prescribing anticoagulation therapy at discharge.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: The measure does not meet the Importance criteria

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-0; M-6; L-17; I-0**

Rationale:

- This measure has been re-specified from a legacy, paper-based measure (#0436) into an eMeasure. The legacy registry measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also believed this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.

Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

- No comments received.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2834 STK 04: Thrombolytic Therapy

Submission | Specifications

Description: This measure captures the proportion of acute ischemic stroke patients who arrive at this hospital within 2 hours of time last known well for whom IV t-PA was initiated at this hospital within 3 hours of time last known well.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. STK-4, Thrombolytic Therapy, is one of six of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Acute ischemic stroke patients for whom IV thrombolytic therapy was initiated at this hospital within 3 hours (less than or equal to 180 minutes) of when it was witnessed or reported that the patient was last known to be without the signs and symptoms of the current stroke or at his or her baseline state of health.

Denominator Statement: Ischemic stroke patients admitted through the Emergency Department whose time of

2834 STK 04: Thrombolytic Therapy

arrival is within 2 hours (less than or equal to 120 minutes) of the 1) time they were known to be at their baseline state of health; or 2) time of symptom onset if time last known at baseline state is not known.

Exclusions: Denominator Exclusions: None.

Denominator Exceptions:

- Patients with comfort measures documented on the day of or the day after arrival
- Patients with intra-venous or intra-arterial Thrombolytic (t-PA) Therapy prior to arrival
- Patients with documentation of a National Institutes for Health Stroke Scale (NIHSS) score of zero in the emergency department
- Patients with Medical Reasons for not initiating IV thrombolytics documented by a physician/APN/PA or pharmacist on the day of or the day after arrival
- Patients with any of the following results within 180 minutes of the 1) time they were known to be at their baseline state of health; or 2) time of symptom onset:
- Prothrombin Time > 15 seconds
- Platelet Count <100,000
- INR >1.7
- Partial Thromboplastin Time > 40 seconds
- Systolic Blood Pressure > 185 mmHg
- Diastolic Blood Pressure > 110 mmHg
- Patient refusal

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **Accepted Prior Evaluation**

<u>Rationale</u>:

- The developer reported that the evidence and opportunity for improvement was identical to the legacy, paper-based measure (#0437 STK04: Thrombolytic Therapy), with the exception of additional exclusions in the electronic version. The Committee then accepted the prior evaluation of this measure on evidence and opportunity for improvement.

2. Scientific Acceptability of Measure Properties: <u>This measure does not meet the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0; M-2; L-12; I-3;** 2b. Validity: **H-4; M-14; L-2; I-3**

<u>Rationale</u>:

- The Committee expressed concern that the eMeasure had not been tested in more than one electronic health record as required by NQF standards. NQF staff clarified that that requirement applied to non-legacy measures and that this measure would be considered a legacy measure since the registry version is in use in federal programs.
- A Committee member disagreed that BONNIE testing was acceptable to meet reliability testing standards.

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NQF staff clarified that if the developer demonstrates data element validity, then additional reliability testing is not required. It was also stated that in the case of this measure, the developer initially had not submitted data on threats to validity. The developer was able to provide this information to the Committee prior to the in-person meeting.

- Another Committee member sought clarity on the wording of the denominator 'time of symptom onset if time last known at baseline state is not known.' The member pointed out that this wording differed from the registry measure denominator statement 'time last known well.' The developer explained that in order to better specify time last known well in the electronic health record, both data elements were included to capture time last known well. The Committee did not reach consensus on the reliability criterion.
- During the Post Comment Call, the Committee reviewed reliability of this measure but still believed that BONNIE testing was not sufficient for reliability testing. Therefore, the Committee did not pass the measure on this criterion.
- The Committee accepted BONNIE testing for measure validity, which included testing in synthetic patient records. One Committee member asked if patients under age 18 were excluded from the measure. The developer confirmed that patients under 18 were excluded. The Committee passed the measure on validity.

3. Feasibility: H-0; M-6; L-1; I-16

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The developer stated that hospitals reporting on this measure attested to the eCQM specifications, indicative of the feasibility of the measure. However, the Committee felt they could not assess feasibility without real-world data. NQF staff stated that a feasibility report was created in lieu of a score card. Staff also clarified that the feasibility assessment was based on BONNIE performance and demonstrated the measure logic was functional. A Committee member then questioned whether evidence that the measure can be implemented in a real electronic health record was required for feasibility, to which NQF staff stated that it was not required for a legacy measure.
- A Committee member asked for further clarity on the synthetic testing and how it is applied in the real world. The developer stated that the BONNIE testing was a proxy for feasibility because it confirms that the measure logic is accurate in all permutations of the data.
- Another Committee member questioned how confirming feasibility through the measure logic differed from validity. The developer responded that CMS had collected data on this measure for some time and that changes have been made to the measure to improve feasibility. The Committee did not pass the measure on feasibility.

4. Usability and Use: H-2; M-11; L-4; I-6

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

Rationale:

- A Committee member stated that usability and use for this measure did not differ much from the registry measure but another member raised concern about the unintended consequences of treating patients experiencing stroke mimics. The Committee did not reach consensus on this criterion.

5. Related and Competing Measures

Measure #2834 is the eCQM version of #0437, and is therefore also related to #1952 Time to Intravenous Thrombolytic Therapy and #0288 Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. These measures have a similar measure population and focus, but #1952 focuses on the timely administration of tPA rather than whether tPA should be administered for eligible patients (i.e., there could be varying reasons that a client is not treated within 60 minutes). The developer stated that measure #0437 and #1952 have been harmonized to the

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extent possible. Measure #0288 is focused on patients with acute myocardial infarction receiving fibrinolytic therapy.
Standing Committee Recommendation for Endorsement: **Y-4; N-19**
6. Public and Member Comment
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2835 STK 05: Antithrombotic Therapy By End of Hospital Day Two
Submission
Description: This measure captures the proportion of ischemic stroke patients who had antithrombotic therapy administered by end of hospital day two (with the day of arrival being day 1). This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-6: Discharged on Statin Medication, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. STK-5, Antithrombotic Therapy By End of Hospital Day Two, is one of six of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program. **Numerator Statement**: Patients who had antithrombotic therapy administered the day of or day after hospital arrival. **Denominator Statement**: Patients with a principal diagnosis of Ischemic stroke. **Exclusions**: Denominator Exclusions: • Patients who have a duration of stay less than 2 days • Patients with comfort measures documented on day or the day after arrival • Patients with intra-venous or intra-arterial Thrombolytic (t-PA) Therapy administered within 24 hours prior to arrival or anytime during hospitalization. Denominator Exceptions: • Patients with a documented reason for not administering antithrombotic therapy the day of or day after hospital arrival. **Adjustment/Stratification**: No risk adjustment or risk stratification. **Level of Analysis:** Facility, Population : National **Setting of Care:** Hospital/Acute Care Facility **Type of Measure**: Process **Data Source**: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy **Measure Steward**: The Joint Commission
STANDING COMMITTEE MEETING [04/04/2016-04/05/2016] **1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>** (1a. Evidence: 1b. Performance Gap) 1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-0; M-3; L-20; I-0**

2835 STK 05: Antithrombotic Therapy By End of Hospital Day Two

Rationale:

- This measure has been re-specified from a legacy, paper-based measure (#0438) into an eMeasure. The legacy registry measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also felt this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.

Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2836 STK-06: Discharged on Statin Medication

Submission | Specifications

Description: This measure captures the proportion of ischemic stroke patients who are prescribed a statin medication at hospital discharge.

This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-8: Stroke Education, and STK-10: Assessed for Rehabilitation) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs. STK-6, Discharged on Statin Medication, is one of six of the measures in this set that have been reengineered as eCQMs and are included in the EHR Incentive Program and Hospital Inpatient Quality Reporting Program.

Numerator Statement: Patients prescribed statin medication at hospital discharge.

Denominator Statement: Patients with a principal diagnosis of ischemic stroke.

Exclusions: Denominator Exclusions:

Patients admitted for elective carotid intervention. This exclusion is implicitly modeled by only including non-elective hospitalizations.

Patients with comfort measures documented.Patients discharged to another hospital

Patients who left against medical advice

Patients who expired

Patients discharged to home for hospice care

Patients discharged to a health care facility for hospice care

Patients with an LDL-c of less than 70 mg/dL <30 days prior to arrival or any time during the hospital stay

Denominator Exceptions:

Patients with a reason for not prescribing statin medication at discharge.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy

2836 STK-06: Discharged on Statin Medication

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure does not meet-the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-5**; **M-11**; **L-1**; **I-0**; 1b. Performance Gap: **H-0**; **M-2**; **L-14**; **I-1**

<u>Rationale</u>:

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Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

One comment was received:

- The American Association of Neuroscience Nurses strongly urges the committee vote on this measure.
- After review of the comment, the Committee discussed that the measure did have sufficient evidence to support the use of statins at discharge. However, after reviewing performance gap and disparities data, the Committee did not believe the data showed an opportunity for improvement as the performance gap had decreased over time. The Committee also noted that the disparities were most notable in older data cohorts, but less so in the more recent cohorts. Therefore, this measure did not pass on this criteria and was not recommended for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2837 STK-10: Assessed for Rehabilitation

Submission

Description: This measure captures the proportion of ischemic or hemorrhagic stroke patients assessed for or who received rehabilitation services during the hospital stay. This measure is a part of a set of eight nationally implemented measures that address stroke care (STK-1: Venous Thromboembolism (VTE) Prophylaxis, STK-2: Discharged on Antithrombotic Therapy, STK-3: Anticoagulation Therapy for Atrial Fibrillation/Flutter, STK-4: Thrombolytic Therapy, STK-5: Antithrombotic Therapy By End of Hospital Day 2, STK-6 Discharged on Statin Medication, and STK-8: Stroke Education) that are used in The Joint Commission's hospital accreditation and Disease-Specific Care certification programs.

Numerator Statement: Ischemic or hemorrhagic stroke patients assessed for or who received rehabilitation services.

Denominator Statement: Patients age 18 and older discharged from inpatient care (non-elective admissions) with a principal diagnosis of ischemic or hemorrhagic stroke and a length of stay less or equal to 120 days.

Exclusions: Patients with comfort measures documented

Patients admitted for elective carotid intervention. This exclusion is implicitly modeled by only including non-elective hospitalizations.

Patients discharged to another hospital

Patients who left against medical advice

Patients who expired

Patients discharged to home for hospice care

2837 STK-10: Assessed for Rehabilitation

Patients discharged to a health care facility for hospice care

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: The measure does not meets the Importance criteria

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-X**; **M-X**; **L-X; IE-X**; **I-X**; 1b. Performance Gap: **H-0; M-2; L-21; I-0**

Rationale:

- This measure has been re-specified from a legacy, paper-based measure (#0441) into an eMeasure. The legacy registry measure did not pass the criterion for opportunity for improvement. Using the same data from the legacy measure to review this eMeasure, the Committee also felt this measure did not demonstrate an opportunity for improvement. Therefore, the measure was not recommended for endorsement.

Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2865 CSTK-02: Modified Rankin Score (mRS) at 90 Days

Submission | **Specifications**

Description: Proportion of ischemic stroke patients age 18 years and older treated with intra-venous (IV) or intra-arterial (IA) thrombolytic (t-PA) therapy or who undergo mechanical endovascular reperfusion therapy for whom a 90 day (greater than or equal to 75 days and less than or equal to 105 days) mRS is obtained via telephone or in-person.

This is the second measure in a set of measures developed for Joint Commission Comprehensive Stroke Certification. The other measures in the set include CSTK-01 National Institutes of Health Stroke Scale (NIHSS) Score Performed for Ischemic Stroke Patients; CSTK-03 Severity Measurement Performed for Subarachnoid Hemorrhage (SAH) and Intracerebral Hemorrhage (ICH) Patients (Overall Rate); CSTK-06 Nimodipine Treatment Administered. Although it is not required that these measures are reported in conjunction with each other, The Joint Commission develops measures in sets in order to provide as comprehensive a view of quality for a particular clinical topic as possible.

Numerator Statement: Ischemic stroke patients for whom a 90 day (greater than or equal to 75 days and less than or equal to 105 days) mRS is obtained via telephone or in-person.

Denominator Statement: Ischemic stroke patients treated with IV or IA thrombolytic (t-PA) therapy or who undergo mechanical endovascular reperfusion therapy.

Exclusions: • Patients less than 18 years of age

• Patients who have a Length of Stay greater than 120 days

2865 CSTK-02: Modified Rankin Score (mRS) at 90 Days

• Patients admitted for Elective Carotid Intervention

• Patients who expire during the hospital stay

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data, Paper Medical Records

Measure Steward: The Joint Commission

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure does not meet the Importance criteria</u>

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-0; M-2; L-3; I-17**; Insufficient Evidence with Exception: **Y-11; N-11**; 1b. Performance Gap: **H-X**; **M-X**; **L-X**; **I-X**

<u>Rationale</u>:

- The Committee noted the measure cited expert opinion and not systematic review of the evidence in support of the 90 day time period for follow up. The developer noted that the 90 day timeframe was chosen based on the NINDS-tPA trial in 1996.
- The Committee debated the appropriateness of holding providers accountable for this measure in the absence of evidence that is linked to the outcome. After failing on evidence, the Committee moved to vote for exception to the empirical evidence criterion but failed to reach consensus. Therefore, the measure failed on this criterion and was not recommended for endorsement.

Standing Committee Recommendation for Endorsement: **No Vote Taken**

6. Public and Member Comment

One comment was received:

- The American Association of Neuroscience Nurses understands that this measure is difficult to implement and for staff but it is the sole outcome measure for stroke care. AANN recommends that this measure be implemented for patient outcomes.
- After a review of the comment, the Committee stated that the measure did not meet NQF criteria for evidence and did not reconsider their recommendation on this measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2870 Overuse of Opioid Containing Medications for Primary Headache Disorders

Submission | Specifications

Description: Percentage of patients aged 12 years and older diagnosed with primary headache disorder, and taking an opioid containing medication who were assessed for opioid containing medication overuse within the 12-month measurement period, and treated or referred for treatment if identified as overusing opioid containing medication.

Numerator Statement: Patients assessed for opioid containing medication overuse within the 12-month measurement period and treated or referred for treatment if identified as overusing opioid containing medication which is defined as: Using opioid containing medication for greater than or equal to 10 days per month for more

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than 2 months.

Denominator Statement: All patients aged 12 years and older diagnosed with a primary headache disorder* and taking opioid containing medication.

*Define Primary Headache: A headache that is not caused by another disease or medical condition. For the purpose of this measure this measure this includes the following types of headache:

Migraine - Migraine without aura, migraine with aura, childhood periodic syndromes that are commonly precursors of migraine, retinal migraine, complications of migraine, probable migraine.

Tension-Type Headache (TTH) - Infrequent episodic TTH, frequent episodic TTH headache, chronic TTH, probable TTH

Cluster Headache (CH) and Other Trigeminal Autonomic Cephalgias: Cluster headache, paraxysmal hemicrania, short-lasting unilateral neuralgia from headache attacks with conjuctival injection and tearing (SUNCT), probably trigeminal autonomic cephalgia

Other Primary Headaches: Primary stabbing headache, primary cough headache, primary exertional headache, primary headache associated with sexual activity, hypnic headache, primary thunderclap headache, hemicrania continua, new daily-persistent headache.

Exclusions: No Exclusions. Medical exceptions for not assessing, treating, or referring patient for treatment of opioid medication overuse include:Patient already assessed and treated for opioid use disorder within the last year. Patient has a documented failure of non-opioid options and is not identified as overusing opioid containing medication. Patient has contraindications to all other medications for primary headache.

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Emergency Medical Services/Ambulance, Hospital/Acute Care Facility, Ambulatory Care : Urgent Care

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: American Academy of Neurology

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure did not meet the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-0**; **L-2**; **I-17**; 1b. Performance Gap: **No Votes Taken**

<u>Rationale</u>:

- This process measure was newly presented to the Committee and was submitted for the NQF Approval for Trial Use program. The developer provided a study of nearly 6,000 patients of which 15.9% were current users of opioids. The study found that rates of rebound headache and healthcare resource utilization were greater for opioid users than non-users.
- The Committee countered the evidence by stating that more intractable patients could have been prescribed opioids resulting in more rebound headaches and greater healthcare resource utilization. The Committee also acknowledged statements by the Centers for Disease Control and Prevention and the Food and Drug Administration, citing the risks of opioid prescriptions. Overall, the Committee believed there was not sufficient evidence to support this measure and did not recommend it for endorsement.

2. Scientific Acceptability of Measure Properties

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-X; M-X; L-X; I-X;** 2b. Validity: **H-X; M-X; L-X; I-X**

3. Feasibility: H-X; M-X; L-X; I-X

2870 Overuse of Opioid Containing Medications for Primary Headache Disorders

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

4. Usability and Use: H-X; M-X; L-X; I-X

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures

No related or competing measures identified.

Standing Committee Recommendation for Endorsement: **No vote taken.**

6. Public and Member Comment

Two comments were received:

- The AAN strongly disagrees with the Committee decision to not recommend this measure for trial use. The introduction to your report states, "Headache disorders are one of the most common disorders of the nervous system. While other classes of medications are considered first line of treatment for migraines, opioids are typically used. Common adverse effects of using opioids include tolerance, dependence and addiction, which in turn have a negative impact on patients, families and communities." It is evident with actions in Congress and in state legislatures that the opioid epidemic is in the forefront of health policy and public health. The AAN believes that use of this measure will 1) assess where improvements to care are needed; 2) demonstrate improved outcomes with counseling; and 3) improve evidence and research surrounding opioid use with headache. Given the prevalence of opioid overuse and their use as a first line treatment despite availability of other medications, a measure focusing on inappropriate treatment is warranted for patients with headache. Measures to decrease the potential for opioid abuse and addiction will greatly benefit our healthcare system. Given the current crisis and focus with opioid medications, this measure addresses a portion of this issue and addresses a major gap. The AAN notes addressing overuse in headache is possible given the existence of first line treatment alternatives, which is not possible for many other chronic pain conditions where few alternative treatments exist. The AAN feels an opportunity to greatly improve care and the outcomes of patients is being missed with the decision by NQF not to endorse this measure.
- The American Association of Neuroscience Nurses feels that this measure should have been implemented on a trial basis.
- After a review of the comments, the Committee decided there was not sufficient evidence for this measure to recommend it for approval for trial use. The Committee did not reconsider their recommendation on this measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2876 Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity

Submission | Specifications

Description: This stroke mortality measure estimates the hospital-level, risk-standardized mortality rate (RSMR) for patients discharged from the hospital with a principal discharge diagnosis of acute ischemic stroke. The outcome is all-cause 30-day mortality, defined as death from any cause within 30 days of the index admission date, including in-hospital death, for stroke patients. This is a newly developed measure with a cohort and outcome that is harmonized with CMS' current publicly reported claims-based stroke mortality measure and

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includes the National Institutes of Health (NIH) Stroke Scale as an assessment of stroke severity in the risk-adjustment model. This measure uses Medicare fee-for-service (FFS) administrative claims for the cohort derivation, outcome, and risk adjustment.

Numerator Statement: The outcome for this measure is 30-day, all-cause mortality. We define mortality as death from any cause within 30 days of the index admission for patients with a principal discharge diagnosis of acute ischemic stroke.

Denominator Statement: The cohort includes inpatient admissions to all non-federal, short-term, acute care hospitals for Medicare FFS patients age 65 years and older with a principal discharge diagnosis of acute ischemic stroke. Additional details are provided in S.9 Denominator Details.

Exclusions: The measure excludes admissions for patients:

1. With inconsistent or unknown vital status or other unreliable data;

2. Enrolled in the Medicare hospice program at any time in the 12 months prior to the index admission, including the first day of the index admission; and

3. Discharged against medical advice (AMA).

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

Adjustment/Stratification: No risk adjustment or risk stratification.

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Other, Electronic Clinical Data : Registry

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

STANDING COMMITTEE MEETING [04/04/2016-04/05/2016]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Y-19; N-0**; 1b. Performance Gap: **H-7; M-12; L-3; I-0**

<u>Rationale</u>:

- The developer highlighted studies demonstrating that appropriate, guideline-recommended care and timely treatment for stroke patients can reduce the risk of mortality within 30 days of hospital admission.
- The Committee agreed the evidence provided adequately supported the measure focus; however, questioned whether mortality is a valid quality indicator for stroke.
- The developer provided risk-standardized mortality rates using two data sources: July 2011 – June 2014 Medicare Administrative claims and 2013 AHA/ASA Get with the Guidelines-Stroke Registry. Both values for the NIHSS were obtained from the registry as a surrogate for NIHSS scores that will be obtained from ICD-10 codes beginning in October 2016. The mean mortality rates display further opportunity for improvement at 14.5%.
- The developer also presented disparities data using three subpopulations (Dual Eligibles, African Americans and AHRQ SES index) and at the hospital level, showing minimal differences in the mortality rates across hospitals.

2. Scientific Acceptability of Measure Properties: <u>This measure does not meet the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1; M-17; L-1; I-3;** 2b. Validity**: H-0; M-5; L-9; I-2**

<u>Rationale</u>:

- The Committee reviewed the Landis and Koch classification for intra-class-correlation coefficients (ICC) in

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considering the reliability of the measure. The developer noted they could compare data from claims and registry to ensure that the NIH stroke scale assessment is accurately captured. The Committee discussed the ICC value of .55, meaning that just over half of the variance in scores was due to differences between hospitals. The Committee wanted to ensure that hospitals of varying sizes were not being mischaracterized by using the ICC. The developer explained they create an interval estimate to protect against mischaracterization of facilities. The Committee questioned if reliability testing had to be performed using the other half of the case volume to determine if hospitals would fall into the same classification. There was also discussion on how the ICC value compares to myocardial infarction, pneumonia and heart failure mortality measures, to which the developer reported that it was similar.

- The Committee noted that face validity with expert opinion and feedback that the NIHSS is an important tool speaks to the measure validity.
- On the other hand, there were several issues raised on validity. Specifically, the Committee reviewed empiric validity testing of the measure score that compared the performance of the risk models for this measure to a similar stroke mortality measure employing registry data from Get with the Guidelines (GWG). The Committee noted that stroke severity from GWG was combined with administrative data to form a simulated data set. Results of validity testing displayed c-statistics of 0.8120 and 0.7939, respectively which showed that both models have a similar discriminating ability to identify the correct patient. A Committee member noted that this testing assumes that the same information pulled from the claims measure (this measure) would be mimicked when pulling from the registry measure (the similar measure), which also included variables that would not have been captured in the claims measure. The Committee also weighed whether the measure was truly assessing quality if patient preferences (e.g., patients with comfort measures had not been considered, noting that two patients with the same stroke severity may still have different care preferences. It was also noted that if patient preferences are not excluded and the patient dies then the death would count against the hospital. This led to a larger concern of the Committee as to whether the measure is actually measuring facility preferences rather than quality of care.
- In regard to missing data, 17% of NIHSS stroke scale scores were missing and the Committee voiced concern that this missing data was based on the simulated data and not real world data. Another issue raised by the Committee was that facilities may have an incentive to not document the stroke scale scores, since multiple imputation could be used to make up for the missing scores.
- The Committee also noted that the SDS factor race was not included in the final risk adjustment model, although race was a strong predictor of mortality. The Committee felt that reduced mortality was not a reflection of the quality of care but on the fact that African-Americans have more aggressive preferences for care.
- Finally, the Committee considered additional factors that could vary at the hospital level such as early 'Do not resuscitate' orders, which are a larger predictor of mortality than age. The Committee again felt that the measure could be measuring hospital preferences and not quality.

3. Feasibility: H-8; M-11; L-2; I-1

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Committee members acknowledged that the data elements are collected based on claims data, and generated or collected by healthcare providers.

4. Usability and Use: H-0; M-18; L-3; I-1

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

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Rationale:

- This measure is not currently in use in any public reported or accountability programs. However, CMS intends to implement this measure in the Hospital IQR program once the new NIH Stroke Scale ICD-10 codes have been in use for three years. This measure requires three years of claims data for calculation. Once one of the new measures (either the claims-based or hybrid measure) is implemented, it could replace the currently reported Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure.
- The Committee noted concerns of unintended consequences due to uncertainties as to how this measure would perform in the real world. They also noted that there seemed to be an incentive not to document NIHSS stroke scale scores.

5. Related and Competing Measures

- Measure #2876 and #2877 Hybrid hospital 30-day, all-cause, risk standardized mortality rate following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity are competing measures as they have the same patient populations and the same focus (ischemic stroke patients and 30-day mortality).
- Measure #2876 uses administrative claims data for risk adjustment. The developer noted that #2876 is otherwise harmonized with #2877.
- Measure #2876 is also related to #0467 Acute Stroke Mortality rate because the focus is on mortality in acute stroke patients. However, measure #0467 captures in hospital deaths per 1,000 discharges with acute stroke as the principal diagnosis for individuals aged 18 and older. Measure #2876 is a 30-day all cause RSMR including Medicare patients, aged 65 and older in the denominator.

Standing Committee Recommendation for Endorsement: **Y-17; N-5**

Rationale

- The Committee could not reach consensus on validity, a must pass criteria. The Committee will revote on the measure during the Post Comment call on June 23, 2016

6. Public and Member Comment

Two comments were received:

- My recollection of the conversation about race was that the concern was less about whether race should be included in the measure and more about whether the race-mortality relationship calls the validity of the measure into question. Specifically, the model finds that African-Americans have much lower mortality than whites. This is a finding that is very surprising and it is virtually impossible to imagine it is mediated through higher quality care. Conversely, it is quite plausible that this finding is mediated by differences in preferences. African-American patients, on average, have preferences for more aggressive care than whites. As such, it may be that race is serving as a partial marker of preferences. Without a measure of preferences, it is also unclear whether race should be accounted for in the model. As it stands, by not accounting for race, hospitals that take care of more African-Americans will have a substantial advantage on the model, whereas if race were included they would have a substantial disadvantage. The Committee did not believe this measure met the validity criterion due to the frequency of missing data and whether the method to assess validity was adequate. The Committee deliberated on whether race should be included in the model but the discussion focused more on the effect of race as a predictor for reduced mortality. The Committee further discussed that it is unlikely that this reflects much better care for African Americans and seems more likely that it reflects different preferences for care by race. One committee member suggested that race, in this specific situation, is a marker of the potential limitation of not understanding patient preferences.

- On April 5, 2016, the National Quality Forum's (NQF) Neurology Standing Committee evaluated NQF

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#2876: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute ischemic stroke hospitalization with claims-based risk adjustment for stroke severity for endorsement. Below we respond to critiques raised by the Committee:

1. "The Committee noted that face validity with expert opinion and feedback that the National Institutes of Health Stroke Severity NIHSS score is an important tool speaks to the measure validity."

   We agree that the addition of the NIHSS score is a critical advancement in measurement of mortality following admission for ischemic stroke and improves the validity of the mortality measure.

2. "On the other hand, there were several issues raised on validity. Specifically, the Committee reviewed empiric validity testing of the measure score that compared the performance of the risk models for this measure to a similar stroke mortality measure employing data from Get with the Guidelines. Results displayed a c-statistic of 0.8120 and 0.7939, respectively which showed that both models have a similar discriminating ability to identify the correct patient. A Committee member noted that NIHSS was present in both models suggesting that they we were not comparing unique models."

   Our test of the validity of the risk model demonstrated that a model that includes the NIHSS score and patient comorbidities from claims data produces similar discrimination as does a model that includes NIHSS score and physiologic data (laboratory test results and vital signs) derived from the registry. The purpose of this test was to compare a model that relies on claims data with one that uses data from the medical record which is considered the gold standard data source. The discrimination of the two models was quite good (0.821 and 0.7939) and greater than that of the currently public reported measure which uses claims without the NIHSS score (c-statistic of 0.74 in the most recent 3-year reporting period). We agree that because NIHSS score is a strong predictor of mortality, it is likely responsible for the increased discriminatory power of both models compared with the currently public reported stroke mortality measure. However, the inclusion of the NIHSS score in both models does not negate their comparison as a test of validity of the claims-based model.

3. "The Committee also weighed whether the measure was truly assessing quality if patient preferences (e.g., patients with comfort measures are not listed as exclusions) had not been considered. They also noted that if patient preferences are not excluded and the patient dies then the death would count against the hospital. This led to a larger concern of the Committee as to whether the measure is actually measuring facility preferences rather than quality of care."

   The measure currently excludes patients who are admitted to hospice before or on the day of admission (within the first 24 hours). In addition, the inclusion of the NIHSS score in the measure risk model mitigates the impact of the unequal distribution of patients with the most severe strokes across hospitals. Although this is not a perfect proxy, these are the patients most likely to face a poor prognosis and elect to receive comfort measures (approximately 3% of stroke patients). We recognize that excluding hospice enrollees in this time window captures a fraction of those who elect to receive comfort measures due to severity of stroke or poor prognosis (one third of the 3%). However, most patients who elect to receive comfort measures do so after the first 24 hours of the admission. Even if the data captured this population perfectly, it is problematic to exclude these patients from the measure because we cannot know whether their decision was due to the severity of the initial stroke and low likelihood of functional recovery or if it was due to poor quality of care delivered after they were admitted to the hospital. Although we agree that it would be ideal to exclude patients for whom avoidance of death is not the desired outcome, it is not feasible to do so perfectly while fully preserving the signal of quality that the measure is deigned to capture. However, the addition of NIHSS better accounts for variation in the proportion of patients with severe stroke, and therefore those most likely to elect for comfort measures across hospitals.

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4. "In regard to missing data, 17% of NIHSS stroke scale scores were missing and the Committee voiced concern that facilities may have an incentive to not document the stroke scale score, since multiple imputation could be used to make up for the missing scores."

   Although imputation was used to develop and test the measure, CMS is not proposing to use this approach for calculating results when the measure is implemented. We used imputation to mitigate the impact of the missing NIHSS values in the stroke registry data and to be able to include the full cohort of eligible admissions in the measure. It was our determination that imputation was the most valid way to develop and test the measure's risk model. However, in order to implement the measure hospitals would need to report the NIHSS on all or nearly all of their ischemic stroke patients. We believe this is feasible given the introduction of International Classification of Diseases 10th revision (ICD-10) codes for NIHSS scores scheduled to begin in October 2016. Additionally, studies have demonstrated the feasibility of collection of NIHSS scores by trained research nurses in both hospital and community settings (Dewey 1999). When this has been studied, the total NIHSS scores between neurologists and research nurses have been found to have a high level of agreement (ICC = 0.92 to 0.96) (Dewey 1999). These data demonstrate that both a variety of physician investigators and trained nurses can reliably apply the NIHSS in the context of an actual clinical trial (Goldstein 1997).
5. "The Committee also noted that the SDS factor race was not included in the final risk adjustment model. Although the data presented showed African Americans as having the lowest risk for mortality with an odds ratio of .62, the Committee noted this group also has preferences for more aggressive treatment, which could explain the lower mortality."

   Although differences in mortality rates were observed among Africa-American patients compared with all other racial groups and among patients with low SES indicators compared with all others, these differences were very small in the fully risk-adjusted model. The mean absolute change in hospitals' RSMRs when adding a dual eligibility indicator was 0.00006%. The mean absolute change in hospitals' RSMRs when adding a low SES AHRQ indicator was 0.00009%. The mean absolute change in hospitals' RSMRs when adding a race indicator was -0.00064%. These findings did not support including these variables in the measure's risk model
6. "Finally, the Committee considered additional factors that could vary at the hospital level such as early 'Do not resuscitate' orders, which are a larger predictor of mortality than age. The Committee again felt that the measure could be measuring hospital preferences and not quality."

   As stated above, we do not believe that the current limitations in identifying patient care preferences invalidate the measure. We do currently exclude patients enrolled in hospice before or on the first day of admission. This exclusion captures a proportion of patients who elect to have life-saving interventions withheld during the admission. However, it remains conceptually problematic to exclude patients who enroll in hospice or convert to comfort measure or DNR after the first 24 hours of the admission. This is due to the difficulty in knowing if that decision is a result of stroke severity and poor prognosis or of poor care. We do believe that the addition of NIHSS score to the measure risk model better adjusts for variation in the proportion of patients with severe strokes and that these are the patients most likely to have care withheld or withdrawn by request.
   - After reviewing the comments, the Committee again discussed the validity of the measure but did not believe it met the criteria for the following reasons: (1) there was no empiric assessment of missing data; (2) the method used to assess validity was not appropriate; and (3) preferences and any other factors that might vary at the hospital level is not accounted for in the model. The Committee did not recommend this measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

8. Board of Directors Vote: Y-X; N-X

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9. Appeals

[i] Centers for Disease Control and Prevention (CDC). Stroke website. http://www.cdc.gov/stroke/facts.htm. Last accessed April 2016.

[ii] Centers for Disease Control and Prevention (CDC). Alzheimer's disease website. http:/www.cdc.gov/aging/aginginfo/alzheimers.htm. Last accessed April 2016.

[iii] Centers for Disease Control (CDC). Epilepsy fast facts website. http://www.cdc.gov/epilepsy/basics/fast-facts.htm. Last accessed April 2016.