

# NATIONAL QUALITY FORUM

## Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

| <b>NQF #:</b> 2022  | <b>NQF Project:</b> <a href="#">Neurology Project</a>                                |
|---|--|
| (for Endorsement Maintenance Review)  |  |
| <b>Original Endorsement Date:</b>   | <b>Most Recent Endorsement Date:</b> Last Updated Date: <a href="#">Jul 17, 2015</a> |
| BRIEF MEASURE INFORMATION   |  |
| <b>De.1 Measure Title:</b> <a href="#">Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Initiated</a>  |  |
| <b>Co.1.1 Measure Steward:</b> <a href="#">AMA-convened Physician Consortium for Performance Improvement</a>  |  |
| <b>De.2 Brief Description of Measure:</b> <a href="#">Percentage of all patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA, for whom t-PA was initiated within three hours of time last known well</a>   |  |
| <b>2a1.1 Numerator Statement:</b> <a href="#">Patients for whom t-PA was initiated within three hours of time last known well</a>   |  |
| <b>2a1.4 Denominator Statement:</b> <a href="#">All patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA</a>   |  |
| <b>2a1.8 Denominator Exclusions:</b> <a href="#">Documentation of medical reason(s) for not initiating Tissue Plasminogen Activator (t-PA) within three hours of time last known well (eg, contraindications, conditions that might lead to increased risk of bleeding or unfavorable outcomes, other medical reasons)</a><br><br><b>Contraindications*</b> <ul style="list-style-type: none"> <li>• <a href="#">CT findings of intracranial hemorrhage, subarachnoid hemorrhage, or major infarct signs</a></li> <li>• <a href="#">History of intracranial hemorrhage, brain aneurysm, vascular malformation, or brain tumor</a></li> <li>• <a href="#">Internal bleeding (less than 22 days)</a></li> <li>• <a href="#">IV or IA t-PA given at a transferring hospital</a></li> <li>• <a href="#">No IV access</a></li> <li>• <a href="#">Platelets less than 100,000, PTT greater than 40 sec after heparin use</a></li> <li>• <a href="#">PT greater than 15 or INR greater than 1.7, or unknown bleeding diathesis</a></li> <li>• <a href="#">Recent intracranial or spinal surgery, head trauma, or stroke (less than 3 months)</a></li> <li>• <a href="#">Recent surgery/trauma (less than 15 days)</a></li> <li>• <a href="#">Seizure with postictal residual neurological impairments</a></li> <li>• <a href="#">Suspicion of subarachnoid hemorrhage</a></li> <li>• <a href="#">Systolic blood pressure greater than 185 or diastolic blood pressure greater than 110 mm hg.</a></li> <li>• <a href="#">Unable to determine eligibility</a></li> </ul> <b>Warnings/Conditions that might lead to increased risk of bleeding or unfavorable outcomes*:</b> <ul style="list-style-type: none"> <li>• <a href="#">Acute pericarditis</a></li> <li>• <a href="#">Advanced age</a></li> <li>• <a href="#">Diabetic hemorrhagic retinopathy or other ophthalmic bleeding</a></li> <li>• <a href="#">Glucose less than 50 or greater than 400 mg/dl</a></li> <li>• <a href="#">Hemostatic defects including those secondary to severe renal or hepatic disease</a></li> <li>• <a href="#">Left heart thrombus</a></li> </ul> |  |

- Life expectancy less than 1 year or severe co-morbid illness
- Patient currently receiving oral anticoagulants (e.g. Warfarin sodium, Coumadin)
- Pregnancy
- Rapid improvement
- Septic thrombophlebitis or occluded AV cannula at seriously infected site
- Stroke severity – Too mild
- Stroke severity – Too severe (e.g., NIHSS greater than 22)
- Subacute bacterial endocarditis

\*Lists harmonized with The Joint Commission measure.

**1.1 Measure Type:** Process

**2a1. 25-26 Data Source:** Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

**2a1.33 Level of Analysis:** Facility

**1.2-1.4 Is this measure paired with another measure?** Yes

2021:Stroke and Stroke Rehabilitation: Tissue Plasminogen Activator (t-PA) Considered/Initiated

**De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):**

This measure is not included in a composite.

#### STAFF NOTES (issues or questions regarding any criteria)

**Comments on Conditions for Consideration:**

**Is the measure untested?** Yes ☒ No ☒ If untested, explain how it meets criteria for consideration for time-limited endorsement:

**1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (check De.5):**

**5. Similar/related endorsed or submitted measures (check 5.1):**

**Other Criteria:**

**Staff Reviewer Name(s):**

#### 1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See [guidance on evidence](#).

**Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. ([evaluation criteria](#))**

**1a. High Impact:** H ☒ M ☒ L ☒ I ☒

(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)

**De.4 Subject/Topic Areas (Check all the areas that apply):** Neurology, Neurology : Stroke/Transient Ischemic Attack (TIA)

**De.5 Cross Cutting Areas (Check all the areas that apply):**

**1a.1 Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, A leading cause of morbidity/mortality

**1a.2 If “Other,” please describe:**

**1a.3 Summary of Evidence of High Impact** *(Provide epidemiologic or resource use data):*

An estimated 7,000,000 Americans > or = 20 years of age have had a stroke. Overall stroke prevalence during this period is an estimated 3.0%.(1)

Stroke is the leading cause of serious long-term disability in the United States.(1)

Stroke is the third most common cause of death in the United States after heart disease and cancer. Tissue plasminogen activator (tPA) was proven useful for acute stroke therapy in 1995 and was approved by the US Food and Drug Administration in 1996. It increases recovery from stroke symptoms by up to 50% with a low serious complication rate. However, only 3% to 8.5% of potentially eligible patients receive tPA. Ideally, more than 40% of all stroke patients should receive tPA.(2)

Acute ischemic stroke patients are infrequently treated with recombinant tissue plasminogen activator (rtPA), despite its proven effectiveness for reducing morbidity after stroke. For example, in the Greater Cincinnati/Northern Kentucky (GCNK) population, the percentage of ischemic stroke patients receiving rtPA is only 3% to 4% and did not change between 1993 to 1994 and 1999, despite Food and Drug Administration approval of rtPA. Similarly, the Paul Coverdell National Acute Stroke registry reported that only 4% of all ischemic stroke patients received rtPA in 2001.(3)

**1a.4 Citations for Evidence of High Impact cited in 1a.3:** 1. Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, et al. Heart Disease and Stroke Statistics-2012 Update: A Report from the American Heart Association. *Circulation* 2012;125:e2-e220.

2. Bambauer KZ, Johnston C, Bambauer DE, Zivin JA. Reasons Why Few Patients with Acute Stroke Receive Tissue Plasminogen Activator. *Arch Neurol* 2006;63:661-664.

3. Kleindorfer D, Kissela B, Schneider A, Woo D, et al. Eligibility for Recombinant Tissue Plasminogen Activator in Acute Ischemic Stroke: A Population-Based Study. *Stroke* 2004;35:e27-e29.

**1b. Opportunity for Improvement: H● M● L● I●**

*(There is a demonstrated performance gap - variability or overall less than optimal performance)*

**1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:**

Tissue-type plasminogen activator (tPA) is a proven intervention for acute ischemic stroke patients. The benefit of intravenous tPA in acute ischemic stroke is strongly time dependent. The therapeutic benefit of tPA is greatest when given early after ischemic stroke onset and declines over 3 to 4.5 hours.(1)

1. Fonarow GC, Smith EE, Saver JL, Reeves MJ, et al. Timeliness of Tissue-Type Plasminogen Activator Therapy in Acute Ischemic Stroke. Patient Characteristics, Hospital Factors, and Outcomes Associated with Door-to-Needle Times within 60 Minutes. *Circulation* 2011;123:750-758.

**1b.2 Summary of Data Demonstrating Performance Gap** *(Variation or overall less than optimal performance across providers): [For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]*

Tissue plasminogen activator (tPA) was proven useful for acute stroke therapy in 1995 and was approved by the US Food and Drug Administration in 1996. It increases recovery from stroke symptoms by up to 50% with a low serious complication rate. However, only 3% to 8.5% of potentially eligible patients receive tPA.

**1b.3 Citations for Data on Performance Gap: [For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]**

Bambauer KZ, Johnston C, Bambauer DE, Zivin JA. Reasons Why Few Patients with Acute Stroke Receive Tissue Plasminogen Activator. Arch Neurol 2006;63:661-664.

**1b.4 Summary of Data on Disparities by Population Group: [For Maintenance –Descriptive statistics for performance results for this measure by population group]**

With regard to the administration of thrombolysis, 1 study analyzed the NIS database for 1999 to 2004, which showed that thrombolysis was used in 1.12% of patients hospitalized for ischemic stroke. Higher use of thrombolysis was noted among whites and patients with private, self-pay health insurance, which suggests a discrepancy; however, these associations were not controlled for SES and are limited in that they cannot discern whether other patient characteristics (particularly the presence of contraindications) or patient preferences could have accounted for the differences noted. In a prospective study of the use of recombinant tissue plasminogen activator in acute ischemic stroke in a sample of US academic centers, investigators found that recombinant tissue plasminogen activator was used fewer times in blacks or African Americans even after controlling for delays to presentation. Although the reason for that finding was unclear, physician biases, cultural barriers, and patient mistrust are possibilities that should be considered for additional study. No data are available in relation to access to endovascular acute stroke interventions. More recently, the Get With the Guidelines-Stroke program showed that blacks or African Americans with stroke were less likely to receive thrombolysis than Hispanic or white patients.

**1b.5 Citations for Data on Disparities Cited in 1b.4: [For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]**

Cruz-Flores S, Rabinstein A, Biller J, Elkind MSV, et al. Racial-Ethnic Disparities in Stroke Care: The American Experience: A Statement for Health care Professionals From the American Heart Association/American Stroke Association. Stroke 2011;42:2091-2116.

**1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.)**

**Is the measure focus a health outcome? Yes ☐ No ☐ If not a health outcome, rate the body of evidence.**

**Quantity: H ☐ M ☐ L ☐ I ☐ Quality: H ☐ M ☐ L ☐ I ☐ Consistency: H ☐ M ☐ L ☐ I ☐**

| Quantity | Quality | Consistency | Does the measure pass subcriterion 1c?  |
|----------|---------|-------------|---|
| M-H      | M-H     | M-H         | Yes <input type="radio"/>   |
| L        | M-H     | M           | Yes <input type="radio"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="radio"/> |
| M-H      | L       | M-H         | Yes <input type="radio"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="radio"/>                            |
| L-M-H    | L-M-H   | L           | No <input type="radio"/>  |

**Health outcome** – rationale supports relationship to at least one healthcare structure, process, intervention, or service

**Does the measure pass subcriterion 1c?**  
Yes ☐ IF rationale supports relationship

**1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-)**

*health outcome; process- health outcome; intermediate clinical outcome-health outcome):*

The process of ischemic stroke patients having t-PA initiated is linked to improved health outcomes such as decreasing preventable complications of stroke, increasing stroke survival rates, and attaining the highest level of personal function after stroke.

**1c.2-3 Type of Evidence** *(Check all that apply):*

Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence), Systematic review of body of evidence (other than within guideline development)

**1c.4 Directness of Evidence to the Specified Measure** *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population):*

The clinical practice guidelines and systematic review state that patients with a stroke diagnosis should receive thrombolytic therapy within 3 hours of the onset of symptoms.

The measure captures all adult patients with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for tPA for whom tPA was initiated within three hours of time last known well. The presentation within two hours of time last known well allows for one hour of administration of the therapy, so the patient will have received the therapy within the 3 hour time limit.

**1c.5 Quantity of Studies in the Body of Evidence** *(Total number of studies, not articles):* The ACCP guideline includes a table containing descriptions of 7 randomized controlled trials of thrombolytics in acute stroke. The guideline also mentions three large formal prospective Phase IV studies, as well as metaanalyses conducted by the Cochrane stroke group.

The AHA/ASA guideline does not address the overall quantity of studies in the body of evidence. The guideline developer indicates that the expert panel reviewed the relevant literature with an emphasis on reports published since 2003.

The Cochrane Review of Thrombolysis for acute ischemic stroke included a review of 26 trials, involving 7152 patients.

An individual study by Hacke et al. is included in the evidence, supporting this measure.

A review of the two National Institute of Neurological Disorders and Stroke (NINDS) rt-PA Stroke studies by Marler et al, is included in the evidence supporting this measure.

A pooled analysis of 3 stroke trials by Hacke et al, is included in the evidence supporting this measure.

An individual study by Kleindorfer et al, is included in the evidence supporting this measure.

**1c.6 Quality of Body of Evidence** *(Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events):* The ACCP guideline includes a table containing descriptions of 7 randomized controlled trials of thrombolytics in acute stroke. The guideline also mentions three large formal prospective Phase IV studies, as well as metaanalyses conducted by the Cochrane stroke group.

The Cochrane Review of Thrombolysis for acute ischemic stroke included randomized trials of any

thrombolytic agent compared with control in patients with definite ischemic stroke. The trials tested urokinase, streptokinase, recombinant tissue plasminogen activator, recombinant pro-urokinase or desmoteplase. Four trials used intra-arterial administration the rest used the intravenous route. About 55% of the data come from trials testing intravenous tissue plasminogen activator. Many trials had some imbalances in key prognostic variables. Several trials did not have complete blinding of outcome assessment.

The quality of the body of evidence supporting the AHA/ASA guideline recommendations are not provided.

The individual study by Hacke et al. is a randomized controlled trial, which evaluated 821 patients.

Part 1 of the NINDS trial assessed changes in neurologic deficits 24 hours after the onset of stroke as a measure of the activity of t-PA. Part 2, the pivotal study, used four outcomes measures representing different aspects of recovery from stroke to assess whether treatment with t-PA resulted in sustained clinical benefit at three months. The authors of the review performed additional analyses to characterize the relationship of onset-to-treatment time to outcome at 3 months, early improvement at 24 hours, and intracranial hemorrhage within 36 hours. The failure to detect the treatment x OTT interaction in the initial analyses of stroke outcome highlights a limitation of hierarchical modeling. In hierarchical modeling, the best set of three variables is chosen from the best set of two plus a new variable chosen from all variables not yet included. The authors acknowledge that if they were truly looking for the best set of three variables, they would choose from along all sets of three variables, not just from the best set of two variables plus one.

Hacke et al pooled common data elements from six randomized placebo-controlled trials of intravenous rt-PA. Using multivariable logistic regression, they assessed the relation of the interval from stroke onset to start of treatment (OTT) on favourable 3-month outcome and on the occurrence of clinically relevant parenchymal hemorrhage. Median age was 68 years, median baseline National Institute of Health Stroke Scale (NIHSS) 11, and median OTT 243 min. Odds of a favourable 3-month outcome increased as OTT decreased ( $p=0.005$ ). Odds were 2.8 (95% CI 1.8—4.5) for 0—90 min, 1.6 (1.1—2.2) for 91—180 min, 1.4 (1.1—1.9) for 181—270 min, and 1.2 (0.9—1.5) for 271—360 min in favour of the rt-PA group. The hazard ratio for death adjusted for baseline NIHSS was not different from 1.0 for the 0—90, 91—180, and 181—270 min intervals; for 271—360 min it was 1.45 (1.02—2.07). Hemorrhage was seen in 82 (5.9%) rt-PA patients and 15 (1.1%) controls ( $p<0.0001$ ). Hemorrhage was not associated with OTT but was with rt-PA treatment ( $p=0.0001$ ) and age ( $p=0.0002$ ).

All ischemic strokes presenting to an emergency department (ED) within a biracial population of 1.3 million were identified. The patient was considered eligible for rtPA on the basis of exclusion criteria from the National Institute of Neurological Disorders and Stroke rtPA trial. Of 2308 ischemic strokes, 1849 presented to an ED. Only 22% of all ischemic strokes in the population arrived in the ED in <3 hours from symptom onset; of these, 209 (51%) were ineligible for rtPA on the basis of mild stroke severity, medical and surgical history, or blood tests.

**1c.7 Consistency of Results across Studies** (*Summarize the consistency of the magnitude and direction of the effect*): The consistency of the body of evidence supporting the ACCP guideline recommendations was not addressed. However, the grade of the body of evidence for the first ACCP recommendation indicates that the evidence results are strong and consistent. The grade also indicates that the evidence consisted of randomized controlled trials, and that there is no heterogeneity within the results.

The consistency of results across studies reviewed is not addressed within the AHA/ASA guideline.

The Cochrane Review showed that treatment within three hours of stroke appeared more effective in reducing death or dependency with no statistically significant adverse effect on death. There was



heterogeneity between the trials in part attributable to concomitant antithrombotic drug use, stroke severity and time to treatment.

Both trials in the NINDS rt-PA Stroke Study demonstrated the effectiveness of recombinant tissue-type plasminogen activator (rt-PA) for the treatment of acute ischemic stroke when started within 3 hours of stroke onset. OTT was shown to be associated with a differential response to treatment both at 24 hours and 3 months after stroke. Due to chance, there was an imbalance in the NIHSS severity of stroke randomized in the two treatment groups at different OTT. Because baseline NIHSS is a good predictor of outcome, this imbalance in the treatment groups increased the number of favorable outcomes in the rt-PA group treated 91 to 180 minutes from stroke onset and reduced them in the group treated with rt-PA between 0 and 90 minutes. The imbalance obscured or confounded the increased response to treatment in the rt-PA group treated early compared to the rt-PA group treated later.

The pooled analysis showed that the sooner rt-PA is given to stroke patients, the greater the benefit, especially if started within 90 min. The results also suggest a potential benefit beyond 3h, although this potential benefit may come with risks.

The study by Kleindorfer et al indicates that in the population in 1993 to 1994, 8% of all ischemic stroke patients presented to an ED within 3 hours and met other eligibility criteria for rtPA. Even if time were not an exclusion for rtPA, only 29% of all ischemic strokes in our population would have otherwise been eligible for rtPA.

**1c.8 Net Benefit** (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms*):

Initiating tPA reduces the rate of disability, morbidity, and mortality among stroke patients. This benefit outweighs the potential risk of bleeding, which can be treated.

**1c.9 Grading of Strength/Quality of the Body of Evidence.** Has the body of evidence been graded? **Yes**

**1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** **ACCP:**

Gregory W. Albers  
Pierre Amarenco  
J. Donald Easton  
Ralph L. Sacco  
Philip Teal

No disclosure is included in the guideline.

The AHA/ASA guideline contains the following information regarding disclosures:

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest. A table containing all disclosures is included in the Guideline document. A list of the group is included below:

Harold P. Adams, Jr. MD, FAHA, Chair  
Gregory del Zoppo, MD, FAHA, Vice Chair  
Mark J. Alberts, MD, FAHA  
Deepak L. Bhatt, MD  
Lawrence Brass, MD, FAHA

Anthony Furlan, MD< FAHA  
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Adnan I. Qureshi, MD, FAHA  
Robert H. Rosenwasser, MD, FAHA  
Phillip A. Scott, MD, FAHA  
Eelco F.M. Wijdicks, MD, FAHA

**1c.11 System Used for Grading the Body of Evidence:** Other

**1c.12 If other, identify and describe the grading scale with definitions:** ACCP Recommendation

A: Methods strong, results consistent - RCTs, no heterogeneity  
B: Methods strong, results inconsistent - RCTs, heterogeneity present  
C: Methods weak, Observational studies

AHA/ASA guideline:

Level of evidence

A Data derived from multiple randomized clinical trials  
B Data derived from a single randomized trial or nonrandomized studies  
C Consensus opinion of experts

Level of evidence for diagnostic recommendtaion

A Data derived from multiple prospective cohort studies that used a reference standard applied by a masked evaluator  
B Data derived from a single grade A study or one or more case-control studies or studies that used a reference standard  
C Consensus opinion of experts

**1c.13 Grade Assigned to the Body of Evidence:** A, A, A

**1c.14 Summary of Controversy/Contradictory Evidence:** A survey of emergency department physicians found that 40% would not use tPA. Sixty percent cited risk of intracerebral hemorrhage as the reason for not using tPA, and one quarter of physicians cited the lack of (perceived) benefits, but when emergency medicine trainees were asked what they would prefer if they personally had a stroke, more than 88% said that they would want tPA treatment.

Bambauer KZ, Johnston C, Bambauer DE, Zivin JA. Reasons Why Few Patients with Acute Stroke Receive Tissue Plasminogen Activator. Arch Neurol 2006;63:661-664.

**1c.15 Citations for Evidence other than Guidelines(*Guidelines addressed below*):**

Wardlaw JM, Murray V, Berge E, del Zoppo GJ. Thrombolysis for acute ischaemic stroke. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.: CD000213. DOI: 10.1002/14651858.CD000213.pub2.

Hacke W, Kaste M, Bluhmki E, Brozman M, et al. Thrombolysis with Alteplase 3 to 4.5 Hours after Ischemic Stroke. N Engl J Med 2008;359:1317-29.



Marler JR, Tilley BC, Lu M, Brott TG, et al. Early stroke treatment associated with better outcome. N Engl J Med 2000;55:1649-1655.

National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group. N Engl J Med 1995;333(24):1581-1587.

Hacke W, Donnan G, Fieschi C, et al. Association of outcome with early stroke treatment: pooled analysis of ATLANTIS, ECASS, and NINDS rt-PA stroke trials. Lancet 2004;363(9411):768-774.

Kleindorfer D, Kissela B, Schneider A, Woo D, et al. Eligibility for Recombinant Tissue Plasminogen Activator in Acute Ischemic Stroke: A Population-Based Study. Stroke 2004;35:e27-e29.

**1c.16 Quote verbatim, the specific guideline recommendation** (Including guideline # and/or page #):  
For eligible patients (see inclusion and exclusion criteria listed below) we recommend administration of IV tPA in a dose of 0.9 mg/kg (maximum of 90 mg), with 10% of the total dose given as an initial bolus and the remainder infused > 60 min, provided that treatment is initiated within 3h of clearly defined symptom onset.(1)

Inclusion criteria: Age > or = 18 years, clinical diagnosis of stroke with a clinically meaningful neurologic deficit, clearly defined time of onset of <180 min before treatment, and a baseline CT showing no evidence of intracranial hemorrhage.(1)

We recommend that patients who are eligible for tPA be treated as quickly as possible within the 3-h time limit.(1)

Intravenous rtPA (0.9 mg/kg, maximum dose 90 mg) is recommended for selected patients who may be treated within 3 hours of onset of ischemic stroke.(2)

**1c.17 Clinical Practice Guideline Citation:** 1. Albers GW, Amarenco P, Easton JD, Sacco RL, Teal P. Antithrombotic and Thrombolytic Therapy for Ischemic Stroke: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest 2008;133:630S-669S.

2. Adams HP, del Zoppo G, Alberts MJ, Bhatt DL, et al. Guidelines for the Early Management of Adults With Ischemic Stroke: A Guideline From the American Heart Association/American Stroke Association Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists. Stroke 2007;38:1655-1711.

**1c.18 National Guideline Clearinghouse or other URL:**  
[http://chestjournal.chestpubs.org/content/133/6\\_suppl/630S.full.html](http://chestjournal.chestpubs.org/content/133/6_suppl/630S.full.html)

**1c.19 Grading of Strength of Guideline Recommendation.** Has the recommendation been graded? **Yes**

**1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** **Please see section 1c.10**

**1c.21 System Used for Grading the Strength of Guideline Recommendation:** **Other**

**1c.22 If other, identify and describe the grading scale with definitions:** **ACCP Recommendation**

- 1: Effect clear - Clear that benefits do (or do not) outweigh risks
- 2: Effect equivocal - Uncertainly whether benefits outweigh risks

**1c.23 Grade Assigned to the Recommendation:** 1, 1, Class I

**1c.24 Rationale for Using this Guideline Over Others:** It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

**Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?**

**1c.25** Quantity: [Moderate](#) **1c.26** Quality: [Moderate](#) **1c.27** Consistency: [Moderate](#)

**1c.28** Attach evidence submission form:

**1c.29** Attach appendix for supplemental materials:

**Was the threshold criterion, *Importance to Measure and Report*, met?**

**(1a & 1b must be rated moderate or high and 1c yes)** Yes ☐ No ☒

**Provide rationale based on specific subcriteria:**

**For a new measure if the Committee votes NO, then STOP.**

**For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.**

## 2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (**evaluation criteria**)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

**S.1 Measure Web Page** (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? [No](#)

**S.2** If yes, provide web page URL:

**2a. RELIABILITY. Precise Specifications and Reliability Testing:** H ☒ M ☒ L ☒ I ☒

**2a1. Precise Measure Specifications.** (*The measure specifications precise and unambiguous.*)

**2a1.1 Numerator Statement** (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

[Patients for whom t-PA was initiated within three hours of time last known well](#)

**2a1.2 Numerator Time Window** (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):

[Once during each hospital stay during measurement period](#)

**2a1.3 Numerator Details** (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

See Guidance for Definitions of Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Created on: 07/30/2015 at 02:50 AM

**Definitions:**

Time last known well- Time at which the patient was last known to be without the signs and symptoms of the current stroke or at his or her prior baseline. Variation may exist if the signs and symptoms are not witnessed. (TJC)

**EHR Specifications:**

eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.

**2a1.4 Denominator Statement** *(Brief, narrative description of the target population being measured):*

All patients aged 18 years and older with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for t-PA

**2a1.5 Target Population Category** *(Check all the populations for which the measure is specified and tested if any):* Senior Care

**2a1.6 Denominator Time Window** *(The time period in which cases are eligible for inclusion):*

Each hospital stay during 12 consecutive month measurement period

**2a1.7 Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):*

**Definitions:**

Eligible- Patients are eligible for t-PA if they have an acute neurologic deficit, a clearly defined time of onset of < 180 min before treatment, and a baseline CT showing no evidence of intracranial hemorrhage

**EHR Specifications:**

eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.

**2a1.8 Denominator Exclusions** *(Brief narrative description of exclusions from the target population):*

Documentation of medical reason(s) for not initiating Tissue Plasminogen Activator (t-PA) within three hours of time last known well (eg, contraindications, conditions that might lead to increased risk of bleeding or unfavorable outcomes, other medical reasons)

**Contraindications\***

- CT findings of intracranial hemorrhage, subarachnoid hemorrhage, or major infarct signs
- History of intracranial hemorrhage, brain aneurysm, vascular malformation, or brain tumor
- Internal bleeding (less than 22 days)
- IV or IA t-PA given at a transferring hospital
- No IV access
- Platelets less than 100,000, PTT greater than 40 sec after heparin use
- PT greater than 15 or INR greater than 1.7, or unknown bleeding diathesis
- Recent intracranial or spinal surgery, head trauma, or stroke (less than 3 months)
- Recent surgery/trauma (less than 15 days)
- Seizure with postictal residual neurological impairments
- Suspicion of subarachnoid hemorrhage
- Systolic blood pressure greater than 185 or diastolic blood pressure greater than 110 mm hg.
- Unable to determine eligibility

**Warnings/Conditions that might lead to increased risk of bleeding or unfavorable outcomes\*:**

- Acute pericarditis
- Advanced age
- Diabetic hemorrhagic retinopathy or other ophthalmic bleeding

- Glucose less than 50 or greater than 400 mg/dl
- Hemostatic defects including those secondary to severe renal or hepatic disease
- Left heart thrombus
- Life expectancy less than 1 year or severe co-morbid illness
- Patient currently receiving oral anticoagulants (e.g. Warfarin sodium, Coumadin)
- Pregnancy
- Rapid improvement
- Septic thrombophlebitis or occluded AV cannula at seriously infected site
- Stroke severity – Too mild
- Stroke severity – Too severe (e.g., NIHSS greater than 22)
- Subacute bacterial endocarditis

\*Lists harmonized with The Joint Commission measure.

**2a1.9 Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):*

The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, contraindications, other medical reason(s)) or patient reason(s) (eg, patient declined, other patient reason(s)) for not initiating Tissue Plasminogen Activator (t-PA) within three hours of time last known well. Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

**EHR Specifications:**

eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.

**Exclusions:**

Not Applicable

**Exceptions:**

**Contraindications\***

- CT findings of intracranial hemorrhage, subarachnoid hemorrhage, or major infarct signs
- History of intracranial hemorrhage, brain aneurysm, vascular malformation, or brain tumor
- Internal bleeding (less than 22 days)
- IV or IA t-PA given at a transferring hospital
- No IV access
- Platelets less than 100,000, PTT greater than 40 sec after heparin use
- PT greater than 15 or INR greater than 1.7, or unknown bleeding diathesis
- Recent intracranial or spinal surgery, head trauma, or stroke (less than 3 months)
- Recent surgery/trauma (less than 15 days)
- Seizure with postictal residual neurological impairments
- Suspicion of subarachnoid hemorrhage

- Systolic blood pressure greater than 185 or diastolic blood pressure greater than 110 mm hg.
- Unable to determine eligibility

Warnings/Conditions that might lead to increased risk of bleeding or unfavorable outcomes\*:

- Acute pericarditis
- Advanced age
- Diabetic hemorrhagic retinopathy or other ophthalmic bleeding
- Glucose less than 50 or greater than 400 mg/dl
- Hemostatic defects including those secondary to severe renal or hepatic disease
- Left heart thrombus
- Life expectancy less than 1 year or severe co-morbid illness
- Patient currently receiving oral anticoagulants (e.g. Warfarin sodium, Coumadin)
- Pregnancy
- Rapid improvement
- Septic thrombophlebitis or occluded AV cannula at seriously infected site
- Stroke severity – Too mild
- Stroke severity – Too severe (e.g., NIHSS greater than 22)
- Subacute bacterial endocarditis

\*Lists harmonized with The Joint Commission measure.

**2a1.10 Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses ):

We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**2a1.11 Risk Adjustment Type** (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): No risk adjustment or risk stratification    **2a1.12 If "Other," please describe:**

**2a1.13 Statistical Risk Model and Variables** (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):

Not applicable

**2a1.14-16 Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

**2a1.17-18. Type of Score:** Rate/proportion

**2a1.19 Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score):

Better quality = Higher score

**2a1.20 Calculation Algorithm/Measure Logic**(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

To calculate performance rates:

- 1) Find the patients who meet the initial patient population (ie, the general group of patients that a set of performance measures is designed to address).
- 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator. (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.
- 3) Find the patients who qualify for exclusions and subtract from the denominator.
- 4) From the patients within the denominator (after exclusions have been subtracted from the denominator), find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator
- 5) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator when exceptions have been specified [for this measure: medical reason(s) (eg, contraindications, conditions that might lead to increased risk of bleeding or unfavorable outcomes, other medical reason(s)) or patient reason(s) (eg, patient declined, other patient reason(s))]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rates (ie, percentage of patients with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

Calculation algorithm is included in data dictionary/code table attachment 2a1.30.

**2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:**

Attachment

[PCPI\\_Measure\\_Calculation\\_V2.0-634717505189678580.pdf](#)

**2a1.24 Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

This measure is not based on a sample or a survey.

**2a1.25 Data Source** (*Check all the sources for which the measure is specified and tested*). If other, please describe:

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

**2a1.26 Data Source/Data Collection Instrument** (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Not applicable

**2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:**

**2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:**

Attachment

[AMA-PCPI\\_4b.STROKE.tPA.initiated\\_MAY2012.pdf](#)



**2a1.33 Level of Analysis** (Check the levels of analysis for which the measure is specified and tested):  
Facility

**2a1.34-35 Care Setting** (Check all the settings for which the measure is specified and tested):  
Hospital/Acute Care Facility, Other:Emergency Department

**2a2. Reliability Testing.** (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)

**2a2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

AMA-PCPI Testing Project

- The data sample came from 4 practice sites representing a range of settings, sizes, locations and medical record systems. 3 had EHR and 1 was paper based
  - o Practice site #1: large group practice in urban Midwest setting with full EHR (Epic)
  - o Practice site #2: medium sized hospital based neurology practice in Midwest with some EHR (IDX transitioning to Epic)
  - o Practice site #3: small-sized group practice in urban South setting with paper and claims data source
  - o Practice site #4: large group practice in urban East coast setting with full EHR (Serono)
- Each of the four practice sites reviewed between 50 and 55 cases. 148 patient charts were eligible for the measure and abstracted.
- Data was collected from January 1, 2009 to December 31, 2009
- Data abstraction was performed in 2010
- Measure tested as part of a paired measure, t-PA considered (NQF #0242). The additional data element "T-PA Administration" was tested as follows –
  - o Instructions: Determine if the patient was administered t-PA.
  - o Yes (1): Select this option if the patient was administered t-PA.
  - ? Date of t-PA administration was recoded in MM/DD/YYYY format
  - ? Time of t-PA administration was recorded in military format HH:MM
  - o No (0): Select this option if the patient was not administered t-PA
  - o Not documented (2): Select this option if the date or time of t-PA was not documented
  - o Unknown (3): Select this option if the date or time of t-PA was documented as unknown

**2a2.2 Analytic Method** (Describe method of reliability testing & rationale):

Data abstracted from randomly sampled patient records were used to calculate inter-rater reliability for the measure.

Data analysis included:

- Percent agreement at the measure numerator, denominator, overall and exception (for those measures with exception)
- Kappa statistic to ensure that agreement rates are not a phenomenon of chance

**2a2.3 Testing Results** (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):

This measure demonstrates perfect agreement.

Reliability: N, % Agreement, Kappa (95% CI)

Numerator: 148, 100.00%, Kappa (N/A)\*

Denominator: 148, 100.00%, Kappa (N/A)\*

Overall: 148, 100.00%, Kappa (N/A)\*

\* Kappa statistics cannot be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

**2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L I**

**2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (criterion 1c) and identify any differences from the evidence:**

The clinical practice guidelines state that patients with a stroke diagnosis should receive thrombolytic therapy within 3 hours of the onset of symptoms.

The measure captures all adult patients with a diagnosis of ischemic stroke who present within two hours of time last known well and who are eligible for tPA for whom tPA was initiated within three hours of time last known well. The presentation within two hours of time last known well allows for one hour of administration of the therapy, so the patient will have received the therapy within the 3 hour time limit.

**2b2. Validity Testing.** (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

**2b2.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

An expert panel was used to assess face validity of the measure. This panel consisted of the following 26 members, with representation from the following specialties: neurology, methodology, neuroradiology, vascular neurology, spinal cord injury, internal medicine, critical care, clinical neurophysiology, neuroscience nursing, emergency medicine, radiology, speech-language pathology, neurological surgery, family medicine, physical medicine and rehabilitation, and a patient representative.

List of Work Group Members:

Joseph Drozda, Jr., MD (Co-Chair) (methodology)  
 Robert G. Holloway, MD, MPH (Co-Chair) (neurology)  
 David Seidenwurm, MD (Co-chair) (neuroradiology)  
 David N. Alexander, MD (neurology, vascular neurology, spinal cord injury)  
 M. Carolyn Baum, PhD, OTR/L (occupational therapy)  
 Christopher Bever, Jr., MD, MBA (neurology)  
 Thomas P. Bleck, MD, FCCM (internal medicine, critical care, neurology, vascular neurology, clinical neurophysiology)  
 John Y. Choi, MD, MPH (neurology)  
 Janet Y. Forbes, MD (internal medicine)  
 Millie Hepburn-Smith, MSN, RN, ACNS-BC (neuroscience nursing)  
 Judith Hinchey, MD, MS (neurology)  
 Peggy Jones (patient representative)  
 Irene Katzan, MD (neurology)  
 Adam Kelly, MD (neurology)  
 Rahul K. Khare, MD, MS, FACEP (emergency medicine)  
 Michael Lev, MD (radiology)  
 David Likosky, MD, SFHM (neurology, internal medicine, vascular neurology)  
 Constantine Moschonas, MD (neurology)  
 Suresh Mukherji, MD, FACR (neuroradiology)  
 Robert C. Mullen, MPH (speech-language pathology)  
 Charles Prestigiacomo, MD (neurological surgery)  
 Eric Russell, MD, FACR (radiology/neuroradiology)  
 Pina C. Sanelli, MD, MPH (radiology/neuroradiology)

Daniel Triezenberg, MD (family medicine)  
Patrick Turski, MD, FACR (neuroradiology)  
Richard Zorowitz, MD (physical medicine and rehabilitation)

**2b2.2 Analytic Method** *(Describe method of validity testing and rationale; if face validity, describe systematic assessment):*

All PCPI performance measures are assessed for content validity by a panel of expert work group members during the development process. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and by also soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All comments received are reviewed by the expert work group and the measures adjusted as needed. Other external review groups (eg, focus groups) may be convened if there are any remaining concerns related to the content validity of the measures.

The expert panel was used to assess face validity of the measure. This panel consisted of 26 members, with representation from the following specialties: neurology, methodology, neuroradiology, vascular neurology, spinal cord injury, internal medicine, critical care, clinical neurophysiology, neuroscience nursing, emergency medicine, radiology, speech-language pathology, neurological surgery, family medicine, physical medicine and rehabilitation, and a patient representative.

The aforementioned panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

**2b2.3 Testing Results** *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):*

The results of the expert panel rating of the validity statement were as follows: N = 18; Mean rating = 4.72 and 94.44% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality

**Frequency Distribution of Ratings**

1 - 0 (Strongly Disagree)

2 - 0

3 - 1 (Neither Agree nor Disagree)

4 - 3

5 - 14 (Strongly Agree)

**POTENTIAL THREATS TO VALIDITY.** *(All potential threats to validity were appropriately tested with adequate results.)*

**2b3. Measure Exclusions.** *(Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)*

**2b3.1 Data/Sample for analysis of exclusions** *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):*  
At the time of testing, the measure did not have exceptions.

**2b3.2 Analytic Method** *(Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):*  
At the time of testing, the measure did not have exceptions.

**2b3.3 Results** (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):

At the time of testing, the measure did not have exceptions.

**2b4. Risk Adjustment Strategy.** (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

**2b4.1 Data/Sample** (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

This measure is not risk adjusted.

**2b4.2 Analytic Method** (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables):

This measure is not risk adjusted.

**2b4.3 Testing Results** (*Statistical risk model:* Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. *Risk stratification:* Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):

Not applicable

**2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:** As a process measure, no risk adjustment is necessary.

**2b5. Identification of Meaningful Differences in Performance.** (The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.)

**2b5.1 Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

No PQRI/S information for this measure.

**2b5.2 Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

No PQRI/S information for this measure.

**2b5.3 Results** (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

No PQRI/S information for this measure.

**2b6. Comparability of Multiple Data Sources/Methods.** (If specified for more than one data source, the various approaches result in comparable scores.)

**2b6.1 Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

This measure was not compared across multiple data sources.

**2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

This measure was not compared across multiple data sources.

**2b6.3 Testing Results** (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

This measure was not compared across multiple data sources.

**2c. Disparities in Care:** H ☐ M ☐ L ☐ I ☐ NA ☐ (If applicable, the measure specifications allow identification of disparities.)

**2c.1 If measure is stratified for disparities, provide stratified results** (Scores by stratified categories/cohorts): We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

**2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:**

The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45 practices including stratification by the aforementioned variables.(1) A 2009 IOM report “recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one’s ancestry) and language need (a rating of spoken English language proficiency of less than very well and one’s preferred language for health-related encounters).”(2)

**References:**

(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at: <http://www.ahrq.gov/research/iomracereport>. Accessed May 25, 2010.

**2.1-2.3 Supplemental Testing Methodology Information:**

**Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (Reliability and Validity must be rated moderate or high) Yes ☐ No ☐**  
Provide rationale based on specific subcriteria:

**If the Committee votes No, STOP**

### 3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (**evaluation criteria**)

**C.1 Intended Actual/Planned Use** (Check all the planned uses for which the measure is intended): Public Reporting, Quality Improvement (Internal to the specific organization)

**3.1 Current Use** (Check all that apply; for any that are checked, provide the specific program information in the following questions): Quality Improvement (Internal to the specific organization)

**3a. Usefulness for Public Reporting:** H ☐ M ☐ L ☐ I ☐ NA ☐  
(The measure is meaningful, understandable and useful for public reporting.)

**3a.1. Use in Public Reporting - disclosure of performance results to the public at large** (If used in a



*public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[For Maintenance** – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]*

The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

**3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting.** If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

**3.2 Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s): This measure may be used in a Maintenance of Certification program.

### **3b. Usefulness for Quality Improvement: H● M● L● I●**

*(The measure is meaningful, understandable and useful for quality improvement.)*

**3b.1. Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s):

**[For Maintenance** – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

**3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement.** If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:

The PCPI believes that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

**Overall, to what extent was the criterion, Usability, met? H● M● L● I●**

**Provide rationale based on specific subcriteria:**

## **4. FEASIBILITY**

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

### **4a. Data Generated as a Byproduct of Care Processes: H● M● L● I●**

**4a.1-2 How are the data elements needed to compute measure scores generated?** (Check all that apply).



Data used in the measure are:  
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

**4b. Electronic Sources: H ☐ M ☒ L ☐ I ☐**

**4b.1 Are the data elements needed for the measure as specified available electronically** (*Elements that are needed to compute measure scores are in defined, computer-readable fields*): ALL data elements in electronic health records (EHRs)

**4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:**

**4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H ☐ M ☒ L ☐ I ☐**

**4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:**

We are not aware of any unintended consequences related to this measurement.

**4d. Data Collection Strategy/Implementation: H ☐ M ☒ L ☐ I ☐**

**A.2 Please check if either of the following apply** (*regarding proprietary measures*):

**4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues** (*e.g., fees for use of proprietary measures*):

This measure was found to be reliable and feasible for implementation.

**Overall, to what extent was the criterion, *Feasibility*, met? H ☐ M ☒ L ☐ I ☐**

**Provide rationale based on specific subcriteria:**

**OVERALL SUITABILITY FOR ENDORSEMENT**

**Does the measure meet all the NQF criteria for endorsement? Yes ☒ No ☐**

**Rationale:**

**If the Committee votes No, STOP.**

**If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.**

**5. COMPARISON TO RELATED AND COMPETING MEASURES**

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

**5.1 If there are related measures** (*either same measure focus or target population*) **or competing measures** (*both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:

0437 : STK 04: Thrombolytic Therapy

**5a. Harmonization**

**5a.1 If this measure has EITHER the same measure focus OR the same target population as [NQF-endorsed measure\(s\)](#): Are the measure specifications completely harmonized?** No

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

This measure is part of a pair. Although the list of potential exceptions has been harmonized with The Joint Commission's Contraindications/Warning lists, they have not been added as exclusions. Exceptions allow for clinical judgment.

#### **5b. Competing Measure(s)**

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

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

Our measure is part of a measure pair, which addresses both consideration and initiation of tPA.

We have developed and will maintain specifications for multiple data sources, including Electronic Health Records (EHRs) and Claims-Based Reporting. Our specifications for EHRs are developed in accordance with the terminology standards (eg, SNOMED, RxNorm, LOINC) named in the Meaningful Use Program (CMS EHR Incentive Program). Our measure specifications include diagnosis codes ICD-9, ICD-10, and SNOMED, whereas the Joint Commission measure only includes ICD-9 codes for diagnosis.

### **CONTACT INFORMATION**

**Co.1 Measure Steward (Intellectual Property Owner):** AMA-convened Physician Consortium for Performance Improvement, 330 N. Wabash Ave., Suite 39300, Chicago, Illinois, 60611

**Co.2 Point of Contact:** Samantha, Tierney, [Samantha.Tierney@ama-assn.org](mailto:Samantha.Tierney@ama-assn.org), 312-464-5524-

**Co.3 Measure Developer if different from Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement, 515 N. State St, Chicago, Illinois, 60654

**Co.4 Point of Contact:** Diedra, Joseph, MPH, [diedra.joseph@ama-assn.org](mailto:diedra.joseph@ama-assn.org), 312-464-4904-

**Co.5 Submitter:** Mark S., Antman, DDS, MBA, [mark.antman@ama-assn.org](mailto:mark.antman@ama-assn.org), 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement

**Co.6 Additional organizations that sponsored/participated in measure development:**

American Academy of Neurology

American College of Radiology

National Committee for Quality Assurance

**Co.7 Public Contact:** Mark S., Antman, DDS, MBA, [mark.antman@ama-assn.org](mailto:mark.antman@ama-assn.org), 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement

### **ADDITIONAL INFORMATION**

**Workgroup/Expert Panel involved in measure development**

**Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**

List of Work Group Members:

Joseph Drozda, Jr., MD (Co-Chair) (methodology)

Robert G. Holloway, MD, MPH (Co-Chair) (neurology)  
 David Seidenwurm, MD (Co-chair) (neuroradiology)  
 David N. Alexander, MD (neurology, vascular neurology, spinal cord injury)  
 M. Carolyn Baum, PhD, OTR/L (occupational therapy)  
 Christopher Bever, Jr., MD, MBA (neurology)  
 Thomas P. Bleck, MD, FCCM (internal medicine, critical care, neurology, vascular neurology, clinical neurophysiology)  
 John Y. Choi, MD, MPH (neurology)  
 Janet Y. Forbes, MD (internal medicine)  
 Millie Hepburn-Smith, MSN, RN, ACNS-BC (neuroscience nursing)  
 Judith Hinchey, MD, MS (neurology)  
 Peggy Jones (patient representative)  
 Irene Katzan, MD (neurology)  
 Adam Kelly, MD (neurology)  
 Rahul K. Khare, MD, MS, FACEP (emergency medicine)  
 Michael Lev, MD (radiology)  
 David Likosky, MD, SFHM (neurology, internal medicine, vascular neurology)  
 Constantine Moschonas, MD (neurology)  
 Suresh Mukherji, MD, FACR (neuroradiology)  
 Robert C. Mullen, MPH (speech-language pathology)  
 Charles Prestigiacomo, MD (neurological surgery)  
 Eric Russell, MD, FACR (radiology/neuroradiology)  
 Pina C. Sanelli, MD, MPH (radiology/neuroradiology)  
 Daniel Triezenberg, MD (family medicine)  
 Patrick Turski, MD, FACR (neuroradiology)  
 Richard Zorowitz, MD (physical medicine and rehabilitation)

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study must be equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

**Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:**

**Measure Developer/Steward Updates and Ongoing Maintenance**

**Ad.3 Year the measure was first released:** 2006

**Ad.4 Month and Year of most recent revision:** 05, 2012

**Ad.5 What is your frequency for review/update of this measure?** Please see section Ad.9

**Ad.6 When is the next scheduled review/update for this measure?** 09, 2013

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**Ad.9 Additional Information/Comments:** Coding/Specifications updates occur annually. The PCPI has a formal measurement review process that stipulates regular (usually on a three-year cycle, when feasible) review of the measures. The process can also be activated if there is a major change in scientific evidence, results from testing or other issues are noted that materially affect the integrity of the measure.

**Date of Submission (MM/DD/YY):** 05/04/2012