NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

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Brief Measure Information

NQF #: 1952

Measure Title: Time to Intravenous Thrombolytic Therapy

Measure Steward: American Heart Association

Brief Description of Measure: Percent of acute ischemic stroke patients receiving intravenous alteplase therapy during the hospital stay who have a time from hospital arrival to initiation of thrombolytic therapy (door-to-needle time) of 60 minutes or less

Developer Rationale: It is estimated that an American has a stroke every 40 seconds, indicating that stroke is a major public health problem in the United States (Benjamin et al., 2019). Between 2013 to 2016, the overall prevalence of stroke amongst Americans was approximately 2.5% (Benjamin et al., 2019), and as Americans are living longer this rate is expected to climb; it is projected that by 2030 the prevalence of stroke will be around 3.6% (Khavjou, Phelps, & Leib, 2016). Each year approximately 795,000 people experience a new or recurrent stroke (Benjamin et al., 2019). In 2015, the total costs of stroke were estimated at $66 billion, and this is expected to increase to $143 billion in 2035 (Khavjou, Phelps, & Leib, 2016). Of all strokes, approximately 87% are ischemic (Benjamin et al., 2019).

Multiple studies have shown that the rapid administration of intravenous recombinant tissue-type plasminogen activator (tPA) to appropriate patients is a proven, effective treatment in restoring blood flow and reducing long-term morbidity for ischemic stroke patients. Every minute an ischemic stroke patient goes untreated, he/she loses 1.9 million neurons and every hour this patient goes untreated, he/she loses 120 million neurons. In comparing normal aging with the aging brain amongst ischemic stroke patients, the ischemic brain ages 3.6 years each hour without treatment (Saver, 2006). The seminal clinical trial conducted by the National Institute of Neurological Disorders and Stroke (NINDS) in 1996 found that timely intravenous alteplase administration improved clinical outcomes for the stroke patient at three months (1995; Demaerschalk et al., 2016). This is the foundation of the American Heart Association / American Stroke Association (AHA/ASA) clinical guidelines on the management of patients with acute ischemic stroke (Hatcher & Starr, 2011). In addition to effectively restoring blood flow and reducing stroke-related morbidity and mortality, patients receiving IV alteplase within 60 minutes were more likely to be discharged to home, and less likely to develop symptomatic intracerebral hemorrhage (ICH) within 36 hours after IV alteplase as compared with those treated beyond 60 minutes (Tong et al., 2018).

Despite the strong evidence for timely alteplase administration amongst ischemic stroke patients, gaps in care remain as is illustrated via performance rates pulled from existing programs as well as the literature. This measure is intended to promote a reduction in door-to-needle times and improvement in the proportion of eligible patients receiving treatment within 60 minutes of hospital arrival.

Citations:

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2. Demaerschalk BM, Kleindorfer DO, Adeoye OM, Demchuk AM, Fugate JE, Grotta JC, Khalessi AA, Levy EI, Palesch YY, Prabhakaran S, Saposnik G, Saver JL, Smith EE; on behalf of the American Heart Association Stroke Council and Council on Epidemiology and Prevention. Scientific rationale for the inclusion and exclusion criteria for intravenous alteplase in acute ischemic stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016;47:581–641.

3. Hatcher, M. A., & Starr, J. A. (2011). Role of Tissue Plasminogen Activator in Acute Ischemic Stroke. Annals of Pharmacotherapy, 45(3), 364–371. doi: 10.1345/aph.1p525

4. Khavjou, O., Phelps, D., & Leib, A. (2016). Projections of Cardiovascular Disease Prevalence and Costs: 2015–2035: Technical Report. RTI International. RTI Project Number 0214680.003.001.001. Retrieved from https://healthmetrics.heart.org/projections-of-cardiovascular-disease/

5. National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group (1995). Tissue plasminogen activator for acute ischemic stroke. The New England journal of medicine, 333(24), 1581–1587. doi:10.1056/NEJM199512143332401

6. Saver, J. L. (2006). Time Is Brain—Quantified. Stroke, 37(1), 263–266. doi: 10.1161/01.str.0000196957.55928.ab

7. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

Numerator Statement: Patients who receive IV alteplase at my hospital within 60 minutes after arrival

Denominator Statement: All patients with a final clinical diagnosis of ischemic stroke who received IV alteplase at my hospital

Denominator Exclusions: Denominator exclusions:

- Age < 18 years
- Stroke occurred after hospital arrival (in ED/Obs/inpatient)
- Patients whose date/time of ED arrival and/or date/time of IV alteplase administration is blank, unknown, or MM/DD/YYYY only.
- Patients with a negative calculated time difference
- Patients with a Date Last Known Well, but no time Last Known Well
- Patients that receive IV alteplase greater than 4.5 hours after Last Known Well
- Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit
- Clinical Trial

Denominator exceptions:

- Patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment

Measure Type: Process

Data Source: Registry Data

Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Nov 01, 2012 **Most Recent Endorsement Date:** Sep 23, 2016

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Evidence Summary or **Summary of prior review in 2016**

- The developer provided a logic model indicated that rapid administration of intravenous tPA treatment → timely restoration of blood flow in ischemic stroke patient → decrease in morbidity and mortality. This is supported by the AHA/ASA 2018 Guidelines and by multiple studies including several meta-analysis, RCT, and observational studies.
- The 2018 AHA/ASA Guidelines for Early Management of Patients with Acute Ischemic Stroke recommend that in patients eligible for intravenous alteplase, benefit of therapy is time dependent, and treatment should be initiated as quickly as possible (Class I; Level of Evidence A). Furthermore, the door-to-needle time (time of bolus administration) should be within 60 minutes from hospital arrival (Class I; Level of Evidence B-NR).
- For recommendation 1, the Guideline was based on 16 randomized control trials, 1 open trial, 32 observational studies, and 4 meta-analyses. For recommendation 2, There are 3 retrospective observational (analytic) studies supporting this recommendation between 2014 and 2017. Combined, these studies looked at 1,943 hospitals.
- Grade definitions were provided, indicating that both recommendations supporting this measure received a Class I (Strong) strength of recommendation. Class I recommendations indicate that the

"Benefit >>> Risk" and are recommended and indicated/useful/effective/beneficial. Level A/B classification indicate high to moderate quality of evidence.

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

- **Updates:**
  - Developers presented the AHA/ASA 2018 Guideline for this measure in patients eligible for intravenous alteplase, benefit of therapy is time dependent, and treatment should be initiated as quickly as possible (Class 1; Level A). Specifically the door-to-needle time (time of bolus administration) should be within 60 minutes from hospital arrival. (Class 1, Level of Evidence B-NR).
  - Developers note that there are no significant updates to the body of evidence since the 2018 guideline supporting this measure, that would contradict or impact the intent of this measure, namely that the benefit of alteplase is time dependent, amongst ischemic stroke patients.

Exception to evidence

- Not applicable

Questions for the Committee:

- *The evidence provided by the developer is updated, directionally the same, and stronger compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence??*

Guidance from the Evidence Algorithm

Box 1: the measure DOES NOT represent an healthcare outcome → Box 3: The developer has provided empirical data to support the measure → Box 4: The developer provides a summary of the quality, quantity, and consisentency of the evidicence → Box 5a: The quality, quantity, and consistency are of high quality, mod/high quantity, and of high consistency → Rate as HIGH

Preliminary rating for evidence: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for evidence: ☐ **Pass** ☐ **No Pass**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- Despite some recent improvements, recent studies have shown that ~50% of patients receive tPA treatment within the guideline-recommended 60 minute door-to-needle times (Tong et al, 2018; Kamal et al., 2017), with a the median door-to-needle time was 71 minutes (Kim et al., 2017). This indicates a substantial gap in the compliance with this measure.
- Recent data from the developer shows that the mean performance score using data from the Get with the Guidelines registry increased from 53.5% to 76.1% (2016 to 2018).

Disparities

- The developer presented data as specified stratified by age, sex, and race/ethnicity, with results indicating lower performance for women compared to men, and higher performance for some minorities but not others.

Questions for the Committee:

- *Is there a gap in care that warrants a national performance measure?*

Preliminary rating for opportunity for improvement: ☒ High ☐ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

Evidence

- **Evidence high and no need for repeat discussion and vote.**
- **Recent evidence is presented to support the direct relationship between the measured process and clinical outcomes. Specifically, the administration of intravenous thrombolytic therapy within 60 minutes (door to needle time) is associated with deceased likelihood of developing ICH.**
- **I amnot aware of any new studies/information that changes the evidence base**
- **Multiple studies have shown that the rapid administration of intravenous recombinant tissue-type plasminogen activator (tPA) to appropriate patients is a proven, effective treatment in restoring blood flow and reducing long-term morbidity for ischemic stroke patients. In addition to effectively restoring blood flow and reducing stroke-related morbidity and mortality, patients receiving IV alteplase within 60 minutes were more likely to be discharged to home, and less likely to develop symptomatic intracerebral hemorrhage (ICH) within 36 hours after IV alteplase as compared with those treated beyond 60 minutes. I am not aware of any new studies/information that changes the evidence base for this measure.**
- **No problems — very strong**

Performance Gap

- **It appears that there has been improvement, but there is still a gap. There are some disparities for sex and race/ethnicity that should also be addressed.**
- **Updated performance data and published evidence was provided that demonstrates a disparity in process between certain groups. Approximately 50% of patients receive tPA within 60 minutes, with women, certain racial/ethnic groups, and less severe strokes had longer door-to-needle times.**
- **there is a gap, disparities for women noted**
- **Although improvements were seen through the years in this cohort, for example in 2008 26.4% of patients had DTN times </= 60 minutes and in 2017 66.2% of patients had door-to-needle times </= 60 minutes (P<0.001), a significant gap, demonstrated from recent years, remains. Get With The Guidelines – Stroke (GWTG-Stroke) results from January 1, 2018 to December 31, 2018 showed that American Indian/Alaska Natives had longer door-to-needle times, as compared to other racial/ethnic groups. Other studies confirm gender, racial, age, and geographic disparities amongst patients with ischemic stroke receiving timely care at the hospital. As a side note, tPA is still not FDA approved for <18 due to the termination of the TIPS trial in 2013 (lack of patient accrual). Although tPA is being used in the pediatric population and the hope is that we will gather data retrospectively.**
- **No problems - large gap**

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

Data source(s):
Specifications:

- This is from a national clinical registry (GWTG-Stroke).
- The level of analysis is at the hospital/facility-level
- The denominator includes acute ischemic stroke patients who received intravenous alteplase during the hospital stay.
- The numerator includes acute ischemic stroke patients aged 18 years and older receiving intravenous alteplase 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.
- The denominator exclusions include patients:
    - Age < 18 years
    - Stroke occurred after hospital arrival (in ED/Obs/inpatient)
    - Patients whose date/time of ED arrival and/or date/time of IV alteplase administration is blank, unknown, or MM/DD/YYYY only
    - Patients with a negative calculated time difference
    - Patients with a Date Last Known Well, but no time Last Known Well
    - Patients that receive IV alteplase greater than 4.5 hours after Last Known Well
    - Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit
    - Clinical Trial
- The denominator exceptions include patients: who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment.
- For data collection the Get with the Guidelines Stroke Data Collection Form is used. This is a paper version of the electronic data collection tool which is called the Patient Management Tool (PMT).

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Prior testing:

- Accuracy for each individual data element and a composite accuracy measure were calculated. Agreement was assessed using kappa (K) statistics for categorical variables and intraclass correlation (ICC) for continuous variables. NQF considers this to be data element validity testing and therefore additional reliability testing isn't required.

Updated testing:

- Empirical reliability testing at the performance measure score level was conducted via a signal-to-noise analysis using the beta-binomial model. This is an appropriate method for testing reliability.
- A signal-to-noise analysis quantifies the amount of variation in performance that is due to differences between hospitals (as opposed to differences due to random measurement error). Results will vary based on the amount of variation between the hospitals and the number of patients treated by each

hospital. This method results in a reliability statistic that ranges from 0 to 1 for each provider. A value of 0 indicates that all variation is due to measurement error and a value of 1 indicates that all variation is due to real differences in provider performance. A value of 0.7 is often regarded as a minimum acceptable reliability value.

- Data used for testing included information from 1,619 of the 2,063 hospitals (78.5%) that reported data on this measure to the GWTG-Stroke registry and had at least one eligible patient for the measure between January 1st, 2018 through December 31st, 2018.
- Developers computed an average reliability statistic that would be achieved if all hospitals had at least one eligible patient.

Results of reliability testing

- The data are for the time period January 1st, 2018 through December 31st, 2018
- The average reliability for hospitals with at least one eligible patient is 0.76
- Of those 2,063 hospitals, 1,619 hospitals (78.5%) had at least one patient who qualified for the measure, after accounting for exclusions and exceptions, for a total of 33,836 eligible patients. The average number of eligible patients is 21 for the 1,619 hospitals. The range of eligible patients for 1,619 hospitals is from 1 to 171.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

Complex measure evaluated by Scientific Methods Panel? ☐ **Yes** ☒ **No**

Prior testing:

- **Data element testing:**

  Agreement was assessed using kappa (K) statistics for categorical variables and intraclass correlation (ICC) for continuous variables. The data submitted to the GWTG-Stroke program were compared against the medical record by a trained coder at the independent statistical coordinating center. No significant differences among participating hospitals were found in overall Inter-rater reliability by bed size, ischemic stroke volume, primary stroke center certification, or Coverdell Registry participation.

- **Face validity:**

  Face validity testing of the measure score as an indicator of quality was systematically assessed as follows:

  - After the measure was fully specified, an expert panel was asked to rate their agreement with the following statement: "The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality."
  - Scale 1-5, where 1= Strongly Disagree; 3= Neither Agree nor Disagree; 5= Strongly Agree
  - The results of the expert panel rating of the validity statement were as follows: N = 20; Mean rating = 4.2 and 85% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

Updated testing:

- **Empirical testing:**

- The developer conducted a correlation analysis using STK 04 Thrombolytic Therapy (NQF 0437) and hypothesized that the higher the hospital performance on time to thrombolytic therapy (i.e. the percent treated with alteplase for acute ischemic stroke within 60 minutes of hospital arrival) the higher hospital performance on STK 04 (i.e. the percent of patients with acute ischemic stroke who arrive within 2 hours that are treated with alteplase within 3 hours).
- Hospitals included in the analysis had at least one patient in the denominator after exclusions and exceptions were removed.
- Data from the AHA/ASA 2018 Get with the Guidelines Stroke Program were used to perform the correlation analysis for this measure.
- Time to Intravenous Thrombolytic Therapy (NQF 1952) was positively correlated with STK 04 Thrombolytic Therapy (NQF 0437) and found to be statistically significant:
  - Coefficient of correlation = 0.43 (Moderate)
  - Alpha level = 0.05
  - P-value = < 0.001
  - Number of shared hospitals based on Hospital identifier = 1,612

2b2-2b6. Potential threats to validity should be assessed/addressed.

2b2. Exclusions:

Exclusions include:

- Age < 18 years
- Stroke occurred after hospital arrival (in ED/Obs/inpatient)
- Patients whose date/time of ED arrival and/or date/time of IV alteplase administration is blank, unknown, or MM/DD/YYYY only
- Patients with a negative calculated time difference
- Patients with a Date Last Known Well, but no time Last Known Well
- Patients that receive IV alteplase greater than 4.5 hours after Last Known Well
- Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit
- Clinical Trial

Exceptions include:

- Patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment.

Results of the exclusions and execptions analyses:

- Amongst the 1,619 included hospitals, there were a total of 12,379 exceptions and exclusions reported. The average number of exceptions and exclusions per hospital in this sample is 7.65. The proportion of exceptions to patients is 0.37. According to the results, 50% of hospitals had 5 or fewer exceptions and exclusions across eligible patients for the year under study.

2b3. Risk adjustment:

Risk-adjustment method ☒ **None** ☐ **Statistical model** ☐ **Stratification**

- Not applicable, as measure is a process measure.

2b4. Meaningful difference:

Table 1. Measures of central tendency, variability, and dispersion (including outliers)

Questions for the Committee regarding reliability:

- *Does the Committee have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?*
- *Does the Committee think there is a need to discuss and/or vote on reliability?*

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The [staff] or [Scientific Methods Panel] is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Guidance from the Reliability Algorithm: (Box 1) Specifications are clear and precise → (Box 2) Empirical testing using statistical tests → (Box 4) score-level testing → (Box 5) appropriate method used (signal-to-noise) → (Box 6b) moderate confidence of reliability → Rate as Moderate

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Guidance from the Validity Algorithm: (Box 1) threats mostly assessed → (Box2) validity testing conducted for measure as specified → (Box 5) empirical testing conducted for measure score → (Box 6) method was described and appropriate → (Box 7b) moderate certainty that data are valid → Rate as Moderate

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

Reliability- Specifications

- **No concerns.**
- **Data elements are clearly defined. No significant concerns about the measure being consistently implemented; testing in 2018 demonstrated average reliability of 0.76.**
- **No concerns currently used.**
- **The AHA/ASA recommends that hospitals document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AHA/ASA also advocates for the systematic review and analysis of each hospital's exceptions data to identify practice patterns and opportunities for quality improvement.**
- **Reliability of denominator exclusions needs to be explored. Particularly, whether a reason for delay was documented.**

Reliability-Testing

- **No concerns.**
- **No significant concerns about reliability. For hospitals with at least one eligible patient, reliability is 0.76, which increases as the sample size increases.**
- **No concerns.**
- **I do not have concerns about the reliability of the measure.**

- **No concerns.**

Validity-Testing

- **New empirical testing shows that time to treatment was positively correlated with thrombolytic administration. No new correlations with outcomes, but administration has been correlated with better outcomes in randomized controlled studies. The 60 minute recommendation is class I, level B-NR evidence (non-randomized trials or meta-analysis of such trials).**
- **No specific concerns with validity testing, although current testing shows only moderate correlation (0.43).**
- **No and understand not an issue for continuing measures.**
- **I do not have any concerns with the testing results.**
- **The correlation with STK_4 is surprisingly low. They are extremely similar measures, yet seem to be measuring different things. Why is that?**

Threats to Validity

- **No concerns.**
- **Submitter notes that they did not expect higher validity correlation due to varied factors influencing eligibility and facilities treating all eligible patients regardless of time needed to treat. Missing and excluded data do not appear to significantly impact the denominator or the overall validity demonstrated through testing.**
- **The small number at some hospitals is concerning 1 patient seems concerning.**
- **Given the small frequency of missing data there is no reason to believe that missing data biased the performance results due to systematic missing data. The results of the expert panel rating of the validity statement were as follows: N = 20; Mean rating = 4.2 and 85% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.**
- **The big problem is missing data/no response. Quality stroke care is about trying to find a last normal time, even when its hard. This measure incentives hospitals to simply not document rather than to find this out. (This may be, in fact, the single most important element to high quality stroke care in the ED!) Similarly, the ability to document any reason at all for non-administration without a test on whether that is a valid reason seems overly broad and makes the measure gamble. In principle, somebody could document, "Dont' believe tPA works" for every patient and their center woudl not receive a score?**

Other Threats

- **Data show fewer exceptions/exclusions than I would have expected.**
- **Exclusions are justified and consistent with evidence presented. No risk adjustment was conducted.**
- **No risk adjustment.**
- **No patients or patient groups are inappropriately excluded from the measure. In order to enhance data quality, they also exclude hospitals that have missing medical history in more than 25% of their submitted cases.**
- **No concerns**

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- This data are collected through a clinical registry, the Get With the Guidelines – Stroke
- The developer states that there are no issues with data collection have been identified and no modifications have been made to this measure, as collected in the GWTG – Stroke registry, due to issues with data collection, sampling or cost.

  The data for this measures are abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

Questions for the Committee:

- *Are the required data elements routinely generated and used during care delivery?*
- *Are the required data elements available in electronic form, e.g., EHR or other electronic sources?*
- *Is the data collection strategy ready to be put into operational use?*
- *If an eCQM, does the eCQM Feasibility Score Card demonstrate acceptable feasibility in multiple EHR systems and sites?*

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

- **No issues with feasibility.**
- **Required data elements are consistently available for collection and analysis, as evidenced by the significant growth in reporting since the last review of this measure. No concerns about data collection strategy being operationalized.**
- **Unable to comment.**
- **Given that the data for this measure are collected through the Get With the Guidelines – Stroke registry, and are not collected in an electronic health record, no feasibility assessment was performed. No issues with data collection have been identified and no modifications have been made to this measure due to issues with data collection, sampling or cost, as collected in the GWTG - Stroke registry.**
- **No concerns.**

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial

endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

- Professional Certification or Recognition Program – Stroke Hospital Recognition Program through the Get with the Guidelines-Stroke; Details of the program including a Web-based Patient Management Tool™, decision support, a robust registry, real-time benchmarking capabilities are provided.
- Quality Improvement with Benchmarking -Stroke Hospital Recognition Program; Achievement Awards recognize hospitals that demonstrate at least 85 percent compliance in each of 7 Get With The Guidelines-stroke Achievement Measures.
- Quality Improvement (Internal to the specific organization); participating hospitals commit to reaching the Target: Stroke performance goal of 50 percent or more of eligible patients treated with thrombolytic within 60 minutes of hospital arrival.
- NQF includes the use of performance results about identifiable accountable entities.

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☒ **No**

Accountability program details

- Professional Certification or Recognition Program -Stroke Hospital Recognition Program through the Get with the Guidelines-Stroke; Details of the program including a Web-based Patient Management Tool™, decision support, a robust registry, real-time benchmarking capabilities
- Quality Improvement with Benchmarking -Stroke Hospital Recognition Program; Achievement Awards recognize hospitals that demonstrate at least 85 percent compliance in each of 7 Get With The Guidelines-stroke Achievement Measures

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The AHA/ASA has an online tool that registry participants can use to provide feedback on this measure or other measures reported in the registry.
- Registry staff respond to all feedback and any comments that may indicate a problem with a measure are escalated to the measures team for evaluation and, if needed, discussed with the expert work group that oversees the GWTG-Stroke program to consider if updates or changes to the measure are needed.
- The developer reports that no feedback has been received from those being measured

Additional Feedback:

- The developer reports that no feedback has been received from others abou the measure

***Questions for the Committee**:*

- *How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?*

- *How has the measure been vetted in real-world settings by those being measured or others?*

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer presented data demonstrating a mean performance score from the Get with the Guidelines registry that increased from 26.4% to 66.2% (2008-2018). This indicates that the implementation of the measure led to a positive trend in the proportion of patients receiving alteplase treatment with a door-to-needle time of 60 minutes or less

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer states that they have not received reports of unexpected findings resulting from the implementation of this measure

Potential harms

- The developer reports that numerous studies have shown that door-to-needle times have not led to unintended consequences such as an increase in mortality or an increase in bleeding complications.
- Despite increased risk of hemorrhagic transformation, there is still proven clinical benefit for patients with severe stroke symptoms. (Demaerschalk et al., 2016). (Class I; Level A)

Additional Feedback:

- There is no feedback on this measure.

***Questions for the Committee**:*

- *How can the performance results be used to further the goal of high-quality, efficient healthcare?*
- *Do the benefits of the measure outweigh any potential unintended consequences?*

Preliminary rating for Usability and use: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

Use

- **No issues detected.**
- **Measure performance is publicly reported and allows for hospitals to be benchmarked against peer hospitals. An online tool exists for participant feedback (no feedback has been received).**
- **No feedback reported.**
- **Public reporting is through Get With the Guidelines - Stroke. Hospitals have three levels of recognition. Target: Stroke Phase II is for hospitals to achieve door-to-needle times within 60 minutes for 75 percent or more of acute ischemic stroke patients treated with intravenous**

alteplase, with a secondary goal of 45 minutes or less door-to-needle times in 50 percent or more of the same category of patients.

- **No concerns.**

Usability

- **A possible unintended consequence would be neglecting the criteria for thrombolytic use in the push to administer quicker to achieve 60 minute times. There is no evidence that this is the case, but it is not clear that this issue has been assessed.**
- **Measure data can be used to monitor performance on the target as well as assess whether or not any unintended consequences (e.g. rushed assessments, incorrect intervention) occur more frequently as a result of shortened door-to-needle time. Data suggest that reducing time to administration is associated with more favorable clinical outcomes, outweighing the risks.**
- **No unintended consequences reported statement that even if hemmorhagic conversion occurs.**
- **Via its interactive patient management tool, the GWTG-Stroke program provides feedback, including benchmarking data and embedded links to clinical evidence supporting best practices, to its participating hospitals. There has not been reports of unexpected findings resulting from the implementation of this measure. Although faster door-to-needle times could lead to rushed assessments and increased complications, the literature demonstrates that as more patients have door-to-needle times within 60 minutes, there is a corresponding improvement in variables such as in-hospital mortality, symptomatic intracranial hemorrhage rates, and discharge to the home.**
- **No concerns**

Criterion 5: Related and Competing Measures

Related or competing measures

Competing measures:

- The current measure (#1952) captures acute ischemic stroke patients aged 18 years and older receiving intravenous alteplase 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.

- #0437 STK 04: Thrombolytic Therapy
  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

Harmonization

These measures are not harmonized.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

- **May need harmonization with #0437 SK 04.**
- **0437: STK 04: Thrombolytic Therapy. This measure addresses the go/no-go administration of therapy, whereas the current measure assesses the time to administration. There is no need to further harmonize these measures.**
- **There are competing measures not harmonized.**

- **The related NQF measure, 0437 : STK 04: Thrombolytic Therapy, has different specifications based on different populations and different focal points of the measure. There are no competing measures listed. Although I am curious if there are measures for endovascular techniques being considered.**
- **No concerns.**

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: Month/Day/Year

- **Of the XXX NQF members who have submitted a support/non-support choice:**
  - XX support the measure
  - YY do not support the measure

Developer Submission

Additional evaluations and submission materials attachments…

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

2019_SUBMISSION_1952_NQF_evidence_attachment_final.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome: Click here to name the health outcome

☐ Patient-reported outcome (PRO): Click here to name the PRO

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

☐ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

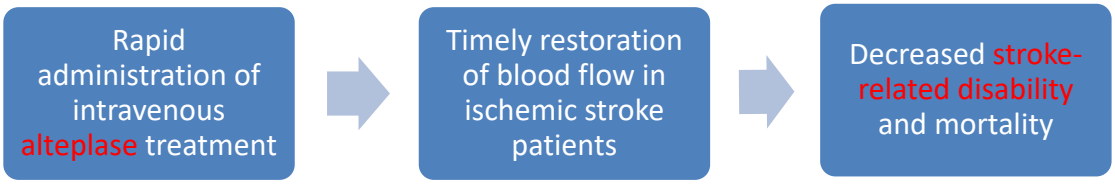
☒ Process: Time from hospital arrival to initiation of intravenous alteplase, among ischemic stroke patients

☐ Appropriate use measure: Click here to name what is being measured

☐ Structure: Click here to name the structure

☐ Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.



1a.3 Value and Meaningfulness: **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including**	**AHA/ASA 2013 Guideline:** **Jauch EC, Saver JL, Adams HP, Bruno A, Connors JJ, Demaerschalk BM, et al; American Heart Association Stroke Council; Council on Cardiovascular Nursing; Council on Peripheral Vascular Disease; Council on Clinical Cardiology. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2013;44(3):870-947.**

• page number • URL	***Note that while the American Heart Association / American Stroke Association (AHA/ASA) has made minor updates to this evidence attachment since the last NQF submission, the underlying evidence and intent of the measure have not changed. Updates were made to capture the current language in the most recent guideline, in support of the measure.*** **AHA/ASA 2018 Guidelines:** **Title: 2018 Guidelines for the Early Management of Patients with Acute Ischemic Stroke** **Author: William J. Powers, MD, FAHA, Chair; Alejandro A. Rabinstein, MD, FAHA, Vice Chair; Teri Ackerson, BSN, RN; Opeolu M. Adeoye, MD, MS, FAHA; Nicholas C. Bambakidis, MD, FAHA; Kyra Becker, MD, FAHA; José Biller, MD, FAHA; Michael Brown, MD, MSc; Bart M. Demaerschalk, MD, MSc, FAHA; Brian Hoh, MD, FAHA; Edward C. Jauch, MD, MS, FAHA; Chelsea S. Kidwell, MD, FAHA; Thabele M. Leslie-Mazwi, MD; Bruce Ovbiagele, MD, MSc, MAS, MBA, FAHA; Phillip A. Scott, MD, MBA, FAHA; Kevin N. Sheth, MD, FAHA; Andrew M. Southerland, MD, MSc; Deborah V. Summers, MSN, RN, FAHA; David L. Tirschwell, MD, MSc, FAHA; on behalf of the American Heart Association Stroke Council** **Date: December 11, 2017** **Citation, including page number: Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; on behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2018;49:e53 and e65. doi: 10.1161/STR.0000000000000158.** **URL: https://www.ahajournals.org/doi/full/10.1161/STR.0000000000000158**
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	AHA/ASA 2013 Guideline: In patients eligible for intravenous rtPA, benefit of therapy is time dependent, and treatment should be initiated as quickly as possible. The door-to-needle time (time of bolus administration) should be within 60 minutes from hospital arrival. (Class I; Level of Evidence A) p. 898 *The AHA/ASA 2018 Guidelines note that the above recommendation from the 2013 Guideline remains unchanged and is reiterated, but re-worded for clarity.* AHA/ASA 2018 Guidelines:

<table>
<tr><td></td><td>Recommendation 1: In patients eligible for IV alteplase, benefit of therapy is time dependent, and treatment should be initiated as quickly as possible. (Class I; Level A)

Recommendation 2: It is recommended that DTN time goals be established. A primary goal of achieving DTN times within 60 minutes in ≥50% of AIS patients treated with IV alteplase should be established. (Class I; Level B-NR)</td></tr>
<tr><td>Grade assigned to the evidence associated with the recommendation with the definition of the grade</td><td>AHA/ASA 2013 Guidelines:
The weight of the evidence in support of the listed AHA/ASA recommendations included in section 1a.4.2 is rated as Level A, as noted parenthetically. Level A evidence refers to “Data derived from multiple randomized clinical trials or meta-analyses.”

AHA/ASA 2018 Guidelines:
Recommendation 1 - Level A:
High-quality evidence from more than 1 RCT
Meta-analyses of high-quality RCTs
One or more RCTs corroborated by high-quality registry studies
Recommendation 2 - Level B-NR (Nonrandomized)
Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
Meta-analyses of such studies</td></tr>
<tr><td>Provide all other grades and definitions from the evidence grading system</td><td>AHA/ASA 2013 Guidelines:
Levels A evidence is described in 1a.7.2. Level B evidence refers to “Data derived from a single randomized trial, or nonrandomized studies.” Level C evidence refers to “Only consensus opinion of experts, case studies, or standard-of-care.” Additional details and information about the evidence rating scheme can also be seen in 1a.4.2. and 1a.4.3.

AHA/ASA 2018 Guidelines:
These classifications apply the American College of Cardiology (ACC)/ AHA 2015 Levels of Evidence (LOE) to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care*. The LOE denotes the confidence in or certainty of the evidence supporting the recommendation, based on the type, size, quality, and consistency of pertinent research findings.

<table>
<tr><th colspan="2">Level (Quality) of Evidence**</th></tr>
<tr><td rowspan="2">Level A</td><td>-High-quality evidence** from more than 1 randomized controlled trials (RCT)</td></tr>
<tr><td>-Meta-analyses of high-quality RCTs</td></tr>
</table>
</td></tr>
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<table>
<tr><td></td><td>
<table>
<tr><td></td><td>-One or more RCTs corroborated by high-quality registry studies</td></tr>
<tr><td rowspan="2">Level B-R (Randomized)</td><td>-Moderate-quality evidence** from 1 or more RCTs</td></tr>
<tr><td>-Meta-analyses of moderate-quality RCTs</td></tr>
<tr><td rowspan="2">Level B-NR (Nonrandomized)</td><td>-Moderate-quality evidence** from one or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies</td></tr>
<tr><td>-Meta-analyses of such studies</td></tr>
<tr><td rowspan="3">Level C-LD (Limited Data)</td><td>-Randomized or nonrandomized observational or registry studies with limitations of design or execution</td></tr>
<tr><td>-Meta-analyses of such studies</td></tr>
<tr><td>-Physiological or mechanistic studies in human subjects</td></tr>
<tr><td>Level C-EO (Expert Opinion)</td><td>-Consensus of expert opinion based on clinical experience</td></tr>
<tr><td colspan="2">Class of Recommendation (COR) and LOE are determined independently (any COR may be paired with any LOE).</td></tr>
<tr><td colspan="2">A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test of therapy is useful or effective.</td></tr>
<tr><td colspan="2">*The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).</td></tr>
<tr><td colspan="2">**The method of assessing quality is evolving, including the application of standardized, widely used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.</td></tr>
</table>
(adapted from AHA/ASA 2018 Guidelines on the Early Management of Patients with Acute Ischemic Stroke)
</td></tr>
<tr><td>Grade assigned to the recommendation with definition of the grade</td><td>AHA/ASA 2013 Guideline:
The AHA/ASA recommendation included in section 1a.4.2. has been assigned a Class I. Class I recommendations refer to “Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.”

AHA/ASA 2018 Guidelines:
Both recommendations supporting this measure received a Class I (Strong) strength of recommendation. Class I recommendations indicate that the “Benefit >>> Risk” and are recommended and indicated/useful/effective/beneficial.</td></tr>
</table>

Provide all other grades and definitions from the recommendation grading system	AHA/ASA 2013 Guidelines: The standard AHA algorithm for classifying recommendations and levels of evidence focuses on therapeutic questions and, consequently, emphasizes evidence from randomized clinical trials. As such, AHA/ASA guideline methodology categorizes indications as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below: Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective. Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. • IIa: Weight of evidence/opinion is in favor of usefulness/efficacy • IIb: Usefulness/efficacy is less well established by evidence/opinion. Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful. • No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit • Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful Additional detail regarding the classification of recommendation and level of evidence is provided in the following table.

Table 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	SIZE OF TREATMENT EFFECT: CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* COR III: No benefit — Procedure/Test: Not Helpful — Treatment: No Proven Benefit COR III: Harm — Procedure/Test: Excess Cost w/o Benefit or Harmful — Treatment: Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Additional detail regarding AHA/ASA's gradation recommendations is provided in the following table.

Table 2. Definition of Classes and Levels of Evidence Used in AHA/ASA Recommendations

Class I	Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.
Class II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa	The weight of evidence or opinion is in favor of the procedure or treatment.
Class IIb	Usefulness/efficacy is less well established by evidence or opinion.
Class III	Conditions for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective and in some cases may be harmful.
Therapeutic recommendations	
Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of Evidence B	Data derived from a single randomized trial or nonrandomized studies
Level of Evidence C	Consensus opinion of experts, case studies, or standard of care
Diagnostic recommendations	
Level of Evidence A	Data derived from multiple prospective cohort studies using a reference standard applied by a masked evaluator
Level of Evidence B	Data derived from a single grade A study or 1 or more case-control studies, or studies using a reference standard applied by an unmasked evaluator
Level of Evidence C	Consensus opinion of experts

ACCF/AHA Task Force on Practice Guidelines. Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines. American College of Cardiology Foundation and American Heart Association, Inc. Cardiosource.com. 2010. Available at: http://assets.cardiosource.com/Methodology_Manual_for_ACC_AHA_Writing_Committees.pdf and http://my.americanheart.org/idc/groups/ahamah public/@wcm/@sop/documents/downloadable/ucm_319826.pdf.

AHA/ASA 2018 Guidelines:

These classifications apply the ACC/AHA 2015 Class of Recommendations (COR) to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care*. The COR reflects the magnitude of benefit over risk and corresponds to the

strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances (Halperin et al., 2016).

Class (Strength) of Recommendation	
Class I (Strong) Benefit >>>Risk	Suggested phrases for writing recommendations: -Is recommended -Is indicated / useful / effective / beneficial -Should be performed / administered / other -Comparative-Effectiveness Phrases**: --Treatment / strategy A is recommended / indicated in preference to treatment B --Treatment A should be chosen over treatment B
Class IIa (Moderate) Benefit >>Risk	Suggested phrases for writing recommendations: -Is reasonable -Can be useful / effective / beneficial -Comparative-Effectiveness Phrases**: --Treatment / strategy A is probably recommended / indicated in preference to treatment B --It is reasonable to choose treatment A over treatment B
Class IIb (Weak) Benefit ≥Risk	Suggested phrases for writing recommendations: -May / might be reasonable -May / might be considered -Userfulness / effectiveness is unknown / unclear / uncertain or not well established
Class III: No Benefit (Moderate) Benefit = Risk	Suggested phrases for writing recommendations: -Is not recommended -Is not indicated / useful / effective / beneficial -Should not be performed / administered / other
Class III: Harm (Strong) Risk>Benefit	Suggested phrases for writing recommendations: -Potentially harmful -Causes harm -Associated with excess morbidity / mortality -Should not be performed / administered / other
COR and LOE are determined independently (any COR may be paired with any LOE).	
*The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).	
**For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.	

	(adapted from AHA/ASA 2018 Guidelines on the Early Management of Patients with Acute Ischemic Stroke)
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	AHA/ASA 2013 Guidelines: Information regarding the total number of studies and type of study designs included in the body of evidence is not available. However, the guidelines cite that 16 randomized control trials, 1 open trial, 32 observational studies, and 4 meta-analyses were reviewed to develop the recommendations provided in 1a4.2 and most relevant to the patient populations addressed in the measure. AHA/ASA 2013 Guidelines: Information regarding the overall quality of evidence across studies is not available. AHA/ASA 2018 Guidelines: Recommendation 1: The Guideline notes that there is no new pertinent evidence for this unchanged recommendation and refers to the 2013 Guideline. The 2013 Guideline cited that 16 randomized control trials, 1 open trial, 32 observational studies, and 4 meta-analyses were reviewed to develop the recommendation. Recommendation 2: There are 3 retrospective observational (analytic) studies supporting this recommendation between 2014 and 2017. Combined, these studies looked at 1,943 hospitals.
Estimates of benefit and consistency across studies	AHA/ASA 2013 Guidelines: The guideline does not include an overall estimate of benefit from the body of evidence. However, they do include the following summary information regarding the benefits of timely rtPA treatment, "Intravenous administration of rtPA remains the only FDA-approved pharmacological therapy for treatment of patients with acute ischemic stroke. Its use is associated with improved outcomes for a broad spectrum of patients who can be treated within 3 hours of the last known well time before symptom onset and a mildly more selective spectrum of patients who can be treated between 3 and 4.5 hours of the last known well time. Most importantly, earlier treatment is more likely to result in a favorable outcome." (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*) AHA/ASA 2018 Guidelines: Recommendation 1: The 2018 Guideline notes that there is no new pertinent evidence for this unchanged recommendation and refers to the 2013 AHA/ASA Guideline. The 2013 Guideline did not include an overall estimate of benefit and

	consistency from the body of evidence supporting the recommendation. As noted in the previous submission, the 2013 Guidelines included the following summary regarding the benefits of timely alteplase administration: "Intravenous administration of rtPA remains the only FDA-approved pharmacological therapy for treatment of patients with acute ischemic stroke. Its use is associated with improved outcomes for a broad spectrum of patients who can be treated within 3 hours of the last known well time before symptom onset and a mildly more selective spectrum of patients who can be treated between 3 and 4.5 hours of the last known well time. Most importantly, earlier treatment is more likely to result in a favorable outcome." Recommendation 2: Per the data supplement to the AHA/ASA 2018 guidelines, the conclusions of the studies supporting the second recommendation are as follows: • The 2017 retrospective observational study looked at 888 hospitals and 16,901 patients with acute ischemic stroke treated with alteplase within 4.5 hours of symptom onset, between June 2014 and April 2015. The study found that the median door-to-needle (DTN) time for alteplase administration was 56 minutes (IQR 42-75) and concluded that a median DTN time of less than 60 minutes were achievable in a majority of patients. • The 2014 retrospective observational study evaluated the pre- and post-Target:Stroke intervention results among 71,169 stroke patients treated with alteplase across 1,030 hospitals between April 2003 and September 2013. This study found that the median DTN time for alteplase administration declined from 77 minutes (IQR 60-98 minutes) during the pre-intervention period to 67 minutes (IQR 51-87 minutes) during the post-intervention period (P<.001). The study concluded that the implementation of the Target:Stroke quality improvement initiative was associated with improved timeliness of tPA delivery, and that a median hospital DTN target times of less than 60 minutes was achievable in over 50% of cases. • The second 2014 retrospective observational study looked at 1,193 acute ischemic stroke patients treated within 4.5 hours of symptom onset, across 25 hospitals between January 2009 and December 2012. The mean DTN time for alteplase administration was 82.9 minutes and the median time was 76 minutes. The study concluded that approximately one-quarter of patients were treated within 60 minutes. In addition, both recommendations supporting this measure received a Class I (Strong) strength of recommendation, which reflects a high magnitude of benefit over risk. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances (Halperin et al., 2016).
What harms were identified?	AHA/ASA 2013 Guidelines: Harms studied focused on the harms of treatment rather than the harms of time-initiated therapy.

	As noted in the AHA/ASA guidelines, intracranial hemorrhages were reported in community based-settings prior to the approval of rtPA as a treatment option. However, the guidelines state it is now clear that the risk of hemorrhage is proportional to the degree to which the NINDS protocol is not followed. Other adverse events studied include systemic bleeding, myocardial rupture if fibroinolytics are given within a few days of acute myocardial infarction and reactions such as anaphylaxis or angioedema also has occurred, but these events are rare. Orolingual angioedema reactions have occurred in 1.3%-5.1% of patients, however, reactions are typically mild. Despite the harms listed, it is ultimately determined that the benefits of timely treatment outweigh all harms studied. Although faster door-to-needle times could lead to rushed assessments and increased complications, the literature demonstrates that as more patients have door-to-needle times ≤ 60 minutes, there is a corresponding improvement in variables such as in-hospital mortality, symptomatic intracranial hemorrhage rates, and discharge to the home. Tong et al. found among patients who received IV alteplase within 4.5 hours of time last known to be well, and as a greater percent of these patients had door-to-needle times ≤ 60 minutes throughout the last decade, in-hospital all-cause mortality decreased from 7.2% in 2008 to 5.1% in 2017 (P<0.001), symptomatic intracranial hemorrhage rates within 36 hours decreased from 6.3% in 2008 to 3.4% in 2017 (P<0.001), and discharge to the home increased from 23.6% 2008 to 50.9% in 2017 (P<0.001) (2018). In addition, a 2016 Scientific Statement put forth by the AHA/ASA addresses the risk of symptomatic intracranial hemorrhages and makes the following recommendation: For severe stroke symptoms, intravenous alteplase is indicated within 3 hours from symptom onset of ischemic stroke. Despite increased risk of hemorrhagic transformation, there is still proven clinical benefit for patients with severe stroke symptoms (Demaerschalk et al., 2016). (Class I; Level A)
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	1. Citation: Fonarow GC, Zhao X, Smith EE, Saver JL, Reeves MJ, Bhatt DL, et al. Door-to-needle times for tissue plasminogen activator administration and clinical outcomes in acute ischemic stroke before and after a quality improvement initiative. JAMA. 2014;311(16):1632-1640. DOI:10.1001/jama.2014.3203. Description: Observational study as a part of Target Stroke Initiative that looked to evaluate door-to-needle times for tPA administration. Additionally the study evaluated the proportion of patients with door-to-needle times of ≤ 60 minutes before and after a quality improvement initiative to determine if improvements in door-to-needle times were associated with improved clinical outcomes. Results: “Importantly, the improvement in timeliness in tPA administration following the start of the program was associated with improved clinical outcomes including lower in-hospital mortality, more frequent discharge to a more independently functioning environment, and lower rates of tPA complications, including symptomatic intracranial hemorrhage. These findings

	further reinforce the importance and clinical benefits of more rapid administration of intravenous tPA." Conclusion: This study further highlights the importance of a door-to-needle time of ≤ 60 minutes for the administration of tPA following an ischemic stroke. While timely administration leads to improved clinical outcomes, the study highlights that less than 30% of patients are receiving treatment within the recommended timeline and further emphasizes the opportunity for improvement for facilities. 2. Citation: Emberson J, Lees KR, Lyden P, Blackwell L, Albers G, Bluhmki E, et al. Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomized trials. Lancet. 2014;384(9958):1929-1935. Description: Meta-analysis of individual patient data from 6756 patients in nine randomized trials comparing alteplase with placebo or open control. The primary goal of the analysis was to explore the extent to which treatment delay affected the effect of the alteplase and to establish if age or stroke severity affected treatment effects. The authors defined good stroke outcome as no significant disability at 3-6 months as defined by a modified Rankin scale of 0 or 1. Additional outcomes included symptomatic intracranial hemorrhage, fatal intracranial hemorrhage within 7 days and 90-day mortality. Results: "Alteplase significantly increased the odds of a good outcome, with earlier treatment resulting in significantly greater proportional benefit increasing proportional benefit with earlier treatment." The study also states, "The effect of alteplase on a good outcome was chiefly driven by treatment delay; after controlling for treatment delay, neither age nor severity of stroke contributed significant additional predictive value." The tables below demonstrate the importance of early treatment for improved outcomes.

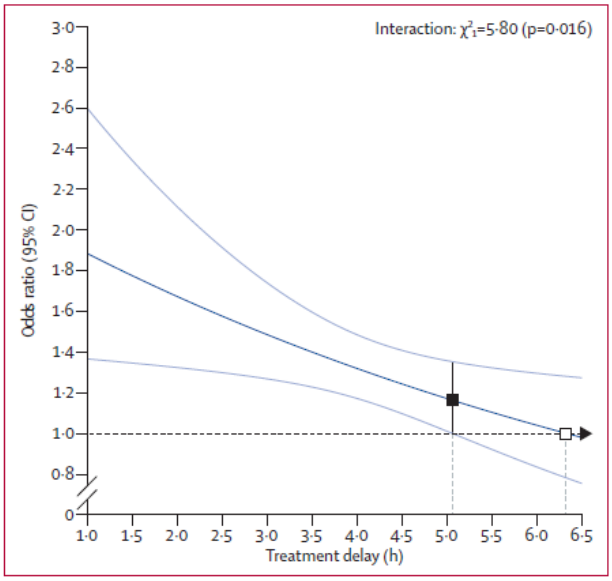

Figure 1: **Effect of timing of alteplase treatment on good stroke outcome (mRS 0–1)**

The solid line is the best linear fit between the log odds ratio for a good stroke outcome for patients given alteplase compared with those given control (vertical axis) and treatment delay (horizontal axis; $p_{interaction}$=0·016). Estimates are derived from a regression model in which alteplase, time to treatment, age, and stroke severity (handled in a quadratic manner) are included as main effects but the only treatment interaction included is with time to treatment. Only 198 patients (159 from IST–3) had a time from stroke onset to treatment of more than 6 h. The white box shows the point at which the estimated treatment effect crosses 1. The black box shows the point at which the lower 95% CI for the estimated treatment effect first crosses 1·0. mRS=modified Rankin Scale.

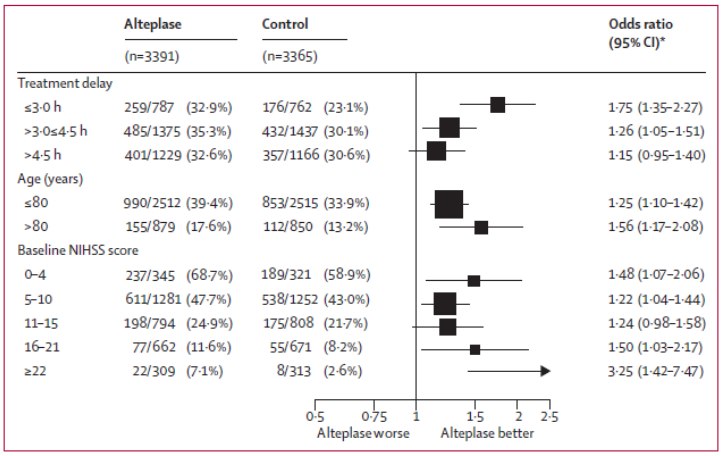

Figure 2: **Effect of alteplase on good stroke outcome (mRS 0–1), by treatment delay, age, and stroke severity**

*For each of the three baseline characteristics, estimates were derived from a single logistic regression model stratified by trial, which enables separate estimation of the OR for each subgroup after adjustment for the other two baseline characteristics (but not for possible interactions with those characteristics). mRS=modified Rankin Scale.

Conclusion: The results of the meta-analysis indicate that the early administration of tPA from symptom onset is effective in improving good outcomes for stroke patients. The meta-analysis further emphasizes the importance of timely administration of tPA and shows a proportional benefit with earlier treatment.

Provided below are the citations of new studies in support of this measure, since the publication of the 2018 AHA/ASA Guidelines. There are no significant updates to the body of evidence since the 2018 guideline supporting this measure, that

	would contradict or impact the intent of this measure, namely that the benefit of alteplase is time dependent, amongst ischemic stroke patients. (1) Ringleb, P., Bendszus, M., Bluhmki, E., Donnan, G., Eschenfelder, C., Fatar, M., … ECASS-4 study group (2019). Extending the time window for intravenous thrombolysis in acute ischemic stroke using magnetic resonance imaging-based patient selection. International journal of stroke : official journal of the International Stroke Society, 14(5), 483–490. doi:10.1177/1747493019840938 (2) Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., …. (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. *Circulation: Cardiovascular Quality and Outcomes, 11*(12). doi: 10.1161/circoutcomes.118.004981

Citations (Note: when applicable, we adhered to journals' request for a specific citation format to be followed for their study; otherwise we followed the APA format for citations):

(1) Demaerschalk BM, Kleindorfer DO, Adeoye OM, Demchuk AM, Fugate JE, Grotta JC, Khalessi AA, Levy EI, Palesch YY, Prabhakaran S, Saposnik G, Saver JL, Smith EE; on behalf of the American Heart Association Stroke Council and Council on Epidemiology and Prevention. Scientific rationale for the inclusion and exclusion criteria for intravenous alteplase in acute ischemic stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2016;47:581‑641.
(2) Halperin JL, Levine GN, Al-Khatib SM, Birtcher KK, Bozkurt B, Brindis RG, Cigarroa JE, Curtis LH, Fleisher LA, Gentile F, Gidding S, Hlatky MA, Ikonomidis J, Joglar J, Pressler SJ, Wijeysundera DN. Further evolution of the ACC/AHA clinical practice guideline recommendation classification system: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2016;133:1426-1428. DOI: 10.1161/CIR.0000000000000312.
(3) Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. *Circulation: Cardiovascular Quality and Outcomes, 11*(12). doi: 10.1161/circoutcomes.118.004981

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

1a.4.2 What process was used to identify the evidence?

1a.4.3. Provide the citation(s) for the evidence.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

It is estimated that an American has a stroke every 40 seconds, indicating that stroke is a major public health problem in the United States (Benjamin et al., 2019). Between 2013 to 2016, the overall prevalence of stroke amongst Americans was approximately 2.5% (Benjamin et al., 2019), and as Americans are living longer this rate is expected to climb; it is projected that by 2030 the prevalence of stroke will be around 3.6% (Khavjou, Phelps, & Leib, 2016). Each year approximately 795,000 people experience a new or recurrent stroke (Benjamin et al., 2019). In 2015, the total costs of stroke were estimated at $66 billion, and this is expected to increase to $143 billion in 2035 (Khavjou, Phelps, & Leib, 2016). Of all strokes, approximately 87% are ischemic (Benjamin et al., 2019).

Multiple studies have shown that the rapid administration of intravenous recombinant tissue-type plasminogen activator (tPA) to appropriate patients is a proven, effective treatment in restoring blood flow and reducing long-term morbidity for ischemic stroke patients. Every minute an ischemic stroke patient goes untreated, he/she loses 1.9 million neurons and every hour this patient goes untreated, he/she loses 120 million neurons. In comparing normal aging with the aging brain amongst ischemic stroke patients, the ischemic brain ages 3.6 years each hour without treatment (Saver, 2006). The seminal clinical trial conducted by the National Institute of Neurological Disorders and Stroke (NINDS) in 1996 found that timely intravenous alteplase administration improved clinical outcomes for the stroke patient at three months (1995; Demaerschalk et al., 2016). This is the foundation of the American Heart Association / American Stroke Association (AHA/ASA) clinical guidelines on the management of patients with acute ischemic stroke (Hatcher & Starr, 2011). In addition to effectively restoring blood flow and reducing stroke-related morbidity and mortality, patients receiving IV alteplase within 60 minutes were more likely to be discharged to home, and less likely to develop symptomatic intracerebral hemorrhage (ICH) within 36 hours after IV alteplase as compared with those treated beyond 60 minutes (Tong et al., 2018).

Despite the strong evidence for timely alteplase administration amongst ischemic stroke patients, gaps in care remain as is illustrated via performance rates pulled from existing programs as well as the literature. This measure is intended to promote a reduction in door-to-needle times and improvement in the proportion of eligible patients receiving treatment within 60 minutes of hospital arrival.

Citations:

1. Benjamin EJ, Muntner P, Alonso A, Bittencourt MS, Callaway CW, Carson AP, Chamberlain AM, Chang AR, Cheng S, Das SR, Delling FN, Djousse L, Elkind MSV, Ferguson JF, Fornage M, Jordan LC, Khan SS, Kissela BM, Knutson KL, Kwan TW, Lackland DT, Lewis TT, Lichtman JH, Longenecker CT, Loop MS, Lutsey PL, Martin SS, Matsushita K, Moran AE, Mussolino ME, O'Flaherty M, Pandey A, Perak AM, Rosamond WD, Roth GA, Sampson UKA, Satou GM, Schroeder EB, Shah SH, Spartano NL, Stokes A, Tirschwell DL, Tsao CW, Turakhia MP, VanWagner LB, Wilkins JT, Wong SS, Virani SS; on behalf of the American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2019 update: a report from the American Heart Association. Circulation. 2019;139:e56–e528. doi: 10.1161/CIR.0000000000000659

2. Demaerschalk BM, Kleindorfer DO, Adeoye OM, Demchuk AM, Fugate JE, Grotta JC, Khalessi AA, Levy EI, Palesch YY, Prabhakaran S, Saposnik G, Saver JL, Smith EE; on behalf of the American Heart Association Stroke Council and Council on Epidemiology and Prevention. Scientific rationale for the inclusion and exclusion criteria for intravenous alteplase in acute ischemic stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016;47:581–641.

3. Hatcher, M. A., & Starr, J. A. (2011). Role of Tissue Plasminogen Activator in Acute Ischemic Stroke. Annals of Pharmacotherapy, 45(3), 364–371. doi: 10.1345/aph.1p525

4. Khavjou, O., Phelps, D., & Leib, A. (2016). Projections of Cardiovascular Disease Prevalence and Costs: 2015–2035: Technical Report. RTI International. RTI Project Number 0214680.003.001.001. Retrieved from https://healthmetrics.heart.org/projections-of-cardiovascular-disease/

5. National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group (1995). Tissue plasminogen activator for acute ischemic stroke. The New England journal of medicine, 333(24), 1581–1587. doi:10.1056/NEJM199512143332401

6. Saver, J. L. (2006). Time Is Brain—Quantified. Stroke, 37(1), 263–266. doi: 10.1161/01.str.0000196957.55928.ab

7. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The AHA/ASA's Get With The Guidelines – Stroke (GWTG-Stroke) is an in-hospital program for improving stroke care. Launched nationally in 2003, over 2,000 hospitals have entered more than 5 million patient records into the GWTG-Stroke database. Data from 2,063 hospitals were analyzed between January 1, 2018 through December 31, 2018; the data were comprised of inpatient/hospital and emergency department services data. Of those 2,063 hospitals, 1,619 hospitals had at least one patient who qualified for the measure, after accounting for exclusions and exceptions, for a total of 33,836 eligible patients. Measures of central tendency, variability, and dispersion were calculated.

01/01/2018 – 12/31/2018 Performance Data

Mean: 76.00%

Standard Error: .006

Median: .84

Standard Deviation: 0.26

Minimum: 0.00

Maximum: 1.00

Interquartile Range	Result %
25	67.00%
50	84.00%
75	95.00%
100	100.00%

Decile	Result
1	0.38
2	0.60
3	0.71
4	0.78
5	0.84

6 0.89

7 0.93

8 0.98

9 1.00

10 1.00

In addition to the most current 2018 data above, prior year data are provided to demonstrate performance over time.

01/01/2017 – 12/31/2017 Performance Data

Mean: 78.00%

Standard Error: 0.01

Median: 0.83

Standard Deviation: 0.21

Minimum: 0.13

Maximum: 1.00

Interquartile Range Result %

25 67.00%

50 83.00%

75 94.00%

100 100.00%

Decile Result

1 0.46

2 0.60

3 0.70

4 0.77

5 0.83

6 0.88

7 0.92

8 0.97

9 1.00

10 1.00

01/01/2016 – 12/31/2016 Performance Data

Mean: 74.00%

Standard Error: 0.006

Median: 0.80

Standard Deviation: 0.22

Minimum: 0.083

Maximum: 1.00

Interquartile Range Result %

25 60.00%

50	80.00%
75	92.00%
100	100.00%

Decile	Result
1	0.42
2	0.53
3	0.66
4	0.75
5	0.80
6	0.85
7	0.90
8	0.94
9	1.00
10	1.00

In addition, we obtained the national aggregate performance rates across all GWTG-Stroke hospitals, which were calculated by taking the aggregate performance scores out of the aggregate total scores for each year:

Year	National Performance Rate %
2016	58.5%
2017	67.7%
2018	76.1%

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

There have been improvements in door-to-needle times for patients with acute ischemic stroke eligible for alteplase, as is further discussed in the "usability" section of this form; however, gaps in care remain as evidenced by the following studies. A 2018 study looked at changes in door-to-needle times among 419 hospitals participating in the Paul Coverdell National Acute Stroke Program, between 2008 and 2017. The study authors Tong et al. analyzed 39,737 acute ischemic stroke patients who received IV alteplase within 4.5 hours of the last known well time* and found that overall 53.4% of these patients had door-to-needle times </= 60 minutes. Although improvements were seen through the years in this cohort, for example in 2008 26.4% of patients had DTN times </= 60 minutes and in 2017 66.2% of patients had door-to-needle times </= 60 minutes (P<0.001), a significant gap, demonstrated from recent years, remains (2018). A multicenter study looked at 1,422 hospitals participating in GWTG-Stroke from October 2012 to April 2015 and found that of the 55,296 patients who received intravenous alteplase, excluding transferred patients and inpatient strokes, only 50.2% had door-to-needle times </= 60 minutes (Kamal et al., 2017). In another study, authors analyzed 6,181 IV t-PA-treated cases from 2010 to 2015 in the National Institute of Neurological Disorders and Stroke (NINDS)-funded Florida-Puerto Rico Collaboration to Reduce Stroke Disparities (FL-PR CReSD), and found that the median door-to-needle time was 67 minutes (IQR, 51–91 minutes) and only 42% of cases had door-to-needle times </= 60 minutes (Oluwole et al., 2017). Lastly, a study analyzing hospitals participating in the GWTG-Stroke registry between January 1, 2009 and September 30, 2013, found that among the 65,384 acute ischemic stroke patients treated with alteplase within 4.5 hours of symptom onset, the median door-to-needle time was 71 minutes (Kim et al., 2017). These data from the literature, along with performance scores pulled from GWTG-Stroke and HFAP, demonstrate a significant gap in care with respect to timely administration of thrombolytic therapy to eligible patients.

*This number excluded patients who received IV alteplase at outside hospitals, had missing door-to-needle times, and arrived at the hospital > 4.5 hours after symptom onset.

Citations:

1. Kamal, N., Sheng, S., Xian, Y., Matsouaka, R., Hill, M. D., Bhatt, D. L., … Smith, E. E. (2017). Delays in Door-to-Needle Times and Their Impact on Treatment Time and Outcomes in Get With The Guidelines-Stroke. Stroke, 48(4), 946–954. doi:10.1161/STROKEAHA.116.015712

2. Kim JT, Fonarow GC, Smith EE, et al. Treatment With Tissue Plasminogen Activator in the Golden Hour and the Shape of the 4.5-Hour Time-Benefit Curve in the National United States Get With The Guidelines-Stroke Population. Circulation. 2017;135(2):128–139. doi:10.1161/CIRCULATIONAHA.116.023336

3. Oluwole, S. A., Wang, K., Dong, C., Ciliberti-Vargas, M. A., Gutierrez, C. M., Yi, L., … FL-PR Collaboration to Reduce Stroke Disparities Investigators (2017). Disparities and Trends in Door-to-Needle Time: The FL-PR CReSD Study (Florida-Puerto Rico Collaboration to Reduce Stroke Disparities). Stroke, 48(8), 2192–2197. doi:10.1161/STROKEAHA.116.016183

4. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Get With The Guidelines – Stroke (GWTG-Stroke) is an in-hospital program for improving stroke care. Launched nationally in 2003, over 2,000 hospitals have entered more than 5 million patient records into the GWTG-Stroke database. We analyzed a dataset from January 1, 2018 through December 31, 2018 which was comprised of inpatient/hospital and emergency department services data. Performance based on several variables, including age, gender, and race/ethnicity, was analyzed to identify disparities in care. The results showed that American Indian/Alaska Natives had longer door-to-needle times, as compared to other racial/ethnic groups. Performance rates for all variables studied are provided.

01/01/2018 – 12/31/2018 Performance Data Across Different Demographic Variables:

Performance mean by Age:

<65 = 83.00%

65-79 = 85.00%

80+ = 86.00%

Performance mean by Gender:

Male = 85.00%

Female = 84.00%

Performance mean by Race/Ethnicity

Hispanic = 84.00%

Black or African American = 84.00%

American Indian or Alaska Native = 73.00%

Asian = 88.00%

White = 85.00%

Native Hawaiian or Other Pacific Islander = 81.00%

Prior year data are also provided to demonstrate performance over time.

01/01/2017 – 12/31/2017 Performance Data Across Different Demographic Variables

Performance mean by Age:

<65 = 81.00%

65-79 = 84.00%

80+ = 85.00%

Performance mean by Gender:

Male = 84.00%

Female = 82.00%

Performance mean by Race/Ethnicity

Hispanic = 83.00%

Black or African American = 83.00%

American Indian or Alaska Native = 77.00%

Asian = 86.00%

White = 83.00%

Native Hawaiian or Other Pacific Islander = 75.00%

01/01/2016 – 12/31/2016 Performance Data Across Different Demographic Variables:

Performance mean by Age:

<65 = 78.00%

65-79 = 80.00%

80+ = 81.00%

Performance mean by Gender:

Male = 81.00%

Female = 78.00%

Performance mean by Race/Ethnicity

Hispanic = 80.00%

Black or African American = 80.00%

American Indian or Alaska Native = 70.00%

Asian = 84.00%

White = 79.00%

Native Hawaiian or Other Pacific Islander = 81.00%

The AHA/ASA Target: Stroke initiative began in 2010 and is a national quality improvement initiative focused on improving door-to-needle times for the administration of alteplase amongst eligible stroke patients. This program is further described in the “use” section of this form. Every two years the program puts out a report on door-to-needle compliance by state which demonstrates geographic variations in care. Target: Stroke Phase II had a goal of achieving door-to-needle times within 60 minutes in 75% or more of acute ischemic stroke patients treated with alteplase. States that missed this target in 2016 included Arkansas, Connecticut, Illinois, Indiana, Iowa, Maine, Massachusetts, Michigan, Mississippi, Nebraska, New Hampshire, North Dakota, West Virginia, and Wisconsin (2016).

Citation:

2016 Door-to-Needle Compliance by state. Retrieved from https://www.heart.org/en/professional/quality-improvement/target-stroke/clinical-tools-and-resources.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

Tong et al. found that among 419 hospitals participating in the Paul Coverdell National Acute Stroke Program between 2008 and 2017, Women and Black Americans were less likely to be treated within 60 minutes as compared with their counterparts (Adjusted OR of 0.83, 95% CI, 0.79–0.87; and 0.86, 95% CI, 0.81–0.92, respectively) (2018). Similarly, Oluwole et al. evaluated 6,181 IV tPA-treated cases from 2010 to 2015 in the NINDS FL-PR CReSD study, and found disparities in time to treatment amongst Women and Black Americans. The median door-to-needle time was 65 minutes amongst men (IQR, 49–88 minutes) and 68 minutes amongst women (IQR, 52–93 minutes). The median door-to-needle time was 68 minutes amongst White Americans (IQR, 52–91 minutes) and 71 minutes amongst Black Americans (IQR, 53–95 minutes) (2017). A study conducted by Fonarow and colleagues evaluated data from acute ischemic stroke patients treated with tPA within 3 hours of symptom onset within the GWTG-Stroke program from 2003 to 2009. Study authors stratified the data by time to tPA to determine what variables contributed to the timely administration of alteplase. They found that older patients, Black Americans, and those with less severe strokes were less likely to receive timely care. The study also concluded that patients administered tPA within 60 minutes were more likely to be younger, male, white, and have no history of stroke. Additionally, hospitals that had less experience providing tPA to ischemic stroke patients were less likely to administer the therapy within 60 minutes (2011). Lastly, a meta-analysis looking at studies within the US and internationally between 1995 and 2008 found that women with acute ischemic stroke were 25% less likely to receive alteplase compared to men, and this disparity was even greater when looking solely at studies from North America. (Reeves et al., 2009). These data from the literature and Target: Stroke confirm gender, racial, age, and geographic disparities amongst patients with ischemic stroke receiving timely care at the hospital.

Citations:

1. Fonarow, G. C., Smith, E. E., Saver, J. L., Reeves, M. J., Bhatt, D. L., Grau-Sepulveda, M. V., … Schwamm, L. H. (2011). 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, 123(7), 750–758. doi:10.1161/CIRCULATIONAHA.110.974675

2. Oluwole SA, Wang K, Dong C, et al. Disparities and Trends in Door-to-Needle Time: The FL-PR CReSD Study (Florida-Puerto Rico Collaboration to Reduce Stroke Disparities). Stroke. 2017;48(8):2192–2197. doi:10.1161/STROKEAHA.116.016183

3. Reeves, M., Bhatt, A., Jajou, P., Brown, M., & Lisabeth, L. (2009). Sex Differences in the Use of Intravenous rt-PA Thrombolysis Treatment for Acute Ischemic Stroke. Stroke, 40(5), 1743–1749. doi: 10.1161/strokeaha.108.543181

4. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

2. Reliability and 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. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Neurology, Neurology : Stroke/Transient Ischemic Attack (TIA)

De.6. Non-Condition Specific*(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Elderly

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

The measure specifications are included as an attachment with this submission.

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** Time_to_Thrombolytic_Data_Dictionary_Updated_07152019.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Supporting guidelines and coding included in the measure are reviewed on an annual basis. This annual review has resulted in changes to the measure language and coding, including: 1) Replacing intravenous tissue plasminogen activator (tPA) with intravenous alteplase as alteplase is currently the only thrombolytic approved for use in acute ischemic stroke and 2) Replacing the exclusion "Patients received in transfer from the inpatient, or outpatient of another facility" with "Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit". Additionally, the wording of the denominator and numerator has been updated to match what currently appears in the Get with the Guidelines (GWTG) Stroke data collection tool. There have not been any changes to the intent of the measure or how it is calculated.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Patients who receive IV alteplase at my hospital within 60 minutes after arrival

S.5. 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, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

All denominator patients with the following:

['Date/time IV alteplase initiated' minus 'Arrival Date/Time'] <= 60 minutes

**Data elements referenced align with information found in Appendix A.1. 'TimetoIntravenousThrombolyticTherapySpecDataCollectionForm_07152019.pdf' attachment.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

All patients with a final clinical diagnosis of ischemic stroke who received IV alteplase at my hospital

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

An ICD-10-CM Principal Diagnosis Code for acute ischemic stroke:

Diagnosis for ischemic stroke ICD-10-CM: I63.00, I63.011, I63.012, I63.013, I63.019, I63.02, I63.031, I63.032, I63.033, I63.039, I63.09, I63.10, I63.111, I63.112, I63.113, I63.119, I63.12, I63.131, I63.132, I63.133, I63.139, I63.19, I63.20, I63.211, I63.212, I63.213, I63.219, I63.22, I63.231, I63.232, I63.233, I63.239, I63.29, I63.30, I63.311, I63.312, I63.313, I63.319, I63.321, I63.322,I63.323, I63.329, I63.331, I63.332, I63.333, I63.339, I63.341, I63.342, I63.343, I63.349, I63.39, I63.40, I63.411, I63.412, I63.413, I63.419, I63.421, I63.422, I63.423, I63.429, I63.431, I63.432, I63.433, I63.439, I63.441, I63.442, I63.443, I63.449, I63.49, I63.50, I63.511, I63.512, I63.513, I63.519, I63.521, I63.522, I63.523, I63.529, I63.531, I63.532, I63.533, I63.539, I63.541, I63.542, I63.543, I63.549, I63.59, I63.6, I63.81, I63.89, I63.9

OR:

'Final Clinical Dx. of stroke' = Ischemic Stroke

AND:

'IV alteplase initiated at this hospital' = Yes*

*Thrombolytic therapy for stroke includes: Activase, Alteplase, IV Alteplase, or Recombinant Alteplase

**Data elements referenced align with information found in Appendix A.1 'TimetoIntravenousThrombolyticTherapySpecDataCollectionForm_07152019.pdf' attachment

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

Denominator exclusions:

- Age < 18 years
- Stroke occurred after hospital arrival (in ED/Obs/inpatient)
- Patients whose date/time of ED arrival and/or date/time of IV alteplase administration is blank, unknown, or MM/DD/YYYY only.

- Patients with a negative calculated time difference
- Patients with a Date Last Known Well, but no time Last Known Well
- Patients that receive IV alteplase greater than 4.5 hours after Last Known Well
- Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit
- Clinical Trial

Denominator exceptions:

- Patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

The AHA/ASA follows the PCPI methodology in distinguishing between denominator exceptions and denominator exclusions.

Denominator exclusions arise when the clinical action indicated in the numerator is not appropriate for a particular group of patients who otherwise meet the denominator criteria. These are absolute and would be removed from the denominator of a measure in order to determine the eligible population. Exclusions are included in the measure specifications.

Denominator exceptions are used to remove a patient from the denominator when the patient does not receive the action required in the numerator AND that action would not be appropriate due to a patient-specific reason(s). The patient would otherwise meet the denominator criteria. Exceptions are not absolute and are based on clinical judgment or individual patient characteristics or preferences. The PCPI methodology includes two categories of exceptions for which a patient may be removed from the denominator of an individual measure: 1) medical OR 2) patient or non-medical reasons. These exception categories are not uniformly relevant across all measures. The denominator exception language may include specific examples of instances that may constitute an exception, which are intended to serve as a guide to hospitals. For measure #1952, Time to Intravenous Thrombolytic Therapy, the exception is patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment. For example, Eligibility reasons include social/religious, initial refusal, and care-team unable to determine eligibility. Medical reasons include hypertension requiring aggressive control with IV medications, further diagnostic evaluation to confirm stroke for patients with hypoglycemia (blood glucose < 50), seizures, or major metabolic disorders, and management of concomitant emergent/acute conditions such as cardiopulmonary arrest, respiratory failure (requiring intubation).

Although this methodology does not require the external reporting of more detailed exception data, the AHA/ASA recommends that hospitals document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AHA/ASA also advocates for the systematic review and analysis of each hospital's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details are as follows:

Measure Exclusions:

'Age' < 18 years

OR

'Patient location when stroke symptoms discovered' = stroke occurred after hospital 'Arrival Date/Time'

OR

'Date/time IV alteplase initiated' < 'Arrival Date/Time'

OR

[´Date/time IV alteplase initiated´ minus ´Date/Time Last Known Well´] > 4.5 hours

OR

'IV alteplase at an outside hospital or EMS / Mobile Stroke Unit' = Yes

OR

'During this hospital stay, was the patient enrolled in a clinical trial in which patients with the same condition as the measure set were being studied' = Yes

OR

If any of the following is unknown, blank, or incomplete (aka, missing time): 'Arrival Date/Time', 'Date/time IV alteplase initiated'

OR

'Date/time Last Known Well' = Date included but time is blank or unknown

Measure Exceptions:

['Date/time IV alteplase initiated' minus 'Arrival Date/Time'] > 60 minutes

AND

Eligibility Reason OR Medical Reason = Present

**Data elements referenced align with information found in appendix A.1 'TimetoIntravenousThrombolyticTherapySpecDataCollectionForm_07152019.pdf' attachment.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

Consistent with CMS' Measures Management System Blueprint and national recommendations put forth by the IOM (now NASEM) and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. 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

S.14. Calculation Algorithm/Measure Logic (*Diagram or 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; time period for data, aggregating data; risk adjustment; etc.)*

Rate is determined by calculating those eligible patients meeting the numerator specification divided by those meeting the denominator specification.

1) Check to see if there is an ICD-10 principal diagnosis of ischemic stroke; exclude those patients without an appropriate diagnosis code.

2) Check to see if patient had an inpatient stroke; exclude those patients with inpatient stroke

3) Check to see if patient is 18 years or older; exclude those patients less than 18 years of age

4) Check to see if patient is enrolled in a clinical trial; exclude those patients who were enrolled, at the time of the hospital stay, in a clinical trial related to the study of patients with the same condition as the measure or measure set.

5) Check to see if patient arrival date is documented; exclude those patients for which arrival date is unable to be determined (blank/unknown/ or MM/DD/YYYY only)

6) Check to see if patient arrival time is documented; exclude those patients for which arrival time is unable to be determined (blank, unknown, or MM/DD/YYYY only)

7) Check to see if patient received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit; exclude those patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit

8) Check to see if patient had IV alteplase initiated; exclude those patients for whom IV alteplase was not initiated

9) Check IV alteplase initiation date; exclude those patients for which alteplase initiation date is unable to be determined (blank, unknown, or MM/DD/YYYY only)

10) Check IV alteplase initiation time; exclude those patients for which alteplase initiation time is unable to be determined (blank, unknown, or MM/DD/YYYY only)

11) IV alteplase Initiation Date/Time should not be less than (aka, should not be documented as occurring prior to) hospital arrival date/time; exclude those patients for whom arrival IV alteplase initiation date/time is less than hospital arrival date/time

12) Check to see date/time last known well; exclude patients for whom time last known well is unable to be determined (blank/unknown)

13) Check to see timing in hours. Timing (IV Alteplase Initiation Date/Time - Date/Time Last Known well) should be less than or equal to 4.5 hours. If greater than 4.5 hours exclude patients.

14) If timing is less than or equal to 4.5 hours, check to see if timing for IV alteplase therapy time (IV Alteplase Initiation Date/Time - Arrival Date/Time) is less than or equal to 60 minutes. If time was greater than 60 minutes, determine if patient had a valid documented exception/reason for delay.

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

For detailed measure algorithm see attached within the Appendix.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

Not applicable. The measure is not based on a sample

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

Not applicable. The measure is not based on a survey

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Get with the Guidelines Stroke Data Collection Form. This is a paper version of the electronic data collection tool which is called the Patient Management Tool (PMT).

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available in attached appendix at A.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

Not applicable. The measure is not a composite.

2. Validity – See attached Measure Testing Submission Form

Time_to_Intravenous_Thrombolytic_Therapy_7.1_Testing_Attachment_Final_07312019.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (***must be consistent with data sources entered in S.17***)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☒ registry	☒ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other: Click here to describe	☐ other: Click here to describe

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

Previous testing

Get With The Guidelines – Stroke (GWTG-Stroke) is a clinical data registry that collects information from hospitals and clinicians on patient demographics, acute outcomes, quality measures, and health outcomes. The registry was piloted in 2001 and nationally implemented in 2003. GWTG-Stroke currently has 2,243 hospitals participating in the program and is managed by the American Heart Association (AHA) and American Stroke Association (ASA).

Current testing

The data source is Registry data from the 2018 Get with The Guidelines Stroke Program.

1.3. What are the dates of the data used in testing?

Previous testing

10/1/2014 – 9/30/2015

Current testing

The data are for the time period January 1st, 2018 through December 31st, 2018.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (***must be consistent with levels entered in item S.20***)	**Measure Tested at Level of:**
☐ individual clinician	☐ individual clinician

☐ group/practice	☐ group/practice
☒ hospital/facility/agency	☒ hospital/facility/agency
☐ health plan	☐ health plan
☐ other: Click here to describe	☐ other: Click here to describe

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

Previous testing

The total number of hospitals reporting on this measure is 841. Of those, 672 hospitals had all the required data elements and met the minimum number of quality reporting events (10) for inclusion in the reliability analysis. For this measure, 79.9 percent of hospitals are included in the analysis, and the average number of quality reporting events is 23.9 for a total of 16,100 events. The range of quality reporting events for 672 hospitals included is from 138 to 10. The average number of quality reporting events for the remaining 20.1 percent of hospitals who aren't included is 6.03.

Current testing

We received data from 2,063 hospitals reporting on this measure through the registry for the AHA/ASA Get with the Guidelines Stroke Program during the period between 1/1/2018-12/31/2018. This data set reflects information at the hospital level and our analysis of the data as a whole is reflected throughout this submission. Of those 2,063 hospitals, 1,619 hospitals had at least one patient who qualified for the measure, after accounting for exclusions and exceptions, for a total of 33,836 eligible patients. The average number of eligible patients is 21 for the 1,619 hospitals. The range of eligible patients for 1,619 hospitals is from 1 to 171.

The AHA/ASA Get with the Guidelines Stroke Program is exclusively an inpatient registry and the dataset is comprised of inpatient/hospital and emergency department services data.

1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

Previous testing

There were 16,100 patients included in this testing and analysis. These were the patients that were associated with hospitals who had 10 or more patients eligible for this measure.

Current testing

There were 33,836 patients included in this reliability testing and analysis. These were the patients that were associated with hospitals who had at least one eligible patient in the year under study.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Previous testing

The same data sample was used for reliability testing and exclusions analysis.

Current testing

The same data samples were used for reliability testing and exclusions/exceptions analysis.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Previous testing

Patient-level socio-demographic (SDS) variables were not captured as part of the testing.

Current testing

We analyzed performance based on a number of variables, including age, gender, and race/ethnicity. Performance rates for these variables are provided below.

	AGE		
	<65	**65-79**	**80+**
Performance Mean	0.83	0.85	0.86

	Gender	
	Male	**Female**
Performance Mean	0.85	0.84

	Race/Ethnicity					
	Hispanic	**Black or African American**	**American Indian or Alaska Native**	**Asian**	**White**	**Native Hawaiian or Other Pacific Islander**
Performance Mean	0.84	0.84	0.73	0.88	0.85	0.81

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Previous testing

Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in hospital performance. Reliability at the level of the specific hospital is given by:

Reliability = Variance (hospital-to-hospital) / [Variance (hospital-to-hospital) + Variance (hospital-specific-error]

Reliability is the ratio of the hospital-to-hospital variance divided by the sum of the hospital-to-hospital variance plus the error variance specific to a hospital. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in hospital performance.

Reliability testing was performed by using a beta-binomial model. The beta-binomial model assumes the hospital performance score is a binomial random variable conditional on the hospital's true value that comes from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates.

Reliability is estimated at two different points, at the minimum number of quality reporting events for the measure and at the mean number of quality reporting events per hospital.

Current testing

Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in site performance and the noise is the total variability in measured performance. Reliability at the level of the specific site is given by:

Reliability = Variance (site-to-site) / [Variance (site-to-site) + Variance (site-specific-error]

Reliability is the ratio of the site-to-site variance divided by the sum of the site-to-site variance plus the error variance specific to a site. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real differences in site performance.

Variance (site-to-site) = p(1-p)/n where p is the passing rate for a site and n is the number of patients for that site

Variance (site-specific-error) = alpha*beta/((alpha + beta + 1)*(alpha + beta)^2)

Reliability testing was performed by using a beta-binomial model. The beta-binomial model assumes the site performance score is a binomial random variable conditional on the site's true value that comes from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates.

For this analysis Alpha = 4.6568 and Beta = 1.1956. These parameters are used to calculate the variance (site-specific-error) which is approximately equal to 0.02. Reliability is then calculated for each site using this value and the variance (site-to-site). Average reliability is reported by averaging reliability for each site with at least 1 patient for the measure.

A reliability of 0.70 – 0.80 is generally considered the acceptable threshold for reliability, 0.80 – 0.90 is considered high reliability, and 0.90 – 1.0 is considered very high. [1]

1. Adams JL, Mehrotra A, McGlynn EA, Estimating Reliability and Misclassification in Physician Profiling, Santa Monica, CA: RAND Corporation, 2010. www.rand.org/pubs/technical_reports/TR863. (Accessed on February 24, 2012.)

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Previous testing

This measure has 0.63 reliability when evaluated at the minimum level of quality reporting events and 0.81 reliability at the average number of quality events.

Current testing

The average reliability for hospitals with at least one eligible patient is 0.76. We also report the average reliability at each decile of the sample shown in the table below.

Reliability Statistics														
Denominator (Patients)	**Mean**	**SD**	**Min**	**Max**	**Decile**									
					1	2	3	4	5	6	7	8	9	10
1+	0.76	0.24	0.16	1.00	0.39	0.54	0.66	0.75	0.83	0.90	0.95	1.00	1.00	1.00

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Current testing

This measure has acceptable reliability and increases as the denominator size increases.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☒ **Empirical validity testing**

☐ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Previous testing

Face validity of the measure score as an indicator of quality was systematically assessed as follows.

After the measure was fully specified, the expert panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality.

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

Current testing

Validity testing method

STK 04 Thrombolytic Therapy (NQF 0437) was chosen as a suitable candidate for correlation analysis due to the similarities in patient population and domain. We hypothesized higher hospital performance on time to thrombolytic therapy (i.e. the percent treated with alteplase for acute ischemic stroke within 60 minutes of hospital arrival) would be correlated with higher hospital performance on STK 04 (i.e. the percent of patients with acute ischemic stroke who arrive within 2 hours that are treated with alteplase within 3 hours). The rationale for this hypothesis is that hospitals with longer time to thrombolytic therapy might not be able to treat as many patients within 3 hours, because they might struggle to start alteplase before 3 hours for patients arriving near the 2-hour mark.

Hospitals included in the analysis had at least one patient in the denominator after exclusions and exceptions were removed. Datasets were reviewed to identify shared hospitals based on the hospital identifier. Comparing performance scores of those shared Hospital IDs, the empirical analysis uses regression with Time to Intravenous Thrombolytic Therapy (NQF 1952) as the outcome and STK 04 Thrombolytic Therapy (NQF 0437) as the predictor. Results identify the multiple R value (the correlation coefficient) and P-value of the regression variables to assess the association between performance scores of these shared Hospital IDs.

We use the following guidance to describe correlation[1]:

Correlation	Interpretation
0.80 – 1.00	Very Strong
0.60 – 0.79	Strong
0.40 – 0.59	Moderate
0.20 - 0.39	Weak
0 – 0.19	Very Weak

1. "11. Correlation and Regression." *The BMJ*, 21 March 2019, https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/11-correlation-and-regression/ .

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Previous testing

The expert panel included 20 members. Panel members were comprised of experts from the AHA Council on Stroke 2015-2016 Leadership Committee. The list of expert panel members is as follows:

Mat Reeves, BVSc, PhD, FAHA

Mai Nguyen-Huynh, MD, MAS

Judith Lichtman, PhD, MPH, FAHA

Edward Jauch, MD, MS, FAHA, FACEP

Jennifer Majersik, MD, MS

Kevin Sheth, MD, FAHA

Phillip Scott, MD

Walter N. Kernan, MD

Brett Cucchiara, MD, FAHA

Mary Ann Bauman, MD

Claranne Mathiesen, MSN, RN, CNRN, SCRN

Karen Furie, MD, MPH, FAHA

Salvador Cruz-Flores, MD, MPH, FAHA, FACP

Alejandro Rabinstein, MD, FAHA

Colin Derdeyn, MD, FAHA

N. Jennifer Klinedinst PhD, PH, RN, FAHA

Jose Romano, MD, FAHA, FAAN

Barbara Lutz, PhD, RN, CRRN, FAHA, FAAN

Pooja Khatri, MD, MSc, FAHA

Kyra Becker, MD

Current Testing

Data from the AHA/ASA 2018 Get with the Guidelines Stroke Program were used to perform the correlation analysis for this measure. Data comes from the Registry version of Time to Intravenous Thrombolytic Therapy (NQF 1952) and STK 04 Thrombolytic Therapy (NQF 0437).

Time to Intravenous Thrombolytic Therapy (NQF 1952) was positively correlated with STK 04 Thrombolytic Therapy (NQF 0437).

NQF #0437

Coefficient of correlation = 0.43
Alpha level = 0.05
P-value = < 0.001
Number of shared hospitals based on Hospital identifier = 1,612

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Previous testing

The results of the expert panel rating of the validity statement were as follows: N = 20; Mean rating = 4.2 and 85% of respondents either agree or strongly agree that this measure can accurately distinguish good and poor quality.

Frequency Distribution of Ratings

1 – 1 response (Strongly Disagree)

2 – 0 responses

3 – 2 responses (Neither Agree nor Disagree)

4 – 8 responses

5 – 9 responses (Strongly Agree)

Current Testing

Time to Intravenous Thrombolytic Therapy has a moderate positive correlation with STK 04 Thrombolytic Therapy. The correlation is highly statistically significant. With a coefficient of correlation of 0.43, the correlation is moderate, significant, and confirms our hypothesis. The moderate positive correlation with STK 04 Thrombolytic Therapy demonstrates the criterion validity of the measure. The strength of the correlation is within our expectations. We did not anticipate higher correlation because there are multiple factors related to identifying eligibility, and treating all eligible patients, that are independent of the time needed to treat.

_____

2b2. EXCLUSIONS ANALYSIS

NA ☐ no exclusions — *skip to section 2b3*

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

Previous testing

Exclusions include:

- Age < 18 years;

- Stroke occurred after hospital arrival (in ED/Obs/inpatient);
- Patients whose date/time of ED arrival and/or date/time of thrombolytic administration are blank, not documented, or N/A;
- Patients with a negative calculated time difference;
- Patients with a Date Last Known Well, but no time Last Known Well just MM/DD/YYYY;
- Patients that receive tPA greater than 4.5 hours after Last Known Well Patients transferred from outside hospital;
- And Clinical Trial.

Exceptions include:

- Documented eligibility or medical reason for delay in treatment.

Exclusions and exceptions were analyzed for frequency across providers.

Current Testing

Exclusions include:

- Age < 18 years
- Stroke occurred after hospital arrival (in ED/Obs/inpatient)
- Patients whose date/time of ED arrival and/or date/time of IV alteplase administration is blank, unknown, or MM/DD/YYYY only
- Patients with a negative calculated time difference
- Patients with a Date Last Known Well, but no time Last Known Well
- Patients that receive IV alteplase greater than 4.5 hours after Last Known Well
- Patients who received IV alteplase at an outside hospital or by EMS/Mobile Stroke Unit
- Clinical Trial

Exceptions include:

- Patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment

Exceptions and exclusions were analyzed for frequency across hospitals and deciles of exceptions were reported.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Previous testing

Exclusions Analysis:

Amongst the 672 hospitals with the minimum (10) number of quality reporting events, there were a total of 1,950 exclusions reported. The average number of exclusions per hospital in this sample is 2.90. The overall exclusion rate is 10.8%. The range of exclusion rates for hospitals included 47% to 0%.

Exceptions Analysis:

Amongst the 672 hospitals with the minimum (10) number of quality reporting events, there were a total of 3,581 exceptions reported. The average number of exceptions per hospital in this sample is 5.32. The overall exception rate is 18.2%. The range of exclusion rates for hospitals included 57% to 0%.

Current Testing

Amongst the 1,619 included hospitals, there were a total of 12,379 exceptions and exclusions reported. The average number of exceptions and exclusions per hospital in this sample is 7.65. The proportion of exceptions to patients is 0.37. Exception deciles illustrate the spread of exceptions amongst hospitals. According to the results, 50% of hospitals had 5 or fewer exceptions and exclusions across eligible patients for the year under study.

Decile	Exceptions + Exclusions
1	1
2	2
3	3
4	4
5	5
6	7
7	9
8	12
9	17
10	72

Exclusions:

LOS: Length of Stay >120 days.

CLINICAL: Clinical Trials.

SYMPLOC: In-hospital Strokes.

IVTPAOUTSIDE: IV alteplase at an outside hospital or EMS / Mobile Stroke Unit

ARRTIME: Arrival Time missing.

TPATIME: IV alteplase Time missing.

NEGTIME: IV alteplase Date/Time before Arrival Date/Time.

SYMPONSET: Symptom on set >4.5 hours.

Exceptions:

IVTPADELAYE: # of Eligibility Reason for delay cases.

IVTPADELAYM: # of Medical Reason for delay cases.

Exclusions								
	LOS	CLINICAL	SYMPLOC	IVTPAOUTSIDE	ARRTIME	TPATIME	NEGTIME	SYMPONSET
Frequency	4	162	2274	742	82	273	291	1261

Exceptions		
	IVTPADELAYE	IVTPADELAYM

Frequency	4910	3588

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis.* *Note*: ***If patient preference is an exclusion****, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

Previous testing

Exclusions arise when patients who are included in the initial patient or eligible population for a measure do not meet the denominator criteria specific to the intervention required by the numerator. Exclusions are absolute and apply to all patients and, therefore, are not part of clinical judgment within a measure. Exclusions, including applicable value sets, are included in the measure specifications.

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons.

Without these being removed, the performance rate would not accurately reflect the true performance of each facility, which would result in an increase in performance failures and false negatives.

AHA/ASA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. AHA/ASA also advocates for the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Current Testing

The AHA/ASA follows the PCPI methodology in distinguishing between denominator exceptions and denominator exclusions.

Denominator exclusions arise when the clinical action indicated in the numerator is not appropriate for a particular group of patients who otherwise meet the denominator criteria. These are absolute and would be removed from the denominator of a measure in order to determine the eligible population. Exclusions are included in the measure specifications.

Denominator exceptions are used to remove a patient from the denominator when the patient does not receive the action required in the numerator AND that action would not be appropriate due to a patient-specific reason(s). The patient would otherwise meet the denominator criteria. Exceptions are not absolute and are based on clinical judgment or individual patient characteristics or preferences. The PCPI methodology includes two categories of exceptions for which a patient may be removed from the denominator of an individual measure: 1) medical OR 2) patient or non-medical reasons. These exception categories are not uniformly relevant across all measures. The denominator exception language may include specific examples of instances that may constitute an exception, which are intended to serve as a guide to hospitals. For measure 1952, Time to Intravenous Thrombolytic Therapy, the exception is patients who received IV alteplase greater than 60 minutes after arrival and have a documented Eligibility or Medical Reason for delay in treatment. For example, Eligibility reasons include social/religious, initial refusal, and care-team unable to determine eligibility. Medical reasons include hypertension requiring aggressive control with IV medications, further diagnostic evaluation to confirm stroke for patients with hypoglycemia (blood glucose < 50), seizures, or major metabolic disorders, and management of concomitant emergent/acute conditions such as cardiopulmonary arrest, respiratory failure (requiring intubation).

Although this methodology does not require the external reporting of more detailed exception data, the AHA/ASA recommends that hospitals document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AHA/ASA also advocates for the systematic review and analysis of each hospital's exceptions data to identify practice patterns and opportunities for quality improvement.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

☒ **No risk adjustment or stratification**

☐ **Statistical risk model with** Click here to enter number of factors **risk factors**

☐ **Stratification by** Click here to enter number of categories **risk categories**

☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

Previous testing

Not applicable

Current Testing

Not applicable

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

Previous testing

Not applicable

Current Testing

Not applicable

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

Previous testing

Not applicable

Current Testing

Not applicable

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

Current Testing

Not applicable

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Previous testing

Not applicable

Current Testing

Not applicable

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Previous testing

Not applicable

Current Testing

Not applicable

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Previous testing

Not applicable

Current Testing

Not applicable

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

Previous testing

Not applicable

Current Testing

Not applicable

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

Previous testing

Not applicable

Current Testing

Not applicable

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

Previous testing

Not applicable

Current Testing

Not applicable

2b3.9. Results of Risk Stratification Analysis:

Previous testing

Not applicable

Current Testing

Not applicable

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

Previous testing

Not applicable

Current Testing

Not applicable

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

Previous testing

Not applicable

Current Testing

Not applicable

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

Previous testing

Measures of central tendency, variability, and dispersion were calculated.

Current Testing

Measures of central tendency, variability, and dispersion were calculated.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Previous testing

Based on the sample of 672 included hospitals, the mean performance rate is 0.70, the median performance rate is 0.73 and the mode is 1.0. The standard deviation is 0.22. The range of the performance rate is 1.0, with a minimum rate of 0.0 and a maximum rate of 1.00. The interquartile range is 0.32 (0.56 – 0.88).

Current Testing

Based on the sample of 1,619 included hospitals, the mean performance rate is 0.76, the median performance rate is 0.84 and the mode is 1.0. The standard deviation is 0.26. The range of the performance rate is 1.00, with a minimum rate of 0.00 and a maximum rate of 1.00. The interquartile range is 0.28 (0.95–0.67). Deciles are provided in the table below:

Decile	Performance
1	0.38
2	0.60
3	0.71
4	0.78
5	0.84
6	0.89
7	0.93
8	0.98
9	1.00
10	1.00

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities?
(i*.e., what do the results mean in terms of statistical and meaningful differences?*)

Previous testing

The range of performance from 0.00 to 1.00 suggests there's clinically meaningful variation across physicians' performance.

Current Testing

The range of performance from 1.00 to 0.00 suggests there's clinically meaningful variation across hospitals'' performance. Outliers are considered to be values less than quartile 1 (0.67) or greater than quartile 3 (0.95) by more than 1.5 the IQR (0.28) and there 99 outliers in the data set.

Quartile	Performance
1	0.67
2	0.84
3	0.95
4	1.00

Excluding those outliers, the range of performance is 0.42 to 1.00 with a mean of 0.81, median of 0.86, and standard deviation less than 0.00. Looking at the performance percentiles without outliers, 50% of the data falls at or below a performance score of 0.86 which demonstrates additional meaningful variation across providers' performance. See table below for performance percentiles with outliers excluded:

Decile	Performance
1	0.50
2	0.67
3	0.75
4	0.80
5	0.86
6	0.90
7	0.94
8	0.99
9	1.00

10	1.00

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note: *This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

Previous testing
This test was not performed for this measure.

Current Testing
Not applicable

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

Previous testing
This test was not performed for this measure.

Current Testing
Not applicable

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

Previous testing
This test was not performed for this measure.

Current Testing
Not applicable

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

Previous testing

Data are not available to complete this testing.

Current Testing

The registry dataset provided to us by the 2018 AHA/ASA Get with the Guidelines Program was examined and tested for missing data prior to sending. The procedure is described as the following: if data uses covariates in statistical analyses, they do imputation if the variable is missing > 15% of the time. In order to enhance data quality, they also exclude hospitals that have missing medical history in more than 25% of their submitted cases.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

Previous testing

Data are not available to complete this testing.

Current Testing

Arrival time missing and IV alteplase time missing were variables included as measure exclusions within the specifications. There were approximately 82 missing cases of arrival time and 273 missing cases of IV alteplase time missing out of the 12,379 exceptions and exclusions reported across 1,619 hospitals.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

Previous testing

Data are not available to complete this testing.

Current Testing

Given the small frequency of missing data there is no reason to believe that missing data biased the performance results due to systematic missing data. Additionally, the imputation and exclusion of missing variables and cases is a statistically acceptable approach to dealing with missing data.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

There are clinical exclusion criteria that may not be part of standard electronic data sets found within the electronic medical records. The AHA/ASA has the ultimate goal to be able to extract all information electronically and plans to work to identify codes and/or value sets that would be needed to identify exclusions and to work with the appropriate organization(s) to develop and implement any additional codes needed to capture information such as medical reasons or patient reasons to remove a patient from the denominator.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (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.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

Given that the data for this measure are collected through the Get With the Guidelines – Stroke registry, and are not collected in an electronic health record, no feasibility assessment was performed. No issues with data collection have been identified and no modifications have been made to this measure due to issues with data collection, sampling or cost, as collected in the GWTG - Stroke registry.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

Not applicable.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Payment Program	Public Reporting Get With The Guidelines®– Stroke https://qualitynearme.heart.org/GWTGPublicReporting Regulatory and Accreditation Programs Healthcare Facilities Accreditation Program (HFAP) https://www.hfap.org/CertificationPrograms/StrokeCertification.aspx Professional Certification or Recognition Program Get With The Guidelines®– Stroke https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke Target: Stroke https://www.heart.org/en/professional/quality-improvement/target-stroke Quality Improvement (external benchmarking to organizations) Get With The Guidelines®– Stroke https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke Quality Improvement (Internal to the specific organization) Get With The Guidelines®– Stroke https://www.heart.org/en/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke Paul Coverdell National Acute Stroke Program https://www.cdc.gov/dhdsp/programs/stroke_registry.htm Target: Stroke https://www.heart.org/en/professional/quality-improvement/target-stroke

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

1. Name of Program and sponsor: Get With The Guidelines – Stroke (GWTG-Stroke); Sponsor is American Heart Association / American Stroke Association.

Purpose: The GWTG-Stroke program was launched in 2003. Participating hospitals are required to enter data on consecutive ischemic stroke patients using an online interactive patient management tool. These data are in accordance with achievement measures and quality metrics. The patient management tool provides decision support and feedback to hospitals and there is an array of online reporting features. Participating hospitals' results are benchmarked against other peer hospitals. Hospitals that participate actively and consistently in GWTG-Stroke are eligible for public recognition. Participation is the first level of recognition and acknowledges

entry of baseline data into the system. Then there are three levels of recognition: Bronze recognizes performance of 90 consecutive days; Silver recognizes performance of 12 consecutive months; Gold recognizes performance of 24 consecutive months or more; and Silver Plus and Gold Plus Quality Awards are advanced levels of recognition acknowledging hospitals for consistent compliance with performance measures embedded in the tool.
Geographic area and number of entities included: National. Over 2,000 hospitals have entered more than 5 million patient records into GWTG-Stroke database. Eligible patients are identified by billing codes, prospective screening of admission logs, or a combination. The diagnosis of ischemic stroke is verified by a trained chart abstractor.
Level of measurement and setting: Hospital-based.
2. Name of Program and sponsor: Target: Stroke; Sponsor is American Heart Association / American Stroke Association.
Purpose: Target: Stroke was launched in January 2010 and is a quality improvement initiative focused on improving acute ischemic stroke care and outcomes by reducing door-to-needle times for eligible patients treated with intravenous alteplase. Target: Stroke Phase II is designed to further the goals of the program by setting more aggressive targets for participating hospitals. The primary goal of Target: Stroke Phase II is for hospitals to achieve door-to-needle times within 60 minutes for 75 percent or more of acute ischemic stroke patients treated with intravenous alteplase, with a secondary goal of 45 minutes or less door-to-needle times in 50 percent or more of the same category of patients. Beginning in January 2015, hospitals also had the opportunity to be recognized with two Target: Stroke Honor Roll levels. The levels include: Target: Stroke Honor Roll: Time to thrombolytic therapy within 60 minutes in 50 percent or more of acute ischemic stroke patients treated with IV tPA; Target: Stroke Honor Roll-Elite: Time to thrombolytic therapy within 60 minutes in 75 percent or more of acute ischemic stroke patients treated with IV tPA and; Target: Stroke Honor Roll-Elite Plus: Time to thrombolytic therapy within 60 minutes in 75 percent or more of acute ischemic stroke patients treated with IV tPA AND time to thrombolytic therapy within 45 minutes in 50 percent of acute ischemic stroke patients treated with IV tPA.
Geographic area and number of entities included: National. There are more than 1200 Target: Stroke hospitals across the United States.
Level of measurement and setting: Hospital-based.
3. Name of program and sponsor: Paul Coverdell National Acute Stroke Registry (PCNASR); Sponsor is the Centers for Disease Control and Prevention – Division of Heart Disease and Stroke Prevention.
Purpose: The CDC launched PCNASR in 2001 and partnered with the Joint Commission and American Heart Association / American Stroke Association to develop performance measures related to stroke. The mission of PCNASR is to: Measure, track, and improve the quality of care and access to care for stroke patients from onset of stroke symptoms through rehabilitation and recovery; Decrease the rate of premature death and disability from stroke; Eliminate disparities in stroke care; Support the implementation of comprehensive stroke systems across the continuum of care; Improve access to rehabilitation and opportunities for recovery after stroke and; Increase the workforce capacity and scientific knowledge of stroke care within stroke systems of care. The near-term goals of the Coverdell program are to encourage the development of statewide systems of care for stroke patients through coordination with emergency medical services and collaboration among statewide partners and; communicate with major stakeholders in stroke care to ensure ongoing improvement in the quality of that care. The long-term goal of PCNASR is to ensure that all Americans receive the highest quality of acute stroke care currently available and to reduce the number of untimely deaths attributable to stroke, prevent stroke-related disability, and prevent stroke patients from suffering recurrent strokes. The program accomplishes its mission and vision in part by providing surveillance on the quality of care of stroke care and implementing targeted interventions to improve pre-hospital and in-hospital quality of acute stroke care and improve transitions from hospital to home.
Geographic area and number of entities included: The program is state-centric, and the CDC currently funds nine states through the Coverdell program: California, Georgia, Massachusetts, Michigan, Minnesota, New

York, Ohio, Washington, and Wisconsin. From 2005 to 2015, more than 620,000 Americans participated via their hospital.
Level of measurement and setting: Hospital-based.
4. Name of program and sponsor: Healthcare Facilities Accreditation Program (HFAP); sponsored by Accreditation Association for Hospitals/Health Systems, Inc. and is authorized by the Centers for Medicare and Medicaid Services.
Purpose: HFAP launched in 1945 and is authorized by the Centers for Medicare and Medicaid Services to provide accreditation to a wide array of healthcare settings, including hospitals, ambulatory care/surgical facilities, physical rehabilitation facilities, clinical laboratories and critical access hospitals. In 2006, HFAP began its certification reviews for hospital stroke guidelines, based on the guidelines of the Brain Attack Coalition and the American Heart Association / American Stroke Association. The Primary Stroke Certification signifies that the hospital has the capacity to stabilize and treat acute stroke patients through safe and efficient administration of tPA and other therapies.
Geographic area and number of entities included: National.
Level of measurement and setting: Hospital-based.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

Not applicable.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

Not applicable.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Via its interactive patient management tool, the GWTG-Stroke program provides feedback, including benchmarking data and embedded links to clinical evidence supporting best practices, to its participating hospitals. The GWTG-Stroke program also provides its hospitals numerous resources such as: access to the most up-to-date research and scientific publications, professional education opportunities, such as workshops and webinars, clinical tools and resources, patient education resources, quality improvement field staff support, national and local recognition for hospital team program achievement, and submission of CMS Core Stroke Measures and other data.

The Target: Stroke program provides a feedback report on stroke quality to its participants. This is a confidential peer-reviewed report that includes door to imaging goals, door to stroke team notification goals, door to needle goals, pre-hospital notifications, and information on preventable delays. A stroke patient time tracker can also be used by hospitals to reduce their door-to-needle times by tracking information such as door to TPA time, door to CT/MRI time, and Door to stroke team notification. For a sample of the patient time tracker see here: https://www.heart.org/-/media/files/professional/quality-improvement/target-stroke/target-stroke-phase-ii/ts_patienttimertracker_ucm_470282.pdf?la=en&hash=9481E1E536240DC1A7C1320204A3E589C2B65E36.

The HFAP provides benchmarking data to its Primary Stroke Centers to place their performance in context with their peer hospitals. This report can then be shared with stroke staff, medical staff, Board, leadership team, marketing team, and other stakeholders to show how patient care is reflected in quality metrics.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

In addition to the educational efforts made, described above, the GWTG-Stroke patient management tool provides hospitals with real-time benchmarking by hospital size, region, and other variables. The program provides feedback on patient-level reporting to identify individual problems, as well as raw-data downloads for additional analytics to fit the hospital's needs for quality improvement. GWTG-Stroke provides point-of-care tools, including referral notes, patient letters, and patient education.

By way of educational efforts, Target: Stroke educates its hospitals on 12 key best practice strategies for reducing door-to-needle times for IV alteplase in acute ischemic stroke. The program also provides tips to avoid laboratory delays to improve patient's door-to-needle times, without compromising patient safety.

HFAP provides the performance measure description, the threshold established by the performance measure, and how the hospital scored. Data are grouped by the size of the patient population, and comments and recommendations for improvement are provided.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

The AHA/ASA has an online tool that registry participants can use to provide feedback on this measure or other measures reported in the registry. Registry staff respond to all feedback and any comments that may indicate a problem with a measure are escalated to the measures team for evaluation and, if needed, discussed with the expert work group that oversees the GWTG-Stroke program to consider if updates or changes to the measure are needed.

Additional feedback is summarized below in the improvement section.

4a2.2.2. Summarize the feedback obtained from those being measured.

We have received no feedback from those being measured.

4a2.2.3. Summarize the feedback obtained from other users

We have received no feedback from other users.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Not applicable based on answers provided in 4a2.2.2 and 4a2.2.3.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

A recent study evaluated temporal changes from 2008 to 2018, in door-to-needle times amongst patients in the Paul Coverdell National Acute Stroke Program. The study analyzed 419 hospitals and 39,737 acute ischemic stroke patients who received IV alteplase within 4.5 hours of the time the patient was last known to be well*. In 2008, 26.4% of these patients had door-to-needle times </= 60 minutes and a substantial improvement was

seen through 2017, where 66.2% of patients had door-to-needle times </= 60 minutes (P < 0.001) (Tong et al., 2018). Another recent study analyzed 1,422 hospitals participating in GWTG-Stroke from October 2012 to April 2015, and found during this time that the proportion of ischemic stroke patients who received alteplase within 60 minutes of arriving at the hospital increased from 42.5% to 56.4% (P<0.001) (Kamal et al., 2017).

*This number excluded patients who received IV alteplase at outside hospitals, had missing DTN times, and arrived at the hospital >4.5 hours after symptom onset.

Citations:

1. Kamal, N., Sheng, S., Xian, Y., Matsouaka, R., Hill, M. D., Bhatt, D. L., … Smith, E. E. (2017). Delays in Door-to-Needle Times and Their Impact on Treatment Time and Outcomes in Get With The Guidelines-Stroke. Stroke, 48(4), 946–954. doi:10.1161/STROKEAHA.116.015712

2. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

We have not received reports of unexpected findings resulting from the implementation of this measure. Although faster door-to-needle times could lead to rushed assessments and increased complications, the literature demonstrates that as more patients have door-to-needle times within 60 minutes, there is a corresponding improvement in variables such as in-hospital mortality, symptomatic intracranial hemorrhage rates, and discharge to the home. Tong et al. found among patients who received IV alteplase within 4.5 hours of time last known to be well, and as a greater percent of these patients had door-to-needle times within 60 minutes throughout the last decade, in-hospital all-cause mortality decreased from 7.2% in 2008 to 5.1% in 2017 (P<0.001), symptomatic intracranial hemorrhage rates within 36 hours decreased from 6.3% in 2008 to 3.4% in 2017 (P<0.001), and discharge to the home increased from 23.6% 2008 to 50.9% in 2017 (P<0.001) (2018). In addition, a 2016 Scientific Statement put forth by the AHA/ASA addresses the risk of symptomatic intracranial hemorrhages and makes the following recommendation: For severe stroke symptoms, intravenous alteplase is indicated within 3 hours from symptom onset of ischemic stroke. Despite increased risk of hemorrhagic transformation, there is still proven clinical benefit for patients with severe stroke symptoms. (Demaerschalk et al., 2016). (Class I; Level A)

Citations:

1. Demaerschalk BM, Kleindorfer DO, Adeoye OM, Demchuk AM, Fugate JE, Grotta JC, Khalessi AA, Levy EI, Palesch YY, Prabhakaran S, Saposnik G, Saver JL, Smith EE; on behalf of the American Heart Association Stroke Council and Council on Epidemiology and Prevention. Scientific rationale for the inclusion and exclusion criteria for intravenous alteplase in acute ischemic stroke: a statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016;47:581–641.

2. Tong, X., Wiltz, J. L., George, M. G., Odom, E. C., King, S. M. C., Chang, T., … . (2018). A Decade of Improvement in Door-to-Needle Time Among Acute Ischemic Stroke Patients, 2008 to 2017. Circulation: Cardiovascular Quality and Outcomes, 11(12). doi: 10.1161/circoutcomes.118.004981

4b2.2. Please explain any unexpected benefits from implementation of this measure.

See 4b2.1.

5. Comparison to Related or 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.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0437 : STK 04: Thrombolytic Therapy

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

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

Measure #1952 assesses the percentage of patients who received alteplase within 60 minutes of door-to-needle, amongst patients who received alteplase within 4.5 hours. This measure focuses on the timely administration of alteplase rather than whether the treatment should be administered. Data demonstrates that shortening door-to-needle times improves outcomes for acute ischemic stroke. Conversely, Measure #0437 assesses whether therapy was administered in eligible patients. As a result, the specifications differ where needed based on different populations and different focal points of the measure.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses 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.)

Not applicable

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested

information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** TimetoIntravenousThrombolyticTherapySpecDataCollectionForm_07152019.pdf

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): American Heart Association

Co.2 Point of Contact: Melanie, Shahriary, melanie.shahriary@heart.org, 301-569-6159-

Co.3 Measure Developer if different from Measure Steward: American Heart Association

Co.4 Point of Contact: Melanie, Shahriary, melanie.shahriary@heart.org, 301-569-6159-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

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

The below volunteers are part of the Get With The Guidelines-Stroke measures workgroup and are responsible for developing and maintaining measures included in the Get With The Guidelines-Stroke module.

*Eric E. Smith, MD, MPH, FRCPC

Chair

Assistant Neurologist

Massachusetts General Hospital

*Lee H. Schwamm, MD, FAHA

Vice Chairman of the Neurology Dept

Massachusetts General Hospital

*Gregg C. Fonarow, M.D., FACC

Professor of Medicine

Director, Ahmanson-UCLA Cardiomyopathy Center

Co-Director, UCLA Preventative Cardiology Program

Jeff Saver, MD, FAHA, FAAN

Professor of Neurology

Geffen School of Medicine at UCLA

Mathew Reeves, PhD, DVM

Associate Professor

Department of Epidemiology

Michigan State University

David Tong MD FAHA

Medical Director, CPMC Comprehensive Stroke Care Center

Director, CPMC Center for Stroke Research (CCSR)

Scott Kasner, MD, MSCE, FAHA

Professor of Neurology

Director, Comprehensive Stroke Center

University of Pennsylvania

Medical Center

Measures were reviewed by the GWTG- Exec Committee which includes the below volunteers as well as those above denoted with an asterisk:

Paul Heidenreich, MD,MS

Associate Professor of Medicine

Stanford University

VA Palo Alto Medical Center

Robert Berg, MD, FAAP, FAHA

Professor & Division Chief

Critical Care Medicine

Children's Hospital Philadelphia

Eric D. Peterson, MD, MPH, FAHA, FACC

Professor of Medicine

Vice Chair for Quality

Duke University Medical Center

Associate Director and Director of CV Research

Duke Clinical Research Institute

Adrian Hernandez, MD

Duke University Medical Cntr

Deepak L. Bhatt, MD, MPH, FAHA, FACC, FSCAI

Chief of Cardiology, VA Boston Healthcare System

Director, Integrated Interventional Cardiovascular Program, Brigham and Women's Hospital & VA Boston Healthcare System

Associate Professor of Medicine, Harvard Medical School

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2003

Ad.3 Month and Year of most recent revision: 11, 2017

Ad.4 What is your frequency for review/update of this measure? Annually

Ad.5 When is the next scheduled review/update for this measure? 10, 2020

Ad.7 Disclaimers: The Measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications.

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Ad.8 Additional Information/Comments: