NATIONAL
QUALITY FORUM

Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 1952
Corresponding Measures:
De.2. Measure Title: Time to Intravenous Thrombolytic Therapy
Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services
De.3. 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
1b.1. 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:
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

S.4. Numerator Statement: Patients who receive IV alteplase at my hospital within 60 minutes after arrival

S.6. Denominator Statement: All patients with a final clinical diagnosis of ischemic stroke who received IV alteplase at my hospital

S.8. 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

De.1. Measure Type: Process

S.17. Data Source: Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Nov 01, 2012 **Most Recent Endorsement Date:** Jul 31, 2020

IF this measure is included in a composite, NQF Composite#/title:
3581:Intravenous Fibrinolytic Treatment Measure Bundle

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not Applicable

1. Evidence, Performance Gap, Priority – 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

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 (<u>current and over time</u>) 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, <u>as specified</u>, 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_11182019-637171204828592523.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

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)

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 <u>and</u> 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): Centers for Medicare & Medicaid Services
Co.2 Point of Contact: Helen, Dollar-Maples, Helen.Dollar-Maples@cms.hhs.gov, 410-786-7214-
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.8 Additional Information/Comments: