SETRAC Stroke Data Points

Question	Definition
ITEM 1 **Total number of patients discharged with a final clinical diagnosis of stroke:**	Final Clinical Diagnosis – The diagnosis defined in the Uniform Hospital Discharge Data Set (UHDDS) as "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care." Usually, this diagnosis is equivalent to the final ICD-10-CM code. Exclude: Inpatient strokes - A patient in your hospital ED, radiology suite, or observation unit experiences a new onset of stroke symptoms. - Stroke symptoms are first discovered after a patient was already admitted to your hospital as an inpatient. Aggregate numbers to be submitted are for: (1a) Total number of Ischemic Strokes. (1b) Total number of Intracerebral Hemorrhages. (1c) Total number of Subarachnoid Hemorrhages. Patients who arrive with symptoms of stroke and have complete resolution after Alteplase/TNK is administered and have no evidence for an infarct on imaging should be diagnosed with "aborted stroke" and should be considered to have a final clinical diagnosis of ischemic stroke. Those with evidence of an infarct should be categorized as an ischemic stroke. The ICD-10-CM Code Tables can be found on the Centers for Medicare & Medicaid Services website. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm
ITEM 2 **Of the patients reported in #1a, how many were greater than or equal to 18 years of age and were not enrolled in a clinical trial for stroke?**	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 (i.e. STK, VTE) To answer "Yes", BOTH of the following must be true: • There must be a signed consent form for clinical trial. For the purposes of abstraction, a clinical trial is defined as an experimental study in which research subjects are recruited and assigned a treatment/intervention and their outcomes are measured based on the intervention received. Treatments/interventions most often include use of drugs, surgical procedures, and devices. Often a

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	control group is used to compare with the treatment/intervention. Allocation of different interventions to participants is usually randomized. • There must be documentation on the signed consent form that during this hospital stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied (i.e. STK, VTE). Patients may either be newly enrolled in a clinical t rial during the hospital stay or enrolled in a clinical trial prior to arrival and continued active participation in that clinical trial during this hospital stay. • Observational studies in which data are being collected on patients without a specific intervention would not qualify for a clinical trial.
ITEM 3 **Of the patients reported in #1a, 1b and 1c, how many received endovascular treatments, including IA mechanical thrombectomy or lytic (Alteplase/TNK), at your facility?**	Endovascular treatments include all uses of intra-arterial (IA) delivery of pharmacologic thrombolytic therapy, as well as the endovascular mechanical devices such as "clot retrieval devices", for acute ischemic stroke. Examples include: • IA Thrombolytic • Retrievable stent • Other mechanical clot retriever device (not retrievable stent) • Clot suction/aspiration device • Intracranial angioplasty, with or without permanent (non-retrieved stent) • Cervical carotid angioplasty, with or without stent • Other Mechanical devices may be used alone or in conjunction with IA thrombolytic therapy. This data element is looking to capture patients that receive IA catheter-based reperfusion therapy for acute ischemic stroke events only, and not those that undergo carotid revascularization for secondary prevention, elective stenting, or purely diagnostic angio. If IA thrombolytic therapy is given regionally (remote from clot due to an inability to access the clot), include the patient in this count.

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ITEM 4 **Of the patients reported in #2:** The following are included: • Activase • Alteplase • IV t-PA (Intravenous Tissue Plasminogen Activator) • Recombinant t-PA Tissue plasminogen activator • TNK	**(4a) How many received Alteplase/TNK at your facility?** The following patients should be included in the count: • patients who begin treatment with Alteplase/TNK but do not get the full dose due to a medical reason like an elevated INR or a newly discovered history element. • patients who received Alteplase/TNK in the ED in your hospital and then were transferred from your ED (without hospital admission) to another acute care hospital. **(4b) How many received Alteplase/TNK at an outside facility?** The following patients should be included in the count: • patients who had Alteplase/TNK initiated at outside facility and not initiated at your facility. • patients transferred from another hospital where Alteplase/TNK was started, even if the infusion continues after the patient arrives at your facility. **(4c) How many did NOT receive Alteplase/TNK?**
ITEM 5 **Of the patients reported in #4a, how many received IV Alteplase/TNK:**	Time of IV t-PA administration is based on arrival time of patient. Consider the date/time that Alteplase/TNK is administered to be the date/time Alteplase/TNK is initiated, i.e., the date/time of bolus administration. Exclude: • Missing or unknown values for arrival date/time or for date/time Alteplase/TNK initiated • Date/time Alteplase/TNK initiated < arrival date/time Indicate the aggregate number of patients that receive Alteplase/TNK within: (5a) ≤ 30 minutes after ED arrival. (5b) Between 31 to 45 minutes after ED arrival. (5c) Between 46 to 60 minutes after ED arrival. (5d) > 60 minutes after ED arrival.

Question	Definition
ITEM 6 **Of the patients reported in #5d, document the reason(s) for delay:**	**Acceptable Reasons for Delay in IV Lytic Therapy** • **Social / Religious reasons** There is a documentation that the patient and/or family refused Alteplase/TNK treatment due to their cultural or religious beliefs, even if they later changed their mind and Alteplase/TNK was administered. • **Initial Refusal** If there is documentation that the patient and/or family initially refused treatment with Alteplase/TNK for any reason other than a social/religious reason. If the physician documents that the patient declines IV alteplase in favor of catheter-based reperfusion or other investigational therapy, select "Pt./Family refused" If the patient could not participate in shared decision making or provide consent, and there is documentation that the delay in treatment with IV rt-PA was due to reasonable attempts to contact a proxy decision maker to obtain consent. • **Care-team unable to determine eligibility** If the diagnosis of stroke was made but eligibility for Alteplase/TNK could not be established or verified by the clinician. e.g., time last known well unknown; lack of accurate medical history; timing of recent surgery cannot be definitively established, multiple TIAs that could make uncertain as to when the stroke actually started, would raise concerns about Alteplase/TNK eligibility. Example: Physician requests CTA of chest prior to administering Alteplase/TNK due to possible chest dissection. • **Hypertension requiring aggressive controls with IV medications** Treatment with intravenous Alteplase/TNK was delayed because aggressive measures (such as continuous infusion or the use of two or more intravenous antihypertensive agents) were first needed to reduce BP to a treatable range. *Elevated blood pressure (systolic > 185 mm Hg or diastolic > 110 mm Hg) despite treatment*

Question	Definition
	• **Further diagnostic evaluation to confirm stroke for patients with hypoglycemia** (blood glucose < 50), seizures, or major metabolic disorders that could potentially mimic stroke symptoms. • **Management of concomitant emergent / acute conditions** Such as CPR, respiratory failure (including intubation) • **Investigational or experimental protocol for thrombolysis** If an investigational or experimental protocol for thrombolysis was used, there should be a signed IRB consent form in the medical record. • **Need for additional PPE for suspected / confirmed infectious disease** Select this option when there is documentation in the patient medical record that treatment was delayed so that health care providers could obtain additional Personal Protection Equipment (PPE) because the patient had a confirmed or suspected infection **Not Acceptable Reasons for Delay in IV Lytic Therapy** • **Delay in stroke diagnosis** Example Patient presents with headache that has persisted for 1 hour and 45 minutes. The patient is seen by an ED physician who believes that the patient has a migraine. The patient is seen by a neurologist several hours later, and after further work-up, is determined to have an ischemic stroke. Medical record documentation by the neurologist states "patient was not a candidate for IV alteplase, as by the time he was diagnosed with an ischemic stroke, 8 hours had passed since he was last known to be well." • **In-hospital time delay** If there is a delay in getting the CT done or read, or a delay in patient evaluation, and/or need for additional imaging (e.g. IV access) • **Equipment-related** Examples of equipment-related delays include a telemedicine equipment issue, CAT Scan/MRI availability, or IV pump malfunction.

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	• **Other** Providing "Other" will automatically be considered an unacceptable delay. A specific reason must be given why there was a delay.
ITEM 7 **Of the patients reported in #4c, how many arrived at your facility within 4.5 hours of last known well?**	Time last known well (LKW) – When the patient was last known to be in his/her usual state of health (without the signs and symptoms of the current stroke) or at his/her baseline state of health. The time last known well might be established by a telephone or in person conversation and should be the time closest to the time of discovery for which there is clear evidence that the patient was at their previous baseline. This is not the same as the time of symptom discovery unless the start of stroke symptoms is clearly witnessed. If the patient's "last known well" date or time cannot be determined, then LKW is considered to be unknown, and the patient should be excluded from this measure. If there is documentation of one or more symptomatic episodes of transient stroke symptoms **and** documentation of symptom resolution between episodes (e.g. patient returns to baseline), use the time of the most recent (last) episode prior to arrival, regardless if all symptoms resolved prior to arrival. If the most recent episode occurs after hospital arrival, the patient is considered to have an inpatient stroke and should be excluded from this measure. If time LKW is documented as a range of time prior to hospital or ED arrival (e.g., "2 - 3 hours ago"), assume the maximum time in that range (e.g., 3 hours). If multiple times LKW are documented, either because subsequent more accurate information became available or because of different levels of expertise in sorting out the actual LKW time, use the time recorded according to the following hierarchy: • neurologist • admitting physician • emergency department physician • ED nursing notes • EMS

ITEM 8 **Of the patients reported in #7, document the contraindications/warnings or hospital – related reasons why Alteplase/TNK was not given** Contraindications/warnings must be mentioned in the context of IV thrombolytics and must be documented by a physician/APN/PA or pharmacist with three exceptions: patient/family refusal, NIHSS score of zero, and initiation of IV or IA thrombolytic at a transferring hospital. These three exceptions may be documented by a nurse. “Additional Warnings 3-4.5 hr.” must be explicitly documented in the context of the 3-4.5 hour treatment window	**ACCEPTABLE REASONS** • **Active internal bleeding** Active internal bleeding (<22 days) • **Pt. refused** If there is documentation that the patient and/or family initially refused treatment with Alteplase/TNK for any reason other than a social/religious reason. If the physician documents that the patient declines IV alteplase in favor of catheter-based reperfusion or other investigational therapy, select "Pt./Family refused" • ***Too severe*** *– field retired June 2022. Use the “**Additional warnings for patients treated between 3 and 4.5hrs: NIHSS > 25”** category instead.* • **CT findings** ICH, SAH, or major infarct signs • **Hx of ICH, etc.** History of intracranial hemorrhage or brain aneurysm or vascular malformation or brain tumor • **Platelets PT INR Levels** Low count, Platelets < 100,000, PTT > 40 sec after heparin use, or PT > 15 or INR > 1.7, or use of NOAC. • **Surgery < 3mo** Recent intracranial or spinal surgery, head trauma, or stroke (<3 mo.) • **SBP, DBP (Hypertension requiring aggressive controls with IV medications)** Treatment with intravenous Alteplase/TNK was delayed because aggressive measures (such as continuous infusion or the use of two or more intravenous antihypertensive agents) were first needed to reduce BP to a treatable range. *Elevated blood pressure (systolic > 185 mm Hg or diastolic > 110 mm Hg) despite treatment* • **Suspicion SAH**

- ***Advanced age*** *– field retired June 2022. Use the "**Additional warnings for patients treated between 3 and 4.5hrs: Age > 80"** category instead.*

- **IV or IA thrombolysis/thrombectomy at an outside hospital prior to arrival**
  IV or IA Alteplase/TNK given or thrombectomy performed at another facility prior to arriving at your hospital.

- **Glucose levels**
  Glucose < 50 or > 400 mg/dL

- ***Patient returned to baseline*** *– field retired June 2022*
  Use the "Too mild (non-disabling)" category instead.

- **Hospital-related or other reasons: Delay in patient arrival**
  Patient arrives to facility > 4.5 hours from last known well

- **Additional warnings for patients treated between 3 and 4.5hrs: Age > 80**
  Include patients previously included in the "Advanced Age" category.

- **Additional warnings for patients treated between 3 and 4.5hrs: Prior Stroke and Diabetes**
  Include patients with a history of both diabetes and prior ischemic stroke.

- **Additional warnings for patients treated between 3 and 4.5hrs: Any prior anticoagulant**
  Include patients taking an oral anticoagulant regardless of INR.

- **Additional warnings for patients treated between 3 and 4.5hrs: NIHSS > 25**
  Select "Severe Stroke NIHSS >25" when the physician notes document "alteplase was withheld due to the severity of the stroke symptoms". Include patients previously listed in the "too severe" category.

  Note: Severe stroke is not an exclusion or relative exclusion to treatment at 0-3 hours of onset of symptoms.

- ***Additional warnings for patients treated between 3 and 4.5hrs: CT findings >1/3 MCA*** *– field retired June 2022. Use the "**CT Findings"** category instead.*

AREAS OF OPPORTUNITY

Recent experience suggests that under some circumstances- with careful consideration and weighting of risk to benefit- patients may receive fibrinolytic therapy despite 1 or more relative contraindications. Consider risk to benefit of IV alteplase administration carefully if any of these relative exclusion criteria are present:
Added from GWTG

- **Stroke severity too mild (non-disabling)**

  Select this category when there is minimal to no disability associated with the stroke symptoms (e.g. numbness, mild weakness, lack of gait impairment). Note that there is no lower limit to NIHSS score that prohibits the use of IV alteplase.

  If the physician documents "no IV alteplase due to low NIHSS or NIHSS = 3," then this would appropriately be categorized as stroke severity too mild.

  If documentation indicates an NIHSS score of zero, then this may be considered the equivalent of documentation that the stroke was too mild, and an explicit statement linking this as the reason for non-treatment is not required.

- **Pregnancy**
  Includes women who are currently pregnant, or within six weeks post-partum

- **Comorbid conditions / life expectancy < 1 year**
  Select when patients are not treated due to coexisting terminal cancer, advanced dementia, severe cardiopulmonary disease or other conditions which severely limit quality of life or life expectancy.

- **Seizure at onset**
  Ischemic stroke patient has a history of seizures and is taking an anti-convulsant. Example: The family states that the patient had twitching of his arm before he became aphasic.

- ***Left heart thrombus*** *– field retired June 2022. This category is no longer considered a reason for not administering Alteplase/TNK.*

- ***Life expectancy < 1 yr.*** *– field retired June 2022. Use the "**Comorbid conditions"** category instead.*

- **Surgery < 15 days**
  Major surgery or serious trauma within previous 14 days

	• **MI in previous 3 months** • **Care-team unable to determine eligibility** If the diagnosis of stroke was made but eligibility for Alteplase/TNK could not be established or verified by the clinician. e.g., time last known well unknown; lack of accurate medical history; timing of recent surgery cannot be definitively established, multiple TIAs that could make uncertain as to when the stroke actually started, would raise concerns about Alteplase/TNK eligibility. **NOT ACCEPTABLE REASONS** • **Rapid Improvement** • **Hospital-related or other reasons: Delay in stroke diagnosis** Example: Patient presents with headache that has persisted for 1 hour and 45 minutes. The patient is seen by an ED physician who believes that the patient has a migraine. The patient is seen by a neurologist several hours later, and after further work-up, is determined to have an ischemic stroke. Medical record documentation by the neurologist states "patient was not a candidate for IV alteplase, as by the time he was diagnosed with an ischemic stroke, 8 hours had passed since he was last known to be well." • **Hospital-related or other reasons: In-hospital time delay** If there is a delay in getting the CT done or read, or a delay in patient evaluation, and/or need for additional Imaging • **Hospital-related or other reasons: No IV access** Unable to establish IV access • **Hospital-related or other reasons: Other** Only use the "Other" field if there is no reason specified that can be accurately captured by the listed choices under Contraindications and Warnings.

ITEM 9 **Of the patients transferred from your facility to another acute care facility for higher level of care, how many were:**	This measure includes: • Patients who were transferred before being admitted to your facility • Patents who were admitted to your facility and then discharged to another acute care hospital. (9a) Ischemic strokes (9b) Subarachnoid hemorrhages (9c) Intracerebral hemorrhages
ITEM 10 **Of the patients reported in #4a, how many were transferred to another acute care facility AFTER receiving Alteplase/TNK at your facility?**	This measure includes the following: • Patients that arrived at the reporting facility's emergency department with signs and symptoms of stroke (no in-house stroke patients.) • Drip-and-ship patients (those who received Alteplase/TNK at your facility but were never actually admitted as an inpatient). Exclude the following: • Patients who were admitted to your facility, received Alteplase/TNK, and then were discharged to another acute care hospital.
ITEM 11 **Of the patients transferred from your facility to another acute care facility, how many patients had door-in and door-out times:**	Door-out time is the time the patient has been discharged from your facility (not EMS hand-off time.) Door-In Door-Out (DIDO) time is for all ischemic strokes, subarachnoid hemorrhages, and intracerebral hemorrhages. This is the time it takes for a patient to leave your facility, once they initially enter, to another acute care facility for a higher level of care. (11a) ≤ 120 minutes

	(11b) > 120 minutes. Of these patients, what were the reasons for the delays? (11c) Unknown
ITEM 12 **Of the patients reported in #1a, 1b, and 1c, how did the patients arrive at your facility?**	**(12a) Number arriving via EMS from home/scene** Patients brought to your hospital from home/scene by EMS, whether by ground EMS or Air EMS. Private ambulance transport would be included in this EMS category. Patients brought by EMS from an Urgent Care Facility, or private physician office are also included in this category. **(12b) Number arriving via Mobile Stroke Unit (MSU)** Patients were brought to your hospital from home/scene by MSU. A Mobile Stroke Unit is a transport unit capable of diagnosing and treating acute strokes in the field. It contains highly specialized staff, imaging capabilities (CT scanner), mobile lab and the ability to administer IV alteplase. **(12c) Number arriving via private transportation/taxi/other from home/scene** Patients arriving from home/scene via cab, bus, car, walk-in, Uber/Lyft etc. **(12d) Number arriving via transfer from another hospital** Patients are transferred from another hospital or satellite/free-standing ED. **(12e) Number with arrival mode not documented or unknown** The medical record or the EMS run sheet does not specify how patient arrived at your hospital.