NINDS Common Data Element (CDE) Project
Stroke Version 2.0 Public Review
Hospital Course and Acute Therapies Subgroup Materials

Instrument:

- Neurobehavioral Symptom Inventory (NSI) ©

Case Report Forms:

- Antithrombotics and Risk Factor Controlling Medications
- Hospital Discharge
- Palliative/Comfort Care and End of Life Issues
- Surgical and Procedural Interventions
- Thrombolytic/Reperfusion Therapies

NINDS CDE Notice of Copyright
Neurobehavioral Symptom Inventory (NSI)
(New for Stroke)

Availability	The instrument is freely available here: Neurobehavioral Symptom Inventory.
Classification	**Supplemental**: Stroke, Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH) and Traumatic Brain Injury (TBI)
Short Description of Instrument	The severity of each symptom on the Neurobehavioral Symptom Inventory (NSI) is measured using a 5-item scale (0-none to 4-very severe) that asks patients to indicate the extent to which each symptom has disturbed them in the previous 2 weeks. The NSI total score is the sum of severity ratings of the 22 symptoms. Patient self-report either through 1) written completion of the questionnaire, or 2) in-person or telephone interview with clinician or research associate. Administration time is 5–10 minutes.
Scoring	Raw scores can be calculated for the four domains (Physical, Cognitive, Affective and Sensory) and for the Total Score.
References	Cicerone KD & Kalmar K. Persistent Post Concussion Syndrome: The structure of subjective complaints after mild traumatic brain injury. J Head Trauma Rehabil. 1995;10(3):1–17. Meterko M, Baker E, Stolzmann KL, Hendricks AM, Cicerone KD, Lew HL. Psychometric assessment of the Neurobehavioral Symptom Inventory-22: the structure of persistent postconcussive symptoms following deployment-related mild traumatic brain injury among veterans. J Head Trauma Rehabil. 2012;27(1):55-62.

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

For some studies (e.g., clinical trials) it may be important to record the details of each medication administered during the study on a Prior and Concomitant Medications form. The General CDEs include a Prior and Concomitant Medications template form.

In-Hospital Medications

1. **Did the participant/ subject receive ~~arterial dose~~ anticoagulants? ☐ Yes ☐ No

   **IF YES, type(s) of anticoagulants received: (choose all that apply)

   - ☐ Unfractionated heparin IV
   - ☐ Full dose LMW heparin (Enoxaparin, Others)
   - ☐ Warfarin (Coumadin)
   - ☐ **Direct oral anticoagulant: (dabigatran, rivaroxaban, apixaban, others)
     - ☐ Direct Thrombin Inhibitor
     - ☐ Factor Xa inhibitor
   - ~~☐ Fondaparinux (Arixtra)~~
   - ☐ Other, specify:

2. **Did the participant/ subject receive ~~arterial dose~~ antiplatelet~~s~~ agents? ☐ Yes ☐ No

   **IF YES, type(s) of antiplatelet~~s~~ agents received: (choose all that apply)

   - ☐ Aspirin
   - ☐ Aspirin/Dipyridamole (in separate formulations or as Aggrenox)
   - ☐ Clopidogrel (Plavix)
   - ~~☐ Ticlopidine (Ticlid)~~
   - ☐ Cilostazol
   - ☐ Other, specify:

3. Was the participant/ subject diagnosed with VTE? ☐ Yes ☐ No (Skip to 4)

   (VTE = extracranial venous thromboembolism)

   A. IF YES, diagnosed with which type(s): (choose all that apply)
      - ☐ Deep venous thrombosis (DVT)
      - ☐ Pulmonary embolism
      - ☐ Other, specify:

   B. IF YES, type(s) of VTE prophylaxis used: (choose all that apply)
      - ☐ Low dose unfractionated heparin (LDUH) ~~(Answer 3C)~~
      - ☐ Low molecular weight heparin (LMWH) ~~(Answer 3C)~~
      - ☐ Intermittent pneumatic compression devices (IPC) e.g. Venous Foot Pump
      - ☐ ~~Factor Xa Inhibitor~~ Direct oral anticoagulant

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Direct Thrombin Inhibitor
- ☐ Factor Xa inhibitor

☐ ~~Warfarin~~

☐ ~~Venousr foot pumps (VFP)~~

☐ ~~Oral Factor Xa inhibitor~~

☐ Other, specify:

~~C. IF heparin (i.e., LDUH/ LMWH) used, provide dose: (include units)~~

Discharge Medications

4. Specify discharging location:

☐ Acute hospital

☐ Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitation units of a hospital: three hours or greater of therapy per day

☐ Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy with Medicare certification in anticipation of skilled care

☐ Medicare certified long term care hospital (LTCH)

☐ Hospice- home or medical facility providing hospice level of care

☐ Other not defined above:

5. **Which class(es) of medications was the participant/ subject prescribed at ~~hospital~~ discharge? (choose all that apply)

☐ Anticoagulant~~s~~ agents (Answer 5A and Skip 6)

☐ Antiplatelet~~s~~ agents (Answer 5B and Skip 6)

☐ Antihypertensive~~s~~ agents (Answer 5C and Skip 6)

☐ Anti-diabetic agents (Answer 5D and Skip 6)

☐ Lipid lowering agents (Answer 5E and Skip 6)

A. **IF anticoagulants prescribed, specify type(s): (choose all that apply)

☐ ~~Unfractionated heparin IV~~

☐ ~~Full dose~~ Low molecular weight heparin (LMW~~H~~) (Enoxaparin, o~~O~~thers)

☐ Warfarin (Coumadin)

☐ Direct oral anticoagulant (dabigatran, rivaroxaban, apixaban, others)

- ☐ Direct Thrombin Inhibitor
- ☐ Factor Xa inhibitor

☐ ~~Fondaparinux (Arixtra)~~

☐ Other, specify:

B. **IF antiplatelet~~s~~ agents prescribed, specify type(s): (choose all that apply)

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Aspirin
- ☐ Aspirin/Dipyridamole (in separate formulations or as Aggrenox)
- ☐ Clopidogrel (Plavix)
- ☐ ~~Ticlopidine (Ticlid)~~
- ☐ Cilostazol
- ☐ Other, specify:

C. **IF antihypertensive medication prescribed, specify type(s): (choose all that apply)

- ☐ Beta-blocker (atenolol, metoprolol, propranolol, others)
- ☐ Calcium channel blocker (amlodipine, diltiazem, nifedipine, verapamil, others)
- ☐ Diuretic (chlorothiazide, hydrochlorothiazide, chlorthalidone, others)
- ☐ ACE-inhibitor (enalaopril, lisinopril, ramipril, others)
- ☐ Angiotensin II receptor blocker (candesartan, losartan, valsartan, others)
- ☐ Alpha blocker (doxazosin, prazosin, terazosin)
- ☐ Combined alpha and beta-blocker (carvedilol, labetalol)
- ☐ Central agonist (alpha methyldopa, clonidine, others)
- ☐ Other, specify:

D. **IF anti-diabetic medication prescribed, specify type(s): (choose all that apply)

- ☐ Insulin
- ☐ Amylin analogs (Pramlintide)
- ☐ Sulfonylureas (glimepiride, glipizide, glyburide, others)
- ☐ Meglitinides (nateglinide, repaglinide)
- ☐ Biguanides (metformin)
- ☐ Thiazolidinediones (pioglitazone, rosiglitazone)
- ☐ Alpha-glucosidase inhibitors (acarbose, miglitol)
- ☐ Dipeptidyl peptidase inhibitors (alogliptin, linagliptin, others)
- ☐ Sodium-glucose co-transporter 2 inhibitors (canagliflozin, dapagliflozin, others)
- ☐ Oral combination drugs
- ☐ Other, specify:

E. **IF lipid lowering medication prescribed, specify type(s) (choose all that apply)

- ☐ Statin (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
- ☐ PCSK9 inhibitors (alirocumab, evolocumab)
- ☐ Selective cholesterol absorption inhibitors (ezetimibe)
- ☐ Bile acid sequestrants (cholestyramine, colestipol, colesevelam)

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Fibrates (gemfibrozil, fenofibrate, clofibrate)
- ☐ Niacin
- ☐ Omega-3 fatty acid ethyl esters (Lovaza, Vascepa)
- ☐ Marine-derived omega-3 polyunsaturated fatty acids
- ☐ Other, specify:

6. Reason(s) antithrombotic therapy (i.e., anticoagulants or~~and~~ antiplatelet~~s~~ agents) was not prescribed at ~~hospital~~ discharge:(choose all that apply)

   - ☐ Allergy ~~to or complication related~~ to aspirin, ~~ticlopidine,~~ clopidogrel, dipyridamole, warfarin, direct oral anticoagulant or heparin~~s~~ (history or current)
   - ☐ Patient/Family refused
   - ☐ Risk for bleeding ~~or discontinued due to bleeding~~
   - ☐ Discontinued due to bleeding
   - ☐ Serious side effect to medication, specify:
   - ☐ Terminal illness/Comfort measures only
   - ☐ Other, specify:

Antithrombotics and Risk Factor Controlling Medications CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to antithrombotics and other medications the participant/ subject is treated with while in the hospital for the stroke event or is prescribed upon discharge from the hospital. Several of the elements were taken from are taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental- Highly Recommended based on study type, disease stage and disease type as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. One element has some additional instructions not included on the CRF:

- Reason(s) for no antithrombotic therapy – If reasons are not mentioned in the context of antithrombotics, do not make inferences (e.g., do not assume that antithrombotics are not being prescribed because of a bleeding disorder unless documentation explicitly states so).

References

Barnes GD, Ageno W, Ansell J, Kaatz S; Subcommittee on the Control of Anticoagulation of the International Society on Thrombosis and Haemostasis. Recommendation on the nomenclature for oral anticoagulants: communication from the SSC of the ISTH [published correction appears in J Thromb Haemost. 2015;13(8):1539]. J Thromb Haemost. 2015;13(6):1154–1156.

Kim BJ, Kwon SU, Park JH, Kim YJ, Hong KS, Wong LKS, Yu S, Hwang YH, Lee JS, Lee J, Rha JH, Heo SH, Ahn SH, Seo WK, Park JM, Lee JH, Kwon JH, Sohn SI, Jung JM, Navarro JC, Kim HY, Kim EG, Kim S, Cha JK, Park MS, Nam HS, Kang DW. Cilostazol Versus Aspirin in Ischemic Stroke Patients With High-Risk Cerebral Hemorrhage: Subgroup Analysis of the PICASSO Trial. Stroke. 2019. STROKEAHA119023855. doi: 10.1161/STROKEAHA.119.023855. [Epub ahead of print].

Hospital Discharge

[Study Name/ID pre-filled]

Site Name:

Subject ID:

**Date of discharge: // (mm/dd/yyyy)

1. Discharge diagnoses:
   a. **Principal discharge diagnosis: (valid ICD-10 code)
   b. Discharge diagnosis related to stroke:
      (valid ICD-10 code):
      ☐ No Stroke/ TIA -related ICD-10 code
2. Were any new diagnoses related to stroke risk factors made during the hospital stay?
   ☐ Yes
   ☐ No
   ☐ Unknown
   IF YES, new diagnosis type(s): (choose all that apply)
      ☐ Diabetes
      ☐ Hypertension
      ☐ Hyperlipidemia
      ☐ Atherosclerosis
      ☐ Persistent or Paroxysmal Atrial Fibrillation/ Flutter
      ☐ Other, specify
3. **Initial residence/ Discharge destination:
   ☐ ~~Discharged to home or self care (routine discharge)~~
   ☐ ~~Discharge/ Trans to a short term/ general hospital for inpatient care~~
   ☐ ~~Discharge/ Trans to skilled nursing facility (SNF) with Medicare certification in anticipation of skilled care~~
   ☐ ~~Discharge/ Trans to a Designated Cancer Center or Children's Hospital~~
   ☐ ~~Discharge/ Trans to home under care of organized home health service organization~~
   ☐ ~~Expired~~
   ☐ ~~Discharge/ Trans to court/ law enforcement~~
   ☐ ~~Discharge/ Trans to a federal health care facility~~
   ☐ ~~Hospice- home~~
   ☐ ~~Hospice- medical facility (certified) providing hospice level of care~~
   ☐ ~~Discharge/ Trans to hospital-based Medicare approved swing bed~~
   ☐ ~~Discharge/ Trans to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital~~
   ☐ ~~Discharge/ Trans to a Medicare certified long term care hospital (LTCH)~~
   ☐ ~~Discharge/ Trans to a nursing facility certified under Medicaid but not certified under Medicare~~

Hospital Discharge

[Study Name/ID pre-filled]

Site Name:

Subject ID:

- ☐ ~~Discharge/ Trans to a psychiatric hospital or psychiatric distinct part unit of a hospital~~
- ☐ ~~Discharged/ Trans to a Critical Access Hospital (CAH)~~
- ☐ ~~Discharge/ Trans to another type of health care institution not defined elsewhere in this code list~~
- ☐ Home with no in-home services
- ☐ Home with home care services
- ☐ Another family member's/ friend's home
- ☐ Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitation units of a hospital: three hours or greater of therapy per day
- ☐ Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy with Medicare certification in anticipation of skilled care
- ☐ Medicare certified long term care hospital (LTCH)
- ☐ Hospice- home or medical facility providing hospice level of care
- ☐ Other not defined above:
- ☐ Expired

4. Is the discharge destination certified by any of the following as a primary stroke center? (choose all that apply)
   - ☐ Joint Commission accredited primary stroke center
   - ☐ Healthcare Facilities Accreditation Program (HFAP) accredited primary stroke center
   - ☐ State accredited primary stroke center
   - ☐ None of the above
   - ☐ Unknown
5. Is the discharge destination a rehabilitation center accredited by the Commission on Accreditation of Rehabilitation Facilities (CARF)?
   - ☐ Yes
   - ☐ No
   - ☐ Unknown

Hospital Discharge CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to data collected at the time of discharge from the acute hospital stay for the stroke event. Several of the elements were taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental - Highly Recommended based on study type, disease stage and disease type as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes all of the instructions available for the data elements at this time.

Palliative/Comfort, Care, and End of Life Issues

[Study Name/ID pre-filled]

Site Name:

Subject ID:

1. Was the participant's/ subject's care restricted to "Comfort Measures Only"?
   ☐Yes ☐No (Skip to 2) ☐Unknown

   A. Earliest documentation of "Comfort Measures Only":
   ☐Day 1 or 2 ☐Day 3 or after ~~☐Timing unclear~~ ☐Not Documented (ND)/Unable to Determine (UTD)

   B. Type(s) of comfort care measures received: (choose all that apply)
   ☐Eliminating sources of discomfort
   ☐Providing effective pain and symptom management through the use of medications and other therapies
   ☐Offering a quiet, private environment that supports the intimate process of dying
   ☐Encouraging personal rituals that may honor or celebrate the person dying
   ☐Providing support, reassurance, and info about grief, bereavement, and the dying process
   ☐Providing spiritual care as desired
   ☐Offering food and fluids as the dying person desires and is able to take
   ☐Preventing constipation, even if oral intake has been minimal
   ☐Positioning at frequent intervals to prevent bedsores
   ☐Offering frequent mouth care for discomfort from drying
   ☐Instilling artificial tears or eye lubricant for discomfort from drying
   ☐Limiting vital signs to respirations (breathing) and temperature
   ☐Stopping medications that are not essential to promoting comfort, including antibiotics
   ☐Stopping needle sticks and blood draws, including finger sticks for blood sugar
   ☐Removing nonessential equipment that may distract care providers and loved ones from focusing on the one who is dying
   ☐Other, specify:

2. Was the participant/ subject made DNR/ DNI during the hospitalization? ☐Yes ☐No (Stop) ☐ Unknown
   (DNR = Do not resuscitate; DNI = Do not intubate)

   IF YES, earliest documentation of DNR/ DNI:

   ☐Day 1 or 2

   ☐Day 3 or after

   ~~☐Timing unclear~~

   ☐ND/UTD

Palliative/ Comfort Care and End of Life Issues CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to whether the participant/ subject is provided with palliative care (a.k.a., comfort care) and whether the participant/ subject has DNR/ DNI orders during the acute hospital stay for the stroke event. Some of the elements were taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Important note: None of the data elements included on this CRF is considered Core (i.e., strongly recommended for all stroke/subarachnoid hemorrhage (SAH) clinical studies to collect). Rather, all of the data elements are supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Comfort Measures Only – indicates if there is any evidence that the participant's/ subject's care was restricted to "Comfort Measures Only". Commonly referred to as "palliative care" in the medical community and "comfort care" by the general public. Palliative care includes attention to the psychological and spiritual needs of the patient and support for the dying patient and the patient's family.
- Earliest documentation of “Comfort Measures Only” – ~~Select “Timing unclear” if there is physician/APN/PA documentation of comfort measures only during this hospital stay, but the earliest documentation of comfort measures only was on day 1 or 2 OR after day 2 is unclear.~~ Select “Not Documented/ Unable to Determine (ND/UTD)” if there is no physician/APN/PA documentation of comfort measures only, or unable to determine from medical record documentation.

Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Surgical or Therapeutic Procedures Data Table

Surgical or Therapeutic Procedure	Inpatient or Outpatient?	Start Date	End Date
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)

Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Surgical or Therapeutic Procedure	Inpatient or Outpatient?	Start Date	End Date
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)

The interview questions that follow are provided to make certain all important surgical/procedural interventions are recorded in the preceding table.

Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

In-Hospital Surgeries/ Procedures

Indicate whether or not the participant/ subject received any of the following interventions while being treated in the hospital for the index stroke event.

~~1. Intubated and placed on a mechanical ventilator: ☐ Yes ☐ No~~

2. Cervical carotid revascularization: ☐ Yes ☐ No
   IF YES, type(s) of carotid revascularization: (choose all that apply)
   - ☐ Carotid endarterectomy (CEA)
   - ☐ Carotid artery stenting (CAS)
   - ☐ Other, specify:
3. Vertebral artery revascularization: ☐ Yes ☐ No
   IF YES, type(s) of vertebral artery revascularization: (choose all that apply)
   - ☐ Angioplasty
   - ☐ Stenting
   - ☐ Surgical reimplantation
   - ☐ Other, specify:
4. Intracranial revascularization: ☐ Yes ☐ No
   IF YES, type(s) of intracranial revascularization: (choose all that apply)
   - ☐ Angioplasty
   - ☐ Stenting
   - ☐ Bypass
   - ☐ Other, specify:
5. Ventricular drainage placed: ☐ Yes ☐ No
   IF YES, type(s) of ventricular drainage placed: (choose all that apply)
   - ☐ Temporary extraventricular drain
   - ☐ Permanent shunt
   - ☐ Other, specify:
6. Thrombectomy: ☐ Yes ☐ No
   IF YES, which artery(ies): (choose all that apply)
   - ☐ MCA:
     - ☐ M1
     - ☐ M2
   - ☐ ICA

Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

- ☐ Basilar artery
- ☐ Posterior cerebral artery
- ☐ Vertebral artery

7. Therapy for increased intracranial pressure: ☐ Yes ☐ No
   IF YES, type(s) of therapy for increased intracranial pressure: (choose all that apply)
   - ☐ Hemicraniectomy
   - ☐ Osmotic therapy
     - ☐ Hypertonic saline
     - ☐ Mannitol
   - ☐ Decompressive craniectomy
   - ☐ Hypothermia
   - ☐ Shunt placement
   - ☐ ~~Inter~~ V~~v~~entricular catheter
   - ☐ Other, specify:

Surgeries/ Procedures after Initial Discharge

Indicate whether or not the participant/ subject received or was evaluated and scheduled for a surgical/ operative procedure as a preventative therapy for stroke after initial hospital discharge for the index stroke/ TIA.

8. Surgical/ Operative preventive treatment: ☐ Yes ☐ No ☐ Unknown
   IF YES, type(s) of surgical/ operative preventive treatment: (choose all that apply)
   - ☐ Cardiac, specify:

   Neurosurgical:
   - ☐ Encephaloduroarteriosynangiosis (EDAS)
   - ☐ Obliteration of vascular malformation
   - ☐ Other, specify:

Surgical and Procedural Interventions CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to surgical and other procedure interventions the participant/ subject is treated with while in the hospital for the index stroke event or after initial discharge from the hospital.

Important note: None of the data elements included on this CRF Module is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Rather, all of the data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Surgical or therapeutic procedure – Choose all that apply. Recommend collection during acute hospital care. In previous studies, information on surgical procedures has typically been documented in free text format, thus often precluding any meaningful analysis. We therefore propose the use of ICD-10 coding
- Inpatient or outpatient status - Choose one.
- Surgical or therapeutic procedure start date and time – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
- Surgical or therapeutic procedure end date and time - Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).

Thrombolytic/ Reperfusion Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Date information collected: mm/dd/yyyy

Intravenous (IV) Thrombolytic Therapy

1. **Was IV tPA initiated at this hospital?

   ☐ Yes- within 0 - 3 hour window ☐ Yes- within 3 - 4.5 hour window ☐ Yes- beyond 4.5 hour using imaging selection ☐ No (Skip to 2)

   A. **Date and Time tPA initiated: (mm/dd/yyyy) (hh:mm, 24 hr clock)

   B. Total IV tPA dose given: (please specify) mg

2. Reason(s) no IV tPA started at this hospital: (choose all that apply)

Contraindications:

☐ Active internal bleeding (<22 days)

☐ CT findings (ICH, SAH, or major infarct signs)

☐ History of intracranial hemorrhage or brain aneurysm or vascular malformation or brain tumor

☐ Platelets <100,000, PTT> 40 sec after heparin use, or PT > 15 or INR > 1.7, or known bleeding diathesis

☐ Recent intracranial or spinal surgery, head trauma, or stroke (<3 mo.)

☐ Recent surgery/trauma (<15 days)

☐ SBP > 185 or DBP > 110 mmHg despite treatment

☐ Seizure at onset

☐ Suspicion of subarachnoid hemorrhage

☐ Subacute Bacterial Endocarditis (SBE)

Hospital-related or Other Factors:

☐ Delay in Patient Arrival

☐ Delay in Stroke diagnosis

☐ In-hospital Time Delay

☐ No IV access

☐ MRI not feasible

☐ CTP not feasible

☐ Other, specify:

~~Warnings~~ Other reasons t-PA is not started:

☐ Advanced age

☐ Care-team unable to determine eligibility

Thrombolytic/ Reperfusion Therapies

[Study Name/ID pre-filled] Site Name:

Subject ID:

☐ Glucose < 50 or > 400 mg/dl

☐ Increased risk of bleeding due to Acute pericarditis, SBE, Hemostatic defects, Diabetic hemorrhagic retinopathy, Septic thrombophlebitis or occluded AV cannula, or currently receiving oral anticoagulants

☐ IV or IA tPA given at outside hospital

☐ Left heart thrombus

☐ Life expectancy < 1 year or severe co-morbid illness or CMO on admission

☐ Pregnancy

☐ Patient/ Family refused

☐ Rapid improvement

☐ Stroke severity nondisabling ~~too mild~~

☐ Stroke severity - Too severe (e.g., NIHSS >22)

~~Additional Warnings~~ Other reasons t-PA is not started for patients treated between 3-4.5 hours:

☐ Age > 80

☐ Prior Stroke AND Diabetes

☐ Any anticoagulant use prior to admission (even if INR < 1.7)

☐ NIHSS > 25

☐ CT findings of >1/3 MCA

***** Other reasons t-PA is not started for patients treated using MRI imaging selection beyond 4.5 hours:**

☐ Treatment cannot be started within 4.5 hours of symptom recognition

☐ Age > 80

☐ Parenchymal hyperintensity visible on FLAIR

☐ NIHSS > 25

☐ CT findings of >1/3 MCA or >50% of ACA or PCA territories, or > 100ml

☐ Any MRI findings indicative of a high risk of SICH

3. Was IV tPA initiated at an outside hospital? ☐ Yes ☐ No ☐ Unknown

Intra-arterial (IA) Thrombolytic Therapy

1. **Was an IA procedure initiated at this hospital? ☐ Yes ☐ No (Skip to 5) ☐ Unknown (Skip to 5)
2. **Type of IA procedure: ☐ Pharmacological ☐ Mechanical ☐ Both
   A. Date and Time of groin puncture for IA procedure:

Thrombolytic/ Reperfusion Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

(mm/dd/yyyy), (hh:mm, 24 hr clock)

B. Date and Time IA catheter-based reperfusion initiated:
(mm/dd/yyyy), (hh:mm, 24 hr clock)

C. Date and Time of last angiographic image or the end time for mechanical/ pharmacologic intervention:
(mm/dd/yyyy), (hh:mm, 24 hr clock)

3. Was IA catheter-based reperfusion initiated at an outside hospital?

☐ Yes ☐ No ☐ Unknown

Intra-sinus Thrombolytic Therapy

4. Was an intra-sinus intervention (i.e., for cerebral venous thrombosis) performed?

☐ Yes ☐ No (Skip to ~~7~~5) ☐ Unknown (Skip to 5)

A. Type of intra-sinus procedure: ☐ Pharmacological ☐ Mechanical ☐ Both

B. Date and Time of groin puncture for intra-sinus procedure:
(mm/dd/yyyy), (hh:mm, 24 hr clock)

C. Date and Time intra-sinus intervention initiated:
(mm/dd/yyyy), (hh:mm, 24 hr clock)

Other Thrombolytic Therapy

5. Do the medical records suggest any type of investigational or experimental protocol for thrombolysis was used during provision of care?

☐ Yes ☐ No ☐ Unknown

If YES, specify:

Thrombolytic/ Reperfusion Therapies CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to thrombolytic/ reperfusion therapy the participant/ subject is treated with during the acute hospital stay for the stroke event. Several of the elements were taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental-Highly Recommended based on study type, recent new data, disease stage and disease type or Exploratory as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended

***Element is classified as Exploratory

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. The following elements have some additional instructions not included on the CRF.

- IV tPA initiated – This refers to IV tPA given at the FDA approved dose and within FDA approved guidelines.
- Date and Time IV tPA initiated - This refers to IV tPA given at the FDA approved dose and within FDA approved guidelines. If there are discrepancies in the documentation of bolus administration, the nursing documentation on the medication administration sheets should be treated as the most reliable source, followed by the stroke physician's documented time or ED note.
- This data element applies only to patients for whom IV thrombolytic therapy was initiated at this hospital. Do not abstract this data element if IV thrombolytic therapy was initiated at another hospital and patient was subsequently transferred to this hospital.
- Total IV tPA dose given - It is important to consult these other data elements when calculating the IV tPA dose: Stroke Onset Time/ Time Patient Last Seen Well and Body Weight in kilograms.
- ~~IA~~ Endovascular procedure initiated - ~~IA~~ endovascular procedures include mechanical thrombectomy and all uses of ~~IA~~ intra-arterial thrombolytic therapy~~, as well as mechanical devices such as "Clot retrieval devices"~~. Mechanical ~~devices~~ thrombectomy may be used alone or in conjunction with ~~IA~~ intra-arterial thrombolytic therapy.
- Date and time ~~IA catheter-based~~ endovascular reperfusion initiated - The start time for ~~IA catheter-based~~ endovascular reperfusion therapy should be either the date and time on the angio showing evidence of treatment, or the start time of the infusion or mechanical deployment if the angio time is not available.
- Date and Time of the last mechanical or pharmacological intervention - If time of the last mechanical or pharmacological intervention not available, use the time on the last angiographic image.
- Intra-sinus Intervention - Relevant to venous sinus and their large draining veins

Thrombolytic/ Reperfusion Therapies CRF Module Instructions

- Date and Time intra-sinus intervention initiated - The start time for IS therapy should be either the date and time on the angio showing evidence of treatment, or the start time of the infusion or mechanical deployment if the angio time is not available.
- Investigational or experimental protocol for thrombolysis - If investigational or experimental protocol was used there should be a signed IRB consent in the medical record.

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