



HCHS/SOL Question by Question Instructions

Stroke Diagnosis Form (STD), Version 1 from 10/13/2020

General Information

A Stroke Diagnosis Form (STD) is completed by the physician reviewer for all physician review packets that are assigned to them by the UNC Department of Biostatistics Collaborative Studies Coordinating Center (CSCC). Events will be classified independently by two physician reviewers with disagreements classified by an adjudicator. Each physician endpoint summary packet will include an Event Summary Form (ESF). The ESF summarizes diagnostic information abstracted from the original medical record by nurse medical data abstractors at the CSCC. It also contains selected information from the participant's study visit. The ESF is accompanied by documents copied from the medical chart to assist with the physician's review and classification of the investigation at hand.

Introduction

The physician reviewer(s) will complete this form for all eligible potential stroke/TIA events, nonfatal or fatal. This form must be entered online in the CDART2 data management system (DMS), developed by the UNC Collaborative Studies Coordinating Center (CSCC).

The Coordinating Center will provide a 'physician review packet' to each reviewer for each investigation that the reviewer is responsible for. Each packet will contain the following items:

The physician reviewer will receive the following items to complete this form:

- A Physician Review Packet assigned by the Coordinating Center
- The individualized physician reviewer data entry ID
- Access to the internet.

It is important that each reviewer use his/her own ID, as this will identify which physician reviewed which case. The Coordinating Center will track how many investigations each physician has reviewed and spread the cases out as evenly as possible.

Question by Question Instructions

The first section of the form is called administrative information (0A-0D). Parts of this will be filled out by the CSCC.

0A. Enter date that you (the reviewer) completed the form.

0B. Enter your staff or reviewer ID number. It can be up to three digits.

0C. Event ID. This number is assigned by the CSCC. It will start with a letter representing the HCHS/SOL field center site and will be pre-filled.

0D. Event Date. This is the date of the hospital admission and will be pre-filled. Please check the medical record to ensure that the admission date throughout it matches the pre-filled date. If not, please contact one of the Endpoints team members at the CSCC.

Answer all questions by selecting one choice from the options provided.

Section A – Primary Diagnosis

Item 1. Diagnosis: Choose the diagnosis that best describes the event from 1. – 3. and record answer in the box provided. (Only one choice allowed).

1. Not a TIA or Stroke (skip to 13)
2. TIA (skip to 13)
3. Stroke

Please consult the HCHS/SOL manual for diagnosis requirements. A diagnosis of TIA would require focal neurologic deficits, but could be interpreted broadly if the region of the brain affected was the brainstem. Retinal infarcts should be coded as a stroke.

If a stroke or TIA is secondary to a traumatic (physical) event, then it should be coded “1. Not a TIA or Stroke” as they will be excluded from Stroke/TIA events in HCHS/SOL.

Section B – Stroke Type

Item 2. Stroke Type: Use imaging reports included in the events review packet to choose the type of brain lesion identified in the participant. Make one choice from code numbers 1-5 and record answer in the box provided. If you identify a hemorrhage, continue on to section D. Otherwise move to Item 3. If 2A. or 2B. is chosen, please specify with a comment at each question. Retinal infarction should be classified as a ‘brain infarction’ but requires documentation by an ophthalmologist. Item B.2.A. “Other stroke type” is reserved for cerebral venous thrombosis or cerebral sinus thrombosis (a rare, $\leq 1\%$ of all strokes).

Section C. - Brain Infarct Subtypes

Item 3. Choice of Subtype: Choose the stroke subtype that best describes the event from codes 0. – 8. and record your answer in the box provided. (Only one choice allowed). Complete 3A. or 3B if appropriate. When evaluating a case for a “complete workup” consider physician interpretations of imaging reports as sufficient stand-ins for the reports themselves.

CODES:

0. N/A
Select this option only if “Other Stroke Type” was specified in question 2 but the event can not be described as an infarct.
1. Large vessel extracranial atheroembolic: This subtype requires documentation of extracranial internal carotid or extracranial vertebral artery stenosis of at least 50% or occlusion in the territory of the stroke (i.e. left extracranial ICA for a left MCA infarct) as documented on reports for CTA, MRA, Carotid Doppler or conventional angiography in the absence of a clear cardiac source (AFIB, prosthetic left-sided heart valve, recent anterior/lateral wall myocardial infarction) or other specific cause (e.g. fibromuscular dysplasia, dissection, vasculitis, drug use- such as cocaine, known hypercoagulable state). It is typically associated with known atherosclerotic risk factors.
2. Large vessel intracranial atheroembolic: This subtype requires documentation of intracranial internal carotid, middle cerebral artery, anterior cerebral artery, posterior cerebral artery, intracranial vertebral artery or basilar artery stenosis of at least 50% or occlusion in the territory of the stroke (i.e. left intracranial ICA for a left MCA infarct) as documented on reports for CTA, MRA, Transcranial Doppler or conventional angiography in the absence of a clear cardiac source (AFIB, prosthetic left-sided heart valve, recent anterior/lateral wall myocardial infarction) or other specific cause (e.g. fibromuscular dysplasia, dissection, vasculitis, drug use- such as cocaine, known hypercoagulable state). It is typically associated with known atherosclerotic risk factors.
3. Cardioembolic: A non-lacunar stroke, typically superficial/cortically located on head CT or brain MRI, often wedged-shaped, or affecting simultaneously different vascular territories (i.e. both hemispheres) associated with a clear cardioembolic source: AFIB, prosthetic heart valve, recent anterior/lateral wall MI, a patent foramen ovale with deep venous thrombosis (DVT) documented.
4. Lacunar Infarction: a small, deep infarct, typically no larger than 10-15 mm in the internal capsule, basal ganglia, thalamus, or pons usually in the presence of hypertension and/or diabetes, and/or hyperlipidemia, and or cigarette smoking.
5. Acute ischemic stroke of other known etiology (specify below): This includes fibromuscular dysplasia, dissection, vasculitis, drug use (such as cocaine or heroin), known hypercoagulable state, sickle cell disease, or other rare causes such as Fabry disease, Susac syndrome, etc.
6. Ischemic stroke of unknown cause (no probable etiology despite complete workup): Non-lacunar stroke with no evidence of large vessel atherosclerotic disease, cardiac embolic source, hypercoagulable state, or specific genetic cause. Complete work up

includes vascular imaging of both extracranial and intracranial vessels, cardiac evaluation for wall motion, valve function, and rhythm.

7. Ischemic stroke of unknown cause (more than one etiology, specify below): When the patient has criteria fulfilling more than 1 of the prior 6 subtypes, it becomes unknown which mechanism predominated. This selection requires a complete workup that includes vascular imaging of both extracranial and intracranial vessels, cardiac evaluation for wall motion, valve function, and rhythm.
8. Ischemic stroke of unknown cause (workup is incomplete) – unclear cause because the diagnostic work up was incomplete.

3a. Acute ischemic stroke of other known etiology specify:

Specify an etiology that is not listed in the choices above.

3b. Ischemic stroke of unknown cause (more than one etiology) specify:

Specify each etiology.

Item 4. Was the Brain Infarction Procedure-Related?

Record No – 0, Yes – 1 or Unknown – 9 if stroke can be related to a procedure undergone by the participant. If No (0) or Unknown (9) skip to Item E, Item 12.

If yes is chosen please specify the procedure involved in Item 4a. If event is only a brain infarction Skip to Section E, Item 12.

Section D. - Hemorrhagic Subtypes

Item 5. Subtype for a subarachnoid hemorrhage (SAH): Record using codes 0-6 and complete item 5a. if "Other" is chosen. If 0 (N/A) is chosen, skip to Item 11.

- 1) N/A Select this option only if "Other Stroke Type" was specified in question 2 but the event can not be described as an SAH.
- 2) Aneurysmal SAH:
 - a) Presence of SAH predominantly in the basal cisterns, and
 - b) Identification of a saccular aneurysm on conventional angiography, CTA or MRA that could account for the hemorrhage
- 3) Sulcal (or convexal) SAH
 - a) Presence of SAH in the sulci of the cerebral convexity (unilateral or bilateral), and
 - b) No basal cistern or ventricular involvement
- 4) Perimesencephalic; use this category when,
 - a) The center of bleeding is located immediately anterior to the midbrain;
 - b) There could be a small extension of blood into the posterior part of the anterior interhemispheric fissure, but not complete filling of the anterior interhemispheric fissure;
 - c) Extension of blood to the basal part of the Sylvian fissure is permitted, but not extension to the lateral Sylvian fissure, except for minute amounts of blood;
 - d) Sedimentation of small amounts of intraventricular blood is allowed, but not frank intraventricular hemorrhage should be observed;
 - e) Absence of intracerebral hematoma
- 5) Other: presence of SAH due to other defined process, including mycotic aneurysm (bacterial endocarditis), arteriovenous malformation, dural arteriovenous fistula, congenital or acquired coagulopathies, vasculitis, cerebral artery dissection, peri-procedural SAH, etc
- 6) Unknown: presence of SAH either in the basal cisterns, ventricles, or cerebral convexity without identifiable cause

Item 6. If a subarachnoid hemorrhage was there an intraventricular extension? Record No (0), Yes (1) or Unknown (9). This requires explicit identification on imaging or interpretation of imaging.

Item 7. If a subarachnoid hemorrhage was there an intraparenchymal extension? Record No (0), Yes (1) or Unknown (9). If only SAH, skip to Item 11. This requires explicit identification on imaging or interpretation of imaging.

Item 8. If an Intracerebral Hemorrhage, what subtype? Record using the codes 0-9. If 0 (N/A) is chosen skip to Item 11. If code 7 'Other' is chosen, please specify by completing Item 8a.

- 1) N/A
Select this option only if “Other Stroke Type” was specified in question 2 but the event can not be described as an intracerebral hemorrhage.
- 2) Small Vessel Hypertensive Vasculopathy
 - a) ICH occurring in a patient with history of hypertension; the diagnosis of hypertension can be satisfied based on EKG or ECHO findings or end-organ damage consistent with chronic hypertension (such as ophthalmologic findings, elevated creatinine, etc)
 - b) Hemorrhage typically affects the basal ganglia, thalamus, pons, or cerebellum
 - c) Evidence of previous cortical and/or subcortical hemorrhages (either ICH or cerebral microhemorrhages). These, however, should be located, primarily, in the basal ganglia, thalamus, pons, or cerebellum.
 - d) Intraventricular extension may occur in ICH; but the epicenter of the hemorrhage is in the parenchyma
 - e) no other cause of hemorrhage
- 3) Cerebral Amyloid. Use this category for ICH patients that present with radiologic evidence of
 - a) Lobar hemorrhage affecting, particularly, the lobar superficial areas;
 - b) There may be extension of the hemorrhage in the subarachnoid (particularly in the convexity), subdural, or intraventricular space. But, in distinction to other cerebral hemorrhages, the epicenter of the hemorrhage is in the parenchyma; and/or
 - c) Evidence of previous hemorrhages (either ICH or cerebral microhemorrhages) restricted to lobar, cortical, or cortical–subcortical regions (cerebellar hemorrhage allowed), and/or
 - d) Evidence of previous convexal superficial siderosis (either focal or disseminated)
 - e) no other cause of hemorrhage
- 4) Vascular Malformation Arteriovenous. Use this category for ICH patients with radiologic evidence of an arteriovenous malformation.
- 5) Vascular Malformation Cavernous. Use this category for ICH patients with radiologic evidence of a cavernous malformation in close proximity to the hemorrhage.
- 6) Endocarditis. Use this category for ICH patients with the diagnosis of endocarditis.
- 7) Primary Intraventricular Hemorrhage. Use this category for patients presenting with primary intraventricular hemorrhage and no evidence of either SAH or parenchymal hemorrhage
- 8) Other (complete Item 8a below). Use this category for patients with other defined cause of intracerebral hemorrhage not covered above, including congenital or acquired coagulopathy, vasculitis, reversible cerebral vasoconstriction syndrome, moyamoya, post-partum vasculopathy, drug-induced ICH, etc
- 9) Unknown

Item 9. If an Intracerebral Hemorrhage, was there an intraventricular extension?

Record No (0), Yes (1) or (9) for Unknown

Item 10. Best description for the core of the hemorrhage: Choose from codes 0-3 or 9 (Unknown) and record in the box provided.

- 1) Lobar hemorrhage. Use this category when the epicenter of the hematoma affects one of multiple cerebral lobes (frontal, parietal, temporal, or occipital).
- 2) Deep hemorrhage. Use this category when the epicenter of the hematoma is located in one of the deep cerebral structures (basal ganglia, thalamus, internal capsule or brainstem).
- 3) Cerebellar hemorrhage. Use this category when the hemorrhage is confined to the cerebellum.

Item 11. Was the Hemorrhagic Stroke Procedure-Related? Record No or N/A (0), Yes (1) or Unknown (9). If No skip to Item 12, if Yes, complete item 11a. by specifying the procedure involved. The event can be considered “procedure-related” if it occurred within 48 hours of a procedure.

Item 12. Reviewer Comments:

This is a where the physician reviewer adds additional information he/she feels is relevant to the review/diagnosis. These comments will be made available to the adjudicator if applicable. Provide any necessary comments and **CLICK “SAVE”** to ensure the form data is saved before closing the tab.