NINDS CDE Project
Stroke Version 2.0
Long Term Therapies Subgroup

Regular subgroup meetings were held to review forms and each section/instrument. CRFs from the Stroke v1.0 and Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage (SAH) CDEs were assigned to the subgroup by the Working Group Co-Chairs. Relevant literature was reviewed for both prior and current information, including elements used in research and clinical practice. The forms were distributed to subgroup members for critical review. Each member reviewed sections of the form, first independently and then as a group. Recommendations were then made for CDEs modification or development of new CDEs.

The instruments/elements recommended differ between the types of stroke. The Long Term Therapies v1.0 recommendations focused on ischemic disease and considered all preventative and antithrombotic options but did not consider the long term rehabilitation part of the purview. For hemorrhagic disease, strategies implemented early on to prevent recurrence of hemorrhage over the long term, whether from aneurysm, vascular malformations or other disease were considered. The recommendations focused on preventative therapies and rehabilitative interventions. For v2.0, the subgroup used the same parameters in developing their revisions to the v1.0 CDEs as well as considered which CDEs from the recently posted SAH recommendations would be appropriate to include.

The instruments/elements recommended differ between adult and pediatric stroke populations. Time-based and tissue-based definitions for adults apply to pediatric strokes, however, pediatric stroke type definitions and subtype classifications are different compared to adult stroke population as follows:

1. Definitions of vascular disease in perinatal period
2. Etiologic Classification System for Childhood Arterial Ischemic Stroke and its subtype
3. Definitions and classification of cerebral arteriopathies during childhood

There are no notable similarities/differences in the CDE recommendations as compared with other standards. There were no issues encountered when developing the CDE standards which are unique to stroke or which highlight a unique concern about stroke data collection.

Unmet needs/ unanswered questions and areas in need of further research and development were identified via the CDE process in stroke:

1. Validation of stroke subtype classification, especially in pediatric stroke population
2. Clinical trials comparing efficacy of antiplatelet versus anticoagulant therapy for primary and secondary stroke prevention in pediatric stroke
3. Surgical and procedural intervention CDEs for intracerebral/intraventricular hemorrhage and arteriovenous or cavernous malformations

Summary of Recommendations

Instrument/CRF Name	Domain/Subdomain	Population	Classification
Antithrombotics and Risk Factor Controlling Medications	Treatment/Intervention Data/ Drugs	Adult and Pediatric	**Supplemental – Highly Recommended:** Anticoagulant agent in hospital indicator; Anticoagulant agent in hospital type; Anticoagulant agent in hospital other text; Antiplatelet agent in hospital indicator; Antiplatelet agent in hospital type; Antiplatelet agent in hospital other text; Medication stroke discharge prescribe category; Anticoagulant agent stroke discharge prescribe type; Anticoagulant agent stroke discharge prescribe other text; Antiplatelet agent stroke discharge prescribe type; Antiplatelet agent stroke discharge prescribe other text; Antihypertensive agent stroke discharge prescribe type; Antihypertensive agent stroke discharge prescribe other text; Anti diabetic agent stroke discharge prescribe type; Anti diabetic agent stroke discharge prescribe other text; Lipid lower agent stroke discharge prescribe type; Lipid lower agent stroke discharge prescribe other text The remaining CDEs are classified as Supplemental.
Lifestyle Modification Therapies	Treatment/Intervention Data/ Therapies	Adult and Pediatric	All CDEs are classified as Supplemental.
Rehabilitation Therapies	Treatment/Intervention Data/ Therapies	Adult and Pediatric	**Supplemental – Highly Recommended**: Follow-up care specialist type All CDEs are classified as Supplemental or Exploratory.
SAH Surgical/Procedural Interventions	Treatment/Intervention Data/ Therapies	Adult and Pediatric	**Supplemental – Highly Recommended:** Vessel repair anatomic site; Subarachnoid hemorrhage ictus elapsed day count; Intervention surgical status; Intervention endovascular status The remaining CDEs are classified as Supplemental or Exploratory.
Stroke Surgical and Procedural Interventions	Treatment/Intervention Data/ Therapies	Adult and Pediatric	All CDEs are classified as Supplemental.
Unruptured Intracranial Aneurysm Management	Treatment/Intervention Data/ Therapies	Adult and Pediatric	All CDEs are classified as Supplemental or Exploratory.