

NINDS CDE Project

Working group: Unruptured intracranial aneurysms

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Please answer the following questions below.

- 1. Approach for selection of elements** (How did you go about drafting the recommendations and/or reviewing the current tools/instruments, and did you have any criteria for selection and classification?)
Incorporation of team of topic-specific experts.
Definition and classification of CDEs through face-to-face meetings, phone calls and emails.
- 2. Differential application to types of subarachnoid hemorrhage** (*Do the instruments/elements you recommended differ between the types of subarachnoid hemorrhage?*)
'Unruptured intracranial aneurysms' belongs only to aneurysmal subarachnoid hemorrhage. If intracranial aneurysms rupture, they lead to an aneurysmal subarachnoid hemorrhage.
- 3. Summary recommendations** (*We could consider a summary table OR each group could summarize their recommendations*).

Instrument / Scale / CRF Name <i>Name and acronym of the instrument/measure that is recommended for inclusion in the CDEs</i>	Domain	Subdomain	Classification (e.g., Core, Supplemental - Highly Recommended, Supplemental, Exploratory)
Demographics UIA CRF	Participant Characteristics	Demographics	Core: Age value Supplemental - Highly Recommended: Sex participant or subject genotype type
Baseline Assessment CRF	Assessments and Examinations	Physical / Neurological Examination	Supplemental
Concomitant Diseases CRF	Assessments and Examinations	Physical / Neurological Examination	Supplemental - Highly Recommended: History/current diagnosis of autosomal-dominant polycystic kidney disease
Concomitant Medications CRF	Treatment / Intervention Data	Drugs	Supplemental & Exploratory elements

Consult/Diagnosis CRF	Disease/Injury Related Events	Classification	Supplemental
UIA Management CRF	Treatment / Intervention Data	Therapies	Supplemental & Exploratory elements
Radiological Findings CRF	Assessments and Examinations	Imaging Diagnostics	Core: Maximum diameter; Height; Width; Morphology type for each UIA Supplemental - Highly Recommended: Imaging modality; Number of UIA; Aneurysm laterality; Neck measurement; Aspect ratio; Size ratio; Bottle neck factor; Shape type; Diameter growth from last imaging indicator; Growth in diameter since last imaging measurement; Time since last imaging; De novo formation of aneurysm since last imaging
Risk factors CRF	Participant History and Family History	General Health History	Core: Hypertension history; Current and past tobacco use; Age started and stopped tobacco use Supplemental - Highly Recommended: Family history of UIA; Family history of SAH due to UIA; Family member with history of SAH; Prior history of SAH due to UIA; Autosomal dominant polycystic kidney disease indicator; Intracranial aneurysm pertinent ethnicity; Blood pressure; Average number of cigarettes smoked per day; Number of pack-years of smoking; Alcoholic drinks per day; Six or more drinks consumption

4. **Comparison to other subarachnoid hemorrhage standards** (Are there any notable similarities/differences in the CDE recommendations as compared with other standards?)
There are no standards concerning 'Unruptured intracranial aneurysms', so mainly new CDEs had to be established.

5. Issues unique to subarachnoid hemorrhage disease (*Were there any issues encountered when developing the CDE standards which are unique to subarachnoid hemorrhage or which highlight a unique concern about subarachnoid hemorrhage data collection?*)

'Unruptured intracranial aneurysms' is a highly prevalent disease leading to aneurysmal subarachnoid hemorrhage.

6. Unmet needs; unanswered questions (*What unmet need / unanswered questions were identified via the CDE process in subarachnoid hemorrhage? What areas are in need of further research and development?)*

- Aneurysm morphology
- Definition of risk factors