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SPECIAL ARTICLE

Common Data Element for Unruptured Intracranial Aneurysm and Subarachnoid Hemorrhage: Recommendations from Assessments and Clinical Examination Workgroup/Subcommittee

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Abstract

Background: Clinical studies of subarachnoid hemorrhage (SAH) and unruptured cerebral aneurysms lack uniformity in terms of variables used for assessments and clinical examination of patients which has led to difficulty in comparing studies and performing meta-analyses. The overall goal of the National Institute of Health/National Institute of Neurological Disorders and Stroke Unruptured Intracranial Aneurysms (UIA) and subarachnoid hemorrhage (SAH) Common Data Elements (CDE) Project was to provide common definitions and terminology for future unruptured intracranial aneurysm and SAH research.

Methods: This paper summarizes the recommendations of the subcommittee on SAH Assessments and Clinical Examination. The subcommittee consisted of an international and multidisciplinary panel of experts in UIA and SAH. Consensus recommendations were developed by reviewing previously published CDEs for other neurological diseases including traumatic brain injury, epilepsy and stroke, and the SAH literature. Recommendations for CDEs were classified by priority into "core," "supplemental—highly recommended," "supplemental" and "exploratory."

Results: We identified 248 variables for Assessments and Clinical Examination. Only the World Federation of Neurological Societies grading scale was classified as "Core." The Glasgow Coma Scale was classified as "Supplemental—Highly Recommended." All other Assessments and Clinical Examination variables were categorized as "Supplemental."

Conclusion: The recommended Assessments and Clinical Examination variables have been collated from a large number of potentially useful scales, history, clinical presentation, laboratory, and other tests. We hope that adherence to these recommendations will facilitate the comparison of results across studies and meta-analyses of individual patient data.

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Introduction

Aneurysmal subarachnoid hemorrhage (SAH) is a neurological emergency associated with high morbidity and mortality rates, and even though prognosis has improved in the last decades [1], it remains one of the most dreaded neurological conditions. Initial assessments and clinical examination in SAH play a vital role in the stratification and prognostication of these patients. However, confusion abounds as there are multiple grading scales and assessments used by investigators in various studies, which makes it difficult to perform pooled and meta-analysis. In addition, there is no consensus as to which laboratory test should be performed, or what prehospital and history data should be collected and analyzed in patients with SAH.

Common Data Elements

Summary

A main goal of the National Institute of Health (NIH)/National Institute of Neurological Disorders and Stroke (NINDS) Unruptured Aneurysms and SAH Common Data Elements (CDE) project was to provide a guideline for future clinical research in this area [32]. This paper outlines the recommendations from the Assessments and Clinical Examination subcommittee on SAH.

Process for Selecting CDEs

Eight working groups (WGs) and a Steering Committee comprised of international SAH experts reviewed existing NINDS CDEs and instruments, created new elements when needed and provided recommendations for SAH clinical research. A summary of the Unruptured Intracranial Aneurysms and SAH CDE project and the variables recommended are presented elsewhere [32]. The WG on Assessments and Clinical Examination incorporated an international and multidisciplinary (emergency medicine, neurology, neurosurgery, neurorehabilitation, statistics and epidemiology, and nursing) ad hoc panel of experts in clinical studies and/or preclinical studies after SAH. The subcommittee was co-chaired by J.I.S and S.M. All subcommittee members were mandated to undergo training by the NIH/NINDS by means of a webinar to use the CDE Web site and online tools prior to the start of project.

Members of the WG performed an extensive review of CDEs from traumatic brain injury [2], epilepsy [3], stroke [4] and other neurological diseases. Following this initial exercise, committee members selected and classified the CDEs by consensus. A list of assessments and clinical examination CDEs relevant to SAH and unruptured cerebral aneurysm was compiled from March 2015—March 2017. Further prospective observational studies and clinical trials on SAH were reviewed to derive a comprehensive list of variables for assessments and clinical examination that were not previously described by other CDE projects. Variables pertaining to SAH research were selected based on whether they have been used in prior SAH studies, and their reliability and validity in wide patient populations. The collected variables were discussed by teleconferences and electronic correspondence. Variables not relevant to SAH research were excluded. All included Assessments and Clinical Examination CDEs were prioritized according to a predefined classification (Table 1). The list was presented at the Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage CDE meeting (May 13–15, 2016, in Houston, TX). Further amendments were made based on feedback received during meeting. A final list of Assessments and Clinical Examination CDEs was submitted to the NINDS in June 2016. The NINDS CDE team combined the reports of all subcommittees to create a document with instructions for internal review. Internal review across subcommittees took place in December 2016. The recommendations were made available for public comments on the NINDS CDE Web site between January 2017 and March 2017.

Classification Into Core, Highly Recommended Supplemental, Supplemental, and Exploratory

In total, 248 variables were identified for Assessments and Clinical Examination. Only the World Federation of Neurological Societies (WFNS) grading scale was classified as "Core." The Glasgow Coma Scale (GCS) was classified as "Supplemental—Highly Recommended." All other Assessments and Clinical Examination variables were categorized as "Supplemental" (Table 2).

Description of Selected CDEs

Below is the description and rationale of variables which were classified as "Core" and "Highly Recommended" along with other selected variables which have been used in SAH research.

Table 1 Classification of outcomes & endpoints according to the level of recommendation. Source: http://www.commondataelements.ninds.nih.gov

Class	Definition
Core	A data element that collects essential information applicable to any study, including either those which span across all disease and therapeutic areas or those that are specific to one disease area. The NINDS and their appointed WGs assign the "Core" classification based on the current clinical research best practices. This term applies to both the General CDEs and the Disease-specific CDEs. In each case, the Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the Core CDEs on any type of study
Supplemental—highly recommended	A data element which is essential, based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design
Supplemental	A data element, which is commonly collected in clinical research studies, but whose relevance depends upon the study design (i.e., clinical trial, cohort study, etc.) or type of research involved
Exploratory	A data element that requires further validation but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use, but limited study has been done in the target group

CDE common data elements, *NINDs* National Institute of Neurological Disorders and Stroke, *WGs* working groups

Table 2 Definition and classification of recommended core and supplemental-highly recommended CDEs

CDE name	Classification (e.g., core)	Definition/description
GCS—motor response scale	Supplemental–highly recommended	GCS—best motor response (M). The GCS is a standardized instrument for assessing the level of consciousness. It evaluates three aspects of responsiveness: eye opening, motor response, verbal response
GCS—verbal response scale	Supplemental–highly recommended	Score that describes the participant's verbal response according to the GCS
GCS—eye response scale	Supplemental–highly recommended	GCS—best eye response (E). The GCS is a standardized instrument for assessing the level of consciousness. It evaluates three aspects of responsiveness: eye opening, motor response, verbal response
WFNS—grading system subarachnoid hemorrhage scale	Core	WFNS grading system for Subarachnoid Hemorrhage Scale

CDE Common Data Elements, *GCS* Glasgow Coma Scale, *WFNS* World Federation of Neurological Surgeons

Grading Scales

Most commonly used scales during clinical presentation includes:

- WFNS [5–8]
- GCS
- Hunt & Hess scale (H&H)

It is well documented [9] that only 19% of SAH trials report any form of grading scales data. In 1988, an expert opinion committee proposed the WFNS scale [10]. Since then, the WFNS scale has been widely used among neurosurgeons and neuro-intensivists alike. A number of randomized controlled trials have used the WFNS score which compresses the GCS into five grades, with the addition of a fourth axis (focal neurological deficit) to differentiate grades 2 and 3 [5–7]. The primary advantages of the WFNS over other scales are that it uses objective terminology and grades each of its axes separately [11]. A systemic review of 11 studies showed that the WFNS was one of the most commonly used variables for clinical prediction models [12]; however, this study lacked external validation. This was addressed in pooled analysis from the SAHIT data [13], which used the WFNS as one of the core measures in its predictive model. This model was validated internally and externally and showed AUC of 0.80–0.81 to predict functional outcome and 0.76–0.78 to predict mortality. Given the above evidence and validation, the WFNS was deemed as a "Core" variable for SAH research. The WFNS also has the advantage of ease of use and low inter- and intra-observer variability [14].

Other clinical grading scales which were reviewed and classified by subcommittee included GCS and H&H. The GCS is the most universally recognized and accepted system for grading level of consciousness. The GCS has been applied as in various neurological conditions, including closed head trauma [15, 16], penetrating head injuries [17, 18], intracerebral hemorrhage [19] and SAH [10, 20, 21]. The inter- and intra-rater reliability of the GCS is strong and superior to other methods of consciousness assessment [22, 23]. Given universal acceptance and high reliability, the GCS was classified as "Supplemental—Highly recommended" for SAH research by the subcommittee. The H&H scale was proposed in 1968 and is one

of the oldest scales used in SAH. The advantage of this scale is that it is widely known and easy to administer; however, it is well recognized that classification within scale are often arbitrary and the margins between categories may be ill-defined [24]. Overall inter- and intra-rater reliability of the scale is much lower than GCS and WFNS [14]. Even though a systemic review of 11 studies does show that the H&H grade was the second most common grading scale used for prediction following WFNS [12], it lacks external validation and robustness of WFNS when applied across the spectrum. For this reason, the H&H scale was classified as "Supplemental."

A brief description of radiologic grading scales that were reviewed and classified as "Supplemental" includes Fisher Scale, modified Fisher Scale (mFS), Hijdra Scale and Graeb Intraventricular Hemorrhage Scale. The Fisher Scale was proposed in 1980 [25] to predict cerebral vasospasm and was validated prospectively [26] and later modified (aka. mFS) to further clarify thickness of SAH with IVH or ICH [27]. Although the Fisher Scale and mFS were designed to predict vasospasm, subsequent studies attempted to determine its predictive value in clinical outcomes by incorporating it along with age and clinical features [28]; regardless, neither Fisher nor mFS as standalone scales are comprehensive enough or adequately validated for outcome prediction.

A hybrid scale proposed by Ogilvy and Carter [28] was reviewed and classified as "Supplemental." The Ogilvy scale is a combination of H&H, Fisher Scale, patient age, aneurysm size, and location to predict outcome. This scale was first proposed in a retrospective study and later tested to predict outcome in a small prospective study. However, this scale lacks robustness of external validation when compared to the WFNS. A detailed list of all reviewed grading scale and its classification can be found in Table 2.

Aneurysm History

History of unruptured aneurysm was classified as "Supplemental," to be recorded as "yes" or "no" response. For patients with a history of aneurysm, the number, location, and size of aneurysm should be recorded; these variables are classified as "Supplemental." A multicenter prospective study demonstrated that history of unruptured aneurysms greater 7 mm and 3 mm in anterior and posterior circulation, respectively, is associated with higher risk of rupture [29]. Size and location of the ruptured aneurysm were part of the validated model for prediction of outcome and mortality [13]. Total of 29 aneurysm history variables (Table 2) were included and classified as "Supplemental."

Prehospital/Emergency Status

The most commonly used prehospital neurologic assessment screens include:

- Cincinnati Prehospital Stroke Scale
- Los Angeles Prehospital Stroke Scale
- Melbourne Ambulance Stroke Scale
- Ontario Ambulance Stroke Screening Tool
- Face Arm Speech Time

None of the above scales exhibited superior performance over another. Among other, pertinent prehospital information includes the last known well, demographic, and relevant co-morbid conditions. Increasing age and systolic hypertension were factors associated with unfavorable outcomes (Glasgow Outcome Scale) at 3 months in a meta-analysis of four randomized clinical trials involving more than 3567 patients [30] and more recent prospective study [31]. Total of 42 variables (Table 2) from the category were included in CDEs and classified as "Supplemental."

Clinical Presentation and Neurological Examination

Clinical presentation and neurological examination form an integral part of early identification and management of SAH patients. Time of symptom onset and a detailed neurological examination, along with GCS, help to grade severity of SAH and are included as CDEs. A total of 73 CDEs (Table 2) were included in the subcategory where all but GCS was classified as "Supplemental," GCS was classified as "Supplemental = Highly Recommended."

Vital Signs and Acute Physiological Measurements

SAH is a neurologic disorder with a wide array of systemic complications, and as such, vital signs and physiological measurements should cover a broad scope of such complications. Physiological measurements and variables that provide a better insight into cardio-respiratory dynamics are as critical as measurements pertaining to cerebral physiology. A total of 64 such measurements (Table 2) were included in CDEs and were classified as "Supplemental."

Laboratory Tests

A broad range of laboratory blood tests was identified and included in CDEs. A total of 17 laboratory test (See Online Supplement) were classified as "Supplemental."

Limitations

Various assessments and clinical examination variables are available for evaluation and prognostication of patients with SAH. Given that there is no gold standard, a more systematic approach should be implemented. Accuracy can be increased by relying upon and using more than one assessment scale and clinical examination variable. As such, recommendations from this subcommittee do not express importance but help in unifying data in future research of SAH.

Next Steps/Future Work

Future studies are needed to investigate which assessments' tools are superior and most practical with which to work. In the ideal world, a single scale which incorporates all previously mentioned aspects of assessments and examination and able to predict outcome and mortality with reliability across the spectrum of aneurysmal SAH patient populations would be the ultimate goal.

Conclusions

The WFNS was classified as "Core." The GCS was classified as "Supplemental—Highly Recommended." The remaining variables and scales were classified as "Supplemental." These recommendations on Assessments and Clinical Examination have been collated from a large number of potentially useful scales, history, clinical presentation, vital signs, neurological examination, laboratory, and other tests. The adherence to these recommendations will facilitate the comparison of results across studies and meta-analyses of individual patient data.

Electronic supplementary material

The online version of this article (https://doi.org/10.1007/s12028-019-00736-1) contains supplementary material, which is available to authorized users.

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Authors Contributions

RD, SM, RD, RHM, PN, DMO, JHMM, SM, ECJ, JM, TM, and JIS helped in protocol development and manuscript writing/editing. The corresponding author confirms that authorship requirements have been met, and the final manuscript was approved by ALL authors, and that this manuscript has not been published elsewhere and is not under consideration by another journal. The UIA and SAH CDEs project adhered to ethical guidelines.

Source of support

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Conflicts of interest

Dr. Damani has nothing to disclose. Dr. Muehlschelegel reports personal fees from American Academy of Neurology, Continuum, during the conduct of the study. Dr. Martin has nothing to disclose. Dr. Mocco reports grants and other from Stryker, grants and other from Penumbra, grants and other from Medtronic, grants and other from Microvention, personal fees and other from Imperative Care, personal fees and other from Cerebrotech, personal fees and other from Viseon, personal fees and other from Endostream, personal fees and other from Rebound Therapeutics, personal fees and other from Vastrax, personal fees and other from Blink TBI, personal fees and other from Serenity, personal fees and other from NTI, personal fees and other from Neurvana, personal fees and other from Cardinal Consulting, outside the submitted work. Dr. Suarez reports being President of the Neurocritical Care Society, a member of the Editorial Board of Stroke Journal, and Chair of the Data and Safety Monitoring Board for the Impact of Fever Prevention in Brain Injured Patients Study sponsored by this is the name of a company, outside of the submitted work. Dr. Mayer reports having received personal consulting fees from Edge Therapeutics and Idorsia Pharmaceuticals outside of the submitted work. Dr. Dhar has nothing to disclose. Dr. Mejia-Matilla has nothing to disclose. Dr. Mutoh has nothing to disclose. Dr. Nyquist has nothing to disclose. Dr. Olson reports Editor, Journal of Neuroscience Nursing, and registry funding from Neuroptics, Inc.

Ethical approval/informed consent

This project did not involve patient contact or review of patient-related information and thus it was not considered human research.

Appendix: SAH Working Group Members

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