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NEUROCRITICAL CARE SOCIETY

INTRODUCTION

The End of the Tower of Babel in Subarachnoid Hemorrhage: Common Data Elements at Last

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Spontaneous subarachnoid hemorrhage (SAH) is a neurological emergency associated with high morbidity and mortality rates and represents 27% of all stroke-related years of potential life lost before the age of 65 [1–5]. In addition, in the case of aneurysmal SAH (the predominant cause), aneurysm rupture leads to major detrimental events which have a significant impact on outcome [6–11]. It also has been estimated that approximately 3% of the adult global population harbors an unruptured intracranial aneurysm (UIA) [12]. The increased availability and usage of high-quality imaging have led to a higher detection rate of these lesions. Several clinical trials investigating neuroprotective measures in SAH have shown neutral results. Multiple reasons have been proposed to explain this failure including inadequate preclinical models and data, underpowered studies, and lack of selection of appropriate patients among others. However, one of the major limitations in UIA and SAH research is the lack of standardized definitions to be able to compare results across observational studies and randomized controlled trials. Thus, investigators are limited in their efforts to reduce the uncertainty regarding the appropriate management of patients with UIA and also management of complications from SAH.

The National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health, is spearheading the effort to harmonize and standardize data collected for clinical studies in neuroscience. To achieve this, NINDS has created and supported the Common Data Elements (CDEs) Project [13, 14]. The aim of the NINDS CDE Project specifically is to develop data standards for clinical research within the neuroscience community. Central to this project is the creation of common definitions and data sets so that information is consistently captured and recorded across studies in case report forms (CRFs). NINDS first developed a set of general CDEs commonly collected in all clinical studies regardless of the type of study or therapeutic area, such as medical history data; scores on neurological assessments; and demographic information. In addition to the general elements, NINDS has also developed sets of CDEs tailored to research involving specific diseases or disorders [15, 16]. The latest addition has been the UIA and SAH CDE Project. The NINDS, in collaboration with the Neurocritical Care Society and the National Library of Medicine convened a group of diverse and multi-professional international experts to create the UIA and SAH CDEs. We had the privilege to co-chair this endeavor and collaborate with a great group of colleagues and investigators from all over the world. Participants were tasked with developing a comprehensive set of CDEs with data definitions, CRFs, and guidelines for use in UIA and SAH clinical research. The results of this project are compiled in 9 manuscripts included in this Supplement of Neurocritical Care [17–25].

We strongly encourage every investigator planning a study on UIA and SAH to use these recommended CDEs. If we speak a similar language, then and only then will we be able to facilitate UIA and SAH clinical research and trial design, data sharing, and analyses of observational retrospective and prospective data. Equally important, it is our strong believe that to ensure that these recommended CDEs are disseminated, implemented, and updated, we must maintain an international and

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multidisciplinary collaboration. The publication of these CDEs is just the first step. The hard work is still ahead of us.

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Author contributions
JIS and RLM protocol development, and manuscript writing/editing. The corresponding author confirms that authorship requirements have been met, the final manuscript was approved by all authors.

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Conflict of interest
Dr Suarez reports being President of the Neurocritical Care Society, a member of the Editorial Board of Stroke Journal, and Chair of the DSMB for the INTREPID Study sponsored by BARD, outside of the submitted work. Dr Macdonald reports personal fees from Edge Therapeutics, and grants from Brain Aneurysm Foundation, outside the submitted work.

Ethical Approval/Informed Consent
The UIA and SAH CDEs project adhered to ethical guidelines.

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