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Author contact	greet.vandenberghe@kuleuven.be *+ 32 (0)16 34 40 21*
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Common Data Elements for Disorders of Consciousness: Recommendations from the Working Group on Physiology and Big Data

Erta Beqiri MD[1], Neeraj Badjatia MD MSc[2], Ari Ercole MD PhD[3], Brandon Foreman MD[4], Peter Hu PhD[5], Xiao Hu PhD[6], Kerri LaRovere MD MMSc[7], Geert Meyfroidt MD PhD[8], Dick Moberg[9], Chiara Robba MD PhD[10,11], Eric Rosenthal MD[12], Peter Smielewski PhD[1], Mark S. Wainwright MD PhD[13], Soojin Park MD[14] and the Curing Coma Campaign and its Contributing Members

Author Affiliations:
[1] Brain Physics Laboratory, Division of Neurosurgery, Department of Clinical Neurosciences, University of Cambridge, UK
[2] Program in Trauma, Department of Neurology, University of Maryland School of Medicine, Baltimore, MD USA
[3] Division of Anaesthesia, University of Cambridge, Cambridge, UK
[4] University of Cincinnati, Cincinnati, OH, USA
[5] Program in Trauma, Departments of Anesthesiology and Surgery, University of Maryland School of Medicine, Baltimore, MD USA
[6] School of Nursing, Emory University, Atlanta, GA, United States
[7] Department of Neurology, Boston Children's Hospital and Harvard Medical School, Boston, MA
[8] Department and Laboratory of Intensive Care Medicine, University Hospitals Leuven and KU Leuven, Herestraat 49, Box 7003, 63 3000, Leuven, Belgium
[9] Moberg Analytics, Inc, Philadelphia, PA, USA
[10] IRCCS Policlinico San martino, Genova, Italy
[11] Dipartimento di Scienze Chirurgiche e Diagnostiche Integrate, University of Genoa, Italy
[12] Department of Neurology, Massachusetts General Hospital, Boston, MA, USA
[13] Division of Pediatric Neurology, Seattle Children's Hospital, University of Washington, Seattle WA, USA
[14] Departments of Neurology and Biomedical Informatics, Columbia University Vagelos College of Physicians and Surgeons, NewYork-Presbyterian Hospital, USA

Corresponding author:
Soojin Park
Sp3291@cumc.columbia.edu

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Abstract

The implementation of multimodality monitoring in the clinical management of patients with Disorders of Consciousness (DoC) results in physiological measurements that can be collected in a continuous and regular fashion or even at waveform resolution. Such data are considered part of the “Big Data” available in intensive care units, and are potentially suitable for healthcare focused artificial intelligence research. Despite the richness in content of the physiological measurements, and the clinical implications shown by derived metrics based on those measurements, they have been largely neglected from previous attempts in harmonizing data collection and standardizing reporting of results as part of Common Data Elements (CDEs) efforts. CDEs aim to provide a framework for unifying data in clinical research and help in implementing a systematic approach that can facilitate reliable comparison of results from clinical studies in DoC as well in international research collaborations. To address this need, the Neurocritical Care Society’s *Curing Coma Campaign* convened a multidisciplinary panel of DoC “Physiology and Big Data” experts to propose CDEs for data collection and reporting in this field. We aimed to define the data elements that are important for researchers to standardize, in the context of Physiologic Data in the study of Disorders of Consciousness.

Introduction

Reliable comparison of results from clinical studies in disorders of consciousness (DoC) depends on studies being performed with standardized data collection and harmonization. Common data elements aim to provide a framework for unifying data in clinical research and help in implementing a systematic approach that can facilitate metanalyses[1].

Physiological measurements that can be collected (given appropriate technical resources) in a continuous and regular frequency or at a waveform resolution level are considered part of the ‘Big Data’ available in intensive care units (ICUs), thanks to the multimodality monitoring adopted for clinical management of patients with DoC[2-5]. Such big data are potentially suitable for healthcare focused artificial intelligence research, whose technology has exceptionally improved in recent years[6,7]. However, the data need to be labelled and harmonized for it to be useful in

statistical or machine learning algorithms[7]. The CENTER-TBI study highlighted existence of significant differences in the data collection policies across the European countries[8]. The same physiological measurement could be reported with different or incomplete labels or contextual data. This makes it impossible to compare them directly or to unify them without a huge data curation effort, which could require further post-hoc data collection. In addition, continuous physiological measurements (waveform level) have also been largely neglected from previous attempts in harmonizing data collection. Given additional technical requirements for enabling high resolution data collection, not yet commonly implemented in ICUs, these data were often considered advanced or not part of core elements[7,8].

To address these historical barriers to data harmonization and to facilitate international collaboration, the Neurocritical Care Society's *Curing Coma Campaign*[9] launched a Common Data Elements (CDE) initiative for DoC in 2020. The overarching goal of this CDE initiative is to provide the global community of DoC researchers and clinicians with tools to collect data in a systematic and consistent way, an approach championed by the National Institutes of Health (NIH) https://www.commondataelements.ninds.nih.gov/)[1]. The *Curing Coma Campaign* convened 10 Working Groups (WG) to create CDEs across the full spectrum of DoC research domains. Here, we report the results of the DoC CDE Physiology and Big Data WG. We aim to define the contextual data elements that are important for researchers to standardize and facilitate international collaboration, in the context of the Physiologic Data in the study of Disorders of Consciousness.

Methods

CDE Classification

All CDEs were classified as "disease core", "basic", "supplemental", or "exploratory" based on the consensus opinion of the WG leaders. This classification nomenclature is consistent with that used in prior NINDS CDE initiative[10]. "Disease core" CDEs are required for all DoC studies. "Basic" CDEs are strongly recommended for all DoC studies. "Supplemental" CDEs are recommended for specific DoC studies, depending on the context. Finally, "exploratory" CDEs can be considered for use in DoC studies but require further validation. We also created a new designation, "key design element

(KDE)" for methodological parameters that are relevant to the acquisition, processing, or analysis of data.

Process for selecting CDEs

The data elements pertaining to Physiologic and Big Data fall into the subtype of CDEs defined by the Curing Coma Campaign of the Neurocritical Care Society as 'key design elements', which are methodological parameters and not CDEs as such. For simplicity, the term 'CDE' will still be used in this manuscript.

The WG consisted of an international and multidisciplinary panel of experts in monitoring of physiological data and big data in neurointensive care. The background of the WG members spanned from clinical to academic, and to industry. All members had previous experience in neuromonitoring and related clinical research. The WG charter was ratified in 2020, and members met four times over four months in 2022, and worked asynchronously in-between meetings to reach internal consensus on the contents of the CRF.

We began by reviewing existing CDEs commissioned by the NINDS (https://commondataelements.ninds.nih.gov)[1]. Our goal was to leverage these existing CDEs and, whenever possible, to use CDEs that were already defined according to established standards. In this process we identified and acknowledged the gap revealed for our specific task.

The process was based on consensus. First, we agreed on the rationale, logic, and structure to follow when developing our set of recommendations. Each member suggested data elements in a shared web-based platform, where all members could review and comment offline. We did not perform a systematic review ahead of the task. Instead, we indicated data elements based on the previously published CDEs and on our personal research experience. The elements were discussed with the panel during regular online meetings through an iterative process, according to the rules set in the initial stages. The decision-making process that led to the inclusion or exclusion of data elements was documented and tracked in the web-based platform. SP led the WG through the process and finalized the CDEs.

In the next paragraphs we summarize the rules and steps involved in our CDE selection.

Rationale

The type of data pertinent to our group was defined as measurements that can be collected in a continuous and regular frequency or at a waveform resolution. Such types of data were not given an identity in previous CDE attempts. Instead, they were considered mostly together with CDEs pertinent to Vital Signs[1].

We sought to standardize the context that we believed was important for future harmonization and interpretation of research datasets pertinent to those type of data. Therefore, we excluded from the data elements every item that could be derived or would be apparent from the data themselves. For example, the waveform data would already come with values, units, and time stamps. Hence, these elements would not be part of our recommendations, with the exception of non-unique type of units per single measurement. Similarly, the treatments and treatment effects on physiological variables could be learned from the data, but the intention to treat cannot. Therefore, the latter would be part of our data elements.

Calculated (non-measured) variables that would be derived from other physiological measurements were excluded, unless they were considered widespread and supported by reports in the literature.

Logic and assumptions

The recommendations aimed to be descriptive and not prescriptive based on the assumption that these would apply primarily to observational research. We also aimed to avoid data entry that would be too episodic, as that would penalize data homogeneity (e.g. every time a patient is turned or suctioned).

We assume (and strongly recommend) that centers have their own in-house research hygiene policies. These concern data acquisition, data curation, labelling etc. For example, if intracranial pressure (ICP) was labelled as ‘icp1’ in their monitor, at the point of data curation this should be labelled ‘ICP’ whenever the variable was considered to be the physiological variable, ICP.

Structure

The format of the data collection case report form (CRF) was designed to be a pdf. This limits the structure of the CRF, as tree-based dependencies would not be easily feasible. We adopted a three part structure where, for each variable, there is a break down into 1) physiological variable elements (metadata related to the value acquired from the monitor); 2) technical aspects of measurement; 3) clinical reasoning behind and around the physiologic measurement, if appropriate. We decided to have one element for each single parameter concerning the variable. For example, left EVD based ICP monitoring and right EVD based ICP monitoring would represent two different elements. For those items that could be repeated more than once during the ICU stay, we advised to repeat them in the CRF every time the repetition would occur.

Overlap with other CDEs

Whenever a variable overlapped with elements found within another working group of the Curing Coma campaign effort, we did not include it in our CDEs, but instead we mention here where the element can be found.

Thresholds for consensus

The elements were kept in the recommendations whenever there was a consensus that the modality met standard of care (i.e. routinely collected clinically for an observational database) or a consensus on how to standardize the structure of the element. In this process, the elements that could not reach such consensus, but were considered important for setting future standards, were grouped in a list of exploratory aspects.

Revision from other WGs

The recommendations were submitted for revision from the different working groups on October 18th 2022. We received public feedback in January 2023, discussed and incorporated the suggestions. Given the rapidly evolving landscape of DoC physiology and big data, the CDEs that we report here (version 1.0) are intended to be a starting point for the standardization of physiology and big data studies. We welcome ongoing feedback from the international community and expect that these CDEs will be iteratively refined as additional discoveries emerge.

Results

Adaptation of Established CDEs for Physiology and Big Data in DoC

The CDEs previously proposed by the NIH that were most relevant to DoC for physiology and big data were all Supplemental CDEs from the "Vital Signs and Acute Physiological Measurements" CRF (developed for Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage) and the "Vital Signs and Blood Gases" CRF (developed for Traumatic Brain Injury)[1]. We used these as a seed for derivation of our CDEs, however we decided not to include any of the previous elements as such in our CDEs. Either they were not structured to reflect the complexity of waveform level data, or they were not adaptable to capture all the variables that we sought to cover.

Common Data Elements output

The CRF designed to capture the "Physiologic and Big Data" Common Data Elements that would be relevant for clinical research in patients with DoC is presented in **Supplementary material 1** (also available on https://zenodo.org/record/8172359). A total number of 61 novel elements were identified. In addition, members of our WG felt it would be appropriate to set standards for future research and outlined exploratory CDEs that could be pursued in more involved or interventional research studies. A total number of 22 elements were identified as Exploratory CDEs. These are presented in **Supplementary material 2**.

Dissemination of CDEs for DoC Physiology and Big Data

We release version 1.0 of the proposed physiology and big data CDEs for patients with DoC as a CRF (https://zenodo.org/record/8172359 and **Supplementary Material 1**). The CDEs underwent a 2-month public feedback period from October to November 2022, which was advertised at the 2022 annual Neurocritical Care Society meeting and via social media. Public feedback was received and incorporated into the final CRFs. For the physiology and big data CDEs, incorporated feedback pertained to the style and formatting of the CRFs. Content related feedback was discussed by the WG

and found to fall within exploratory CDEs which are shared in the Supplement and discussed.

We encourage ongoing feedback regarding modifications to the CDEs, which can be submitted via email to cde.curingcoma@gmail.com. Suggestions to edit or add to the current list of CDEs will be evaluated by the WG on an as-needed basis, and changes to the CRFs will be posted on the zenodo website with new version numbers. We are committed to an adaptive approach based on emerging evidence, with rapid distribution of modifications using online scientific portals.

Discussion

Our WG identified the Physiologic data and Big data key design elements suitable for observational clinical research for DoC. Each physiologic modality was divided in three sections (physiological variables, technical aspects, clinical reasoning). Exploratory data elements and future challenges were discussed within the WG and are presented in this manuscript.

Physiology and Big Data items selected by the WG

The items considered by the WG and the contextual data that were included in the key data elements and/or in the exploratory elements are presented in **Table 1**.
Electroencephalography is included in the CDE 'EEG resting state'.
Pupillometry and optical nerve sheath were discussed and not included, given they would be spot imaging data and not a source of continuous data or waveform data. Additionally, pupillometry is covered in the prior CDE 'Vital Signs and Acute physiology'[1]. Other non-invasive monitoring tools, like skull distensibility monitoring, were not included as they are not currently widely adopted.

Physiological variables

The physiological variables section aims to collect metadata related to the value acquired from the monitor. For those variables where the units are standardized (i.e ICP), the sampling modality is the only additional information that appeared relevant for any research on these data. Sampling can be adjudicated by a nurse or digitized.

Temperature and EtCO2 are measured and reported with different units across different countries, hence their units are recommended to be reported in the CRF. Summary values of modalities like intracranial pressure (ICP), cerebral perfusion pressure (CPP), arterial blood pressure (ABP), near infra-red spectroscopy (NIRS) derived rSO2, flow velocity (FV) and brain tissue oxygen (PbtO2), were considered relevant by the WG and were mentioned in previously existing CDEs. For example, in the "Vital Signs and Acute Physiological Measurements" CRF (developed for Unruptured Cerebral Aneurysms and Subarachnoid Hemorrhage), ICP was recommended to be reported as 5 minute average, as well as hourly average or daily average, minimum and maximum daily values, duration of pressure over (non-specified) thresholds. However, we could not agree on specific time intervals, nor specific summaries that could meet standard of care for ICP, nor for the other physiological modalities. Hence, we agreed that asking a general researcher to report such summaries would be too prescriptive for a CRF. Therefore, these were not included in the key data elements, but are reported as exploratory (**supplementary material 2**).

Similarly, systolic and diastolic blood pressure do not appear in the list of elements as they can be calculated/derived from the raw data, and we could not decide on a particular evidence-based summary statistic for those parameters.

FV variables related to specific diagnosis (stenosis, vasospasm, brain death) are described in the Stroke CDE Version 3.0 for Vessel Imaging TCCS[1] and are not included in this WG CDEs.

Cerebral microdialysis variables are not included in this section as there are no metadata required beyond the raw dataset acquired. Currently, microdialysis data are acquired only intermittently and the time stamp would be available with the measurements. However, there is ongoing research that aims to monitor microdialysis analytes in a continuous fashion[11]. Hence this was considered in the exploratory elements as a future standard.

Heart rate, PRx and CPPopt are not included in this section as we did not identify any metadata relevant for clinical research.

Technical aspects

Our WG identified several technical aspects to consider for harmonization of physiological measurements data reporting in the CRFs.

Firstly, the WG considered important to report the technical aspects related to the physiological variables' measurements. For example, if ICP was measured via a parenchymal probe, then the date of insertion and removal of the probe should be reported. In addition, the researcher should indicate which device was used for monitoring of ICP (example: Raumedic, Integra, Sophysa etc). The reason for reporting the device used for monitoring is that this would implicate device-based protocols for signal measurement, signal processing (artefact detection and removal) and data output. The researcher should also state whether the source of ICP data acquisition was from the multiparametric patient monitor (which has a dedicated key element in the CRF) or directly from the device.

Secondly, because of the dynamic nature of the medical device industry, with regards to the manufacturer and the device name, it was discussed that it is ideally preferable to use the Unique Device Identifier (UDI). However, we believe that it is not feasible to ask clinicians and researchers to accurately identify this retrospectively for a CRF. Consequently, this poses challenges for the future mapping of the devices. It would be desirable to set a standard for using the UDIs in future settings.

Third, the WG discussed the issue of reliability of measurements and whether a metric of reliability should be reported. For example, invasive ABP should be validated with non-invasive ABP, and the accuracy then reported. However, the group felt that reporting this kind of accuracy would be too episodic. It was decided not to include the accuracy of the measurements in the CRF in the interest of homogeneity of data entry, but to consider it in the exploratory elements. The committee trusted that if the clinical team did not consider the measurements reliable for clinical management, then these would not be reported by the researchers in observational studies. However, the committee is also aware that unless the clinical team reports the accuracy of measurements, then this would be impossible to derive from the high-resolution data acquisition.

Fourth, when an external ventricular drain (EVD) is used for monitoring of ICP, the EVD can be managed with different opening-closing intervals. In theory, we should be able to understand the periods of EVD open and closed by the ICP waveform data, if these are collected. Members of the committee felt that this would not be the case and instead it would be desirable to collect the date and time of opening and closure, together with the reason for this management, and with the related CSF

output. We decided not to include this in the CRF as it would be too prescriptive and not feasible. However, the EVD height was considered contextual information that is vital to interpret CSF output and ICP measurement. This was included in the WG CDEs.

Fifth, the autoregulation-based metrics PRx and CPPopt are not measured variables, but they are calculated and derived from other physiological entities. The WG felt these are widespread and recommended by the clinical community[5,12], and there is a large amount of research that reports these metrics[13]. Hence, they warrant a place in the CRF. Given the methods used for these calculations are still not standardized, the WG advised that if they are used clinically and reported in observational studies, then the researchers should state which was the intracranial component used for the calculations of PRx, as well as which calculations or algorithms were used for PRx and CPPopt.

Lastly, we recommend that the technical aspects related to probes or catheter insertions are to be repeated every time a new probe or catheter is placed. The technical aspects related to cerebral FV measurements (such as type of probe or depth) belong to the imaging CRF.

Clinical reasoning

The third section of the CRF includes information regarding the indications for monitoring the physiological variables, local protocols of management, or further contextual information necessary for data interpretation. These include the management protocols for treatment of raised ICP, the protocols for opening and closing of EVD, the local protocols for measurement location and levelling of ABP, the indication for monitoring ICP, PbtO2 and PRx/CPPopt, and the placement reasoning for ICP and microdialysis probes. These aspects were not considered in previously existing CDEs, except for the ICP treatment threshold value. In our effort, for example, we implemented such elements as “Intracranial Pressure Management Local Protocol” which has two subitems: actively targeted goal (in mm Hg or cm H20) and modalities implemented in the tiered therapy (CPP and/or PbtO2).

Members of the group pointed out the importance of collecting timed interventions that affect ICP measurement, such as nursing maneuvers or medications. These are contextual data that could allow interpretation of ICP waveform patterns, as well as understanding the clinical impact of different types of high ICP insults. We concluded

that, while this would be informative, there does not exist a good way to standardize the element, nor literature to support the effort.

Challenges and future directions

The main challenges that the group faced were the diverse monitoring practices across the world as well as lack of previously structured CDEs, and the lack of evidence or literature support on the clinical impact of many physiological measurements in DoC, despite the measurements being considered relevant in daily clinical practice. Developing shared definitions and common reporting practices for these physiologic parameters are a prerequisite to determining their impact on clinical outcome after brain injury.

The WG discussed the issue of the broad range of experience amongst end-users of the CRF. We discussed whether the CRF should be tailored to the end-user, with higher levels of details (for example as outlined in the exploratory elements) required from experts. We did not reach a consensus on how to define the levels of expertise. This should be taken into consideration for future CDE development.

The knowledge of reliability or accuracy of physiological measurements was considered relevant for clinical research. Having a standardized metric of reliability for each of the measurements of physiological entities would be desirable for future research and the scientific community should investigate methods for assessment of reliability.

Tables

Table 1. List of Items included in the Key Data Elements and/or in the Exploratory Elements

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Table 1. List of Items included in the Key Data Elements and/or in the Exploratory Elements

List of items included in the key data elements and/or in the exploratory elements
Intracranial pressure
Brain temperature
Core temperature
Targeted temperature management applied temperature
Cerebral perfusion pressure
Arterial blood pressure
Brain tissue oxygen
Near infrared spectroscopy
External ventricular drain
Cardiac output
Parenchymal regional cerebral blood flow
Cerebral blood flow velocity
End-tidal carbon dioxide
Respiratory rate
Tidal volume
Photoplethysmography
Systemic oxygen saturation
Cerebrospinal fluid output
Cerebral microdialysis
Pressure reactivity index
Optimal cerebral perfusion pressure
Heart rate monitoring devices

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