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NEUROCRITICAL CARE SOCIETY

EDITORIAL

Common data elements for disorders of consciousness

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Since the foundational descriptions of the comatose [1], vegetative [2], and minimally conscious [3] states in the late twentieth and early twenty-first centuries, there has been rapid progress in elucidating the pathophysiologic mechanisms [4], clinical phenotypes [5], and recovery trajectories [6, 7] of patients with disorders of consciousness (DoC). Diagnostic classification systems have evolved from a behavior-centric paradigm to a multimodal paradigm that considers covert forms of cognition [8] detected by advanced neurotechnologies, such as task-based functional magnetic resonance imaging [9–12] and electroencephalography [7, 13–15]. Accordingly, clinical guidelines [16, 17] and expert consensus recommendations [18] now endorse the use of advanced neurotechnologies to evaluate patients with DoC. In this rapidly evolving landscape, investigational insights have often outpaced the diagnostic nomenclature, leading to variability in how patients are classified in research studies and in clinical settings [19, 20].

To bring clarity to the dynamic field of DoC research and to facilitate the international collaboration that is essential for further progress, the Neurocritical Care Society launched the Curing Coma Campaign in 2019 [21, 22], bringing together the worldwide community of DoC clinicians and researchers in common cause. The Campaign's overarching goal is to address the "grand challenge" of improving the management and outcomes of patients with DoC. To achieve this goal, the Campaign is pursuing a broad range of initiatives [23], which include identification of current gaps in knowledge [24–26], establishing infrastructure for multicenter prospective studies [27], and developing a standardized framework and shared nomenclature for conducting future research studies. Central to this latter effort is the development of common data elements (CDEs), the building blocks for data harmonization, data sharing, and multisite collaboration. Inspired by similar initiatives led by the National Institutes of Health (NIH) that provide CDEs for a range of neurological diseases (https://www.commondataelements.ninds.nih.gov/), and with guidance provided by the NIH National Institute of Neurological Disorders and Stroke, the Curing Coma Campaign's DoC CDE initiative aimed to bring together the international community to create a common language for future research.

The DoC CDE initiative was thus launched in 2020 and included ten working groups in the domains of behavioral phenotyping [28]; hospital course, confounders, and medications [29]; neuroimaging [30]; electrophysiology [31]; biospecimens and biomarkers [32]; physiology and big data [33]; therapeutic interventions [34]; goals of care and family/surrogate decision-making [35]; pediatrics [36]; and outcomes and end points. These working groups met regularly via teleconference for 2 years to develop CDEs specific to patients with DoC. Each working group leveraged existing NIH CDEs developed for other conditions (e.g., traumatic brain injury, ischemic stroke, and aneurysmal subarachnoid hemorrhage) whenever possible to ensure that the DoC CDEs were consistent with established standards. Wherever existing NIH CDEs did not sufficiently address data elements relevant to DoC research, the working groups proposed new CDEs based on consensus opinion.

All CDEs were then classified as "disease core," "basic," "supplemental," or "exploratory," consistent with the classification system used in prior NIH CDE initiatives [37–39]. We assigned the disease core designation to CDEs that are required for all DoC studies, the basic designation to CDEs that are strongly recommended

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for all DoC studies, the supplemental designation to CDEs that are recommended for specific DoC studies (i.e., depending on the context and goals of the study), and the exploratory designation to CDEs that can be considered for use in DoC studies but require further validation. Finally, we included a designation of "key design element" for methodological parameters relevant to the acquisition, processing, or analysis of data.

The result of this international, multiyear effort was a set of case reports forms, containing all DoC CDEs and key design elements, which we released in preliminary form on www.zenodo.org (version 0.0) in October 2022 for a 2-month public feedback period, which was advertised at the 2022 Neurocritical Care Society annual meeting and via social media (i.e., Twitter). Public feedback was then incorporated into the final case report forms, which were released as version 1.0 at https://zenodo.org/records/8172359. We encourage ongoing feedback, which can be submitted via email to cde.curingcoma@gmail.com. All suggestions will be evaluated by the relevant working groups, and changes to the case report forms will be posted on the zenodo website with new version numbers. This adaptive approach is crucial to allow integration of emerging evidence, given ongoing rapid developments in the field.

Looking to the future, we encourage the international community of DoC investigators to use these CDEs, which are freely available and downloadable in domain-specific case report forms. By harmonizing our classification systems and nomenclature, we will ensure that researchers worldwide are speaking the same language as we continue to advance knowledge in our field. The dissemination of DoC CDEs is thus a foundation on which the overarching goal of the Curing Coma Campaign—to improve management and outcomes for patients with DoC—can be realized.

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References

1. Plum F, Posner JB. Diagnosis of stupor and coma. Philadelphia: F.A. Davis Company; 1966.
2. Jennett B, Plum F. Persistent vegetative state after brain damage. A syndrome in search of a name. Lancet. 1972;1:734–7.
3. Giacino JT, Ashwal S, Childs N, Cranford R, Jennett B, Katz DI, et al. The minimally conscious state: definition and diagnostic criteria. Neurology. 2002;58:349–53.
4. Edlow BL, Claassen J, Schiff ND, Greer DM. Recovery from disorders of consciousness: mechanisms, prognosis and emerging therapies. Nat Rev Neurol. 2021;17:135–56.
5. Kondziella D, Menon DK, Helbok R, Naccache L, Othman MH, Rass V, et al. A precision medicine framework for classifying patients with disorders of consciousness: Advanced Classification of Consciousness Endotypes (ACCESS). Neurocrit Care. 2021;35:27–36.
6. Hammond FM, Giacino JT, Richardson RN, Sherer M, Zafonte RD, Whyte J, et al. Disorders of consciousness due to traumatic brain injury: functional status ten years post-injury. J Neurotrauma. 2019;36:1136–46.
7. Egbebike J, Shen Q, Doyle K, Der-Nigoghossian CA, Panicker L, Gonzales IJ, Grobois L, et al. Cognitive-motor dissociation and time to functional recovery in patients with acute brain injury in the USA: a prospective observational cohort study. Lancet Neurol. 2022;21:704–13.
8. Schiff ND. Cognitive motor dissociation following severe brain injuries. JAMA Neurol. 2015;72:1413–5.
9. Owen AM, Coleman MR. Detecting awareness in the vegetative state. Ann N Y Acad Sci. 2006;313:1402.
10. Monti MM, Vanhaudenhuyse A, Coleman MR, Boly M, Pickard JD, Tshibanda L, et al. Willful modulation of brain activity in disorders of consciousness. N Engl J Med. 2010;362:579–89.
11. Stender J, Gosseries O, Bruno MA, Charland-Verville V, Vanhaudenhuyse A, Demertzi A, et al. Diagnostic precision of PET imaging and functional MRI in disorders of consciousness: a clinical validation study. Lancet. 2014;384:514–22.
12. Edlow BL, Chatelle C, Spencer CA, Chu CJ, Bodien YG, O'Connor KL, et al. Early detection of consciousness in patients with acute severe traumatic brain injury. Brain. 2017;140:2399–414.
13. Cruse D, Chennu S, Chatelle C, Bekinschtein TA, Espejo D, Pickard JD, et al. Bedside detection of awareness in the vegetative state: a cohort study. Lancet. 2011;378:2088–94.
14. Goldfine AM, Victor JD, Conte MM, Bardin JC, Schiff ND. Determination of awareness in patients with severe brain injury using EEG power spectral analysis. Clin Neurophysiol. 2011;122:2157–68.
15. Claassen J, Doyle K, Matory A, Couch C, Burger KM, Velazquez A, et al. Detection of brain activation in unresponsive patients with acute brain injury. N Engl J Med. 2019;380:2497–505.
16. Giacino JT, Katz DI, Schiff ND, Whyte J, Ashman EJ, Ashwal S, et al. Practice guideline update recommendations summary: disorders of consciousness: report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology; the American Congress of Rehabilitation Medicine; and the National Institute on Disability, Independent Living, and Rehabilitation Research. Neurology. 2018;91:450–60.

17. Kondziella D, Bender A, Diserens K, van Erp W, Estraneo A, Formisano R, et al. European Academy of Neurology guideline on the diagnosis of coma and other disorders of consciousness. Eur J Neurol. 2020;27:741–56.
18. Comanducci A, Boly M, Claassen J, De Lucia M, Gibson RM, Juan E, et al. Clinical and advanced neurophysiology in the prognostic and diagnostic evaluation of disorders of consciousness: review of an IFCN-endorsed expert group. Clin Neurophysiol. 2020;131:2736–65.
19. Schnakers C, Bauer C, Formisano R, Noé E, Llorens R, Lejeune N, et al. What names for covert awareness? A systematic review. Front Hum Neurosci. 2022;16: 971315.
20. Young MJ, Fecchio M, Bodien YG, Edlow BL. Covert cortical processing: a diagnosis in search of a definition. Neurosci Conscious. 2024. https://doi.org/10.1093/nc/niad026.
21. Provencio JJ, Hemphill JC, Claassen J, Edlow BL, Helbok R, Vespa PM, et al. The curing coma campaign: framing initial scientific challenges-proceedings of the first curing coma campaign scientific advisory council meeting. Neurocrit Care. 2020;33:1–12.
22. Claassen J, Akbari Y, Alexander S, Bader MK, Bell K, Bleck TP, et al. Proceedings of the first curing coma campaign NIH symposium: challenging the future of research for coma and disorders of consciousness. Neurocrit Care. 2021;35:4–23.
23. Olson DM, Hemphill JC, Provencio JJ, Vespa P, Mainali S, Polizzotto L, et al. The curing coma campaign and the future of coma research. Semin Neurol. 2022;42:393–402.
24. Edlow BL, Sanz LRD, Polizzotto L, Pouratian N, Rolston JD, Snider SB, et al. Therapies to restore consciousness in patients with severe brain injuries: a gap analysis and future directions. Neurocrit Care. 2021;35:68–85.
25. Claassen J, Kondziella D, Alkhachroum A, Diringer M, Edlow BL, Fins JJ, et al. Cognitive motor dissociation: gap analysis and future directions. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01769-3.
26. Cho SM, Robba C, Diringer MN, Hanley DF, Hemphill JC, Horn J, et al. Optimal design of clinical trials involving persons with disorders of consciousness. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01813-2.
27. Helbok R, Rass V, Beghi E, Bodien YG, Citerio G, Giacino JT, et al. The curing coma campaign international survey on coma epidemiology, evaluation, and therapy (COME TOGETHER). Neurocrit Care. 2022;37:47–59.
28. Yakhkind A, Niznick N, Bodien YG, Hammond FM, Katz D, Luaute J, et al. Common data elements for disorders of consciousness: recommendations from the working group on behavioral phenotyping. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01844-9.
29. Barra ME, Zink EK, Bleck TP, Cáceres E, Farrokh S, Foreman B, et al. Common data elements for disorders of consciousness: recommendations from the working group on hospital course, confounders, and medications. Neurocrit Care. 2023;39(3):586–92.
30. Edlow BL, Boerwinkle VL, Annen J, Boly M, Gosseries O, Laureys S, et al. Common data elements for disorders of consciousness: recommendations from the working group on neuroimaging. Neurocrit Care. 2023;39(3):611–7.
31. Carroll EE, Der-Nigoghossian C, Alkhachroum A, Appavu B, Gilmore E, Kromm J, et al. Common data elements for disorders of consciousness: recommendations from the electrophysiology working group. Neurocrit Care. 2023;39(3):578–85.
32. Shah VA, Hinson HE, Reznik ME, Hahn CD, Alexander S, Elmer J, et al. Common data elements for disorders of consciousness: recommendations from the working group on biospecimens and biomarkers. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01883-2.
33. Beqiri E, Badjatia N, Ercole A, Foreman B, Hu P, Hu X, et al. Common data elements for disorders of consciousness: recommendations from the working group on physiology and big data. Neurocrit Care. 2023;39(3):593–9.
34. Monti MM, Beekman R, Spivak NM, Thibaut A, Schnakers C, Whyte J, et al. Common data element for disorders of consciousness: recommendations from the working group on therapeutic interventions. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01873-4.
35. Jaffa MN, Kirsch HL, Creutzfeldt CJ, Guanci M, Hwang DY, LeTavec D, et al. Common data elements for disorders of consciousness: recommendations from the working group on goals-of-care and family/surrogate decision-maker data. Neurocrit Care. 2023;39(3):600–10.
36. Boerwinkle VL, Appavu B, Cediel EG, Erklaurer J, Ganesan SL, Gibbons C, et al. Common data elements for disorders of consciousness: recommendations from the working group in the pediatric population. Neurocrit Care. 2023. https://doi.org/10.1007/s12028-023-01870-7.
37. Saver JL, Warach S, Janis S, Odenkirchen J, Becker K, Benavente O, et al. Standardizing the structure of stroke clinical and epidemiologic research data: the National Institute of Neurological Disorders and Stroke (NINDS) Stroke Common Data Element (CDE) project. Stroke. 2012;43:967–73.
38. Hicks R, Giacino J, Harrison-Felix C, Manley G, Valadka A, Wilde EA. Progress in developing common data elements for traumatic brain injury research: version two–the end of the beginning. J Neurotrauma. 2013;30:1852–61.
39. Suarez JI, Sheikh MK, Macdonald RL, Amin-Hanjani S, Brown RD Jr, de Oliveira Manoel AL, et al. Common data elements for unruptured intracranial aneurysms and subarachnoid hemorrhage clinical research: a national institute for neurological disorders and stroke and national library of medicine project. Neurocrit Care. 2019;30:4–19.