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## COMMON DATA ELEMENTS FOR DISORDERS OF CONSCIOUSNESS

# Common Data Elements for Disorders of Consciousness: Recommendations from the Working Group on Hospital Course, Confounders, and Medications

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**Abstract**

The convergence of an interdisciplinary team of neurocritical care specialists to organize the Curing Coma Campaign is the first effort of its kind to coordinate national and international research efforts aimed at a deeper understanding of disorders of consciousness (DoC). This process of understanding includes translational research from bench to bedside, descriptions of systems of care delivery, diagnosis, treatment, rehabilitation, and ethical frameworks. The description and measurement of varying confounding factors related to hospital care was thought to be critical in furthering meaningful research in patients with DoC. Interdisciplinary hospital care is inherently varied across geographical areas as well as community and academic medical centers. Access to monitoring technologies, specialist consultation (medical, nursing, pharmacy, respiratory, and rehabilitation), staffing resources, specialty intensive and acute care units, specialty medications and specific surgical, diagnostic and interventional procedures, and imaging is variable, and the impact on patient outcome in terms of DoC is largely unknown. The heterogeneity of causes in DoC is the source of some expected variability in care and treatment of patients, which necessitated the development of a common nomenclature and set of data elements for meaningful measurement across studies. Guideline adherence in hemorrhagic stroke and severe traumatic brain injury may also be variable due to moderate or low levels of evidence for many recommendations. This article outlines the process of the development of common data elements for hospital course, confounders, and medications to streamline definitions and variables to collect for clinical studies of DoC.

**Keywords:** Coma, Consciousness, Clinical studies, Common data elements, Standardization

## Introduction

An evolving understanding of coma, disorders of consciousness (DoC), and the emerging potential for functional recovery necessitates a detailed understanding of potential confounding factors introduced throughout the care continuum, particularly in the early days and weeks after injury that can impact patient outcome. The Curing Coma Campaign (CCC) [1] of the Neurocritical Care Society has drawn attention to subclassifications of DoC including cognitive motor dissociation and covert consciousness in which patients do not demonstrate motor output; however, using advanced imaging and neurophysiologic testing of neural activation consistent with cognition can be detected in some cases [2, 3]. Intensive

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and acute care are inherently variable in terms of monitoring, medication regimens, procedures, and medical and surgical management, and the need to characterize the impact that intensive and acute interdisciplinary care can have on patient outcomes is paramount to determine a pathway forward. Novel models of care for patients with DoC for whom aggressive and comprehensive long-term supportive care is provided have been suggested and require further development and testing [4].

The effect of physiologic parameters on brain injury is well known. For example, early hypoperfusion and hypoxia are known to exacerbate secondary brain injury and thresholds for treatment are well established; however, systems of care for patients with traumatic brain injury differ across geographical areas, and the use of monitoring systems as well as frequency of monitoring varies as treatment algorithms, which may impact patient outcome [5–7]. Serial neurologic assessment by nurses varies in terms of content, frequency, and training in the performance of the assessment and should be well defined and collected in all studies [8]. Management of increased intracranial pressure (ICP), particularly in traumatic brain injury, is largely driven by guidelines based heavily on consensus. Outstanding questions remain regarding the choice of osmotic therapy (e.g., mannitol, hypertonic saline) and the use of salvage therapies such as barbiturate induced coma and surgical decompression, monitoring frequency, and ICP management [6, 9–12]. New therapeutic targets for cerebral resuscitation in severe traumatic brain injury remain under investigation, such as brain tissue oxygenation values and cerebral metabolites [13, 14]. Practice patterns for monitoring ICP and intracranial metabolism differ according to specialty expertise and access to resources.

Systemic complications resulting from immobility and chronic critical illness are associated with increased mortality in the first year after brain injury with DoC, and early supportive care can have a significant impact on outcome [15]. Early medical and nursing management of these systemic complications in severe brain injury such as hemodynamic instability and respiratory failure are associated with outcome [9]. Assessment of risk and implementation of preventive strategies for sequelae of brain injury such as venous thromboembolism, ventilator-associated events, hospital-acquired infection and hospital-acquired pressure ulcers, and intensive care unit–acquired weakness and contracture require interdisciplinary team involvement of nursing, medicine, pharmacy, and respiratory and rehabilitation therapies [16]. Defining the elements of supportive care within an ethical context should include specific monitoring parameters and treatment algorithms and is integral in developing a holistic understanding of patient response

in coma and DoC and in generating research findings that are generalizable [17]. The composition of interdisciplinary teams and categorization of specialty neurosciences units may represent an important confounder as the presence of neurointensivists, critical and acute care specialist pharmacy practitioners and specialty trained nurses has been associated with improved outcomes in independent studies [18–20]. Models of nursing care throughout the care continuum are important to define and describe in terms of ratio and specialty training [21]. Access to rehabilitation therapists with defined frequencies and intensity could confound functional outcomes and are necessary to measure [22]. Additional mobilization such as passive range of motion and progressive mobilization as well as use of rehabilitation equipment and additional modalities (e.g., neuromuscular stimulation, cycle ergometry, transcranial direct current stimulation) should be collected.

Results of the Coma Epidemiology, Evaluation, and Therapy survey of the CCC characterized significant variation of assessment, treatment, and follow-up of patients with DoC [23]. Capabilities and resources in different hospital systems across the United States and internationally could impact outcomes [24]. For example, differing medical provider and nursing ratios as well as access to technology for hemodynamic, respiratory, and neurologic monitoring is important to describe and quantify. Systems for quantifying level of care such as the therapy intensity level scale or the Therapeutic Intensity Scoring System may provide an objective structure within which patient care can be measured [25, 26]. Heterogeneity in acute and supportive care poses a challenge to evaluating the impact of early neurocritical care interventions and comparison of subsequent outcomes across cohorts. A growing understanding of the potential for meaningful recovery in some patients with DoC mandates a new paradigm of care that goes beyond prevention of complications and targets recovery [27]. Guidelines have defined and outlined recommendations for assessing patients with DoC suggesting that longer trajectories of recovery should be facilitated to identify emerging signs of consciousness awareness [15]. The CCC, in the 2020 Proceedings of the Second CCC National Institutes of Health Symposium, listed care of patients in coma as one of the domains for actionable research targets [28].

A common nomenclature and consensus-based collection of common data elements (CDEs) is necessary to conduct meaningful investigation on the effects of different care pathways for patients with DoC. Moreover, the use of CDEs will standardize data across platforms and improve the ability to accurately describe and adjust for confounding factors. The benefit of collecting data in a consistent manner has been shown for other neurological

diseases, and it is supported by the National Institutes of Health, which provides CDEs for a range of neurological diseases (https://www.commondataelements.ninds.nih.gov/) [29]. To facilitate a similar CDE development process for patients with DoC, the CCC convened ten work groups to create CDEs for the broad spectrum of DoC research domains. Here, we report the results of the DoC CDE Hospital Course, Confounders, and Medications Work Group. We aim for these Hospital Course, Confounders, and Medications CDEs to support progress in DoC research and facilitate international collaboration.

## Methods

There is a lack of standardized definitions for data elements in observational studies and randomized controlled trials in coma and DoC [30]. Therefore, results cannot be compared across studies, and investigators are limited in their efforts to reduce uncertainty regarding the appropriate management of patients with coma and DoC. The goal of the DoC CDE Hospital Course, Confounders, and Medications Work Group was to provide guidance for future clinical research in coma, consciousness, and DoC by doing the following: (1) identifying particular medication regimens, which may confound results in investigations focused on patients with DoC; (2) outlining the details of the hospital course that are feasible to collect; and (3) recommending measures to quantify illness severity, intervention intensity, and specific outcomes. We anticipate that these CDEs will continue to be refined over time in concert with technological advances in neurocritical care and in the variety of specialties involved in the care of patients with DoC. The methods of data acquisition will likely continue to evolve so that high frequency data can be captured when feasible and may necessitate revision of these CDEs [31]. Therefore, the CDEs that we report here (version 1.0) are intended to serve as a starting point for future efforts by the international medical and scientific community to standardize the Hospital Course, Confounders, and Medications CDEs.

### CDE Development Meetings

An 11-member Hospital Course, Confounders, and Medications Work Group was convened as part of the CCC to develop standardized Hospital Course, Confounders, and Medications CDEs for patients with DoC. This work group incorporated an international and multidisciplinary (neurology, nursing, adult and pediatric intensive care, pharmacology) ad hoc panel of experts in clinical studies and preclinical studies in patients with coma and DoC. The subcommittee was charged with recommending CDEs for patients who may be exposed to confounding medications or who may receive inpatient care during acute injury, or those who may be involved in research and experience changes in consciousness prior to or during study initiation.

The work group met virtually once per month from 2021 to 2023 and communicated regularly via email correspondence, with the goal of creating Hospital Course, Confounders, and Medications CDEs for patients with DoC. Because a primary aim was support from both single-center and multicenter clinical trials, the work group developed the CDEs to capture data from commonly available sources (e.g., vital signs captured from bedside telemetry), as well as physiological data captured using advanced data acquisition employed for ICP, cardiovascular, and pupillometry monitoring [31]. Work group members with subspecialized knowledge were self-assigned to domain-specific case report forms (CRFs). Each CRF team, consisting of at least two work group members, developed the final product through internal consensus. The full Hospital Course, Confounders, and Medications Work Group evaluated all CRFs for final approval and harmonization.

### Selection of CDEs for Hospital Course, Confounders, and Medications of DoC

Members of the work group performed an extensive review of CDEs from traumatic brain injury, epilepsy, stroke, subarachnoid hemorrhage, and other neurologic diseases from the CDE repository commissioned by the National Institute of Neurological Disorders and Stroke (NINDS) (https://commondataelements.ninds.nih.gov) [32]. Following this initial exercise, work group members selected and classified the CDEs by consensus. A list of assessments and clinical examination CDEs relevant to coma and DoC was compiled between May 2021 and January 2022. The goal was to leverage these existing CDEs and, whenever possible, to use CDEs that were already defined according to established standards [16, 29, 33–39]. Additional variables pertaining to coma and DoC not previously described were derived from observational studies and clinical trials by consensus from work group members after consideration of their reliability and validity in heterogenous patient populations. Variables not relevant to coma and DoC research were excluded.

Subsequently, the work group organized the DoC Hospital Course, Confounders, and Medications CDEs into CRFs. We selected previously published, disease-specific CDEs and CRFs, when relevant, and we proposed new CDEs and CRFs that capture the unique Hospital Course, Confounders, and Medications considerations associated with the population of patients with DoC, across the age spectrum from neonatal through adulthood.

## CDE Classification

We classified the CDEs as "disease core," "basic," "supplemental," or "exploratory" based on the consensus opinion of the work group. This classification nomenclature is consistent with that used in prior NINDS CDE projects [16, 29, 33–39]. The disease core designation applies to all CDEs that are required for all DoC studies. Excessive data entry may result in incomplete CRFs and reduced participation in multicenter international trials. Therefore, we intended to limit the number of disease core CDEs to reduce the burden of data entry. The basic designation corresponds to CDEs that are strongly recommended for all DoC studies. The supplemental designation is intended for CDEs that are recommended for specific DoC studies depending on their aims and hypotheses, and the exploratory designation applies to CDEs that can be considered for use in DoC Hospital Course, Confounders, and Medications studies but require further validation. We also included the designation "key design element" to any methodological parameter that is relevant to the acquisition, processing, or analysis of data.

## Results and Description of Selected CDEs

The work group collated existing CDEs and created new CDEs relevant to coma and DoC. We created five CRFs, as follows: (1) Prior and Concomitant Medications; (2) Surgeries and Other Procedures; (3) Nursing Care; (4) Vital Signs and Physiologic Measures; and (5) Therapy Intensity Level. The CRFs have been included in the Online Supplement. None of the CDEs were classified as "disease core."

### Prior and Concomitant Medications

Acute DoC may be attributed to the presence of sedating medications or illicit substances [15]. The findings from neurologic examinations may also be confounded by the presence of sedating or psychoactive medications. Thus, consideration of recent or ongoing exposures is of paramount importance in evaluating causes of coma or DoC and neuroprognostication efforts [8, 15, 40]. We included CDEs in the prior and concomitant medications subcategory. For the latter, the following were considered basic: presence of and description prescription; nonprescription; herbal supplements; or illicit substances within an investigator-defined period of time before, during or after the study. Medication classes of interest include, but are not limited to, central nervous system (CNS) acting agents that may be categorized as sedative or sleep aids, narcotic pain medications, antipsychotic medications, stimulant, antiseizure, antimicrobial, neuromuscular blocking agents, and neuromuscular or other CNS acting agents (see Online Supplement). The use of

medication therapies, such as vasopressors, sedatives, and hyperosmolar therapies, that may imply intensity of care are incorporated under the subsequent "Therapy Intensity Level" section. We also suggest reporting exposures to CNS-acting herbal supplements or illicit substances. Reporting of dose and frequency, along with administration time association with outcomes, should be considered.

### Surgeries and Other Procedures

Reporting of neurosurgical procedure subtype received (e.g., craniotomy, craniectomy, cranioplasty, evacuation of subdural hematoma, evacuation of intracerebral hemorrhage/contusion, evacuation of epidural hematoma, repair of dural sinus, cerebral spinal fluid [CSF] drainage with external ventricular catheter, invasive monitoring device [tunneled, bolt, or other device fixation], subdural strip electrode placement, elevation of depressed skull fracture, cranialization of sinus injury, other craniofacial surgery, and spinal decompression or other spinal surgery) was the only variable considered "supplemental" information for research in coma and DoC. When incorporating procedure variables in research of coma and DoC, key design elements for neurosurgical procedures may include regional location of surgery (right hemisphere, left hemisphere, bifrontal, suboccipital, spine), CSF closing pressure value, purpose of CSF drainage (e.g., therapeutic, sample collection, or monitoring of ICP), surgical timing (e.g., emergent or unplanned, elective or planned, or emergent return to operating room), and complications of the procedure. Key design elements relating to thoracic and airway procedures, abdominal and urinary tract procedures, soft tissue procedures, and orthopedic procedures may also be considered and included in the CDE (see Online Supplement).

### Nursing Care and Vital Signs and Physiologic Measures

A range of nursing care assessments and interventions have been identified and are included in the CDEs. Specific nursing care CDEs associated with caring for the patient in coma or the patient with DoC were not accounted for by previously published CDEs. Therefore, after examining the appropriate literature, we created new CDEs based on consensus opinion. Nursing interventions CDEs (see Online Supplement) were classified as "supplemental."

Vital signs and physiologic measures that should be considered highly recommended supplemental information for research studies on coma and DoC include heart rate (beats per minute), blood pressure (mm Hg), temperature (Fahrenheit or Celsius), method or source for temperature (oral, rectal, axillary, tympanic, bladder, esophageal, brain, or other), respiratory rate (breaths

per minute), oxygen saturation (percentage), height (inches or centimeters), weight (pounds or kilograms), body mass index (kg/m$^2$), ICP monitor placement (yes or no), head circumference in study participants < 1 year of age (centimeters), status of fontanelle in study participants < 3 months of age (flat, sunken, or bulging), and measures of pupillary light reflex assessments. We suggest separate reporting of left and right pupil assessments including assessment method (pupillometer or subjective assessment), neurologic pupil index, pupil diameter before and after stimulus, shape (round, oval, or unknown), constriction velocity (mm/s), and characterization (brisk, sluggish, or nonreactive). A number of other vital signs and physiologic measures that may be included based on study-specific designs are further outlined in the CRF (see Online Supplement). The frequency and timing of the vital signs and physiologic measures will vary according to study design.

## Therapy Intensity Level

Basic CDE classification included patient location (emergency department, nonneuroscience ward, neuroscience ward, nonneurointensive care unit, neurointensive care unit), descriptors of intensity of neurocritical care, descriptors of general critical care, and intensity of acute rehabilitative interventions. For example, descriptors of intensity of neurocritical care include the global categorization of therapy intensity level for ICP control ranging from 0 to 4 on an ordinal scale, ICP control procedures (yes or no) to determine therapy intensity levels for ICP control (e.g., low-dose or high-dose sedation, metabolic suppression using high-dose barbiturates or propofol, neuromuscular blockade, CSF drainage < or ≥ 120 mL/day, vasopressor therapy, mild [PaCO$_2$ 35–40 mm Hg] to intensive [PaCO$_2$ < 30 mm Hg] hypocapnia, hyperosmolar therapy, targeted temperature management, unscheduled intracranial operation for progressive mass lesion, decompressive craniectomy, head elevation for ICP control), whether a procedure was administered (yes or no), pediatric intensity level of therapy (scored 0–38), and procedures performed (yes or no) for reasons other than ICP control (e.g., sedative infusions, neuromuscular blockade, vasopressor therapy, hyperosmolar therapy, targeted temperature management, brain tissue oxygen monitoring, cerebral microdialysis, thermal diffusion cerebral blood flowmetry, jugular venous oxygen monitoring, extracorporeal membranous oxygen, intraaortic balloon pump, or electroencephalography using surface, strip, or depth electrodes). Descriptors of acute rehabilitative interventions include receipt (yes or no) of physical therapy, occupational therapy, speech therapy, swallowing evaluation, therapeutic devices, music therapy, administration of pharmacological neurostimulants, surgical neurostimulation, or noninvasive neurostimulation.

## Release of CDEs and Public Comments

We released version 1.0 of the proposed Hospital Course, Confounders, and Medications CDEs for patients with DoC as a set of five CRFs (see Supplementary Materials). As planned, the CDEs underwent a 2-month public feedback period from October through November 2022, following a summary presentation at the 2022 Annual Meeting of the Neurocritical Care Society, and subsequent advertisement via social media outlets such as Twitter. Public feedback, mostly related to the style and formatting of the CRFs, was received and incorporated into the final CRFs.

We encourage and expect ongoing feedback regarding modifications to the CDEs, which can be submitted via email to cde.curingcoma@gmail.com. The recommendations received will be evaluated by the Hospital Course, Confounders, and Medications Work Group, and modifications to the CRFs will be posted on the zenodo website (https://zenodo.org/record/8172359) with new version numbers.

## Discussion

Ongoing research progress and advancement of the field of coma and DoC depends on the development of harmonized and uniform data elements. A multidisciplinary team with interest and experience in coma and DoC convened work groups to establish CDEs for DoC research. In this article, we propose and disseminate the Hospital Course, Confounders, and Medications CDEs agreed on by an international group of collaborators. The work group designed the DoC Hospital Course, Confounders, and Medications CDEs with the intended purpose for broad accessibility and pragmatic implementation at both academic medical centers and community hospitals. The work group also, whenever possible, leveraged previous CDE efforts supported by NINDS to ensure consistency across various disease states that result in, or are associated with, coma or DoC. In addition, the work group created de novo CDEs specific to patients with DoC, when gaps and voids were found, based on a review of DoC studies. All DoC Hospital Course, Confounders, and Medications CDEs, organized in five CRFs, are now publicly available at (see Supplementary Materials and https://zenodo.org/record/8172359). The work from this work group represents the first effort to define hospital course, confounders, and medications CDEs for DoCs. As such, the proposed CDEs have limitations. The CDEs released were agreed on by consensus. A systematic approach should be used when incorporating supplemental and exploratory medication and hospital course

confounders in research on coma and DoC, given the lack of existing standards. However, recommendations from this subcommittee may assist in unifying data for future research in coma and DoC.

Future studies are needed to investigate the extent to which various exposures of medications may influence neurologic examinations in patients with coma and DoC and the association of nursing and rehabilitative therapies and treatment intensities impact outcomes or influence treatment effects. This CDE development effort is a dynamic process, and we anticipate revisions that reflect ongoing progress in the field of DoC.

## Conclusions

The recommendations relating to hospital course, confounders, and medications have been collated from many useful scales and descriptors. Adherence to these recommendations will facilitate the comparison of results across studies and meta-analyses of individual patient data.

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## Publisher's Note

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