



Cognitive Outcomes and NeuroStimulants among the Cerebrally Injured & Obtunded in the United States: The CONSCIOUS Study

Data Dictionary

Intake Details	
Site	Your center's name
Pt. Number	Deidentified patient number
Date of admission/presentation	mm/dd/yy; include time (if possible)
GCS (Glasgow coma scale) score	Enter numeric scores for eyes, verbal, and motor
Marshall class	I (no visible pathology seen on CT scan) II (Cisterns are present with 0–5 mm midline shift and/or lesion densities present; no high- or mixed-density lesion >25 mL includes bone fragments or foreign bodies) III (cisterns compressed or absent with midline shift 0-5 mm; no high or mixed-density lesion > 25 mL) IV (midline shift > 5 mm; no high or mixed-density lesion > 25 mL) V (any mass lesion surgically evacuated) VI (high or mixed-density lesion > 25 mL that is not surgically evacuated)
tSAH (traumatic subarachnoid hemorrhage)	Is a tSAH present? If so, check box.
Contusion [cerebral, etc.]	Is a contusion present? If so, check box.
AIS (abbreviated injury score)	Enter numeric value beneath each body region.
ISS (injury severity score)	Enter numeric calculated score.

Patient History	
Age	Enter numeric value in years.
Sex, Race, Comorbidities	Check the boxes that apply.

Neurostimulant Therapy	
Neurostimulant, dose, frequency, start/stop date	Enter values that apply (if applicable).
Questions	Check the boxes that apply. Free text the name of the drug(s) (if applicable).

Hospital Course	
Interventions, Adverse events, Discharge disposition	Check boxes that apply. Record the corresponding date of event/procedure/etc.
Length of stay (LOS)	Enter date of discharge as well as number of days for each LOS category.

Adverse Outcome (definitions)	
AKI (acute kidney injury)	Serum creatinine 3x baseline; OR an increase in serum creatinine to ≥ 4.0 mg/dl; OR the initiation of renal replacement therapy; OR urine output < 0.3 ml/kg/h for > 24 hours <i>*exclude patients with renal failure prior to injury.</i>
ARDS (acute respiratory distress syndrome)	<ul style="list-style-type: none"> • Within 1 week of clinical insult • Bilateral opacities (not explained by effusions, collapse, nodules) • Respiratory failure (not explained by cardiac failure/fluid overload) • $\text{PaO}_2/\text{FiO}_2 \leq 300$ mm Hg AND with a PEEP ≥ 5
Bacteremia	A laboratory-confirmed bloodstream infection.
Cardiopulmonary arrest	Sudden cessation of cardiac activity with no normal breathing and no signs of circulation.
DVT (deep venous thrombosis)	Confirmed by venogram, ultrasound, or CT
MI (myocardial infarction) <i>*either criteria acceptable</i>	ECG changes (one or more of the following three): 1. ST elevation > 1 mm in \geq two contiguous leads 2. New left bundle branch block 3. New q-wave in two or more contiguous leads New elevation in troponin greater than 3x upper level of the reference range in the setting of suspected myocardial ischemia
PE (pulmonary embolism)	Confirmed by pulmonary arteriogram or CT angiogram
Pneumonia [ventilator-associated]	Mechanical ventilation for > 2 days AND diagnostic criteria for pneumonia.
Tachyarrhythmia	Abnormal heart rhythm with a ventricular rate of ≥ 100 bpm.
Seizure	Clinical picture AND supported by electroencephalogram data.
Sepsis <i>*either criteria acceptable</i>	A documented infection AND ≥ 2 of the following: <ul style="list-style-type: none"> • Temperature $> 38^\circ$ or $< 35^\circ$ • Heart rate > 90 bpm • Respiratory rate > 20 breaths/min • WBC $> 12,000$ or $< 4,000$ A documented infection AND an acute increase of ≥ 2 Sequential [Sepsis-related] Organ Failure Assessment (SOFA) points.
Unplanned operative intervention	Unplanned trip to the operating room (related only to a neurosurgical intervention).
Unplanned reintubation	Occurs if patient requires reintubation > 24 hours after extubation and occurs because of the onset of respiratory or cardiac failure.
Unplanned readmission to ICU	Readmitted to the ICU after a transfer to the floor.

Cognitive Outcomes	
Assessment (with date)	Record the date of each assessment in provided area. Note: follow-up is preferably at 3-months, but any outpatient follow-up is sufficient.
Glasgow Coma Scale (GCS)	Enter numeric values for Eyes, Verbal, Motor
Disability Rating Scale (DRS)	Enter numeric values for each column. Use accompanying DRS rating scale to assign numeric values.
Glasgow Outcome Score-Extended (GOS-E)	Check Y/N boxes as appropriate. Check the subcategory boxes only if indicated.

Disability Rating Scale		
Eye opening	1: spontaneous	eyes open spontaneously.
	2: to speech	a response to any verbal approach, whether spoken or shouted, not necessarily the command to open the eyes.
	3: to pain	tested by a painful stimulus.
	4: none	no eye opening.
Verbal	0: oriented	patient can tell you: who he/she is, where he/she is, why he/she is there, the season, year, month, day, and time of day.
	1: confused	attention can be held, and patient responds to questions, but responses are delayed and/or disoriented and confused.
	2: inappropriate	intelligible articulation but speaks only in an exclamatory or random way; no sustained communication exchange
	3: incomprehensible	moaning, groaning or sounds without recognizable words
	4: none	no sounds or communications signs from patient.
Motor	0: follows commands	obeying commands. Do not include grasp or other reflex responses.
	1: localizes	a painful stimulus at more than one site causes limb to move (even slightly) in an attempt to remove it.
	2: withdraws	any generalized movement away from a noxious stimulus that is more than a simple reflex response
	3: flexes	painful stimulation results in either flexion at the elbow, rapid withdrawal with abduction of the shoulder or a slow withdrawal with adduction of the shoulder.
	4: extends	painful stimulation results in extension of the limb.
	5: none	no response can be elicited.
Feeding	0: complete	continuously shows awareness that he/she knows how to feed and can convey unambiguous information that he/she knows when this activity should occur.
	1: partial	intermittently shows awareness that he/she knows how to feed and/or can intermittently convey reasonably clearly information that he/she knows when the activity should occur
	2: minimal	shows infrequent awareness that he/she knows in a primitive way how to feed and/or shows infrequently that he/she is vaguely aware when activity should occur.
	3: none	shows virtually no awareness at any time that he/she knows how to feed and cannot convey that he/she knows when the activity should occur.
Toileting	0: complete	continuously shows awareness that he/she knows how to toilet and can convey unambiguous information that he/she knows when this activity should occur.
	1: partial	intermittently shows awareness that he/she knows how to toilet and/or can intermittently convey reasonably clearly information that he/she knows when the activity should occur.
	2: minimal	shows infrequent awareness that he/she knows in a primitive way how to toilet and/or shows infrequently that he/she is vaguely aware when activity should occur.
	3: none	shows virtually no awareness at any time that he/she knows how to toilet and cannot convey that he/she knows when the activity should occur.

Grooming	0: complete	continuously shows awareness that he/she knows how to groom self and can convey unambiguous information that he knows when this activity should occur.
	1: partial	intermittently shows awareness that he/she knows how to groom self and/or can intermittently convey reasonably clearly information that he/she knows when the activity should
	2: minimal	shows infrequent awareness that he/she knows in a primitive way how to groom self and/or shows infrequently that he/she is vaguely aware when the activity should occur.
	3: none	shows virtually no awareness at any time that he/she knows how to groom self and cannot convey that he/she knows when the activity should occur.
Functioning	0: completely independent	able to live as he wishes, requiring no restriction due to physical, mental, emotional or social problems.
	1: independent in special environment	capable of functioning independently when needed requirements are met (mechanical aids).
	2: mildly dependent	able to care for most of own needs but requires limited assistance due to physical, cognitive and/or emotional problems (e.g., needs non-resident helper).
	3: moderately dependent	able to care for self partially but needs another person at all times (person in home).
	4: markedly dependent	needs help with all major activities and the assistance of another person at all times.
	5: totally dependent	not able to assist in own care and requires 24-hour nursing care.
Employability	0: not restricted	can compete in the open market for a relatively wide range of jobs commensurate with existing skills; or can initiate, plan execute and assume responsibilities associated with homemaking; or can understand and carry out most age relevant school assignments.
	1: selected jobs/ competitive	can compete in a limited job market for a relatively narrow range of jobs because of limitations of the type described above and/or because of some physical limitations; or can initiate, plan, execute and assume many but not all responsibilities associated with homemaking; or can understand and carry out many but not all school assignments.
	2: sheltered workshop/ non-competitive	cannot compete successfully in a job market because of limitations described above and/or because of moderate or severe physical limitations; or cannot without major assistance initiate, plan, execute and assume responsibilities for homemaking; or cannot understand and carry out even relatively simple school assignments without assistance.
	3: not employable	completely unemployable because of extreme psychosocial limitations of the type described above, or completely unable to initiate, plan, execute and assume any responsibilities associated with homemaking; or cannot understand or carry out any school assignments.

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Intake Details													
Site:	Pt Number:	Date of admission:											
Mechanism:	<input type="checkbox"/> Fall (ground level)	<input type="checkbox"/> Fall (> 8 feet)	<input type="checkbox"/> Motor-vehicle related	<input type="checkbox"/> Pedestrian struck	<input type="checkbox"/> Assault								
Index GCS score: E ___ V ___ M ___	Marshall class:	<input type="checkbox"/> I	<input type="checkbox"/> II	<input type="checkbox"/> III	<input type="checkbox"/> IV	<input type="checkbox"/> V	<input type="checkbox"/> VI	DAI <input type="checkbox"/>	tSAH <input type="checkbox"/>	Contusion <input type="checkbox"/>			
AIS:								ISS:					
Head		Face		Neck		Thorax		Abdomen		Spine		Extremities	

Patient History			
Demographics:	Age:	Sex: Male <input type="checkbox"/> Female <input type="checkbox"/> Other <input type="checkbox"/>	
	Race:	<input type="checkbox"/> African American/Black <input type="checkbox"/> Asian <input type="checkbox"/> Caucasian/White <input type="checkbox"/> Hispanic <input type="checkbox"/> Other: _____	
Comorbidities:	<input type="checkbox"/> ADHD	<input type="checkbox"/> Cirrhosis	<input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> PTSD
	<input type="checkbox"/> Alcohol abuse disorder	<input type="checkbox"/> Congestive heart failure	<input type="checkbox"/> History of MI <input type="checkbox"/> Schizophrenia
	<input type="checkbox"/> Anxiety	<input type="checkbox"/> COPD	<input type="checkbox"/> History of CVA <input type="checkbox"/> Substance abuse disorder
	<input type="checkbox"/> Bipolar disorder	<input type="checkbox"/> Dementia	<input type="checkbox"/> Hypertension <input type="checkbox"/> Other: _____
	<input type="checkbox"/> Chronic Kidney Disease	<input type="checkbox"/> Depression	<input type="checkbox"/> Parkinson's disease

Neurostimulant Therapy				
Is this patient receiving scheduled amantadine, methylphenidate, or modafinil? <input type="checkbox"/> Y <input type="checkbox"/> N				
<i>If your response was "NO" please skip the table below and only complete the accompanying 5 questions if applicable.</i>				
Neurostimulant	Dose (mg)	Frequency (times/day)	Start date	Stop date
Are any beta-blockers being given concurrently with neurostimulants? If yes, which drug(s)? <input type="checkbox"/> Y <input type="checkbox"/> N _____				
Are any anti-epileptic drugs being given beyond 7-days of prophylaxis? If yes, which drug(s)? <input type="checkbox"/> Y <input type="checkbox"/> N _____				
Are any scheduled oral anti-psychotics being given to this patient? If yes, which drug(s)? <input type="checkbox"/> Y <input type="checkbox"/> N _____				
Are any scheduled oral anti-depressants being given to this patient? If yes, which drug(s)? <input type="checkbox"/> Y <input type="checkbox"/> N _____				
Are any other scheduled neuromodulating medications being given to this patient? If yes, which drug(s)? <input type="checkbox"/> Y <input type="checkbox"/> N _____				

Hospital Course								
Interventions: <i>(with date of procedure)</i>	<input type="checkbox"/> Craniotomy/Craniectomy		<input type="checkbox"/> ICP monitoring device		<input type="checkbox"/> Gastrostomy		<input type="checkbox"/> Tracheostomy	
Adverse events: <i>(with date of first occurrence)</i>	<input type="checkbox"/> AKI _____	<input type="checkbox"/> MI _____	<input type="checkbox"/> Tachyarrhythmia _____					
	<input type="checkbox"/> ARDS _____	<input type="checkbox"/> PE _____	<input type="checkbox"/> Unplanned ICU readmission _____					
	<input type="checkbox"/> Bacteremia _____	<input type="checkbox"/> Pneumonia _____	<input type="checkbox"/> Unplanned OR intervention _____					
	<input type="checkbox"/> Cardiac arrest _____	<input type="checkbox"/> Seizure _____	<input type="checkbox"/> Unplanned reintubation _____					
	<input type="checkbox"/> DVT _____	<input type="checkbox"/> Sepsis _____	<input type="checkbox"/> Other _____					
Length of stay (LOS):	Date of discharge:	Hospital LOS:	ICU LOS:	Ventilator duration:				
Discharge Disposition:	<input type="checkbox"/> Home	<input type="checkbox"/> Rehab	<input type="checkbox"/> LTACH	<input type="checkbox"/> SNF	<input type="checkbox"/> Hospice	<input type="checkbox"/> Other	<input type="checkbox"/> Dead	

Cognitive Outcomes

Glasgow Coma Scale			
Assessment (with date)	Eyes (1 to 4)	Verbal (1 to 5)	Motor (1 to 6)
7-day: _____	_____	_____	_____
14-d: _____	_____	_____	_____
21-d: _____	_____	_____	_____
28-d/discharge: _____	_____	_____	_____
Follow-up: _____	_____	_____	_____

Disability Rating Scale								
Assessment (with date)	Eyes (0 to 3)	Verbal (0 to 4)	Motor (0 to 5)	Feeding (0 to 3)	Toileting (0 to 3)	Grooming (0 to 3)	Functioning (0 to 5)	Employability (0 to 3)
7-day: _____	_____	_____	_____	_____	_____	_____	_____	_____
14-d: _____	_____	_____	_____	_____	_____	_____	_____	_____
21-d: _____	_____	_____	_____	_____	_____	_____	_____	_____
28-d/discharge: _____	_____	_____	_____	_____	_____	_____	_____	_____
Follow-up: _____	_____	_____	_____	_____	_____	_____	_____	_____

Glasgow Outcome Score – Extended (at 28-d/discharge)		
Can the patient obey simple commands or say any words?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Is the assistance of another person at home essential every day for some activities of daily living?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Does the patient need frequent help or someone to be at home most of the time?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Was assistance at home essential before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Can the patient shop without assistance?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Was the patient able to shop without assistance before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Can he/she travel locally without assistance?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Was he/she able to travel without assistance before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Is he/she currently able to work to his/her previous capacity?	<input type="checkbox"/> N	<input type="checkbox"/> Y
If NO, to which degree: Reduced capacity <input type="checkbox"/> Non-competitive job/unable to work <input type="checkbox"/>		
Was he/she working (or seeking employment) before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Is the patient able to resume regular social and leisure activities outside home?	<input type="checkbox"/> N	<input type="checkbox"/> Y
If NO, how much participation: A bit less <input type="checkbox"/> > 50% reduction <input type="checkbox"/> Rarely/unable <input type="checkbox"/>		
Did the patient engage in regular social and leisure activities outside home before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Have there been psychological problems resulting in ongoing family or friendship disruption?	<input type="checkbox"/> N	<input type="checkbox"/> Y
If YES, how often: Less than weekly <input type="checkbox"/> Weekly <input type="checkbox"/> Daily <input type="checkbox"/>		
Were there problems with family or friends before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Are there other current problems relating to the injury which affect daily life?	<input type="checkbox"/> N	<input type="checkbox"/> Y
Were similar problems present before the injury?	<input type="checkbox"/> N	<input type="checkbox"/> Y