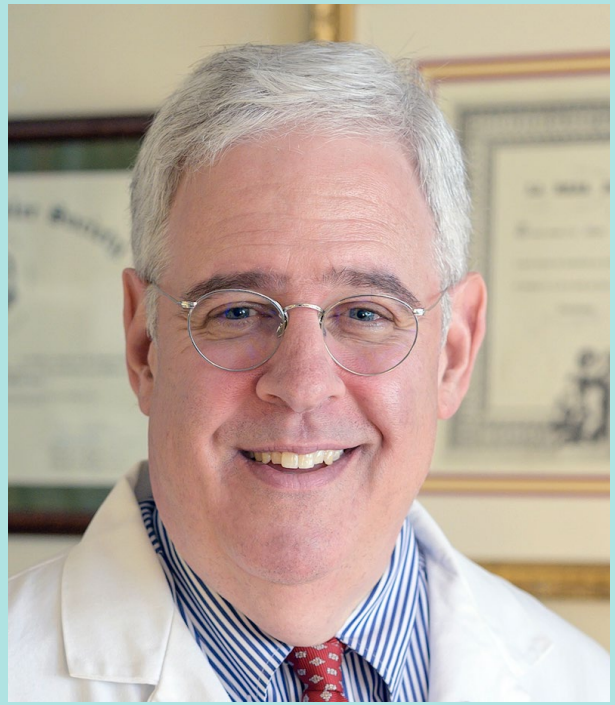
Brain Injury, Neuroethics & The Mandate for Rehabilitation

Spaulding-HMS TBI Summit
22 November 2024



Joseph J. Fins, M.D., D. Hum. Litt., M.A.C.P., F.R.C.P.
The E. William Davis, Jr., M.D. Professor of Medical Ethics
Chief, Division of Medical Ethics & Professor of Medicine
Professor of Medical Ethics in Neurology & Medicine in Psychiatry
Professor of Medical Ethics in Rehabilitation Medicine
Weill Cornell Medical Medicine & New York Presbyterian Hospital

Co-Director, C.A.S.B.I.
Consortium for the Advanced Study of Brain Injury
Weill Cornell Medicine and The Rockefeller University

Visiting Professor of Law
Solomon Center Distinguished Scholar in Medicine, Bioethics and the Law
Yale Law School

Weill Cornell Medicine

NewYork-Presbyterian
The University Hospital of Columbia and Cornell

Yale Law School

The Rockefeller University 1901

Systematic Review
New Practice Guidelines
Ethical Analysis

September 2018

SPECIAL ARTICLE

Comprehensive systematic review update 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

Joseph T. Giacino, PhD, Douglas I. Katz, MD, Nicholas D. Schiff, MD, John Whyte, MD, PhD, Eric J. Ashman, MD, Stephen Ashwal, MD, Richard Barbano, MD, PhD, Flora M. Hammond, MD, Steven Laureys, MD, PhD, Geoffrey S.F. Ling, MD, Risa Nakase-Richardson, PhD, Ronald T. Seel, PhD, Stuart Yablon, MD, Thomas S.D. Getchius, Gary S. Gronseth, MD, and Melissa J. Armstrong, MD, MSc

Correspondence
American Academy of Neurology
guidelines@aan.com

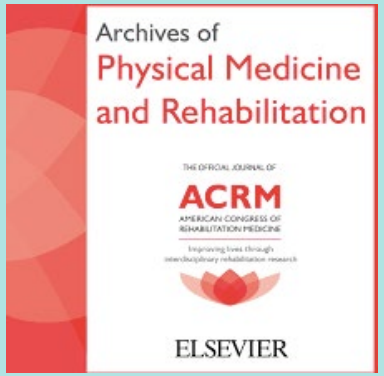
Neurology® 2018;91:461-470. doi:10.1212/WNL.0000000000005928

Abstract

Objective

To update the 1995 American Academy of Neurology (AAN) practice parameter on and the 2002 case definition for the minimally conscious state (MCS) by reviewing the l natural history, prognosis, and treatment of disorders of consciousness lasting at least

Neurology®



SPECIAL ARTICLE LEVEL OF RECOMMENDATION

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

Joseph T. Giacino, PhD, Douglas I. Katz, MD, Nicholas D. Schiff, MD, John Whyte, MD, PhD, Eric J. Ashman, MD, Stephen Ashwal, MD, Richard Barbano, MD, PhD, Flora M. Hammond, MD, Steven Laureys, MD, PhD, Geoffrey S.F. Ling, MD, Risa Nakase-Richardson, PhD, Ronald T. Seel, PhD, Stuart Yablon, MD, Thomas S.D. Getchius, Gary S. Gronseth, MD, and Melissa J. Armstrong, MD, MSc

Correspondence
American Academy of Neurology
guidelines@aan.com

Neurology® 2018;91:450-460. doi:10.1212/WNL.0000000000005926

Abstract

Objective

To update the 1995 American Academy of Neurology (AAN) practice parameter on persistent v state and the 2002 case definition on minimally conscious state (MCS) and provide care mendations for patients with prolonged disorders of consciousness (DoC).

Methods

Recommendations were based on systematic review evidence, related evidence, care principles, and i using a modified Delphi consensus process according to the AAN 2011 process manual, as amend

VIEWS & REVIEWS

Ethical, palliative, and policy considerations in disorders of consciousness

Joseph J. Fins, MD, MACP, and James L. Bernat, MD

Correspondence
Dr. Bernat
bernat@dartmouth.edu

Neurology® 2018;91:471-475. doi:10.1212/WNL.0000000000005927

Abstract

This essay complements the scientific and practice scope of the American Academy of Neurology Guideline on Disorders of Consciousness by providing a discussion of the ethical, palliative, and policy aspects of the management of this group of patients. We endorse the renaming of "permanent" vegetative state to "chronic" vegetative state given the increased frequency of reports of late improvements but suggest that further refinement of this class of patients is necessary to distinguish late recoveries from patients who were misdiagnosed or in cognitive-motor dissociation. Additional nosologic clarity and prognostic refinement is nec-
essary to preclude overestimation of low probability events. We argue that the new descriptor

RELATED ARTICLES

Practice guideline update recommendations summary: Disorders of consciousness: Report of the Guideline Development, Dissemination, and Implementation

Highlights: Systematic Review and Practice Guidelines

- **Landmark statement** AAN, College of PMR, National Institute of Disability, Independent Living, and Rehabilitation Medicine
- Significance of **joint publication** in *Neurology* as well as *Archives Physical Medicine and Rehabilitation*
- Improved diagnostic accuracy: **Serial exams CRS-R**, use of emerging neuroimaging technologies *f*MRI, SPECT
- **Evolving treatments**, Amantadine, **not** proof of principle data if <20 subjects; eg. Neuromodulation (DBS, TCM, Ultrasound)
- **Amelioration/prevention** of confounding conditions that impinge diagnosis and/or adversely effect morbidity & mortality (eg. pneumonia, bedsores etc.)
- **Chronic Vegetative State**
- **Calls for standards of care, yet paradoxical decline in rehab days over prior 15 years → How can patients then benefit from this golden age of brain science?**

The New York Times

April 7, 1964 -
March 29, 2022

Terry Wallis, 57, Dies; Awoke 19 Years After a Traumatic Brain Injury

Long after a car accident left him in a minimally conscious state in 1984, he woke up one day and said, “Mom.” Then he kept talking.

Terry Wallis at his home in Arkansas in 2006, three years after he regained the ability to speak. “He’s a unicorn in the sense that he emerged so late,” a doctor said. “We’ll never know exactly why he emerged after 19 years.” Ron Phillips for The New York Times

By Richard Sandomir

Published April 5, 2022 Updated April 7, 2022

Terry Wallis: How far we have come… and how far we have to go….

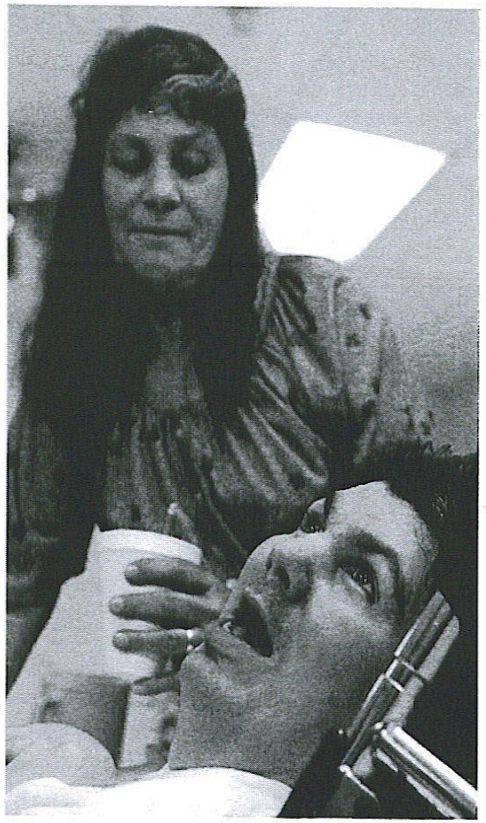
- 39 year old Arkansan in “coma” since 1984
- “Miracle awakening” from “coma / persistent vegetative state” on July 11, 2003 while in “custodial care”
- “Mom”, “Pepsi”, weeks greater fluency
- Reagan was still president
- Review of behaviors – not VS but MCS (Error rates estimated at 30 - 40% in nursing homes for “VS” when actually “MCS”)
- Wallis un-assessed by neurologist x 19 years, per father
- Contractures. Body is not up to recovering brain …
- "Mama, Life is good" –2009

Schiff ND and Fins JJ. *Cerebrum*, 2004.

Fins, Schiff and Foley. Neurology 2007.

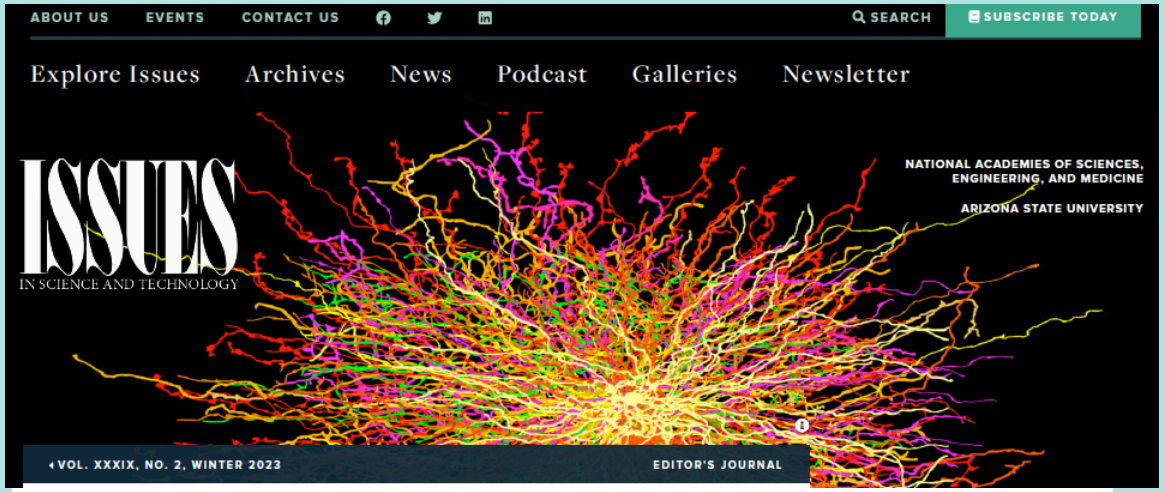
Fins *Cambridge Quarterly*, 2009

Fins, Rights Come to Mind, 2015



REPRINTED WITH PERMISSION FROM
CEREBRUM
Volume 5 Number 4 Fall 2003 The Dana Foundation New York

by Nicholas D. Schiff, M.D., and Joseph J. Fins, M.D.



JOSEPH J. FINS

The Complicated Legacy of Terry Wallis and His Brain Injury

An Arkansas man's unprecedented recovery of consciousness, and his recent death, demonstrate why progress in neuroscience must be matched by new standards of care for patients that protect their civil rights.

Daily Mail.com

- An extraordinary life
- An all too ordinary death
- Promise and Peril of Brain Injury
- Even Terry Wallis was vulnerable…

Fins JJ. The Complicated Legacy of Terry Wallis and his Brain Injury. *Issues in Science and Technology*. Winter 2023, volume 29(2):41-47.
https://issues.org/terry-wallis-brain-injury-neuroscience-care-fins/

A Biography of a Brain Injury: The Final Chapter*

Terry Wallis (1964–2022) out with his family on a mountain in Arkansas. His brother George pushes his chair with his brother Perry behind. Terry's sister, Tammy Baze, is reflected in his glasses. (Photo courtesy of Tammy Baze.)

- February 2022 call from Terry's sister
- Pneumonia on a ventilator
- Doctors want to remove life-sustaining
- They could not imagine his was a life worth living
- But treatable pneumonia
- Terry seemed withdrawn
- Brain function unchanged, he had a heavy heart
- Grieving his mother Angilee who died in 2018
- A doctor asked if he wanted to be with his mother, he indicated "yes"
- Sister alarmed, he just missed Angilee…

* with the permission of the Wallis Family

A Biography of a Brain Injury: The Final Chapter

Terry's funeral floral arrangement courtesy of Tammy Baze

- Needed more care; not less
- Need for rehabilitation could not be met in rural Arkansas
- Only out of state; too frail
- Died of pulmonary complications
- Intersectionality of: disability; cross-currents of right to die movement; poverty; access to care in rural US
- Compounding vulnerabilities
- Need for greater protections: access to care and human rights protections

From: Tammy Baze
Subject: RE: [EXTERNAL] The Complicated Legacy of Terry Wallis and His Brain Injury
Date: January 30, 2023 at 9:33 PM
To: Joseph J Fins jjfins@med.cornell.edu

Thank you for putting into words that I didn't even know existed and maybe helping others that are going through or might go through the same thing we did,, you are so right,, his death was a needless tragedy. One that no matter what I did I couldn't stop. There were so many good times we had with Terry, even in the state he was in, he loved us and we loved him,, he sure told us very loud and clear sometimes many times a day. Moms death hurt him so very badly, just as it has me Perry and George too,, she was a saint we didn't deserve a mother like her but I am so grateful to God that we had her. There were a lot of words in that article I didn't understand but you had me in tears. I think you did an awesome job on it and I pray that your message gets where it needs to be to help others. Thank you for your tribute! You are a wonderful person with a heart of gold,, I really appreciate all that you have done for us, the whole family but especially mom and Terry . reading this article really brought the tears out.. that ok too. Thank you Joe for caring and trying to help me in a hopeless cause.

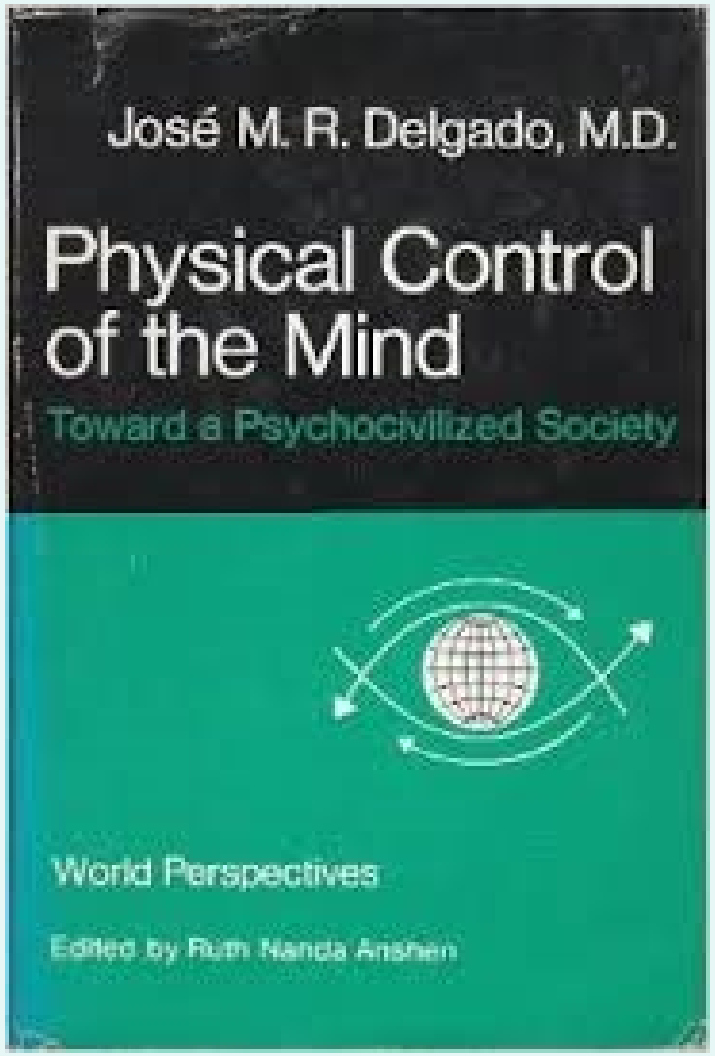
Please keep in touch with me
The best to you Sir,,
Heartfelt thanks
Tammy

Sent from Mail for Windows

From: Joseph J Fins
Sent: Monday, January 30, 2023 7:00 PM
To: Tammy Wallis/Baze
Subject: The Complicated Legacy of Terry Wallis and His Brain Injury

Hi Tammy,
Hope you and yours are doing well. The article about Terry came out today. Below is the link. If you remind me of your home address I'll ask that they send a physical copy of the magazine. By the way did the book I sent ever arrive? Hope so!
All best,
Joe

Neglect amidst Therapeutic & Rehabilitative Potentiality …



Potentiality is like a beautiful highway, able to accommodate traffic and facilitate the exchange of visitors among the many cities. The highway, however, cannot create cars, trucks, merchandise, businessmen, workers, and all the life which circulates along it. The road makes functions possible, but by itself is a useless stretch of pavement.

JMR, Delgado, 1969

History of Neuroscience

José Manuel Rodríguez Delgado, Walter Freeman, and Psychosurgery: A Study in Contrasts

The Neuroscientist
2023, Vol. 29(5) 618–631
© The Author(s) 2022
Article reuse guidelines:
sagepub.com/journals-permissions
DOI: 10.1177/10738584221086603
journals.sagepub.com/home/nro
SAGE

Joseph J. Fins[1,2,3] and John S. Vernaglia[4]

Abstract
History has conflated the legacies of José Manuel Rodríguez Delgado and Walter Freeman, midcentury proponents of somatic therapies for neuropsychiatric conditions. Both gained notoriety. Delgado after he appeared on the front page of the *New York Times* having used his *stimoceiver* to stop a charging bull in Spain; Freeman as the proponent of lobotomy. Both were the object of critique by the antipsychiatry movement and those who felt that their methods and objectives posed a threat to personal liberty. Using archival sources, we demonstrate that this conflation is a misrepresentation of the historical record and that their methods, objectives, ethics, and philosophical commitments differed widely. Accurate knowledge about historical antecedents is a predicate for ethical analysis and becomes especially relevant information as neuroscience develops circuit-based treatments for conditions such as Parkinson disease, depression, and brain injury. Part of that corrective is to counter the conflation of Delgado's and Freeman's life and work. Appreciating their distinctive legacies can help guide neuropsychiatric research done today that might yet haunt future generations.

Keywords
José Manuel Rodríguez Delgado, Walter Freeman, psychosurgery, neuroethics, history of medicine

It is easy to get lost in the frontal lobe, and sometimes with results ranging from the negligible to the disastrous.

—Walter Freeman (Freeman 1972)

A Response to Lobotomy

In a late-life interview, José Manuel Rodríguez Delgado (1915–2011) spoke of how he became interested in the electrical stimulation of the brain (Horgan 2005). Delgado had gained international fame as the developer of the stimoceiver, a radio-operated brain electrode, that stopped a charging bull in his tracks in a small bullring outside of Cordoba, in his native Spain (Fig. 1). That story made the front page of the *New York Times* in 1965 (Delgado 1981; Osmundsen 1965). Ever since, Delgado was famous and infamous. Famous for his precocious midcentury abilities with emerging neurotechnology. Infamous for the ways in which people feared that these devices might be used and abused. Concerns about the latter were heightened by the publication of his monograph *Physical Control of the Mind: Toward a Psychocivilized Society* (Delgado 1969).

Like many books with an evocative title, the message was more complex than it first appears. Delgado's objective was not mind control, as some have too easily alleged, but rather a deeper understanding of the neurophysiology of aggression and violence, with an eye toward mitigation of personal and societal strife (Delgado 1969). But no matter. Amid the antipsychiatry movement of the 1960s and 1970s (Dain 1989; Nasser 1995), Delgado was often viewed in conspiratorial hues, linking

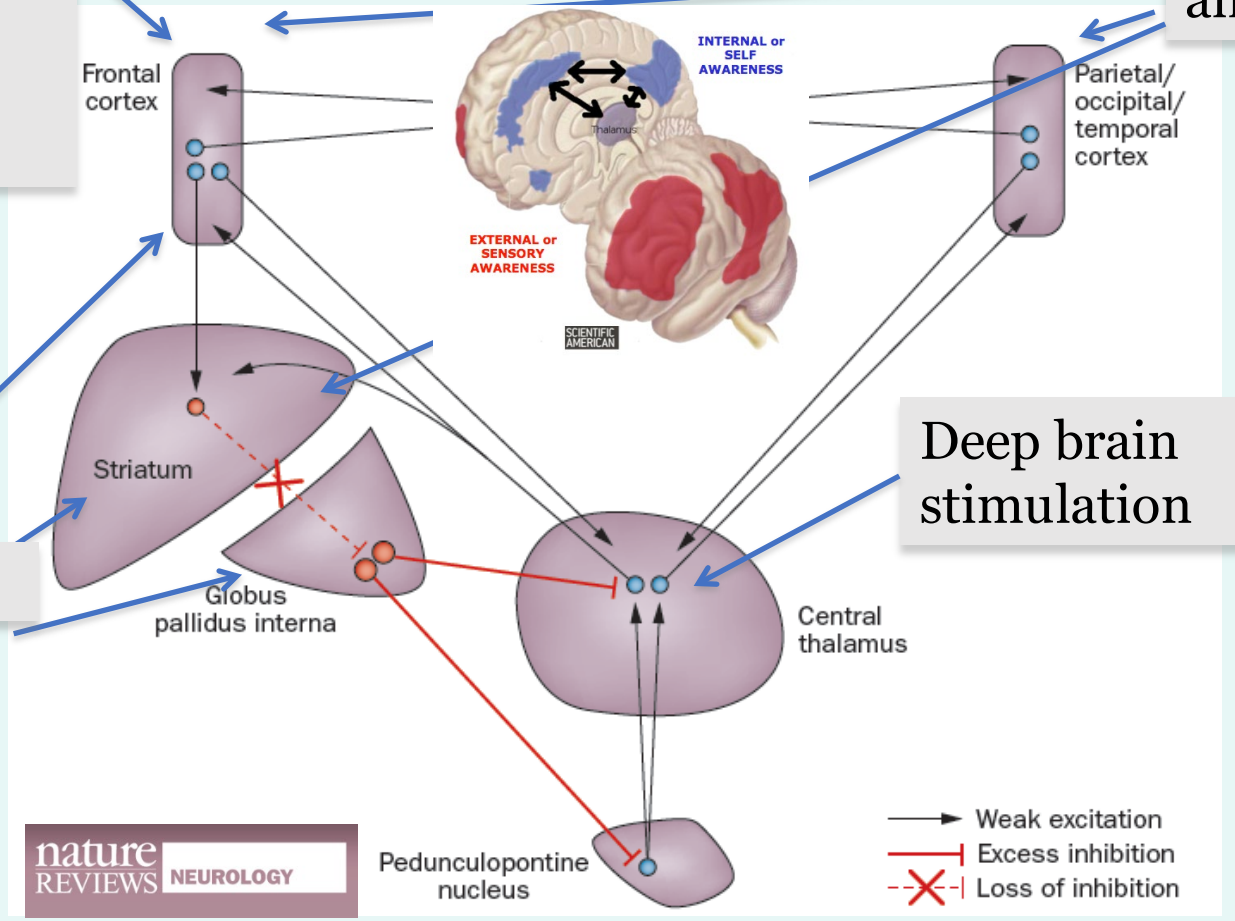
[1]Weill Medical College of Cornell University, New York, NY, USA
[2]The Consortium for the Advanced Study of Brain Injury, Weill Cornell Medical College and The Rockefeller University, New York, NY, USA
[3]Solomon Center Distinguished Scholar in Medicine, Bioethics and the Law, Yale Law School, New Haven, CT, USA
[4]The College of Social Studies, Wesleyan University, Middletown, CT, USA

Corresponding Author:
Joseph J. Fins, Division of Medical Ethics and CASH, Weill Cornell Medical College, 435 East 70th Street, Suite 4.4, New York, NY 10021, USA.
Email: jjfins@med.cornell.edu

Mesocircuit-fronto-parietal model

transcranial Direct Current Stimulation

amantadine



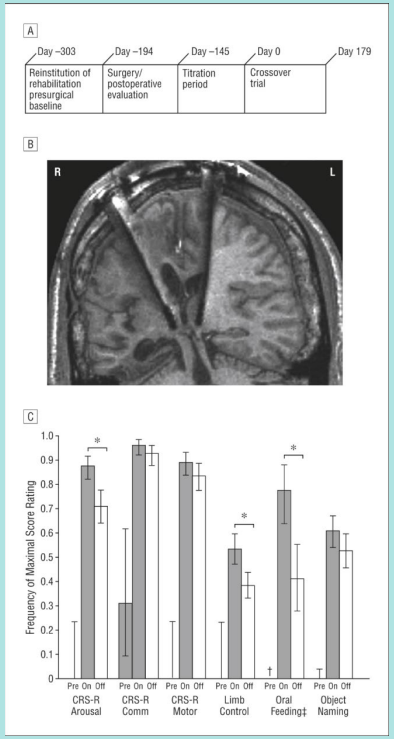
Deep brain stimulation

zolpidem

Giacino, Fins, Laureys, Schiff, *Nature Rev Neurol* 2014

Behavioral Improvements with Thalamic Stimulation after Severe Traumatic Brain Injury.

- Single Subject, Severe TBI, (low level MCS) 6 years post injury
- 6 month double blind cross-over study
- Bilateral thalamic DBS
- Increased
  - cognitively-mediated behaviors, language
  - Limb control
  - Oral feeding vs PEG
- Observed improvements correlate w stimulation
- First evidence DBS can promote late recovery from severe TBI
- Progress in face of ignorance --Tempered humility



Behavioral Improvements with Thalamic Stimulation after Severe Traumatic Brain Injury. Schiff ND, Giacino JT, Kalmar K, Victor JD, Baker K, Gerber M, Fritz B, Eisenberg B, O'Connor J, Kobylarz EJ, Farris S, Machado A, McCagg C, Plum F, Fins JJ, Rezai AR. *Nature* 2007;448(7153): 600-603.

ORIGINAL ARTICLE

Cognitive Motor Dissociation in Disorders of Consciousness

Y.G. Bodien, J. Allanson, P. Cardone, A. Bonhomme, J. Carmona, C. Chatelle, S. Chennu, M. Conte, S. Dehaene, P. Finoia, G. Heinonen, J.E. Hersh, E. Kamau, P.K. Lawrence, V.C. Lupson, A. Meydan, B. Rohaut, W.R. Sanders, J.D. Sitt, A. Soddu, M. Valente, A. Velazquez, H.U. Voss, A. Vrosgou, J. Claassen, B.L. Edlow, J.J. Fins, O. Gosseries, S. Laureys, D. Menon, L. Naccache, A.M. Owen, J. Pickard, E.A. Stamatakis, A. Thibaut, J.D. Victor, J.T. Giacino, E. Bagiella, and N.D. Schiff

ABSTRACT

BACKGROUND

Patients with brain injury who are unresponsive to commands may perform cognitive tasks that are detected on functional magnetic resonance imaging (fMRI) and electroencephalography (EEG). This phenomenon, known as cognitive motor dissociation, has not been systematically studied in a large cohort of persons with disorders of consciousness.

METHODS

In this prospective cohort study conducted at six international centers, we collected clinical, behavioral, and task-based fMRI and EEG data from a convenience sample of 353 adults with disorders of consciousness. We assessed the response to commands on task-based fMRI or EEG in participants without an observable response to verbal commands (i.e., those with a behavioral diagnosis of coma, vegetative state, or minimally conscious state–minus) and in participants with an observable response to verbal commands. The presence or absence of an observable response to commands was assessed with the use of the Coma Recovery Scale–Revised (CRS-R).

RESULTS

Data from fMRI only or EEG only were available for 65% of the participants, and data from both fMRI and EEG were available for 35%. The median age of the participants was 37.9 years, the median time between brain injury and assessment with the CRS-R was 7.9 months (25% of the participants were assessed with the CRS-R within 28 days after injury), and brain trauma was an etiologic factor in 50%. We detected cognitive motor dissociation in 60 of the 241 participants (25%) without an observable response to commands, of whom 11 had been assessed with the use of fMRI only, 13 with the use of EEG only, and 36 with the use of both techniques. Cognitive motor dissociation was associated with younger age, longer time since injury, and brain trauma as an etiologic factor. In contrast, responses on task-based fMRI or EEG occurred in 43 of 112 participants (38%) with an observable response to verbal commands.

CONCLUSIONS

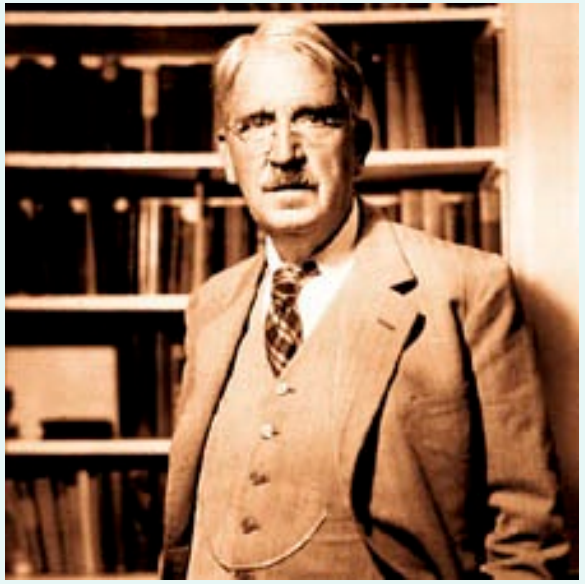
Approximately one in four participants without an observable response to commands performed a cognitive task on fMRI or EEG as compared with one in three participants with an observable response to commands. (Funded by the James S. McDonnell Foundation and others.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Schiff can be contacted at nds2001@med.cornell.edu or at the Feil Family Brain and Mind Research Institute, 1300 York Ave., New York, NY 10065.

N Engl J Med 2024;391:598-608.
DOI: 10.1056/NEJMoa2400645

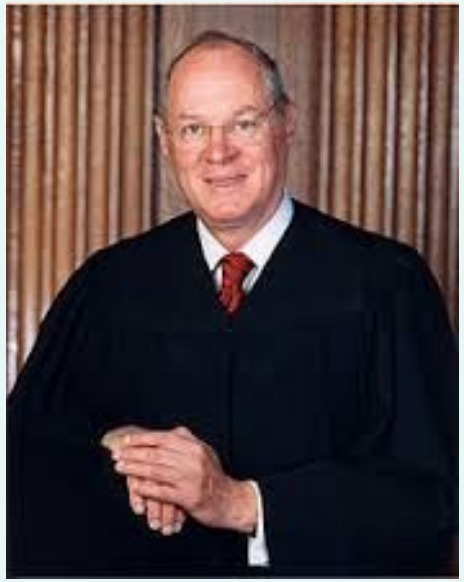
The added complexity and possibilities of Covert Consciousness

A Reframing: New Science and Evolving Ethics



" Inventions of new agencies and instruments create new ends; they create new consequences which stir men to form new purposes."

John Dewey
Common Sense and Scientific Inquiry (1938)



"...[N]ew insights and societal understandings can reveal unjustified inequality within fundamental institutions that once passed as unnoticed and unchallenged.

Justice Anthony Kennedy
Obergefell v. Hodges, 135 S. Ct 2584, 2603 (2015)

Disability Rights…

- Brain Injured individuals, ignored, sequestered, potentially salvageable
- Two tier system of care
- Young people with brain injuries **segregated in nursing homes by the three hour rule…**
- Ill-equipped for medical management
- Absence of rehabilitation
- Pain management
- Civil/Disability Rights

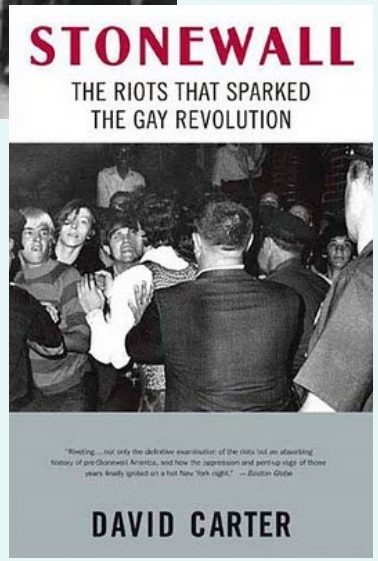
Fins JJ Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness. Cambridge University Press, 2015

From Separate to Equal…

- Violation of human rights
- Americans with Disability Act (ADA)
- UN Convention on Disability
- Right to be maximally integrated into society

Fins JJ. *Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness.* Cambridge University Press, 2015

Wright MS and Fins JJ. Rehabilitation, Education, and the Integration of Individuals with Severe Brain Injury into Civil Society: Towards an Expanded Rights Agenda in Response to New Insights from Translational Neuroethics and Neuroscience. *Yale Journal of Health Policy, Law, and Ethics* 2016;16(2): 233-288.



TOWARDS…A NEW RIGHTS MOVEMENT

Before seen by society as patients covered by such legislation, need to secure basic rights of citizenship, to have rights enjoyed by majority. Old story, new population.

From Seneca Falls

[Women's Suffrage/Women's Rights]

To Selma

[US Civil Rights/Integration]

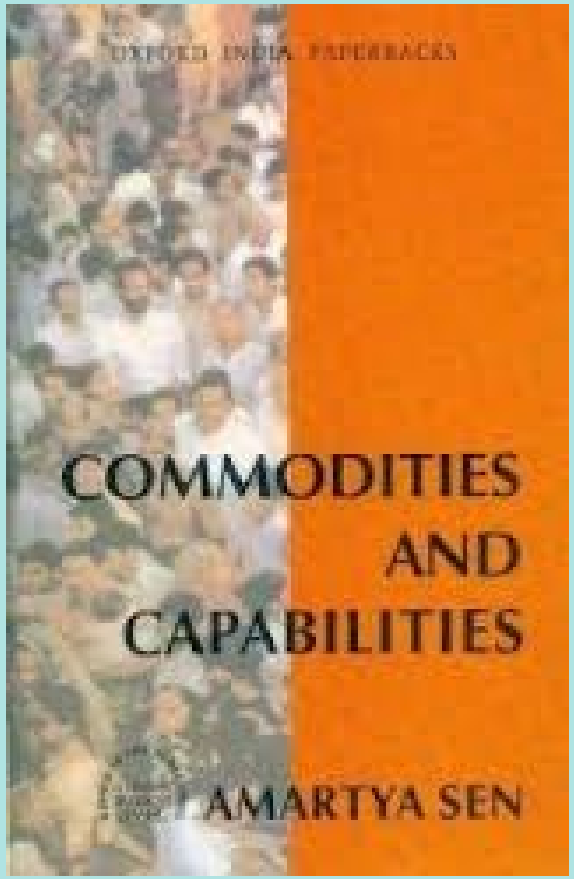
And Stonewall

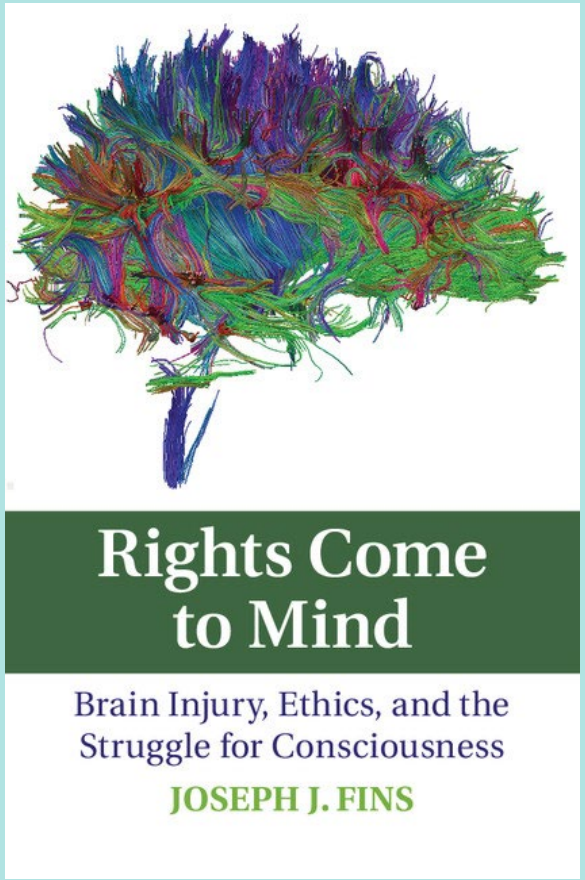
[Gay Rights/Marriage]

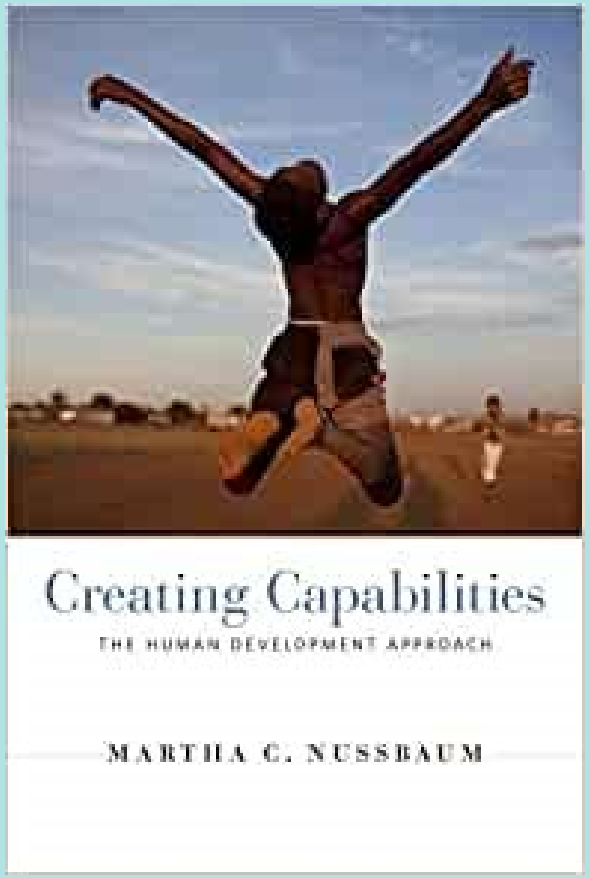
Dispossessed Groups had to appeal for rights enjoyed by other citizens…struggles continue

From Rights to Capabilities:

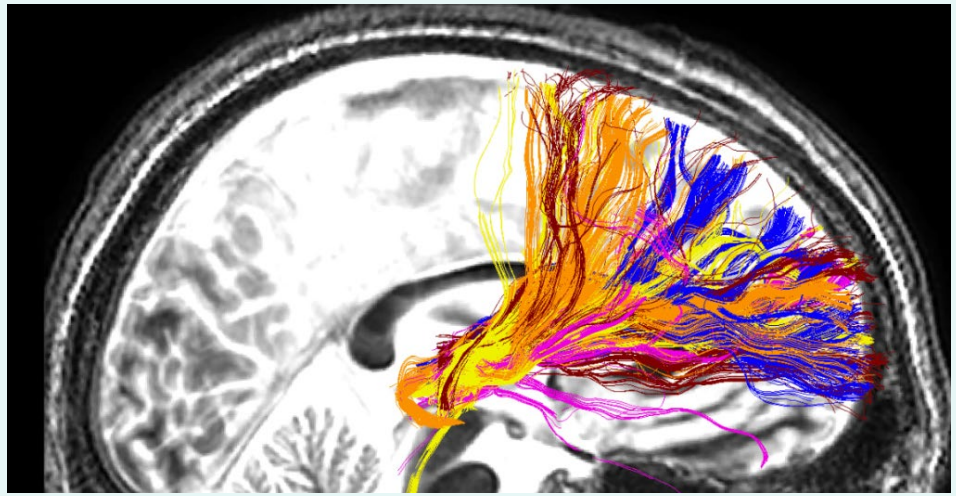
A Novel Argument for Neurotech Justice…







Central Thalamic Stimulation for Traumatic Brain Injury Study [UH3 NS095554-01]



- 5 completed study. All >10% improvement Trail-Making Test part B; measure of processing speed; improved executive function
- 2/5 subjects one point increase in GOS-E with just 3 months of stimulation **Historic inflection point**

nature medicine

Article

https://doi.org/10.1038/s41591-023-02638-4

Thalamic deep brain stimulation in traumatic brain injury: a phase 1, randomized feasibility study

Received: 11 August 2023

Accepted: 10 October 2023

Published online: 04 December 2023

Check for updates

Nicholas D. Schiff[1,2], Joseph T. Giacino[3,4], Christopher R. Butson[5,6], Eun Young Choi[7], Jonathan L. Baker[1], Kyle P. O'Sullivan[5], Andrew P. Janson[5,8], Michael Bergin[3], Helen M. Bronte-Stewart[7], Jason Chua[9], Laurel DeGeorge[1], Sureyya Dikmen[10], Adam Fogarty[7], Linda M. Gerber[9,11], Mark Krel[7], Jose Maldonado[12], Matthew Radovan[13], Sudhin A. Shah[14], Jason Su[15], Nancy Temkin[16], Thomas Tourdias[17], Jonathan D. Victor[1,2], Abigail Waters[3], Stephanie A. Kolakowsky-Hayner[7], Joseph J. Fins[11], Andre G. Machado[18], Brian K. Rutt[19,20,21] & Jaimie M. Henderson[7,20,21]

Converging evidence indicates that impairments in executive function and information-processing speed limit quality of life and social reentry after moderate-to-severe traumatic brain injury (msTBI). These deficits reflect dysfunction of frontostriatal networks for which the central lateral (CL) nucleus of the thalamus is a critical node. The primary objective of this feasibility study was to test the safety and efficacy of deep brain stimulation within the CL and the associated medial dorsal tegmental (CL/DTTm) tract. Six participants with msTBI, who were between 3 and 18 years post-injury, underwent surgery with electrode placement guided by imaging and subject-specific biophysical modeling to predict activation of the CL/DTTm tract. The primary efficacy measure was improvement in executive control indexed by processing speed on part B of the trail-making test.
All six participants were safely implanted. Five participants completed the study and one was withdrawn for protocol non-compliance. Processing speed on part B of the trail-making test improved 15% to 52% from baseline, exceeding the 10% benchmark for improvement in all five cases.
CL/DTTm deep brain stimulation can be safely applied and may improve executive control in patients with msTBI who are in the chronic phase of recovery.
ClinicalTrials.gov identifier: NCT02881151.

msTBI often leads to enduring physical, cognitive, emotional and behavioral impairments[1–7]. Cognitive dysfunction is the dominant factor underlying persistent functional disability following msTBI[5,6,8] and correlates with both injury severity and performance on standardized neuropsychological assessments[9]. Characteristically, cognitive dysfunction in msTBI impacts executive control underlying task-switching and organizing activities, sustained attention, information-processing speed and resistance to mental fatigue[5–8,10]. The msTBI population is estimated to number more than 5 million individuals in the United States[11] who remain unable to return to previous levels of functioning within their communities[12]. At present, there is no effective therapy for the disabling effects of injury-related impairments in attention,

A full list of affiliations appears at the end of the paper. e-mail: nds2001@med.cornell.edu; henderj@stanford.edu

Schiff ND, Giacino JT, Butson CR, Baker JL, Bergin M, Bronte-Stewart HM, Choi EY, DeGeorge L, Gerber LM, Janson AP, Shah SA, Su J, Waters A, Temkin N, Kolakowsky-Hayner SA, Fins JJ, Machado AG, Rutt BK, Henderson JM. Thalamic Deep Brain Stimulation in Traumatic Brain Injury: A Phase 1, Randomized Feasibility Study. *Nature Medicine*. 2023.

Cambridge Quarterly of Healthcare Ethics (2023), 1–24
doi:10.1017/S0963180123000518

CAMBRIDGE UNIVERSITY PRESS

ARTICLE

Subject and Family Perspectives from the Central Thalamic Deep Brain Stimulation Trial for Traumatic Brain Injury: Part II

Joseph J. Fins[1,2], Megan S. Wright[1,3], Kaiulani S. Shulman[1], Jaimie M. Henderson[4] and Nicholas D. Schiff[1,5]

[1]Division of Medical Ethics, Weill Cornell Medical College, New York, NY, USA
[2]Solomon Center for Health Law & Policy, Yale Law School, New Haven, CT, USA
[3]School of Law, Pennsylvania State University, State College, PA, USA
[4]Department of Neurosurgery, Stanford School of Medicine, Palo Alto, CA, USA
[5]Feil Family Brain and Mind Research Institute, Weill Cornell Medical College, New York, NY, USA
Corresponding author: Joseph J. Fins; Email: jjfins@med.cornell.edu

Abstract

This is the second paper in a two-part series describing subject and family perspectives from the CENTURY-S (CENtral Thalamic Deep Brain Stimulation for the Treatment of Traumatic Brain InjURY-Safety) first-in-human invasive neurological device trial to achieve cognitive restoration in moderate to severe traumatic brain injury (msTBI). To participate, subjects were independently assessed to formally establish decision-making capacity to provide voluntary informed consent. Here, we report on post-operative interviews conducted after a successful trial of thalamic stimulation. All five msTBI subjects met a pre-selected primary endpoint of at least a 10% improvement in completion time on Trail-Making-Test Part B, a marker of executive function. We describe narrative responses of subjects and family members, refracted against that success. Interviews following surgery and the stimulation trial revealed the challenge of adaptation to improvements in cognitive function and emotional regulation as well as altered (and restored) relationships and family dynamics. These improvements exposed barriers to social reintegration made relevant by recoveries once thought inconceivable. The study's success sparked concerns about post-trial access to implanted devices, financing of device maintenance, battery replacement, and on-going care. Most subjects and families identified the need for supportive counseling to adapt to the new trajectory of their lives.

Keywords: brain injury; deep brain stimulation; cognitive restoration; disability rights; post-trial obligations

Introduction

This is the second paper[1] in a two-part series describing subject and family perspectives from the CENTURY-S (CENtral Thalamic Deep Brain Stimulation for the Treatment of Traumatic Brain InjURY using the Medtronic PC + S) [UH3 NS095554, NCT 02881151] first-in-human invasive neurological device trial to achieve cognitive restoration in moderate to severe traumatic brain injury (TBI), with subjects who were deemed capable of providing voluntary informed consent. In this follow-up paper, we report on interviews conducted postoperatively after a successful trial of thalamic stimulation which met targeted milestones for improved executive dysfunction in chronic brain injury with at least a 10% improvement in completion time on Trail Making Test-Part B, which evaluates executive function.

Results of the CENTURY-S Study for Moderate to Severe TBI

In the CENTURY-S study, deep brain stimulation (DBS) electrodes were placed in six participants with moderate to severe TBI (Glasgow Coma Scale Extended GOSE 5–7) to modulate cognitive impairment.

Subject is a "totally different person"... the essence of my daughter had changed forever... knowing she could never be who she was before...I raised her all over again"

"I got my daughter back. I got my daughter back. It's a miracle. It's so profound for us. It's a profound change. Now here comes the tears. If somebody told me in August we would be sitting here having this kind of conversation in January. I never would've believed it. It's beyond my hopes, beyond anticipation. Somebody turned the lights back on."

Fins et al. Subject and Family Perspectives from the Central Thalamic Deep Brain Stimulation for Traumatic Brain Injury Study, Part I & 2. *Cambridge Quarterly of Healthcare Ethics,* 2022 & 2023.

Three Hour Rule is Ethically Unjustified and Likely a Violation of Disability Law

- Ethically unjustified
- Precludes recovery before it starts
- Segregates patients in chronic care, never to return
- Violation of the ADA, is this something we could litigate?
- Early prognostication is inconsistent with the temporal course of recovery
- Negates hidden potential of CMD
- Disregards emerging therapeutic and rehabilitative efficacy

EDITORIAL

Wait, Wait . . . Don't Tell Me

Tuning In the Injured Brain

ARCH NEUROL/VOL 69 (NO. 2), FEB 2012 WWW.ARCHNEUROL.COM
159

Brains recover by biological mechanisms not reimbursement criteria

FEDACE

Federación Española de Daño Cerebral

Una vida salvada merece ser vivida

2014
26 de octubre
día del daño cerebral adquirido

FEDACE

Federación Española de Daño Cerebral

Disclosures & Acknowledgements

Special Thanks:

The families who have consented to participate in our studies and shared their insights with us and the broader clinical community.

Colleagues

Nicholas D. Schiff, M.D.

Joseph T. Giacino, Ph.D.

Jaimie Henderson, M.D.

Andre Machado, M.D., Ph.D.

Megan Wright, Ph.D., J.D.

Kaiulani Shulman, B.A.

Zachary E. Shapiro, J.D., M.S.E.

Jennifer Hersh, B.A., M.B.E.

Mary Conte, Ph.D.

Jon Victor, M.D.,Ph.D.

CASBI @ YLS Students

Fred Plum, M.D., *in memorium*

Funders:

NIH BRAIN Initiative (Fins)
Robert Wood Johnson Foundation
Health Policy Investigator Award (Fins)
The Buster Foundation (Fins)
Weill Cornell CTSC Ethics Core (Fins)
The Charles A. Dana Foundation
(Schiff and Fins)
Project on Death in Faculty Scholar Award (Fins)
The Jerold B. Katz Foundation (Schiff and Fins)
The James S. McDonnell Foundation (Schiff)
Greenwall Foundation (Fins and Wright)
Terry Scholar Fund, Yale University (Fins)
Weill Cornell-New York Presbyterian Hospital
NIH Clinical Research Center (Schiff and Fins)
Cleveland Clinic Foundation (Project support)
National Institutes of Health (NINDS) (Schiff/ Fins)
IntElect Medical Inc. Fins (unfunded co-investigator)

Disclosures:

Book royalties:
Cambridge Univ Press:
Rights Come to Mind
Oxford University Press;
Stupor and Coma

Weill Cornell Medicine

NewYork-Presbyterian
The University Hospital of Columbia and Cornell

Yale Law School

The Rockefeller University 1901