

The Office on Disability, US Department of Health and Human Services
and the Cleveland Clinic Center for Neurological Restoration present

Brain Pacemakers:

A New Era of Hope for Neurological
and Psychiatric Disorders



A One Day Symposium
on Current Practices and
Emerging Applications
of Deep Brain Stimulation

Tuesday, May 6, 2008
Hubert H. Humphrey Building
Washington, DC





About the Symposium

Deep brain stimulation (DBS), or brain pacemaker technology, is an area of rapid growth in medicine with more than 40,000 implants in patients worldwide.

Initially developed for the treatment of movement disorders, DBS also has enormous potential for treating various chronic and disabling neurological conditions. Scientific literature has demonstrated its long-term safety and benefits, and the FDA currently approves DBS in the United States for the treatment of movement disorders such as Parkinson's disease, essential tremor and dystonia.

Current research is expanding the use of DBS to include treatment for other types of neurological and neuropsychiatric disorders. Promising data are emerging regarding the benefit of DBS in the treatment of individuals with obsessive compulsive disorder, depression, epilepsy and traumatic brain injury.

The positive impact of DBS in Americans with neurological disorders and disability cannot be disregarded. For many individuals, DBS therapy is life-altering. Various studies clearly indicate profound improvements in quality of life for many people who have exhausted most, if not all other treatment options.

The use of this innovative approach also presents ethical challenges that must be addressed. In this symposium, we will review the current indications for DBS and its multifaceted impact on individuals' lives. We will also explore emerging applications for clinical practice and the future direction of the field. The program will include prominent guests and leading faculty representing clinicians, neuroscientists, those with neurological disorders, advocacy groups and representatives from various government agencies.

Lectures and discussions will focus on the impact of DBS on patients' quality of life, level of functioning and return to work and society. Emphasis will also be placed on access to care, medical innovation, healthcare economics and ethics. The format will consist of didactic lectures and video presentations, followed by panel discussions, comments by individuals who have undergone this treatment, and will include time for audience questions and answers.

Symposium Objectives

After attending the symposium, participants will be able to:

- Describe the basic rationale and components of deep brain stimulation.
- Review the current FDA-approved clinical indications for DBS.
- Discuss the emerging applications and preliminary findings for DBS for those with disabling neurological and psychiatric disorders.
- Examine the ethical considerations associated with brain pacemaker technology.
- Discuss research and future applications.
- Describe neurological and psychiatric disorders and their associated impairment, disability, suffering, and compromise to quality of life.
- Discuss the impact of the disease on patients, families, and the cost to society.

Intended Audience

Biomedical Engineers; Centers for Disease Control; Centers for Medicare and Medicaid Services; Department of Defense; Department of Health & Human Services; Food and Drug Administration; Health Care Practitioners; Indian Health Services; Medical Device Industry; National Institutes of Health; Patient Advisory Groups; Patients and Families; Physicians; Scientists; Substance Abuse and Mental Health Services Administration; and the Veterans Administration.



Symposium Faculty

Symposium Co-Chairs

Margaret Giannini, MD, FAAP

Director, Office on Disability, US Department of Health and Human Services

Ali R. Rezai, MD

Director, Center for Neurological Restoration
Neurological Institute
Cleveland Clinic

Distinguished Speakers

Andrew C. von Eschenbach, MD

Commissioner of the US Food and Drug Administration

Rear Admiral Steven K. Galson, MD, MPH

Acting US Surgeon General

Michael Kinsley

Journalist

The Honorable Bill Pascrell, Jr.

New Jersey 8th Congressional District
Co-Chair, Congressional Brain Injury Task Force

Faculty

Kristen Bowsler, PhD

FDA, Division of Restorative Devices
Rockville, MD

Benjamin Greenberg, MD, PhD

Brown University
Providence, RI

James McNulty

National Alliance for the Mentally Ill
Arlington, VA

David Charles, MD

Vanderbilt University
Nashville, TN

Col. Robert Labutta, MD

Army Office of the Surgeon General
Falls Church, VA

Martha Morrell, MD

Stanford University
Stanford, CA

John Corrigan, PhD

Ohio State University
Columbus, OH

Frederick Lenz, MD

Johns Hopkins University
Baltimore, MD

Maria Mouratidis, PsyD

National Naval Medical Center
Bethesda, MD

Ann Costello, PhD, DMD

FDA, Division of Restorative Devices
Rockville, MD

Peter LeWitt, MD

Wayne State University
Clinical Neuroscience Center
Southfield, MI

Joseph Pancrazio, PhD

NIH/NINDS Neuroscience Center
Rockville, MD

Joseph Fins, MD

Weill Medical College of Cornell University
New York, NY

Col. Geoffrey Ling, MD, PhD

Defense Advanced Research Projects Agency/
Defense Sciences Office (DARPA/DSO)
Arlington, VA

Steve Phurrough, MD, MPA

Centers for Medicare and Medicaid Services
Baltimore, MD

Joseph Giacino, PhD

JFK Johnson Rehabilitation Institute
Edison, NJ

Donald Malone, MD

Cleveland Clinic
Cleveland, OH

Ashwini Sharan, MD

Thomas Jefferson University
Philadelphia, PA

Wayne Goodman, MD

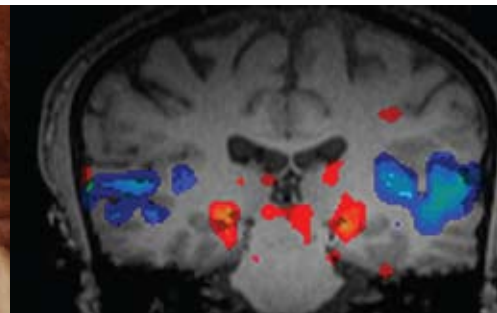
National Institute of Mental Health
Rockville, MD

Helen Mayberg, MD

Emory University
Atlanta, GA

Nicholas Schiff, MD

Weill Medical College of Cornell University
New York, NY





Symposium Agenda

- 8:15 - 8:25 Welcome
Margaret Giannini, MD, Director, Office on Disability and Program Co-Chair
Ali R. Rezai, MD, Director, Cleveland Clinic Center for Neurological Restoration and Program Co-Chair
- 8:25 - 8:35 Opening Remarks
Distinguished Guest

Keynote Address

- 8:35 - 8:55 Medical Device Innovation: Improving the Healthcare and Quality of Life for Americans
Andrew C. von Eschenbach, MD, Commissioner, US Food & Drug Administration

DBS: Progress and Promise

- 8:55 - 9:05 Deep Brain Stimulation: A Scientific Primer
Frederick Lenz, MD, Johns Hopkins University
- 9:05 - 9:25 Current State of DBS
Ali R. Rezai, MD, Cleveland Clinic and Symposium Co-Chair
- 9:25 - 9:45 DBS: Ethical Considerations
Joseph Fins, MD, Weill Medical College of Cornell University

9:45 - 10:00 Break

Movement Disorders

- 10:00 - 10:15 A Conversation with **Michael Kinsley**
- 10:15 - 10:30 DBS for Parkinson's Disease: Outcomes and Quality of Life Changes
David Charles, MD, Vanderbilt University
- 10:30 - 10:45 DBS for Essential Tremor and Dystonia: Outcomes and Quality of Life Changes
Peter LeWitt, MD, Wayne State University
- 10:45 - 11:15 Panel Discussion
Moderator: Joseph Pancrazio, PhD, NIH/NINDS Neuroscience Center
DBS Patient
David Charles, MD, Vanderbilt University
Peter LeWitt, MD, Wayne State University
Steve Phurrough, MD, MPA, Centers for Medicare and Medicaid Services

Epilepsy

- 11:15 - 11:25 Epilepsy and Impact on Disability
Martha Morrell, MD, Stanford University
- 11:25 - 11:35 DBS for Epilepsy
Ashwini Sharan, MD, Thomas Jefferson University
- 11:35 - 11:45 Panel Discussion
Epilepsy DBS Patient
Martha Morrell, MD, Stanford University
Ashwini Sharan, MD, Thomas Jefferson University

11:45 - 12:45 Lunch Break

Special Presentation

12:45 - 1:00 **Rear Admiral Steven K. Galson, MD, MPH**, Acting US Surgeon General

Psychiatric Disorders

- 1:00 - 1:15 Evolving Neuroscience of Psychiatric Disorders
Wayne Goodman, MD, National Institute of Mental Health
- 1:15 - 1:30 DBS for Obsessive Compulsive Disorder and Depression
Benjamin Greenberg, MD, PhD, Brown University
- 1:30 - 1:45 DBS: Targeting Depression
Helen Mayberg, MD, Emory University
- 1:45 - 1:55 DBS for Psychiatric Disorders: Outcomes and Quality of Life
Donald Malone, MD, Cleveland Clinic
- 1:55 - 2:25 Panel Discussion
Moderator: Benjamin Greenberg, MD, PhD, Brown University
OCD DBS Patient
Depression DBS Patient
Helen Mayberg, MD, Emory University
Steven Grant, PhD, National Institute on Drug Abuse
Ann Costello, PhD, DMD, FDA, Division of Restorative Devices
James McNulty, National Alliance for the Mentally Ill

2:25 - 2:40 Break

Special Presentation

2:40 - 2:50 TBI in America
The Honorable Bill Pascrell, Jr., New Jersey, 8th Congressional District and Co-Chair, Congressional Brain Injury Task Force

Traumatic Brain Injury (TBI)

- 2:50 - 3:00 TBI and Long Term Disability – The TBI Model Systems of Care
John Corrigan, PhD, Ohio State University
- 3:00 - 3:10 DBS for TBI – Scientific Rationale
Nicholas Schiff, MD, Weill Medical College of Cornell University
- 3:10 - 3:20 DBS for TBI – Clinical Outcomes
Joseph Giacino, PhD, JFK Johnson Rehabilitation Institute
- 3:20 - 3:40 Panel Discussion: TBI in the Civilian and Military Sectors: Bridging the Gap
Co-Moderators: Joseph Giacino, PhD, JFK Johnson Rehabilitation Institute, and **Ali R. Rezai, MD**, Cleveland Clinic
Col. Robert Labutta, MD, Army Office of the Surgeon General
Maria Mouratidis, PsyD, National Naval Medical Center
Nicholas Schiff, MD, Weill Medical College of Cornell University
John Corrigan, PhD, Ohio State University
Col. Geoffrey Ling, MD, PhD, DARPA/DSO

Future Directions: From Research to Therapy

Moderator: Joseph Fins, MD, Weill Medical College of Cornell University

- 3:40 - 4:20 Panel Discussion
Kristin Bowsher, PhD, FDA, Division of Restorative Devices
Wayne Goodman, MD, NIH/National Institute of Mental Health
Benjamin Greenberg, MD, PhD, Brown University
Joseph Pancrazio, PhD, NIH/NINDS Neuroscience Center
Michael Kinsley, Journalist
Ali R. Rezai, MD, Cleveland Clinic
Margaret Giannini, MD, FAAP, Office on Disability, HHS
Steve Phurrough, MD, MPA, Centers for Medicare and Medicaid Services
- 4:20 - 4:30 Closing Comments
Margaret Giannini, MD and Ali R. Rezai, MD





General Information

Location

Health and Human Services Hubert H. Humphrey Building
Great Hall
200 Independence Avenue S.W.
Washington, D.C., 20201

Parking

There are several public parking lots in the area with varying rates as well as metered parking up to 2 hours.

Locations of parking lots/garages open to the public:

- 3rd & E Streets SW
- 4th & C Streets SW
- 6th & C Streets SW

For participants traveling by Metro:

Take the Orange or Blue lines to the Federal Center SW Station. To get from the Metro Station to the Humphrey Building, exit station using main exit. Walk approximately 2 blocks North on 3rd Street SW, turn right on Independence Avenue SW. Walk approximately 1 block East on Independence Avenue SW. The Humphrey Building is across from the Botanical Gardens on Independence Avenue.

Accreditation

The Cleveland Clinic Foundation Center for Continuing Education is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Cleveland Clinic Foundation Center for Continuing Education designates this educational activity for a maximum of 6.75 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity may be submitted for American Osteopathic Association Continuing Medical Education credit in Category 2.

Faculty Disclosure

The Cleveland Clinic Foundation Center for Continuing Education has implemented a policy to comply with the current Accreditation Council for Continuing Medical Education Standards for Commercial Support requiring resolution of all faculty conflicts of interest. Faculty declaring a relevant commercial interest will be identified in the activity syllabus.

Special Needs

The Cleveland Clinic Foundation Center for Continuing Education fully intends to comply with the legal requirements of the Americans with Disabilities Act. If you need assistance, please notify Martha Tobin at 216-445-3449 or tobinm@ccf.org at least two weeks prior to the activity.

Program Support

The Cleveland Clinic Foundation Center for Continuing Education acknowledges educational grants for partial support of this activity from: ANS, a St. Jude Medical Company; Medtronic, Boston Scientific, and IntElect Medical.

Additional Information

For further information, please contact: Martha Tobin, 800-223-2273, ext 53449, or tobinm@ccf.org



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MOP _____	CXL/Fee _____

Tuesday, May 6, 2008
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C., 20201

Registration Form

Please Note: There is no cost to attend this program, but registration is required and space is limited. The deadline for advance registration is Thursday, May 1, 2008. After May 1, please call 216-445-3449 for instructions about registering on site if space is still available.

Name _____ Degree _____

Organization _____

Address _____

Home Business

City / State / Zip Code _____

Telephone _____ Fax _____

E-mail _____ Specialty _____

Two Ways To Register

- 1 Internet: Register online at www.cfcme.org/dbs (deadline is Thursday, May 1, 2008)
- 2 Fax: Fax registration form to 216-445-9406 (deadline is Thursday, May 1, 2008)

<p>Please note: All participants will be required to show a valid picture ID when checking in for the symposium on May 6. Registration will be from 7:30 - 8:15 AM.</p>
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