

Exploring the Adoption of Implantable Brain Stimulation into Standard of Care for Central Nervous System Disorders

A Workshop

Keck Center (Room 100) | 500 Fifth Street, NW, Washington, DC 20001

October 31, 2023, 9:00am - 4:30 pm ET

WORKSHOP OBJECTIVES

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a one-day public workshop that brings together experts and key partners from academia, industry, government, philanthropic foundations, disease-focused non-profit organizations, and individuals with lived experience to examine the role of implantable brain stimulation to treat central nervous system (CNS) disorders. The workshop will explore barriers to adopting implantable brain stimulation into the standard of care across CNS disorders, and potential strategies and collaborations to develop sustainable and scalable utility in the future.

Invited presentations and discussions may:

- Review the current state of knowledge regarding the clinical utilization of implantable brain stimulation across various CNS disorders and consider the future potential to improve quality of life for patients.
- Explore barriers and potential solutions to adopting implantable brain stimulation into standard of care such as: safety and efficacy, scalability, and regulatory support.
- Discuss the ethical and equity implications associated with reimbursement practices, accessibility, and technological distribution.
- Examine opportunities to enhance health professional and patient education to ensure informed access to implantable brain stimulation.

The planning committee will develop the agenda for the workshop, select and invite speakers and discussants, and moderate the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

TUESDAY, OCTOBER 31, 2023 (All times listed in ET)

9:00–9:05am

Welcome

FRANCES JENSEN, University of Pennsylvania; *Co-chair, Forum on Neuroscience and Nervous System Disorders*

JOHN KRYSTAL, Yale University; *Co-chair, Forum on Neuroscience and Nervous System Disorders*

9:05–10:00am

Session 1: Crossing the Chasm – Lessons Learned Across Technologies

Session Objectives:

- Review the current state of knowledge regarding the clinical utilization of implantable brain stimulation across various CNS disorders and consider the future potential to improve quality of life for patients.

- Discuss the lessons learned from other technologies that have or have not “crossed the chasm” to become adopted into clinical care.
- Consider how these lessons learned might be applied to implantable brain stimulation.

9:05–9:15am

Workshop Overview

TIM DENISON, University of Oxford; *Workshop Co-Chair*

HELEN MAYBERG, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*

- Share the scope of the workshop and what will *not* be covered.
- Introduce technology adoption theory as the theme for this workshop.
- Highlight that scalability, technology, co-morbidities considerations, and opportunities to overcome these barriers will be implicit throughout the workshop.

9:15-9:20am

Setting The Stage: Where Do We Want To Be

BRIAN LITT, University of Pennsylvania

- What does it mean to be a part of the standard of care?
- Provide a brief history about cardiac pacemakers and defibrillators.
- What would be required for implantable brain stimulation to be adopted into the standard of care?

9:20-9:45am

Lessons Learned Across Therapeutic Areas

- Provide an overview of the therapy and the patient need that was being addressed.
- Share insights into why the therapy has been or not been adopted into clinical care.
- What are some of the lessons learned that should be considered for any new implantable brain stimulation therapy?

Overview of Approved Neuromodulation Therapies

VIVEK PINTO, Food and Drug Administration

Cochlear implants and retinal implants

CARLA MANN WOODS, Adventus Ventures

Responsive neurostimulation for Epilepsy

MINDY GANGULY, University of Pennsylvania

Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD)

BENJAMIN GREENBERG, Brown University

9:45-10:00am

Moderated Discussion

Moderator: BRIAN LITT, University of Pennsylvania

10:00am-11:05am **Session 2: Benefits and Challenges Experienced by Individuals with Lived Experience**

Session Objectives:

- Explore what patients need from implantable brain stimulation to define it as a successful treatment.
- Discuss how adoption of this technology can impact patients and their quality of life.
- Consider what challenges and barriers prevent patients from selecting this treatment or causes patients to perceive the treatment as a failure.

10:00am-10:05am **Session Overview**
LAURA LUBBERS, CURE Epilepsy

10:05–10:25am **Speaker Remarks**

STEVE AUSTIN, CURE Epilepsy
JIM MCNASBY, The Michael J. Fox Foundation for Parkinson’s Disease
JON NELSON, Jon Nelson Advisors, LLC
CLAUDIA GARRIDO-REVILLA, The Michael J. Fox Foundation for Parkinson’s Disease

10:25-10:55am Moderated Discussion

10:55am-11:05am **BREAK**

11:05–12:10pm **Session 3: Practical Barriers I - Patient Selection and Engagement**

Session Objectives:

- Review the challenges associated with patient selection and engagement; and managing expectations of patients and their families.
- Consider the ethics of ensuring equitable access to all patients and demographics.
- Explore the potential opportunities or collaborations that are needed to develop informed patient selection practices and equitable access to the technology.
- Review the concerns of patients regarding the possible complications and side effects of implantable brain stimulation and potential educational campaigns to increase patient awareness of and comfort with the technology.

11:05–11:10am **Session Overview**
SARAH PERIDES, Evelina London’s Children Hospital

11:10am-12:10pm

Moderated Panel and Audience Q&A

JOSEPH CANDELARIO-MCKEOWN, National Hospital for Neurology and Neurosurgery
RACHEL DAVIS, University of Colorado, Anschutz School of Medicine
NITA FARAHANY, Duke University (*Zoom*)
DORIS WANG, University of California, San Francisco (*Zoom*)
ALIK WIDGE, University of Minnesota

12:10–12:55pm

LUNCH

12:55–2:10pm

Session 4: Practical Barriers II - Health Professional Education & Adoption

Session Objectives:

- Discuss the current barriers to increase training and engagement among health professionals on implantable brain stimulation; and barriers of current practices.
- Explore what relationships might need to be developed across different specialties and clinical practices to facilitate referrals and continuance of care.

12:55–1:00pm

Session Overview

DAVID MCMULLEN, Food and Drug Administration

1:00–2:00pm

Moderated Panel and Audience Q&A

LAUREN HAMMER, University of California San Francisco (*Zoom*)
JOAN MIRAVITE, Icahn School of Medicine at Mount Sinai
MARTHA MORRELL, NeuroPace, Inc
MICHAEL OKUN, University of Florida
YAGNA PATHAK, Abbott

2:00-2:10pm

BREAK

2:10pm-3:25pm

Session 5: Practical Barriers III - Reimbursement and Other Economic Considerations

Session Objectives:

- Consider the current economic barriers and technological limitations that prevent implantable brain stimulation from becoming scalable.
- Discuss what ongoing or future approaches need to be taken to improve the benefit-cost ratio and allow brain stimulation to be scalable for wider application in CNS disorders.
- Review the current status of reimbursement for implantable brain stimulation and discuss opportunities to increase reimbursement.

2:10–2:15pm

Session Overview

YAGNA PATHAK, Abbott

2:15pm-3:15pm

Moderated Panel and Audience Q&A

JULIE BROWN, Spark Biomedical (*Zoom*)

KEVIN MAHONEY, University of Pennsylvania Health System

SUSAN MILLER, Centers for Medicare & Medicaid Services (*Zoom*)

PETER SILBURN, Queensland Brain Institute (*Zoom*)

3:15-3:25pm

BREAK

3:25–4:30pm

Session 6: Synthesis of Workshop Themes

Session Objectives:

- Review the core themes and takeaways shared across the previous sessions.
- Based on previous discussions, explore creative approaches or collaborations needed to move the field forwards towards the end goal of adoption of implantable brain stimulation into the standard of care.
- Discuss the implications of comorbidities and opportunities to develop technologies and treatments to holistically treat patients.

3:25–3:30pm

Session Overview

TIM DENISON, University of Oxford; *Workshop Co-Chair*

HELEN MAYBERG, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*

3:30–4:25pm

Moderated Panel and Audience Q&A

BRANDY ELLIS, Neuromodulation Patient Advocate

LAUREN HAMMER, University of California San Francisco (*Zoom*)

DOUG KELLY, Food and Drug Administration

SARAH HOLLINGSWORTH LISANBY, National Institute of Mental Health

KEVIN MAHONEY, University of Pennsylvania Health System

CHRIS PULLIAM, Case Western University

4:25-4:30pm

Synthesis and Concluding Remarks

TIM DENISON, University of Oxford; *Workshop Co-Chair*

HELEN MAYBERG, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*