Institute of Medicine of the National Academies

Non-Invasive Neuromodulation of the Central Nervous System:

A Workshop

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Session IV: Reimbursement

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Conflict of interest

- TMS-NIRS-fMRI sponsored in part by Neuronetics, NARSAD (Y. Tong)
- Deep TMS Coil for Smoking Cessation and dTMS Coils for OCD and PTSD sponsored by Brainsway
- Patent device: intracranial seizure therapy (ICEST) owned by McLean Hospital, inventor Morales.

America an exceptional country

Founded on values and ideals: self-reliance, liberty, freedom of speech, religion, expression, doing what is right and looking for the well being of others.

A society that embraces health, knowledge, science, education, technology and innovation as a mean to achieve the commonwealth.

A society dedicated to justice and fairness.

1940 ECT introduced to the US
1940-1950: widespread use unmodified ECT
1950-1970: modified ECT. Decline in use
1970: APA Task Force
1976 : Constant current brief pulse sine wave
1985: NIMH consensus on ECT. TMS BARKER
1990: APA Task Force
1993: Hoflich U-Bonn TMS TRD #2 subjects
2001: APA Task Force
2008: FDA approves Neuronetics TMS for MDD
2011: FDA Panel reviews ECT classification
2011: Medicare LCD Massachusetts approves cover
(MA, NY, CT, ME, NH, VT, RI)
2013: FDA approves Brainsway deep TMS for MDD
2015: TMS (Neuronetics, Brainsway) universal cover
Massachusetts (Federal, State, Private).
US population cover by some estimates over 130 million population.

- 2009: McLean Hospital TMS inaugurated
- 2009-2011 Self-pay Service
- 2011-2015 Self-pay, Medicare, gradually insurance companies started covering (current universal cover)

McLean TMS Service Policy

TMS SERVICE CONCEPT

The TMS Service is an integral part of the Psychiatric Neurotherapeutics Program (PNP) at McLean Hospital. TMS Service specializes in neuro-modulation and neuro-stimulation with magnetic fields and technologies for the treatment and study of psychiatric disorders.

The TMS Service is dedicated to treating psychiatric illness using a collaborative, team approach. Our Service seeks to build on the fundamental treatments of psychiatry including psychotherapy, psychiatric medications, and psychosocial programs, by incorporating magnetic neuron-stimulatory treatments. Our program encompasses clinical, educational and research activities.

Our treatment approach in close collaboration with McLean psychotherapy, psychiatric medications and psychosocial programs provide the platform for a unique model of treatments and interventions, maximizing the effectiveness of basic psychiatric treatments with TMS technologies, techniques and interventions.

INDICATORS

· The clinician providing the TMS must document an explanation as to why TMS is prescribed.

· Acceptable indications for TMS include poor response to antidepressant medications and past positive response to TMS. Other possible indications include patient's preference, limited response or tolerance to other treatment modalities

· The provision of maintenance TMS must include documentation that other prophylactic care is inadequately effective

· Indications and exclusionary criteria for TMS are those consistent with FDA-approved TMS devices, in conjunction with clinical judgment and the published evidence base for this treatment modality.

INFORMED CONSENT

The process of informed consent must be documented. The risks, benefits and alternatives to TMS must be discussed with the patient and the consent form must be signed by the patient and by a witness. The consent form must be signed before the start of any TMS treatment and every 20 TMS treatments or six months for continued outpatient TMS treatment.

MEDICAL REVIEW

Required documentation of patient's general health and appropriateness for TMS include a pre-TMS medical evaluation and clearance at McLean Internal Medicine with subsequent review and approval by the physician performing TMS.

· In the event of a significant change in the patient's medical status, a medical assessment by internal medicine or PCP will be requested

CARE OF THE TMS PATIENT

· The designated Director of TMS Service, or his/her designee, is responsible for establishing a schedule on all TMS treatment days that ensures maximum safety and efficiency.

Concurrent/continued use of psychotropic medications (prescribed by the patient's outpatient psychiatrist) during adjunct TMS is determined before TMS treatment. Changes to ongoing pharmacotherapy may be recommended by the psychiatrist prescribing TMS treatments.

Response to seizure, medical emergency, or urgent medical situation occurring during TMS or in the TMS suite should follow the approved McLean Hospital Policies.

Procedures for TMS treatments are listed in the TMS Procedure Manual. Information specifically pertaining to the TMS device is in the Users Manual (binder). Both manuals are located in the TMS Suite.

Prior to each TMS treatment, two sources of identification (e.g., name and date of birth) should be used to confirm appropriate delivery of TMS therapy to the correct patient. A "TIME OUT:" will be taken prior to the start of each treatment

ROLES OF CLINICIANS DELIVERING TMS

Referring Mental Health Professional – a licensed physician/nurse prescriber or therapist who refers a patient to a psychiatrist in the McLean Hospital TMS Service. This person maintains primary responsibility for prescribing medications and/or providing psychotherapy to the patient throughout and after the course of TMS therapy. The referring clinician works collaboratively with the McLean TMS Attending Physician while a patient is undergoing TMS.

TMS Attending Physician – a psychiatrist with established TMS credentials at McLean Hospital who is responsible for safe and appropriate treatment with TMS Therapy. TMS Attending Physician Roles include:

Determining if a patient qualifies for TMS Therapy and documentation of same.

Determination of a patient's motor threshold location, treatment power level, and the treatment parameters to be utilized for a patient's TMS therapy sessions, and documentation of same.

Serial evaluation of the patient at TMS sessions to monitor

TMS Registered Nurse – a trained and qualified individual supervised by the TMS Attending Physician to assist in the delivery of TMS Therapy treatments and trained on use of the TMS device system at McLean Hospital. He/she has knowledge of safety considerations and precautions associated with TMS. Responsibilities include:

Positioning of the patient in the TMS device prior to initiation of treatment by the TMS Attending.

Operation of the software associated with the device.

Monitoring of the patient during the conduct of a recurring TMS treatment session. The TMS Registered Nurse must observe the patient's physical status for the potential occurrence of adverse events throughout the entire TMS treatment session.

Making routine adjustments to the device as required and consistent with product labeling (e.g., to ensure contact between patient's head and treatment coil) during the TMS treatment. The TMS Registered Nurse may not make any revision to pre-determined stimulation dose or treatment coil position parameters prescribed by the TMS Attending Psychiatrist without consultation with him/her.

Determining circumstances under which treatment interruption or treatment termination should be made (e.g., patient expresses urgency to move position) and stopping or pausing treatment as indicated. The TMS Registered Nurse contacts the TMS Attending Physician and provides a clear verbal report of clinical events that

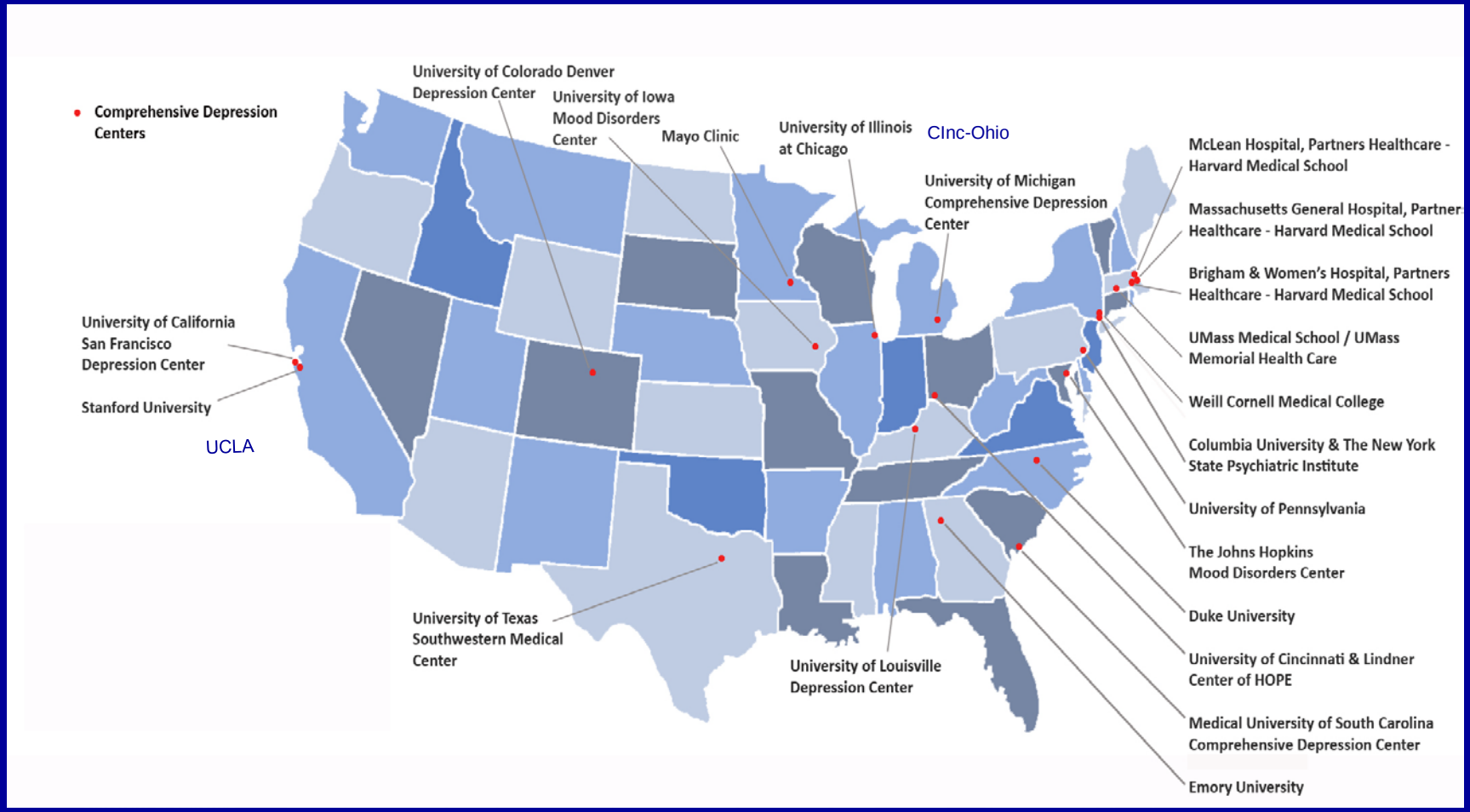
TMS Volume one year to 04, 2015

- Estimated 2400 clinical treatment sessions
- Average monthly 200
- Average weekly 50
- Average daily 10-15
- Devices for Clinical treatments: one NeuroStar, one Brainsway
- TMS Lab: deep TMS device coil for Smoking Cessation multicenter trial (for FDA) and early phases of deep TMS coils research for OCD and PTSD multicenter trials

Clinical outcome measurement

- HAMD
- QIDS-SR 16
- Adverse childhood experience questionnaire
- Work and social adjustment scale
- Self- administered comorbidity questionnaire
- Patient health questionnaire PHQ-9
- Generalized anxiety disorder scale
- Altman self rating mania
- C-SSRS (safety and suicide)
- McLean BASIS-24 Survey

National Network of Depression Centers (NNDC) and its NNDC-TMS committee
Total of # 23 US major academic centers



NNDC by the numbers

- 23 centers of excellence
- > 200 individual members participants and > 20 disciplines
- ~ 20,000 inpatient admissions
- ~ 400,000 outpatient visits
- The nation's leading clinical and research experts in 18 areas including:

  TMS and treatment resistant depression

  Collaborative clinical TMS treatment outcome study and TMS for depression guidelines or treatment recommendations

Reimbursement
in my opinion should consider

- Universal cover and access
- Does Payers reimbursement process foster competition in the industry?
- How does Medicare and private health insurance companies rewards development of evidence, science based TMS practice and treatment?
- How does reimbursement decisions reinforce patient centered care?
- How does a decision nurtures the concept of a patient as a consumer?

RECOMMENDATIONS

Reimbursement based on FDA approval criteria and development of evidence

Standard criteria for reimbursement nation wide

Standardized measurement of clinical outcomes

Measurement of function outcomes

Discuss advantages/disadvantages of a NCD

Guidelines for the practice of TMS by APA-NNDC

Urgency of proper education and training (Medical School, Residency, department of Psychiatry, public

Close interaction providers, payers, industry, regulators, neuroscientists, researchers

Potential for research and combined use of FDA approved technologies (ECT-TMS) for clinical treatments