MHSA Innovation 4 Project
Mobile Transcranial Magnetic Stimulation (TMS)
Re-Posting of Innovation Plan

Los Angeles County Department of Mental Health (LACDMH) proposes to implement an FDA-approved treatment that has become a standard treatment in private practice and in academic centers but has not been used in public mental health settings, mobile Transcranial Magnetic Stimulation (TMS). *It should be noted that TMS is not at all related or similar to Electro-convulsive Treatment (ECT).*

TMS is FDA approved for the treatment of depression and is a non-invasive treatment that can enhance or suppress the activity of neurons in targeted areas of the brain through the use of electromagnetic stimulation. According to the American Psychiatric Association best practice guidelines for the treatment of major depressive disorder, TMS is now a first-line treatment for depression that has not responded to one antidepressant medication (APA 2010) as well as being effective for treatment-resistant depression. In addition, recent clinical studies suggest that TMS can be an effective treatment for a number of other psychiatric disorders, including substance use disorders, schizophrenia, obsessive-compulsive disorder, and post-traumatic stress disorder.

TMS uses precisely targeted magnetic pulses similar to those used in Magnetic Resonance Imaging (MRI) to stimulate key areas of the brain that are underactive in patients with depression. The patient reclines comfortably in the treatment chair and is awake and alert during treatment. An electromagnetic coil is then placed directly to the target area of the brain where the device generates magnetic fields that alter the electrical activity of neurons. The enhancing or suppressing of neuron activity depends upon a number of variables including the frequency of the TMS pulses. During treatment, the patient hears a clicking sound and feels a tapping sensation on the head. The patient can go back to their normal activities immediately after treatment. Treatment can last between 10-45 minutes and is administered once per day for five (5) consecutive days per week for 4-8 weeks.

LACDMH proposes to implement a mobile TMS program for individuals residing in Board and Care (B&C) facilities that suffer from treatment-resistant depression that is not responsive to antidepressant medication or therapy. The ultimate goal of this project is to reduce the burden of symptoms in this population and increase their social and occupational functioning. Treatment refractory depression often results in Board and Care facilities with residents who experience very poor qualities of life, do not progress in their recovery and spend hours each day engaging in unhealthy activities such as smoking. LACDMH estimate serving 384 clients a year across approximately 8 Board and Care facilities.

Innovation Primary Purpose

Overall, the primary purpose of this Innovation project is to improve the quality of mental health services and achieve greater outcomes by providing new and effective treatment to clients with chronic and severe mental illness.

Qualification as an Innovation Project

This project seeks to introduce a new approach or approach that is new to the overall mental health system, including, but not limited to, prevention and early intervention.

The goals of this project include:

- Provide access to new and effective treatment to clients with chronic and severe mental illness
- Increase adherence to treatment by bringing the treatment to the client
- Reduce use of other resources (i.e., psychiatric hospitalization, Emergency Room visits, intensive supportive services, etc.)
- Improve social and occupational functioning that would lead to successful community reintegration
- Collect and analyze data to support treatment efficacy for treatment-resistant depression and other psychiatric conditions in this population

The project would be a 3 year demonstration project.

Target Population

The target population includes individuals residing in board and care facilities that have a depression as a major part of their psychiatric symptoms and ***one or more of the following****:*

- Resistance to treatment with psychopharmacologic agents as evidenced by a lack of a clinically significant response to at least two (2) psychopharmacologic agents in the current depressive episode; or
- Inability to tolerate psychopharmacologic agents as evidenced by two trials of psychopharmacologic agents from two different agent classes; or
- History of response to TMS in a previous depressive episode; or
- A history of response to ECT in a previous or current episode or an inability to tolerate ECT, or is a candidate for, but has declined ECT and TMS is considered a less invasive treatment option.

However, because of the nature of the TMS treatment, we would exclude individuals with a history of seizure disorder and those with metal implants in the head or upper torso (e.g., cardiac pacemakers).

Informed Consent Process

In order to ensure that each patient is freely participating in this treatment, the treating psychiatrist will obtain informed consent from the patient. This will require that the patient understand the nature of the treatment, its potential for benefit, and its potential risks, the treating psychiatrist will obtain informed consent for each patient. The procedure will be described in detail the procedures involved in the treatment including the use of a magnetic coil, the sensations associated with the treatment (tactile, auditory), the approximate duration of each session, the frequency of sessions, the approximate number of sessions and the potential need for maintenance treatments in order to prevent relapse.

Potential risks that will be discussed include the following:

- The potential for a tapping sensation that can be annoying or painful at the site of stimulation (reported by approximately one third of patients and usually improves over course of treatment). The person administering the treatments may make adjustments in order to ensure that the treatment is tolerable for each patient.

- The treatment can also produce contractions of superficial facial or jaw muscles occurring only during the treatment and that do not persist after treatments.
- Headaches may also occur as a result of the treatment (reported in approximately 50% of patients). These usually improve over the course of treatment and can be alleviated by over-the-counter pain medication
- TMS produces a loud clicking sound. Therefore we require patients to wear ear plugs during the treatments. There is no evidence that TMS permanently affects hearing if earplugs are worn.
- A seizure is the most serious risk associated with TMS. The risk of seizures, however, is exceedingly low (<1/30000 treatments).
- There is also a risk that the patient may not improve or may experience worsening mood or anxiety. If these issues arise, they will be addressed by the treating TMS psychiatrist.
- Finally, as with all treatments, there are unforeseeable risks that we do not yet know about or that are not currently recognized. If possible, we will continue to follow the cohort of patients in this project longitudinally in order to further define such as yet unknown risks.

Potential Benefits of TMS that will be discussed:

- TMS has been shown to lead to a remission of depressive symptoms in between 30-68% of patients with treatment refractory depression.
- TMS may also improve symptoms of other psychiatric disorders including PTSD, psychosis, substance use disorders, autism, and eating disorders. However, more studies are needed in order to know how likely TMS is to be effective for these issues

The Unmet Need

Treatment refractory depression (TRD), defined as depression that has not responded to at least one antidepressant medication, affects approximately 4.2 million Americans. According to Los Angeles County Department of Mental Health (LACDMH) records, in the 2016-2017 fiscal year, approximately 42,000 individuals are being treated for major depressive disorder and an additional 23,000 individuals are receiving treatment for other disorders in which depression plays a key role (bipolar disorder and schizoaffective disorder). Based upon the literature, we estimate that at least 35% of these individuals have depressive symptoms that are treatment refractory. Among these individuals, people who reside in B&C facilities have some of the most severe, treatment refractory symptoms which prevent them from living independently. In LACDMH, there were approximately 4000 residents of B&C facilities who were receiving mental health services in 2016-2017. Of these, 24% had a primary diagnosis of major depressive disorder and 29% had primary diagnosis of either bipolar disorder or schizoaffective disorder. These numbers show that there are thousands of individuals within LA County, and especially in B&C facilities, who need for treatments to reduce symptoms that have not been alleviated by medications or therapy alone.

Mobile TMS Implementation Process

The components of this Innovation project are as follows:

1. Purchase TMS device and accessories including modified van that will transport the treatment to contracted board and care facilities in Los Angeles County.

2. A lead psychiatrist will oversee initial TMS treatment sessions and track progress by collecting symptoms and functional outcomes that can, in turn, be used to judge the efficacy of this program.

3. Hire and train staff (Nurse, Psychiatric Technician) to operate equipment.

4. Identify Board and Care facilities with higher numbers of clients who meet criteria listed in *Target Population* above and engage and educate facility operators.

5. Engage Board and Care operators and clients at facilities through talks, videos and, after services start, using peers who have received treatment as engagers as well as the peer staff/community worker position. Once clients have been identified and agree to treatment, they will be seen 1 times per day for 5 consecutive days per week for 4-8 weeks.

6. As clients begin treatment, client satisfaction, and reactions and weekly outcome data will guide use of TMS within each facility.

Evaluating the Efficacy of TMS

A depression outcome measure will be administered at the beginning of treatment and weekly throughout the course of treatment. Measures may include: Quick Inventory of Depressive Symptoms (QIDS-16, patient rated), the Hamilton Depression Rating Scale (HDRS, clinician rated), and a measure for adaptive daily living and quality of life. Additional rating scales may be used to track comorbid symptoms as appropriate. These assessment tools will enable clinicians to track improvements in depressive symptoms and functional outcomes that can, in turn, be used to judge the efficacy of this program.

Overarching Learning Questions

1. Will these individuals be adherent with a mobile TMS treatment program?
2. Is TMS an effective treatment for this population?
3. Does TMS for depression lead to improvement in comorbid symptoms (i.e., substance use, psychotic symptoms, etc.)?
4. If TMS is an effective treatment for this population, should the program be expanded to treat a larger part of the population?

Stakeholder involvement in proposed Innovation Project

LACDMH's stakeholder process meets Welfare and Institutions Code 5848 on composition of the System Leadership Team (SLT) and meaningful involvement of stakeholders related to mental health planning, policy, implementation, monitoring, quality improvement, evaluation and budget allocations. The composition of the System Leadership Team meets California Code of Regulations Section 3300 on stakeholder diversity. Planning for this project began in the spring of 2017, but has been a focus of Dr. Sherin since becoming the Director of the Los Angeles County Department of Mental Health. A proposal was presented to the System Leadership Team on October 18, 2017 with a request for feedback. The feedback received was overwhelmingly positive. Stakeholders expressed an interest in expanding the target population to include other severely mentally ill individuals in other mental health settings than just B&C residents. In response to this feedback, it was explained that one of the goals of the project was

to collect enough data to support an expansion of the target population. Feedback beyond that has been categorized in the following manner:

- Populations of interest:
  - Request to include FSP clients that have been identified as having more severe symptomatology.
  - Individuals who may reside in Institutions of Mental Disease (IMD) who may benefit from TMS treatment.
- Concern regarding painful side effects of the treatment.
- Clarification and differentiation between Electroconvulsive Therapy (ECT) and TMS treatment.
- Consider other funding sources to pay for TMS treatment.

Feedback has been considered and much of it incorporated into the proposal or will be incorporated into the implementation phase of this project.

In addition, we plan to solicit peer involvement by engaging individuals with lived experience in our peer resource center and those who have undergone TMS treatment to assist others that may be contemplating this type of treatment.

The Department's Mental Health Commission Executive Committee was briefed on January 11, 2018, with a formal presentation to the Commission on January 25, 2018. Board Deputy briefings were completed during January 2018.

After an initial presentation to the MHSOAC, the Department chose to add a community worker/peer staff to the TMS team, reflecting a change to the overall budget of the proposed project.

Timeframe of the Project and Project Milestones

Upon approval from the Mental Health Services Oversight and Accountability Commission, the Department will issue a solicitation to identify one or more companies with capacity to immediately initiate the deliverables in this project proposal including retrofitting a Transit Van with TMS medical device and accessories. The projected timeframe is as follows but, due to the innovative nature of this project, actual implementation steps may deviate in terms of sequence and/or timeframes:

- October 27, 2017: 30 Day Public Posting of Proposed Project
- February 22, 2018: Presentation to the MHSOAC
- March 14, 2018: Re-posting of proposal with the addition of a peer staff
- April 26, 2018: Re-presentation to the MHSOAC
- June 2018: Van retrofitting with TMS medical device.
- July-August 2018: Hire and train staff to administer treatment and collect outcome measures. In addition, identify eligible clients at board and care facilities that are willing to participate in TMS treatment.
- July-August 2018: Launch project by beginning treatment and tracking progress weekly.
- FY 2018-2019: Development, testing and implementation of deliverables.
- FY 2019-2020 through FY 2020-2021: Continued use, evaluation and scaling and a final evaluation to the Department.

As with all components of the MHSA, implementation and preliminary outcomes will be reviewed with the LACDMH's SLT periodically and will be reported on in MHSA Annual Updates/MHSA Three Year Program and Expenditure Plans.

Budget

Fiscal Year 2018-19:

Modified Van:	$89,195 (One-time cost)
Magventure TMS (1 device):	$69,433 (One-time cost)
Laptop:	$2,000 (One-time cost)
Van Maintenance Plan:	$6,000
Mental Health Psychiatrist:	$316,775 (Salary and Employee Benefits)
Mental Health Counselor, RN:	$151,234 (Salary and Employee Benefits)
*Clinical Psychologist II:	$133,863 (Salary and Employee Benefits)
Psychiatric Technician II:	$65,322 (Salary and Employee Benefits)
Community Worker:	$53,950 (Salary and Employee Benefits)
Intermediate Typist Clerk:	$51,014 (Salary and Employee Benefits)
Operating Cost for 1 clinical position:	$4,000 (One-time cost)
Total Cost:	**$942,786**

Fiscal Year 2019-20:

Van Maintenance Plan:	$6,000
Mental Health Psychiatrist:	$316,775 (Salary and Employee Benefits)
Mental Health Counselor, RN:	$151,234 (Salary and Employee Benefits)
*Clinical Psychologist II:	$133,863 (Salary and Employee Benefits)
Psychiatric Technician II:	$65,322 (Salary and Employee Benefits)
Community Worker:	$53,950 (Salary and Employee Benefits)
Intermediate Typist Clerk:	$51,014 (Salary and Employee Benefits)
Total Cost:	**$778,158**

Fiscal Year 2020-21:

Van Maintenance Plan:	$6,000
Mental Health Psychiatrist:	$316,775 (Salary and Employee Benefits)
Mental Health Counselor, RN:	$151,234 (Salary and Employee Benefits)
*Clinical Psychologist II:	$133,863 (Salary and Employee Benefits)
Psychiatric Technician II:	$65,322 (Salary and Employee Benefits)
Community Worker:	$53,950 (Salary and Employee Benefits)
Intermediate Typist Clerk:	$51,014 (Salary and Employee Benefits)
Total Cost:	**$778,158**

*** The Psychologist will assume responsibility for the evaluation**

Summary by Fiscal Year:

FY 18-19 Estimated Cost	$942,786
FY 19-20 Estimated Cost	$778,158
FY 20-21 Estimated Cost	$778,158
Total 3 year Project Cost:	**$2,499,102**

Note - *the cost of the evaluation is the cost of the Psychologist conducting it: $401,590*

Budget Narrative:

(1) Mental Health Psychiatrist: The psychiatrist will participate in outreach and education in B&C facilities with staff, providers and potential patients. The psychiatrist will also perform in-person evaluations to determine if a referred patient meets criteria for and may benefit from TMS treatment. The psychiatrist will prescribe and manage the TMS treatments. Initially, the psychiatrist will be on site for treatments. However, the psychiatrist may be off site and manage daily TMS sessions via tele-psychiatry in conjunction with the mental health nurse and psychiatric technician who will always be on site.

(1) Mental Health Counselor, RN: The Mental Health Counselor RN will deliver the daily TMS treatment sessions and perform daily assessments of the patient's symptoms and any side effects that will be communicated to the psychiatrist. They will also administer patient rating scales. This team member will also be trained to provide first-aid and Basic Life Support (BLS) in case of emergency.

(1) Clinical Psychologist II: The Clinical Psychologist will assume responsibility for the evaluation of this project and will establish a database into which rating scales and other clinical data will be entered in order to track patient progress/response to treatment, side effects, and treatment parameters. They will analyze this data which can then be de-identified and used for outcomes measurement reporting. The Clinical Psychologist will also provide outreach and education regarding outcomes of this project to other providers throughout L.A. County and the state of California.

(1) Psychiatric Technician II: The Psychiatric Technician will be driving the mobile TMS unit to treatment sites throughout L.A. County, will assist the Mental Health Counselor, RN with setup of the TMS device for each treatment session, will help administer clinical rating scales and will interface with B&C staff regarding patient progress.

(1) Community Worker: The Community Worker will be someone with lived TMS experience that will outreach and engage potential patients, family members and/or care givers at B&C to orient them to TMS treatment process. They will assist and support the TMS staff in conducting community presentations and disseminate TMS informational materials. Additional duties include, but are not limited to, facilitating relations between the agency and patient; serves as an advocate for patient access to departmental and community resources; acts as interpreter for client population; supports/assists in administering required outcome measures; and may accompany patients to TMS treatment sessions to provide additional support.

(1) Intermediate Typist Clerk: The Intermediate Typist Clerk will provide administrative support to the mobile TMS team. This includes, but is not limited to, securing TMS education presentation locations; preparing educational packets; registering attendees; sending registration confirmations; setting up the audio visual equipment for meetings; provide phone coverage for mobile TMS team; assist in the preparation of TMS related community meetings; responsible for maintaining records and the upkeep for the county TMS van; and serve as backup timekeeper and travel coordinator for the team.

This project will be entirely funded by MHSA Innovation Plan.