

**MHSA Innovation 4 Project  
Mobile Transcranial Magnetic Stimulation (TMS)  
Mid-Year Adjustment to MHSA 3 Year Program and Expenditure Plan  
Fiscal Years 2017-18 through 2019-20**

Los Angeles County Department of Mental Health (LACDMH) proposes to implement Transcranial Magnetic Stimulation (TMS) as a treatment for psychiatric disorders. TMS 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. Currently, TMS is F.D.A. approved for the treatment of depression and, 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 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.

B&C residents are some of the most impaired individuals in the county, with symptoms that are often refractory to treatment with multiple medications. As such, treatment with other, non-pharmacologic modalities is warranted and may be effective. Although we propose to initially focus on B&C residents with treatment refractory depression, these individuals may also have other psychiatric disorders that may respond to TMS. The ultimate goal of this project is to reduce the burden of symptoms in this population and increase their social and occupational functioning. A major barrier to improving the functioning of this population is the combination of a lack of access to the most effective treatments and difficulty with adherence to such treatment when available. The development of a mobile TMS program would both bring a novel, effective treatment to this population and also overcome a major barrier to treatment adherence because the treatment would be brought directly to their place of residence. We plan to purchase and retrofit a large sprinter van that will contain the TMS device, coil holder, coil cooling system, and a TMS chair. It will be equipped with a generator that can power the TMS system as well as an internet link for charting, medical records and telepsychiatry.

TMS has become a standard treatment in private practice and in academic centers across the country. However, this treatment has been unavailable to clients in the Specialty Mental Health system. Therefore, we propose the development of an innovative mobile TMS treatment network that directly brings this treatment to individuals with chronic mental disorders.

The goals of this project include:

- Provide access to new and effective treatment to clients with chronic and severe mental illness
- Increase access and 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.

### **Innovation Primary Purpose**

Overall, the primary purpose of this Innovation project is to increase access to mental health care by providing new and effective treatment to clients with chronic and severe mental illness.

This project will reduce the significant symptom burden of individuals with chronic severe mental illness that continue to suffer in spite of great efforts to treat them with standard care or with more intensive treatment programs. Los Angeles County expends a disproportionate amount of resources on people with severe chronic mental illness who require high levels of mental health care (including recurrent hospitalizations), are unable to care for themselves, and thus live in supervised residential settings such as board and care facilities (B&C). Due to their functional impairments and socio-economic status, these individuals often lack access to the most up-to-date and effective treatments for their mental illness. They also often are unable to adhere to treatments. If available and delivered in a manner that can be adhered to, such treatments may alleviate their symptoms and improve their level of functioning in the community.

### **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 a single trial of 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).

### **Mobile TMS**

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. 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.
5. Administer outcome measures at the beginning and end of each week of treatment. Outcome measures may include the following: 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.

## Qualifications for Innovation Project

<p><b>“Innovative Project”:</b> This is a project that the county designs and implements for a defined time period, and evaluates to develop new best practices in mental health. An Innovative Project meets one of the following criteria:</p>	<p><b>Select One</b></p>
<p>1. <b>Introduces a new approach or approach that is new to the overall mental health system, including, but not limited to, prevention and early intervention.</b></p>	<p>X</p>
<p>2. Makes a change to an existing practice in the field of mental health, including but not limited to, application to a different population</p>	
<p>3. Introduces a new application to the mental health system of a promising practice or approach that has been successful in a non-mental health context</p>	

### The challenge to be addressed by this Innovation Project:

This project seeks to test out a novel approach to the treatment of individuals with chronic severe mental illness specifically those with treatment-resistant depression, delivered by trained personnel.

One of the primary objectives of the Mental Health Services Act is to increase access to mental health services. Los Angeles County Department of Mental Health, through the Mental Health Services Act, has funded outreach and engagement staff, Service Area Navigators, Promotors to outreach and engage individuals with mental health needs into mental health care. However, increasing access to mental health services does not only involve outreach and engagement, but it entails offering individuals access to the most effective and innovative treatments available. This project seeks to expand the range of mental health services offered by the Los Angeles County Department of Mental Health to treat those individuals most in need and that have not been successful in alleviating their symptoms with standard treatment.

This project is a collaboration between the LACDMH and the board and care (B&C) facilities within Los Angeles County. We will create a mobile TMS treatment center that is initially focused on treating residents of B&C with chronic mood disorders (major depressive disorder, bipolar depression, schizoaffective disorder with depression). Several factors led to an initial focus on B&C residents. First, many individuals with serious mental health problems are unable to live independently and thus reside in B&C. These individuals also often have great difficulty with adherence to mental health treatment and ongoing symptoms in spite of great efforts to alleviate them. TMS may be an effective treatment for some of these individuals. Yet currently they lack access to it. This project is therefore aligned with several MHSA Innovative Program goals including enhancing collaboration between agencies (Los Angeles County DMH and B&C programs), increasing access to care, and improving quality of treatment and the outcomes in this vulnerable population.

In addition to treating major depressive disorder, a number of trials have shown TMS to be effective for the treatment of medication resistant depression in bipolar disorder (Dell’Osso et al 2009) which is important because most patients with bipolar disorder spend much more time depressed than in manic episodes. Also of great potential use for the treatment of patients with chronic severe mental illness is the finding the TMS

may be effective for the treatment of schizophrenia (Cole et al. 2015). While more studies are needed, data suggests that TMS can be helpful for reducing debilitating auditory hallucinations and negative symptoms that are part of schizophrenia. Another common comorbidity in chronic mental illness is substance use. Ongoing research suggests that TMS may be used to reduce craving of substances such as cocaine and nicotine (Hanlon et al. 2015). Finally, a number of studies have found TMS to reduce symptoms in post-traumatic stress disorder (PTSD, Karsen et al. 2015).

### **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.

To create meaningful stakeholder involvement, LACDMH convenes a 58 member SLT is composed of individuals representing the following organizations, cultures and interests:

- *LA County Chief Executive Office*
- *Representation from each Service Area Advisory Committee*
- *Consumer and family member representation, including NAMI, self-help and the LA County Client Coalition*
- *Department of Public Social Services*
- *Health Care, including the Hospital Association and LA County Department of Public Health, LA County Department of Health Services*
- *LA Police Department*
- *Probation*
- *Housing development*
- *Older Adult service providers and LA County Community and Senior Services*
- *Under-Represented Ethnic Populations, including Asian Pacific Islanders, American Indian, African American, Latino and Middle Eastern/Eastern European perspectives*
- *Clergy*
- *City of Long Beach*
- *Veterans*
- *LA County Mental Health Commission*

- *Unions*
- *Co-Occurring Joint Action Council*
- *Education, including the LA Unified School District, universities and charter schools*
- *Lesbian, Bisexual, Gay, Transgender and Questioning (LBGTQ)*
- *LA Department of Children and Family Services*
- *LA County Commission on Children and Families*
- *Junior blind*
- *Statewide perspective*
- *Mental health providers, including the Association of Community Human Service Agencies (ACHSA)*

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.

### **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 2017 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:

- Week of October 23, 2017: 30 Day Public Posting of Proposed Project
- January, 2018: Anticipated presentation and approval from the MHSOAC
- February 2018: Van retrofitting with TMS medical device.

- March 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.
- April 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.

### **Proposed Implementation and Dissemination Strategies**

The Los Angeles County Department of Mental Health has conducted preliminary meetings with Board and Care facilities to present TMS and assess the degree of need for this treatment. Based on preliminary findings, there is a genuine interest from providers in implementing TMS with their eligible residents. LACDMH will continue to research and analyze outcomes data (i.e., demographics, diagnoses, patient treatment history, etc.) to identify appropriate candidates for treatment and work with facilities in offering TMS to their residents. In addition, LACDMH will begin systematic outreach to B&C facilities in order to educate residents, staff and treatment providers about TMS. This outreach will disseminate knowledge about this treatment and expand the recruitment of individuals for whom TMS may be an appropriate treatment. Although we will initially focus on B&C residents with treatment refractory depression, these patients also may have other psychiatric disorders that may respond to TMS. Patients taking medications will not be excluded; however, because of the nature of the TMS treatment, we will exclude patients with metal implants in the head or upper torso (e.g., cardiac pacemakers). Eventually, we hope that the outcomes collected for this project will support the expansion of the target population to include eligible individuals outside of B&C facilities (e.g., LACDMH operated facilities) that are suffering and would benefit from TMS treatment.

The mobile TMS project will be overseen by a lead psychiatrist that will be providing outreach, engagement and education to B&C facilities, and eventually, to other contracted and directly operated facilities throughout the county that provide mental health services to seriously mentally ill individuals. Outreach and engagement may consist of, but is not limited to, in-person presentations, webinars, and other forms of social media. The lead psychiatrist will manage LACDMH staff comprised of a Mental health Counselor, RN; Clinical Psychologist II; and a Psychiatric Technician that will assist in the roll-out of this project, including:

- Develop and distribute informational brochures, flyers, and other handouts relating to TMS treatment.
- Establish specific protocol for TMS treatment administration and follow-up.
- Provide assistance in engaging potential patients at B&C facilities that would benefit from TMS treatment.
- Transport TMS equipment to facilities and assist in administering treatment.

- Track and monitor patient progress weekly by use of outcome measures.
- Analyze and report on aggregate outcome measure data.
- Prepare and distribute outcome measures findings on a quarterly basis and share internally within the Department and County.

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.

Within Los Angeles County a steering committee would be formed consisting of interested stakeholders and key LACDMH staff that would review progress, available data and inform implementation. If new target populations are identified based on the data collected, mid-course implementation shifts will be made accordingly.

LACDMH will actively participate in Mental Health Services Oversight and Accountability Commission sponsored Innovation Summits and resulting forums for cross-county learning and support related to the use of TMS in the mental health system.

### **Overall Approach to Evaluation**

This project will be evaluated by using weekly symptom and functional based outcome measures to track treatment progress. Specific outcomes include:

1. Reduction in depressive symptoms.
2. Increased social and occupational functioning.
3. Increased adherence to treatment.
4. For high utilizers of inpatient or emergency services, decreases in utilization for those services.
5. Increased wellbeing as evidenced by increased social connectedness, and engaging in meaningful activities.

### **Disseminating Successful Learning**

The Department will responsibly and appropriately share the findings of this project with providers and the larger community. Findings related to effective implementation of TMS treatment, establishment of best practices, barriers to implementation, the utility of program expansion will be discussed with the mental health community so that this program, if successful, may be expanded within Los Angeles County and in other counties and states. Data will be aggregated and shared internally within the Department and County; and externally throughout California via in-person facilitation/workshops, webinars, and educational materials that will educate individuals about TMS and best practices for action planning and further implementation. Within the Department/County LACDMH will provide regular reports to Service Area Advisory Committees (SAACs), the System Leadership Team or through other broader countywide opportunities. Outcome data reports will be available for distribution on a quarterly basis, and may include the following data elements: number of clients served,



demographic information, diagnoses, Pre/Post scores and percent change for depression, adaptive daily living and quality of life scales.

Impact, reach, implementation status and outcomes will be documented in Annual Updates and MHSA 3 Year Program and Expenditure Plans. In addition, LACDMH will seek to present the project and its outcomes throughout the project at statewide conferences, meetings and perhaps at relevant national conferences. LACDMH will also seek to partner with other counties who may be engaging in similar work, through venues such as the County Behavioral Health Directors' Association (CBHDA). Finally, there may be opportunity to partner on articles submitted to peer-reviewed journals.

### **Sustainability**

Analytics associated with mobile TMS, coupled with a comprehensive evaluation, will inform actions taken by the Department at the conclusion of the third year of the project. Factors to be taken into account will include user satisfaction and outcomes, advances in TMS at the conclusion of the project and the overall effectiveness of this treatment for specific populations. At the conclusion of the third year, DMH will explore continuing deemed services by maintaining operating staff through the MHSA Community and Service Supports (CSS) plan.

### **Estimated Annual Innovation Budget:**

<b>FY 17-18 Estimated Cost (Effective January 1, 2018 thru June 30, 2018):</b>	<b>\$552,240</b>
<b>FY 18-19 Estimated Cost (July 1, 2018 thru June 30, 2019):</b>	<b>\$724,208</b>
<b>FY 19-20 Estimated Cost (July 1, 2019 thru June 30, 2020):</b>	<b>\$724,208</b>
<b>FY 20-21 Estimated Cost (July 1, 2020 thru December 30, 2020):</b>	<b><u>\$387,612</u></b>

**Total 3 year Project Cost: \$2,388,268**

### **Budget Narrative:**

1 Mental Health Psychiatrist, 1 Mental Health Counselor, RN, 1 Clinical Psychologist II, 1 Psychiatric Technician II, and 1 Intermediate Typist Clerk are funded through MHSA Innovation to conduct assessments, transport and administer treatment, take vitals, collect outcome measures, and track and monitor patient progress weekly.