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## Implementation of a Guideline for Major Depressive Disorder in a Private Practice Clinic

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IMPLEMENTATION OF A GUIDELINE FOR MAJOR DEPRESSIVE DISORDER  
IN A PRIVATE PRACTICE CLINIC

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Doreen Phillips

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### **Abstract**

Major depressive disorder (MDD) is a chief mental health illness that carries a profound economic burden. Many who suffer from MDD find little to no relief with traditional pharmacological interventions. The 2010 American Psychiatric Association Guidelines for Treatment of Patients with MDD recognized TMS as a second-line treatment choice. Several double-blind, randomized controlled trials illustrated the efficacy and safety of TMS as a viable treatment option for MDD. The purpose of this project was to implement standardized processes through the use of a treatment guideline to help provide comprehensive treatment options for patients suffering from moderate to severe major depressive disorder (MDD). Secondary aims involved staff training on the subjective and objective components of the patient health questionnaire (PHQ-9), along with the incorporation of collateral information in determining the severity rating of depression. The final project goal was centered on patient and staff education of transcranial magnetic stimulation (TMS) as a second-line treatment option for MDD. The Plan-Do-Study-Act cycle was used to improve clinical staff knowledge on the appropriate use of clinical observations combined with collateral inputs in the scoring of the PHQ-9 scores. The number of patients diagnosed with MDD totaled 185: only 90 (48.6%) qualified for TMS. A remarkable increase in patient interest in TMS was realized after patient education was conducted, as shown by a 32.2% increase from the pre-intervention number of 3 (3.3%). The outcomes suggest standardized treatment guidelines improved patient education on alternative treatment choices. The project illustrates the importance of using guidelines to help foster equitable care.

*Keywords:* Transcranial magnetic stimulation, depression, guidelines, screenings

## **Implementation of a Guideline for Transcranial Magnetic Stimulation in a Private Practice Clinic**

Depression is the leading cause of disability worldwide, accounting for an estimated 322 million people (World Health Organization, 2017). MDD is a global issue, within the United States, it affects 17.3 million people; women make up the majority (8.6% ) of the total population compared to men (5.3%), according to the National Institute of Health (NIH, 2017). A significant percentage of MDD patients go untreated from their symptoms, creating a healthcare dilemma. Depression is viewed as a causal risk factor for heart disease (Dhar & Barton, 2016). Those who suffer from depression increase their risk of coronary artery disease by 64% (NIH, 2017). There are many economic burdens from MDD as well. MDD accounted for 210.5 billion dollars of expenditures in 2010, of which 50% was directed to workplace cost, 45% direct cost, and 5% suicide-related cost (Greenberg et al., 2015). The rise in suicide rates is most concerning, considering it is estimated that 60% of suicides are linked to people who have an MDD diagnosis (Ng et al., 2017).

### **Screening Tools**

Screening tools such as the Patient Health Questionnaire-9 (PHQ-9) are used to help diagnose, evaluate, and treat patients suffering from depression. In the case of treatment resistant MDD, there is a lack of robust tools to help providers screen and offer more effective treatment options (Kerr & Kerr, 2010). Many tools do not account for cultural factors or racial and gender prejudices. The growing Spanish speaking population in the United States can be negatively impacted by the limited predictive power and validity when tools such as the Beck Depression Inventory are translated (Kerr & Kerr, 2010). According to U. S. Preventive Services Task Force (2016), there is a need for more favorable screening approaches for older adults that should

include protocols for positive screens that focus on evidence-based treatments (USPSTF, 2016).

These shortcomings can result in inaccurate diagnoses and severity ratings.

### **Transcranial Magnetic Stimulation**

Transcranial magnetic stimulation (TMS) is being heralded as a nonpharmacological breakthrough for treatment resistant MDD. The U.S. Food & Drug Administration approved TMS treatment for MDD in 2008 then expanded it to the treatment of pain caused by migraines in 2013. In 2018, obsessive-compulsive disorder was added validating TMS's effectiveness (U.S. Food & Drug Administration, 2018). TMS stimulates the brains' nerve cells with the use of a magnetic field, which creates electrical impulses in the left prefrontal cortex. Studies continue to show that a lack of perfusion in the prefrontal cortex region can lead to depression (Kaya & McCabe, 2019). Clinical trials have shown an improvement in the symptoms of people who suffer from drug resistant MDD when treated with TMS (Yesavage et al., 2018). Evidence-based findings within studies have shown patients that suffer from MDD have an opportunity to reduce the number of drugs used to manage symptoms along with decreasing the dosage amounts thereby reducing side effects from antidepressant (Tavares et al., 2017). The startup cost for providing TMS services are high, but the reimbursement rates are equally high, helping to alleviate the initial investment. The average medicare reimbursement are \$206 per session for a total of 30 to 36 sessions; commercial plans pay up to an estimated \$600 (Voigt et al., 2017). Practical tools are needed to ensure economies of scale can be realized to encourage providers to offer or refer patients for TMS treatments.

### **Statement of the Problem**

This quality improvement project focused on the implementation of a treatment guideline for MDD patients in a private mental health clinic situated in a large, culturally diverse



metropolis. The population included patients 18 years and older on a commercial or managed care insurance plan. The individually owned private practices recently leased a Brainsway dTMS machine to administer TMS to its MDD patient population. It was determined that the APA MDD treatment guideline was not being used with patients. Patients were not being made aware of alternative treatment options after multiple drug failures or side effects. Current patients were not accurately assigned severity ratings, which impacted their eligibility for alternative treatments. A review of the evidence suggests the use of the PHQ-9, provides insight into the efficacy of alternative treatments similar to TMS, through continuously documented screenings (Perera et al., 2016). The practice embedded the PHQ-9 in their electronic healthcare record (EHR) along with a TMS questionnaire. The practice had three patients undergo alternative treatments (TMS), even though appropriately 80% of their patient population suffers from MDD. The marketing of the TMS treatment offering was limited to email blasts to patients. The practice was not able to increase the use of TMS treatment for over 3 months.

### **Clinic Assessment**

The private mental health practice has been going through rapid expansion and changes in the last year. They recently moved from the second floor of a six-story building to the third floor and now have nine assessment rooms, a TMS treatment room, two auxiliary rooms, a therapy, conference, office manager, and provider office. The new waiting room has sitting that can comfortably accommodate 10 patients, and the staff has a spacious breakroom with bar and stools. There is ample parking for patients and free covered parking. The practice is in proximity to three major highways with restaurants and commercial buildings within half a mile. The practice serves the needs of minority groups and offers culturally based care with providers that speak two different languages (Spanish and Mandarin).

The owner who is the primary provider serves as a catalyst for innovative and progressive change in how mental health is managed. She expressed her eagerness to implement a guideline that would provide her patients with better treatment options while growing her practice. The office manager is the facilitator for TMS treatment and has been certified to conduct all patient sessions as the TMS operator. She has a master's in business administration and oversees all nurse practitioners, students, and administrative staff.

The clinic recently received approval to offer dTMS and has not established a process to prescreen existing and new patients. The clinic has been marketing the new service offering in hopes of generating interest in TMS by mailing brochures to current patients, and they are also listed in the online Brainsway directory. The office manager and provider were eager for assistance and feedback on how to successfully screen and leverage their existing EHR. The owner identified the need to implement a guideline for TMS during an initial information session and stated they were in the process of recruiting suitable patients for treatment. The practice employs four nurse practitioners to conduct patient assessments. During the assessment and follow up visits, there are very few patients that are identified and screened for further evaluation for TMS even though they have a diagnosis of MDD.

### **Project Identification**

The purpose of this project is to educate staff on using screening tools to determine severity ratings, increase patient awareness of treatment options, and increase the number of patients receiving alternative treatments for better health outcomes. Secondary aims are to use the existing EHR as an analytic tool for sustainable screening and treatment management. The overall goal is to provide patient-centered care and enable the provider to achieve an economy of scale with their investment in the Brainsway TMS technology.

## **Objectives**

The objectives of this study were twofold:

1. Implement a guideline tool for patients (18 years and older) who are diagnosed with MDD. The guideline will be embedded in the existing EHR to allow for standardization and audit controls.
  - a. Train all providers on APA Treatment Guideline
  - b. Provide patient education on treatment options for MDD highlighting TMS
2. Secondary to implementing the core objective is to train staff on rating the severity for MDD.

## **Anticipated Aims**

By executing the objectives as mentioned above, the practice would possess a sustainable guideline that helps them provide patient-centered care, thereby increasing alternative treatment choices. The aims of this project align with the Agency for Healthcare Research and Quality Strategic Plan to improve quality care to Americans through evidence-based practices (2016). The clinical practice will be able to reach break-even on the financial expenditures on the Brainsway treatment and reduce the economic burden of MDD by: (a) maintaining 95% accuracy in the severity rating of MDD patients, (b) increasing the number of patients applying for alternative treatments to 45% by the third quarter, and (c) educating 100% of providers on severity rating along with TMS criteria.

## **Summary and Strength of the Evidence**

The systematic review of literature was used to search for the topics of treatment resistant MDD, TMS, depression screening and guidelines. Databases used for the search included PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL),

Cochrane Library, and Google Scholar. The searches produced 320 articles and studies in academic journals. Inclusion and exclusion criteria centered on the date of publication, relevancy, peer review, study population age, diagnosis, and first-line drug failure. Exclusion criteria were studies that included adolescent, dual diagnosis, or other psychiatric disorders such as obsessive-compulsive disorder. The literature review identified significant findings on second-line treatment options and gaps in practice that may be hindering positive outcomes. The framing of the project was made based on the findings.

### **Safety and Efficacy**

The efficacy of TMS for MDD has been proven through several studies that suggest the magnetic stimulation enhances the neurocognition (Kavanaugh et al., 2018). The site of action is the left prefrontal cortex. The American Psychiatric Association (2010) lists TMS as a second-line treatment option. Electroconvulsive therapy has been used in mental health since the 1970s, compared to TMS, which received approval in 2008 (APA, 2010). Comparisons of the two nonpharmacological alternatives for treatment resistant MDD show that TMS has fewer side effects.

In a double-blind sham-controlled randomized trial (RCT) of 164 veterans, 39% experienced clinically significant improvement in depression symptoms when they received rTMS (Yesavage et al., 2018). Another RCT double-blind study with 43 participants showed the efficacy of TMS in MDD patients who failed to receive relief from their symptoms by other methods. The results revealed a 48% response in the TMS patients compared to 24% of the sham participants (Taveres et al., 2017).

### **Comorbidities**

Chronic conditions among patients diagnosed with depression are estimated to be 81.7% (Dogu & Aydemir, 2018). Depression was found to predispose individuals to adverse health outcomes. An estimated 8% of depressed patients were known to have developed comorbidities, namely cardiac (Akincigil & Matthews, 2017). Viable treatment options can have a significant effect on health outcomes among cardiac patients (O'Neil et al., 2011). Studies have indicated improved outcomes for cardiac patients when depression has been addressed. A cross-sectional study of  $N = 301$  patients found that depression was a common comorbidity among chronically ill patients, which lead to poor health outcomes if not addressed (Dogu & Aydemir, 2018).

### **Financial Implication**

The economic burden of depression continues to rise within the United States and worldwide. Europe has experienced a 4% increase in depression rates from the previous year after contributing over €113.4 billion to address the disorder (Fernandez et al., 2018). Approximately 6%-7% of U.S. workers experience MDD, a majority of which are women (Greenberg et al., 2015). Disability and Family Medical Leave ACT claims account for a large portion of the estimated 10.2 million people who experience severe impairment from MDD (Colorafi et al., 2017). Expenditures over the last 5 years have accounted for a 21.5% increase, leading to a significant strain on families, businesses, and government bodies (Greenberg et al., 2015). Studies have shown that even undiagnosed individuals suffering from depression are less productive, which accounts for a loss of \$233 billion per year (Williams et al., 2017).

### **Depression Screening**

Rating depression is an intricate art that requires input from multiple factors such as patient input, collateral, and questionnaires (National Collaborating Centre for Mental Health,

2010). Diagnoses typically focus on dimensions of severity (a PHQ-9 score) compared to categorical decisions that factor in clinical observation, patient input, and collateral data (Gautam et al., 2017). A history must be obtained from all sources, especially family. The latter incorporates symptomatology, course, and social impairment along with the duration. Symptomatology, as a sole measure for severity, has negative implications, namely the treatment choice. The choice of treatment is another complicated process that should involve patient input. EHR are useful tools in improving the disparities in depression screening and can be utilized to help incorporate the complexities inherent in the diagnosis and treatment of MDD (Akincigil & Matthews, 2017). EHR can provide insight into data collected through screenings helping providers synthesize key information from multiple sources.

### **Clinical Practice Guidelines**

The Department of Veterans Affairs and the Department of Defense developed the 2016 guideline for the management of MDD based on a systematic review of clinical and epidemiological evidence from multidisciplinary experts. The target audience included adult veterans and active duty service members. The literature review of interventions included studies from 2007 to 2015 focused on best practices that were patient centered. The findings from three meta-analyses that compared rTMS to sham treatment in patients found that 25% of the patients responded positively to the TMS treatments and achieved 17% remission. Conclusions from the studies illustrate the benefit of rTMS outweigh the low risks and side effects and lead to its recommendation for treatment resistance MDD after multiple drug failures.

The 2010 APA Guideline for the Treatment of Depression recommends TMS as a second-line treatment for patients with treatment resistant MDD who have failed first-line treatment and are in an acute phase. Their findings were based on meta-analyses that supported

high-frequency TMS over ECT. TMS was preferred due to its safety profile and tolerability over electroconvulsive therapy.

Kaiser Permanente Care Management Institute 2012 Guideline cited Kauffmann's (2004) double-blind placebo-controlled study results, which saw a decrease in the depression screening result of TMS patients from 21.86 to 11.29 ( $p < .02$ ), after 10 days. A double-blind placebo-controlled study by Rumi (2005) found that TMS accelerated the effects of antidepressants and had an overall higher response rate of 95% compared to 46% in the sham group. The second-line treatment of MDD was listed in the KP Care guideline, but samples for the study's references were below 25, limiting the strength of the study results (National Clinical Practice Guideline, 2012).

The National Institute for Health and Care Excellence (2015) list TMS as a specialized second-line therapy for non-psychotic MDD in the Adult Depression in Primary Care Guideline, citing its tolerability and safety as a benefit over ECT. New studies have improved methodological limitations. An intention-to-treat sample of 190 patients shows a higher remittance rate among the rTMS patients, 14.1% compared to the sham 5.1%. O'Reardon's large multicentered randomized controlled trial of rTMS (301 patients) showed a remission rate of 14.2% versus the sham of 5.2% (Institute for Clinical Systems Improvement, 2013).

Royal Australian and New Zealand College of Psychiatrist's clinical practice guidelines for mood disorders mentioned TMS being used in clinical practices in Australia with indication of its future use as a maintenance treatment. They found the efficacy of TMS to be similar to that of ECT without the risk of cognitive side effects. The studies used focus on patients who have failed two or more antidepressants. Based on studies by Schutter (2014) conclusions reach state

rTMS should be considered after one or more failed trails and is preferred before using ECT due to the more favorable side effect profile.

## **Methods**

### **Screening Tools**

A gap analysis was utilized to identify the current state of events at the practice and to identify gaps in practice that were hindering progress and formulate a solution for reaching key goals. The low utilization of TMS treatment was identified as a critical event, and the providers' goal of increasing usage was targeted as a critical aim. The gaps in practice were identified as lack of patient knowledge in treatment choice and lack of providers continuing education in rating the severity of MDD. Education and practice guideline implementation were marked as critical bridges to close the practice gaps.

The Model for Improvement Plan Do Study Act was incorporated into screening MDD patients for medication failures and chart audits on severity ratings. Key actions included updating diagnosis severity ratings based on collateral and clinical observation and implementing the APA treatment guideline. The dashboard was used to track changes and study the effects of the intervention. At the same time, continuing education was incorporated as a corrective measure to metrics that were not being met on the dashboard.

A systemic review was done on the cost-effect analysis of screening tools and found many tools lacked treatment pathways, which is a critical component for something that is viewed as the cornerstone in preventive care (Iragorri & Spackman, 2018). Based on study results, the PHQ-2 is best for routine and annual checks where the PHQ9 is best used to gauge severity and diagnosis (Ebel, 2008). Current validated depression screening tools that are recommended for use do not factor in treatment options. The U.S. Preventive Services Task



Force (2016) recommends screening for depression that will ensure effective treatment.

Education is paramount in the shared decision-making model, which helps ensure that patients are engaged throughout the process.

### **Project Intervention and Implementation Process**

The project was carried out in three phases beginning with the implementation of a standardized guideline for TMS treatment criteria. The APA guideline (Appendix A) was adopted based on the ease of use, the strength of evidence and, endorsement as a second-line treatment. The second phase involved educating all nurse practitioners and students on how to rate the severity of MDD by using the PHQ-9. The PHQ-9 is not a diagnostic tool but can facilitate in diagnosis and the rating of the severity of MDD when combined with clinical observation and collateral information. The final phase consisted of chart audits that ensured every MDD patient had an appropriate diagnosis assigned with the correct severity. Descriptive statistics in the form of central tendency were used to evaluate the outcomes. Attendance logs for in-services were evaluated by the investigator (Student). Patient chart audits were evaluated by the practice owner and investigator to track the effectiveness of the treatment guideline.

### **Ethical Considerations**

The project proposal was sent to the University of the Incarnate Word Institutional Review Board and approved. The project was found to be a quality improvement project and cleared for implementation since the project did not meet the regulatory definition of research with human subjects. All patient information was kept strictly confidential while adhering to the Health Information Portability and Accountability Act privacy laws during data collection.

## Results

The project was carried out over 12 weeks. Retrospective chart reviews were conducted between January and June of 2020. In the month before implementation, the TMS application rate was 3%. A total of 185 MDD candidates were contacted and educated on TMS as a treatment choice. The top indicators for TMS were identified as multiple drug failures (65%) and side effects (35%). The clinic patient demographics (Appendix B) included European American (32%) Asian (26%) Hispanic (22%), followed by African American (20%).

The number of patients who were diagnosed with MDD totaled 185; only 90 (48.6%) of them qualified for TMS. A remarkable increase in patient interest in TMS was realized after patient education was conducted, as shown by 32 (35.5%) patients applying for treatment post-intervention, which resulted in a 32.2.% increase overall from the pre-intervention number of 3 (3.3%). Some patients were indecisive about TMS treatment while others cited work, distance, and the number of treatments needed as determining factors.

The objective of implementing a guideline for MDD was met with 100% adherence by clinical staff. Every provider attended a brief educational virtual meeting on the use and purpose of the MDD guideline. The Socratic method was used to review case studies to determine how to assign severity ratings based on PHQ-9 criteria appropriately. The process incorporated clinical observation and collateral information. Based on post-intervention audits, which were checked by the practicing medical doctor and owner, the education was successful. Attendance and discrepancy were tracked, and monthly rates were tallied on a scoreboard (Appendix C). The finale objective of increasing alternative treatment by 45% was not met. Treatments for TMS were suspended in March due to the Coronavirus (COVID-19) pandemic. The objective of increasing TMS treatment was substituted with applying for TMS treatments and was measured

by the number of patients who applied for TMS treatments. Positive unattended consequences included an increase in patients 37 (20%) requesting psychotherapy.

### **Discussion**

The secondary objective of achieving a 45% increase in patients receiving alternative treatments was not met, but the project objectives highlighted the importance of patient education. Patient-centered care was an underlying theme of the project, and it facilitated shared decision making. Patients were presented with treatment options and were educated on guidelines for the treatment of MDD. The ultimate choice of how to treat MDD was given to the patient. The dialogue between provider and patient allowed for a deeper understanding of the patients' values and treatment preferences.

Provider education on the importance of collateral information made providers more aware of the importance of incorporating subjective history. Careful consideration of biases was addressed by stressing the use of collateral information only when it supported the patient's history and or clinical observation. Providers noted a need to elaborate on what 2 weeks consisted of (14 days) for patients, along with the need to review scores to ensure accuracy. Providers noted improvement in severity ratings after attending the education session.

### **Limitations**

The primary limitations arose from the COVID 19 pandemic that gripped the world during the Spring of 2020. The state of Texas implemented stay at home orders, and only essential workers were permitted to travel, putting a halt to all in-office visits. An increase in cases involving anxiety and depression may have been a direct result of COVID 19, which may have also had an impact on the increase of psychotherapy requests. TMS services were not permitted, and the project objective changed to tracking patients that expressed an interest in

TMS and wanted to submit paperwork for insurance approval. The patient distance from the providers' office may have been a determinant in low interest in conjunction with the frequency of treatment 3 to 4 times a week for 2 to 3 months. A majority of patients (95%) were seen through telehealth services limiting the providers' ability to view clinical observation such as psychomotor agitation or retardation. Many patients raised concerns about the distance and the challenges of coming to the main practice office for multiple TMS sessions for 2 to 3 months.

Once the COVID-19 stay at home orders are removed, the clinics should track the number of patients that undergo TMS and other alternative treatments. Chart audits should continue to be done to ensure consistency among providers. Annual training for providers should be implemented to ensure best practices in diagnosing and treating patients. Guidelines serve as an excellent measure for standards of practice and can also provide insight into gaps in practice.

### **Implication for Practice**

This quality improvement project illustrated the importance of educating patients on treatment options and using treatment guidelines to increase positive patient outcomes. National guidelines for alternative treatments would be instrumental in providing MDD patients with effective relief from their depressive symptoms. Providers should be employing tools and harnessing the capabilities of EHRs to provide value-based care that is patient-centered. There is a need for more quality improvement projects focused on the use of guidelines to evaluate the impact guidelines have on healthcare outcomes. The philosophical inquire into how guidelines can help bring about positive outcomes is fundamental to the Doctor of Nursing practice essential competencies. This project was centered on population outcomes for MDD patients and emphasized the importance of conducting an organizational assessment within a practice to help facilitate organizational change.

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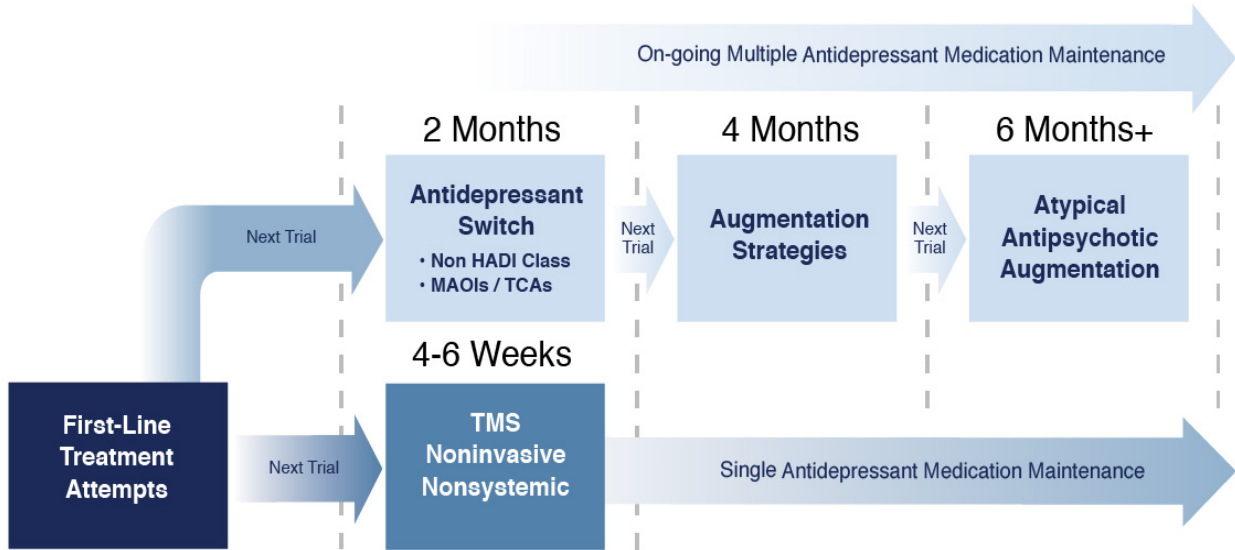
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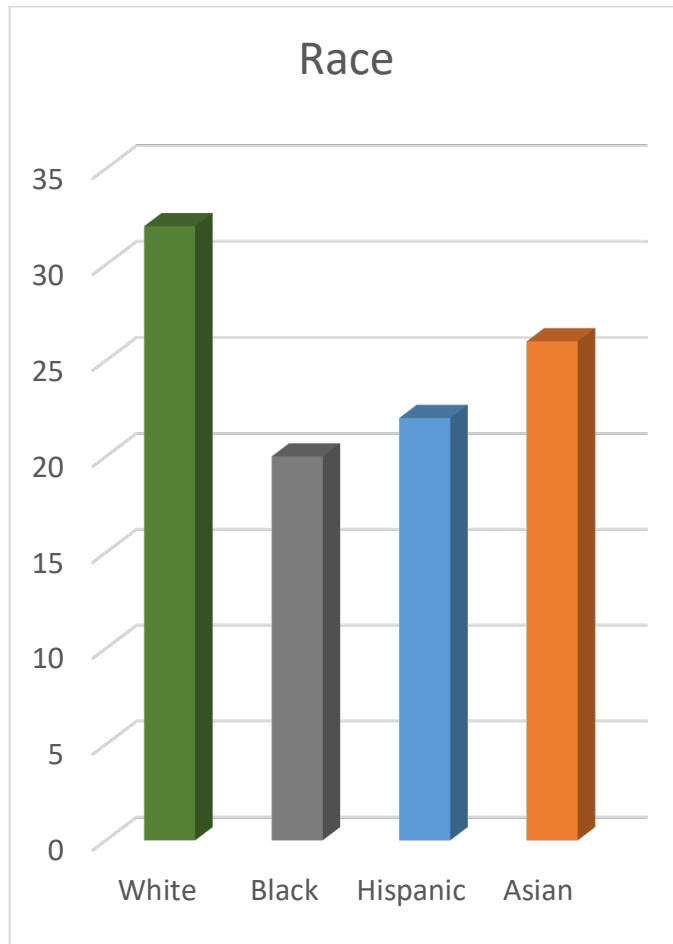
Appendix A

APA Treatment Guideline for Depression

**Best Practices Treatment Guideline for Depression**  
Based on 2010 APA guidelines and NeuroStar TMS Therapy® indication for use



**Appendix B**  
**Demographics**



**Appendix C**

**Scoreboard**

<b>Goal</b>	<b>Target</b>	<b>Owner</b>	<b>Review Frequency</b>	<b>Jan-20</b>	<b>May-20</b>	<b>June-20</b>	<b>July-20</b>
Provider Education on Dx Tools, DSM-V & PHQ-9	100%	Practice Owner	Quarterly	60%	90%	100%	100%
Patient Screenings for TMS	100%	Facilitator	Daily	20%	85%	98%	100%
Accurate Dx with a severity rating	95%	Practice Owner	Weekly	70%	85%	93%	95%
Application for TMS	45%	Office Manager	Weekly	3%	14%	28%	32%

**Appendix D**

**Letter of Support**

UNIVERSITY OF THE

INCARNATE WORD

ILA FAYE MILLER SCHOOL OF NURSING AND

HEALTH PROFESSIONS

The Doctor of Nursing Practice Student and I met today to discuss issues of confidentiality about the patient medical record and the policies and procedures in place in this clinical facility. The student is aware of and agrees to follow any patient information privacy policies and procedures of the school and this clinical agency. The student has had the opportunity to ask questions about the agency and the school's privacy policies, procedures, and practices. The student agrees to keep confidential any information about patients and to share such information only with authorized school or agency personnel. I will assist the student in obtaining any data in compliance with HIPAA regulations.

Sincerely,

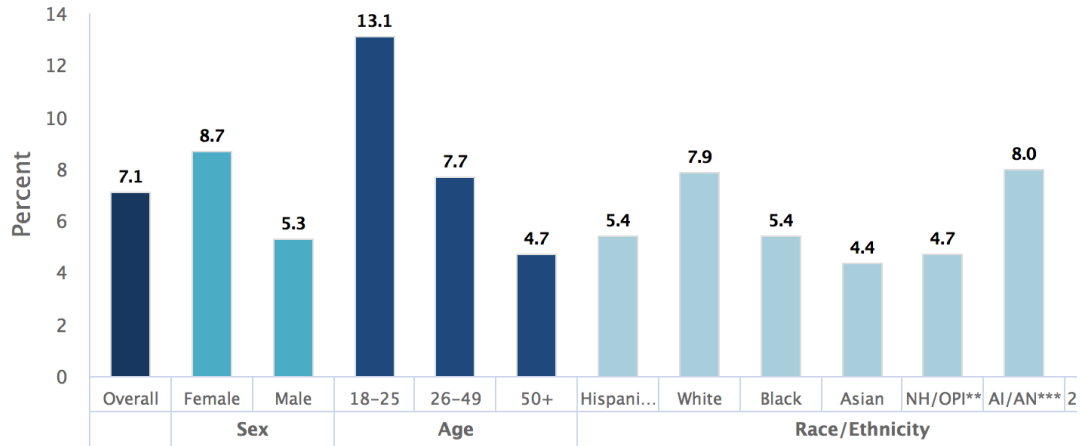
Dr. Xu

**Appendix E**

**Prevalence of MDD**

Past Year Prevalence of Major Depressive Episode Among U.S. Adults (2017)

Data Courtesy of SAMHSA



**Appendix F**

**TMS Pre- & Post-Implementation**

