

# The Clinical Application of Transcranial Magnetic Stimulation

Todd M. Hutton, MD, FAPA

## ABSTRACT

Transcranial magnetic stimulation (TMS) provides psychiatrists with a new treatment offering in clinical practice. Providing an office-based procedure is new for psychiatrists, and incorporating this procedure into practice has brought new challenges. The clinical delivery of TMS has various possibilities for office operations, management, and overall structure. Different clinical models and providers include traditional private practices, device partnerships, networked practices, institutions, and dedicated TMS centers. Practical considerations of using TMS, such as office set-up, training, staffing, and safety considerations are reviewed. More insurance plans are now covering TMS, but usually only after failure of multiple antidepressant medications. Criteria vary, but they play a large role in shaping the practice. TMS treatments can be clinically categorized as acute, tapering, booster, or maintenance treatments, depending on when they are being delivered.

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*Todd M. Hutton, MD, FAPA, is Associate Clinical Professor of Psychiatry, USC Keck School of Medicine; and Medical Director, Southern California TMS Center.*

*Address correspondence to: Todd M. Hutton, MD, FAPA, 180 S. Lake Avenue, Suite 615, Pasadena, CA 91101; email: todd@socaltms.com.*

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Figure 1. Neuronetics' NeuroStar TMS Therapy system, which uses a highly focused, pulsed magnetic field to stimulate function in targeted brain regions.

Transcranial magnetic stimulation (TMS) has created a new paradigm for psychiatric treatment. For decades, psychotherapy and prescription pads have dominated psychiatry, but now, with the advent of TMS, there is a medical procedure that can be performed right in the doctor's office. It is easy to underestimate how different this is for psychiatrists, who are now in the position of actively delivering a treatment to a mostly passive patient. TMS is expanding what constitutes traditional psychiatric practice.

In October 2008, Neuronetics (Malvern, PA) received clearance from the U.S. Food and Drug Administration (FDA) for the first TMS machine (the NeuroStar TMS Therapy System) (Figure 1), and they began installing machines in 2009. The Deep TMS System device (Brainsway, Jerusalem, Israel) (Figure 2), which utilizes a magnet with a different geometry and magnetic field than the NeuroStar device, was approved by the FDA in January 2013. Now, not only is TMS finding its role in psychi-

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atric practices across the country, there are also choices in the marketplace for psychiatrists providing the treatment.

The practical application of this therapy means that we must consider the business models used, office set-up, clinical decisions, and how to utilize the treatment protocol in the best manner possible.

## CLINICAL PRACTICE MODELS

TMS is frequently performed on an outpatient basis. Neuronetics initially envisioned that hospitals and institutions, with greater access to staff, space, and capital, would become the primary purchasers of TMS systems. However, in the 5 years since initial clearance by the FDA, the majority of installations have been in private practice settings, according to Mark Demitrack, MD, Chief Marketing Officer of Neuronetics (written communication).

Establishing a new procedure in any medical practice has its challenges, but when a practice has never offered any sort of procedure, and the procedure in itself is new, the challenges are even greater. For the psychiatrist who is beginning to utilize TMS, there has been an evolution of the traditional medication and therapy practice model in terms of both operation and management. The possibilities are numerous, but these new TMS practice models can generally be classified into five categories: (1) traditional private practices incorporating TMS, (2) TMS device partnerships, (3) networked practices, (4) institutions, and (5) dedicated TMS centers.

### Private Practices

As mentioned previously, private practitioners have been the fastest to adopt TMS. Even solo practitioners have begun using it, perhaps because there are fewer obstacles to making the decision to provide the service. Patients may come from within the practice, from referrals, and from outreach efforts. In this

model, the treating psychiatrist assumes all of the clinical duties, as well as handling all of the business elements of marketing, staffing, and supervising the daily operations. Successfully managing each of these facets is one of the greatest challenges in this model.

### TMS Device Partnerships

To achieve greater efficiencies in delivering treatment, separate practices can partner on the acquisition and operation of a machine. Even though the capital costs of a TMS practice are not large (relative to other medical specialties), it can be hard for a single practice, especially a solo one, to fully utilize a machine without marketing outside the practice. With the TMS partnership model, the burdens and cost of operations can be shared. Physicians treat their own patients using a jointly owned machine. This may be an attractive solution for a psychiatrist wanting to utilize TMS but who does not want to take on the necessary space and staff. The challenge that should be examined in this model is how to structure a partnership among competing physicians who might use the machine at different rates.

### Networked Practices

A third model of organization is a TMS network. In this model, an overarching management company either places treatment systems in individual practices or links existing TMS practices under a single name. The psychiatrist handles all of the clinical issues, whereas the management entity can now represent the group as a single unified brand, creating efficiencies of scale in advertising and marketing. They may also provide the TMS technicians, secure insurance authorizations, and handle billing for the group. One of the greatest benefits of a TMS network is that the clinicians gain the ability to provide TMS in their practice and are able to focus on clinical care without the added responsibility of the day-to-day operations.



Photo courtesy of Brainsway LTD.

Figure 2. Brainsway's Deep TMS System device, which uses a unique, patented coil design to produce directed electromagnetic fields that can induce excitation or inhibition of neurons deep inside the brain.

### Institutions

TMS is now increasingly present in the hospital setting. Because inpatient care is dwindling, hospitals are more focused on providing outpatient services and generally have the staff, infrastructure, and market presence to easily add another line of treatment. This segment has recently drawn renewed attention from equipment providers.

### TMS Centers

The final model that we examine is centers that exclusively perform TMS. Modeled on procedure-specific facilities, such as those that perform LASIK eye surgery, this type of office provides TMS with few or no other psychiatric services. There are dedicated staff psychiatrists to do the treatment, and patients are referred or self-referred for treatment. The largest example of a dedicated facility is the Shinjuku Mental Clinic in Tokyo, Japan, which has 63 treatment systems installed in one loca-

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tion (with 42 in actual use).<sup>1</sup> Depending on its structure, a dedicated center may also allow independent practitioners to use the facility (much like a surgery center). This is another method allowing independent psychiatrists to treat their own patients with TMS without the overhead, capital outlay, and management duties of running their own machine.

## MARKETING

How one markets the fact that they are now a TMS provider remains a challenge. Awareness of TMS as a treatment modality in the lay public is still low. Knowledge of TMS among psychiatrists is also low, as most physicians have no training in the technique, never had a patient in treatment, or even seen a TMS machine. This causes a lack of confidence in making referrals. A TMS provider needs to assess which model will work for his or her individual practice. If there are not enough patients to benefit from TMS within the practice, than sourcing outside the practice may be necessary.

Many patients seek out TMS on their own without referral from their treating psychiatrist. They generally locate providers from Internet searches. If a psychiatrist is trying to reach patients outside his or her own practice, a functional website is a must. Other marketing avenues can also be used to build patient flow, such as online advertising, multimedia marketing, traditional advertising campaigns, and social media. In addition, an outreach campaign building awareness of this new treatment can be valuable when targeted to existing patients and referral sources. This may include newsletters, open-house events, and patient seminars.

## OFFICE SET-UP

Configuring the office is one of the first considerations in adding TMS to a practice. The TMS treatment room should be large enough to accommo-

date a treatment chair, the magnet, and console, while allowing room for staff to maneuver from all sides and also room for a paramedic's gurney. Currently, Neuronetics recommends a room at least 12 feet by 15 feet, with a bare minimum space of 10 feet by 12 feet.<sup>2</sup> A Brainsway system needs less space because the patient is sitting up and not in a reclining chair. For patient comfort, more space is ideal, as is having a window to create an unconfined feeling.

Other comforts should also be considered, because the patient will be sitting still in treatment between 20 minutes and 1 hour or more. Even with earplugs muffling the noise, a television can be useful for patients to watch during their treatment if other activity is not planned. Distraction by television or music can help patients tolerate the scalp discomfort that can occur during treatment.

The magnetic pulses do generate some noise, just as a magnetic resonance imaging machine does. Generally, most offices can accommodate the noise without adverse disruption to other office operations. However, the sound level should be a consideration before TMS is installed in an office with other activities being conducted during treatment times.

## STAFFING

At the initial TMS treatment, the psychiatrist determines the treatment settings, which include the exact positioning of the treatment magnet and the strength of the magnet field to be used for that patient. This is determined by finding the patient's motor threshold (MT), which is the minimum power needed to observe a visible finger twitch when a single pulse is applied to the motor cortex.

Once the MT is established, in lieu of the psychiatrist performing each of the subsequent treatments, trained TMS technicians may also be employed to administer the future treatments based on these parameters and the physician's

prescription for treatment. A physician should be available to the technician while treatment is being delivered.

No formal credentials or licensure are required for the technician other than certification on the device that is being used to administer the treatment. The manufacturers generally provide this training and certification.

Finding the right staff can be challenging. Some offices use psychiatric registered nurses or licensed vocational nurses to deliver the treatments. Others use various mental health professionals, and still others use technicians who may have no health or mental health degree or experience. A skilled technician can deliver the treatment in a way that minimizes patient discomfort and increases patient compliance. Skill is also needed to ensure that the treatments are delivered in an effective manner by reliably replicating the placement of the magnet as determined by the physician at the original treatment. This consistent replication of the treatment settings is important to ensure that the treatments will be therapeutic. Capable technicians also are needed to closely monitor the patient throughout the treatment and keep them calm and relatively still.

One other challenge with a treatment that is administered daily is staff coverage, as disruptions in care might affect efficacy of treatment. Every office needs to consider how to manage the daily treatment process in the event the primary technician or physician is sick or on vacation. The backup staff needs to keep current on their skills and treatment knowledge. Having a well-trained and competent staff in a TMS practice is a large part of the investment in both time and cost.

In addition, a TMS technician should have certain skills that go beyond the technical aspects of performing the treatment. Patients undergoing TMS treatment for major depression are typically in severe phases of the illness, often on

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the verge of hospitalization. Technicians should be experienced in how to manage depressed and potentially suicidal patients. The 20 to 60 minutes of a typical treatment performed 5 days per week also offers a unique opportunity for intensive psychotherapeutic intervention that even a psychoanalyst would envy.

## SAFETY CONSIDERATIONS

The most common serious adverse effect of TMS is the induction of a seizure. The magnetic pulses administered are designed to stimulate neurons to fire, and there is the potential for overstimulation to trigger a generalized seizure. The reported rates at which this occurs varies with the machine and depth of the magnetic field generated, but Neuronetics reports with their device an occurrence of 1 in 30,000 treatments, or approximately 1 in 1,000 typical patients treated.<sup>2</sup> Treatment protocols are designed to avoid overstimulation, but seizures can still occur. This is made more likely if the individual administering the treatment is unaware of changes in medications or drug and alcohol use. Therefore, technicians should inquire about this prior to each treatment. If seizures do happen, however, they happen during the treatment, while the patient is in the treatment chair and accompanied by a technician.

Management of a seizure should adhere to the idea of “first, do no harm.” Beyond preventing the patient from falling from the chair and ensuring the airway is patent, the seizure should be allowed to run its course. There should be access to emergency care via ambulance for a seizure that persists. Some insurers require that when TMS is being administered, oxygen, suction, and intravenous medications should be available to stop seizures, but this is not required by current device manufacturers’ guidelines. The argument can be made that these procedures would be used so

rarely that the major risks would be iatrogenic in nature.

A seizure disorder is not by itself a contraindication to treatment. A contraindication is the presence of ferromagnetic metal within 30 cm of the magnet, which basically means above the neck.<sup>2</sup> Fortunately, dental implants and other surgical metals like titanium are paramagnetic and not problematic. A pacer

maker implanted in the chest would merit caution but does not rule out treatment.

As mentioned previously, the machines can generate a noise approaching 85 decibels. This is the threshold at which ear protection is recommended by hearing experts. Although most treatments do not occur at these levels, the magnet is situated very close to the patient’s ear, so earplugs are recommended. They are also recommended for the technicians, who may be exposed to the sound for hours at a time.

## MALPRACTICE INSURANCE

Most malpractice carriers do not have a surcharge for TMS practice, as is common with electroconvulsive therapy (ECT). In a partnered, networked, or dedicated-center model, additional attention needs to be paid to liability of the larger entity. This may simply be a matter of ensuring that the other practitioners remain current on their individual malpractice, but may require a corporate structure with its own liability insurance. However, for the individual psychiatrist, generally no additional insurance premiums apply. Regardless of the

clinical model that is chosen, the physician should notify the carrier of his or her practice regarding TMS and discuss the physician’s individual policy.

## INSURANCE REIMBURSEMENT

When first introduced, TMS was largely funded on a cash basis, and this is still the form of payment for some patients whose insurance provider does not cover the treatment. Now, however, hundreds of insurance companies recognize the benefit of TMS and provide coverage for treatment. These include some of the nation’s largest carriers, and the insurance landscape is continually evolving. However, the authorization process, criteria for authorizing treatment, and coverage benefits are far from being standardized. Carriers also vary in how and when concurrent authorizations are handled.

Typical criteria for authorization may include (1) diagnosis of major depression, severe; (2) lack of response or failure to tolerate one to four antidepressant medications; or (3) failure of a course of psychotherapy.

At the time of this writing, Anthem Blue Cross and Blue Shield, the largest commercial carrier in the United States, in addition to requiring the failure of four antidepressant medications, also requires the failure of two evidence-based augmentation strategies such as aripiprazole or lithium.<sup>3</sup> Alternate criteria used might include a history of previous response to TMS or failure of ECT.

Currently, Medicare does not cover TMS on a nationwide basis, although it is covered in approximately 10 states by decision of the local Medicare intermediary. The intermediaries in these areas have chosen to add it as a benefit even though they are not required to do so.

Some carriers have hard limits on the number of treatments they will cover based on FDA labeling, whereas others recognize that some patients will achieve remission with greater numbers of treat-

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ments, as observed in the National Institute of Mental Health's Optimization of TMS (OPT-TMS) study.<sup>4</sup> A separate study by Brainsway showed increased improvement when additional treatments were given, after the usual acute course, on a schedule of 1 to 2 times per week extended over many weeks.<sup>5</sup> Many carriers have rigid views of TMS treatment that do not allow for booster and maintenance treatments as described in the following text.

## CATEGORIES OF CLINICAL TREATMENT

TMS treatments can be given in varying schedules that can be classified into four broad categories. The first is acute treatment. This is generally 5 days per week, for a period of 4 to 6 weeks, and is used for treating an acute episode of depression. The 5-day per week standard is often referred to as "Eloise's rule," after the wife of Mark George, MD, who threatened to divorce him if he did not take off weekends from work.<sup>6</sup>

A second category is tapering treatments. Tapering treatments are used in winding down from a 5-day per week schedule. There is little research on the importance of tapering treatments versus abrupt discontinuation, despite it being clinically intuitive. Brainsway's standard protocol calls for following 4 weeks of acute treatment with 5 weeks of treatments performed twice per week, whereas Neuronetics recommends a taper of 3 treatments to 2 treatments to 1 treatment per week over the course of 3 weeks.

A third classification of treatments is booster or rescue treatments. Although TMS is generally considered to have durable effects, major depression is a recurrent and chronic condition. Booster treatments are initiated when a patient who has previously responded to treatment becomes symptomatic and shows early signs of relapse. In

one study, when booster treatments were used (in varying numbers and frequency), 84% of those patients showing symptom relapse were able to retrieve their clinical response.<sup>7</sup> There are clinical data supporting this practice from follow-up studies up to 12 months where booster treatments and medications were allowed.<sup>8</sup> When booster treatments are provided early, sometimes only a few may be needed.

The fourth category of treatment is maintenance treatment. These are treatments delivered to patients at risk for relapse and given on a schedule, regardless of symptomatology, for the purpose of ensuring improvement. Although the critical importance of maintenance treatment of depression with medication has been clearly demonstrated, and maintenance treatment with ECT is also widely accepted, these findings have not been extrapolated to TMS. Studies on the role of TMS maintenance are needed, but funding these studies is likely to be difficult.

Unfortunately, many insurers only recognize acute treatment as a covered benefit, citing lack of clinical data supporting other uses. Treating early with booster treatments can save a full relapse into a major depression, which (ironically) would be covered if the patient were allowed to worsen. Maintenance treatment is also frequently specifically excluded, even though TMS is often reserved for patients proven to be resistant to other modalities, and this may be the only treatment that has shown them any benefit.

## CONCLUSION

TMS has provided psychiatrists with a new tool for treatment and has benefited patients for whom traditional treatments have fallen short. Incorporating it into psychiatry has brought changes to how physicians practice.

Where TMS eventually fits in the treatment algorithm has yet to be de-

termined, but its use is being shaped by evolving insurance coverage. New machines and magnets with differently shaped magnetic fields have come to market, and there is room for more in the future. Treatment protocols have yet to be optimized. How best to utilize this tool and deliver treatment over the long term is still being determined.

TMS promises to help more patients as the treatment reaches broader use. The field is certain to evolve as new machines arrive, research grows, and clinical experience accumulates.

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