FOUNDATIONAL KNOWLEDGE FOR THE TMS TREATER:

CLINICAL TRANSCRANIAL MAGNETIC STIMULATION SOCIETY

Agenda

Introduction to TMS

Basic Neuroanatomy

Global Approvals

Research Advancements

TMS Treatment Parameters (and Protocols)

TMS Devices

TMS Safety and Tolerability

TMS Treater Scope of Practice

TMS Treater Ethical Guidelines

Learning Objectives

- Describe the history, mechanism of action, clinical application, and safety of TMS
- Develop a basic understanding of TMS terminology and neuroanatomy
- Describe practice scope and ethical guidelines for global TMS treaters

The Clinical TMS Society (CTMSS) is an international organization that provides clinical training standards and consensus statements

Audience: TMS Treater

A "TMS Treater" is a trained professional who administers Transcranial Magnetic Stimulation (TMS) therapy under the supervision of a licensed TMS prescriber. TMS treaters may include medical doctors, nurses, medical assistants, nurse practitioners, physician assistants, and therapists. The TMS treater may be referred to as different titles in different countries, such as TMS Technician (United States) or TMS Operator (Europe and Australia). While they may have a range of educational and practical experience, all have received specific training in the administration of TMS.

Glossary of Common TMS Terms

- MDD: Major Depressive Disorder
- TRD: Treatment Resistant (Refractory) Depression
- TMS: Transcranial Magnetic Stimulation
- rTMS: Repetitive Transcranial Magnetic Stimulation
- dTMS: Deep Transcranial Magnetic Stimulation
- aTMS: Accelerated Transcranial Magnetic Stimulation
- TBS: Theta Burst Stimulation
- iTBS: Intermittent Theta Burst Stimulation
- cTBS: Continuous Theta Burst Stimulation
- SAINT/SNT: Stanford Accelerated Intelligent Neuromodulation Therapy
- MT: Motor Threshold
- rMT: Resting Motor Threshold
- DLPFC: Dorsolateral Prefrontal Cortex
- DMPFC: Dorsomedial Prefrontal Cortex
- OFC: Orbitofrontal Cortex
- Quantitative-EEG (qEEG)-Guided rTMS

INTRODUCTION TO TMS

History and Basics of TMS

Why do we do TMS

- Major Depressive Disorder (MDD) is the single most common psychiatric condition
  - *Depression affects 3.8-5.7% of the global population and is a leading cause of disability worldwide*
  - *Psychotherapy/Antidepressant medications are first-line MDD treatments. Frequently, there is a lack of response to standard medications and psychotherapy*
- Response and remission rates decrease with each subsequent treatment trial that a patient undergoes during a Major Depressive Episode
- The STAR*D Study showed that by the fourth consecutive medication trial,
  - *Remission rate was only 6.9%*
  - *Drop-out rates due to adverse effects increased to 40%*
- Per DSM-5-TR
  - *MDD prevalence increased from 2005 to 2015*
  - *Age-adjusted rates of suicide in the US increased from 10.5 to 14.0 per 100,000 people over the preceding 20 years*

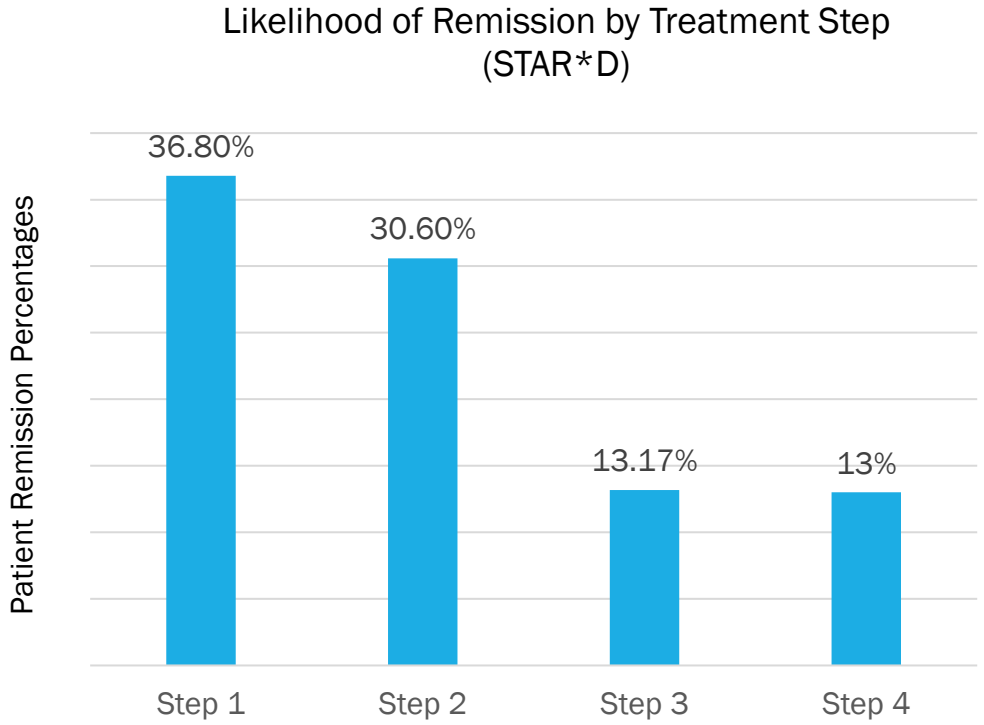
(Trivedi et al. American Journal of Psychiatry, 2006)
(American Psychiatric Association. DSM-5-TR, 2022)
(World Health Organization, 2025)

When Medications Plateau

TABLE 3. Acute Treatment Outcomes by Treatment Step

Feature	Treatment Step[a]							
	Step 1 (N=3,671)		Step 2 (N=1,439)		Step 3 (N=390)		Step 4 (N=123)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
QIDS-SR$_{16}$ score at entry to step	15.4	4.3	12.3	4.9	13.4	4.6	14.0	4.6
QIDS-SR$_{16}$ score at exit from step	8.6	5.8	9.4	5.8	11.5	5.5	12.0	5.7
Change in QIDS-SR$_{16}$ during step (%)	−43.4	36.1	−20.3	51.9	−12.3	34.4	−11.6	37.1
Weeks to remission[b] (for those remitting)	6.3	3.8	5.4	4.5	5.6	4.4	7.4	4.8
Weeks to response[c] (for those responding)	5.5	3.5	6.5	4.0	6.4	4.1	8.3	4.4
Weeks in treatment	10.1	4.1	9.3	5.0	8.6	5.2	9.2	5.3
Cumulative weeks in treatment	10.1	4.1	19.1	6.9	28.1	8.6	37.9	8.9
	N	%	N	%	N	%	N	%
Remission at each step exit	1,346	36.8	439	30.6	53	13.7	16	13.0
Response in each step	1,776	48.6	408	28.5	65	16.8	20	16.3
Intolerable side effects[d]	599	16.3	281	19.5	100	25.6	37	30.1

[a] Sums do not always equal N due to missing values. Percentages are based on available data.
[b] Exit QIDS-SR$_{16}$ ≤5.
[c] 50% or more reduction in QIDS-SR$_{16}$ score from entry score at each step.
[d] Proportion of participants who left the level prior to 4 weeks for any reason and those who left thereafter whose exit form indicated intolerance.



(Rush et al. Controlled Clinical Trials, 2004)

What is TRD?

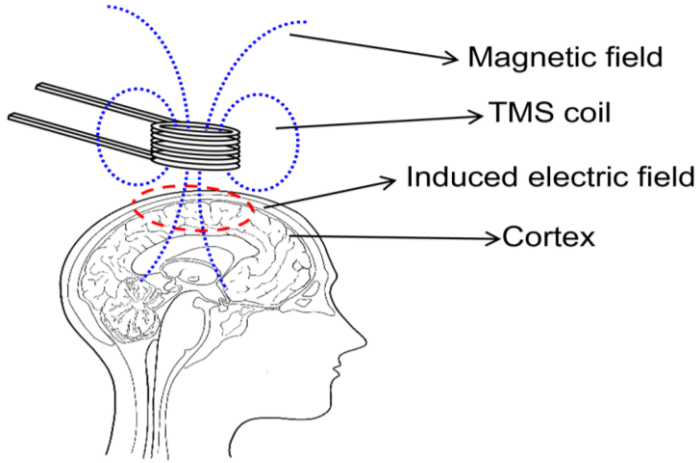
Treatment Resistant or Treatment Refractory Depression is typically defined as an episode of major depressive disorder that has failed to respond to at least two antidepressant trials, from different medication classes, and of sufficient dose and duration.

What is TMS?

- A non-invasive neuromodulation procedure
  - *Used internationally*
  - *Treats many neuropsychiatric and related disorders*
  - *Used in research to improve understanding of neurophysiology and brain circuits*



- Health Canada approved TMS for the treatment of depression in 2002
- FDA cleared the first device in 2008
  - *Followed the pivotal trials in 307 patients with MDD*
  - *Indicated for MDD that has not responded to traditional treatments (adults and adolescents)*
  - *Also indicated as adjunct for Obsessive Compulsive Disorder, Smoking Cessation, and PTSD*



(O'Reardon et al. Biological Psychiatry, 2007)

How does TMS work?

TMS is based on the principle of electromagnetic conduction discovered by Michael Faraday in 1831

The TMS device (stimulator) creates a time varying magnetic field that induces an electric field in superficial (cortex) layer of brain.

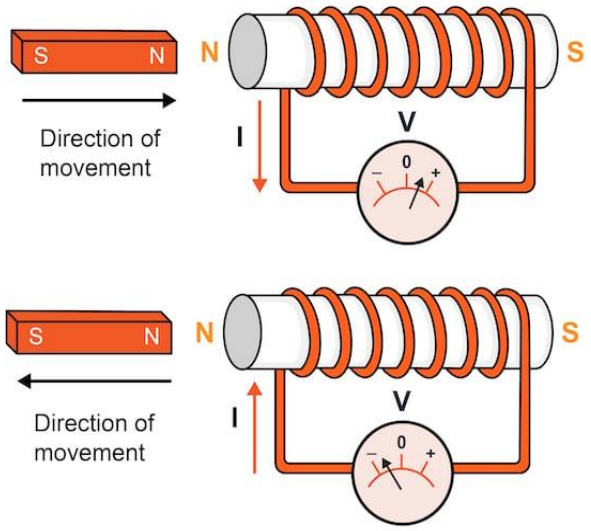
That leads to the neurons firing (depolarization via Na+ and Cl- ions) in the stimulated area

The brain, as a conductor, transmits the electrical signals from neurons to deeper neuronal circuits (downstream) via neurotransmitter chemicals acting at synapses

TMS devices

- *Generate a magnetic field between 1.5-2.5 tesla*
- *Pass through the skull and tissue unimpeded*
- *Create an electrical field in the cortex ~2-4 cm below the surface*

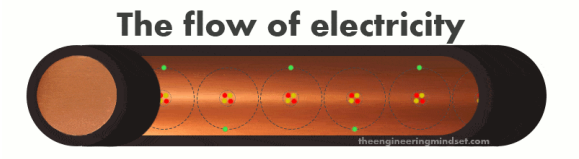


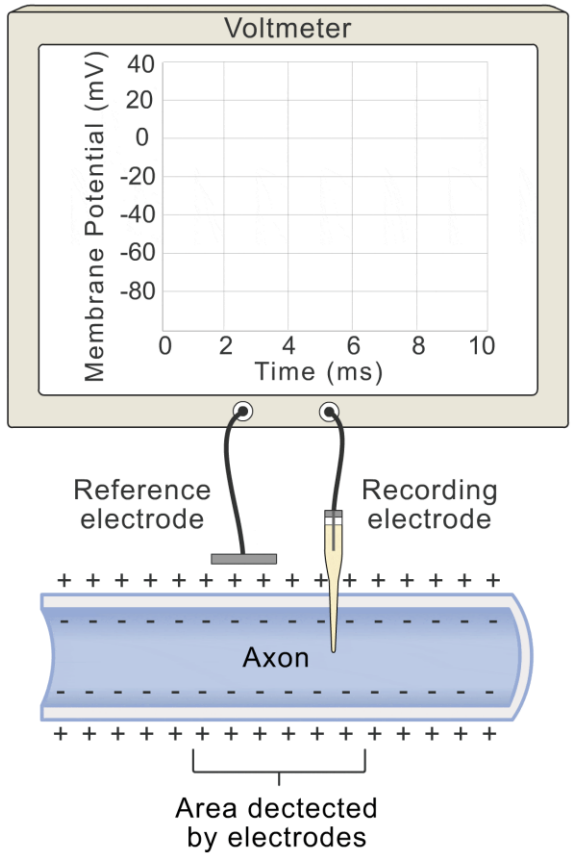


* for typical figure 8 coils

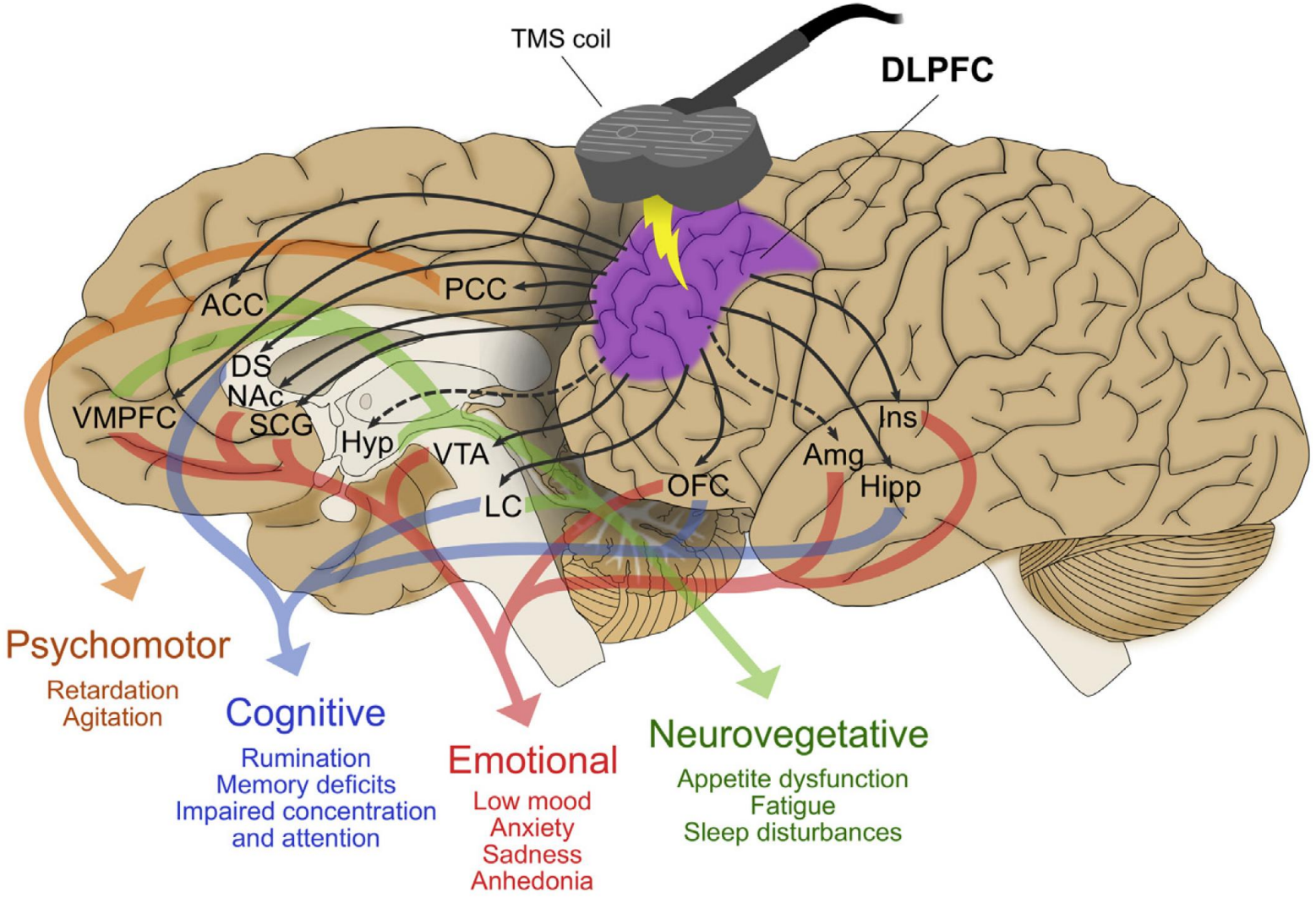
How does TMS work?

- In copper conductors, current flows via electrons
- In neurons, current flows via Na^+ and Cl^- ions
- Once depolarized, these neurons carry that signal to the next neuron
- This results in not only induction of current flow within directly stimulated neurons, but activation of neurons and circuits downstream via neurotransmitter signalling (serotonin, dopamine, etc)





TMS Neuroplasticity Effects on Structural and Functional Connectivity



(Anderson et al. Clinical Neurophysiology, 2016)

Who Developed TMS?

- Professor Anthony Barker and colleagues at the University of Sheffield in 1985
  - *Originally working on a method for non-invasive evaluation of upper motor neurons (UMNs)*
  - *Used to evaluate motors neurons in both healthy and pathologic states*

- Progress in TMS device design has led to advancements in stimulation parameter complexity
  - *Single pulse (sTMS)*
  - *Repetitive (rTMS)*
  - *Repetitive trains delivered at varying frequencies*
  - *Different pulse patters (theta burst)*



(Barker et al. The Lancet, 1985)

Early Development of TMS

- Pioneering rTMS studies in the early 1990s demonstrated different cortical effects when stimulating at different frequencies over the motor cortex

  - *5Hz or greater (high frequency stimulation)*
    - Increased motor evoked potentials, indicating increased cortical excitability

  - *1Hz (low fraequency stimulation)*
    - Decreased motor evoked potentials, indicating decreased cortical excitability

(Pascaul-Leone et al. Brain, 1994)
(Chen et al. Neurology, 1997)
(Di Lazzaro et al. Brain Stimulation, 2008)
(Malcolm et al. Journal of Clinical Neurophysiology, 2015)

Where to Stimulate with TMS?

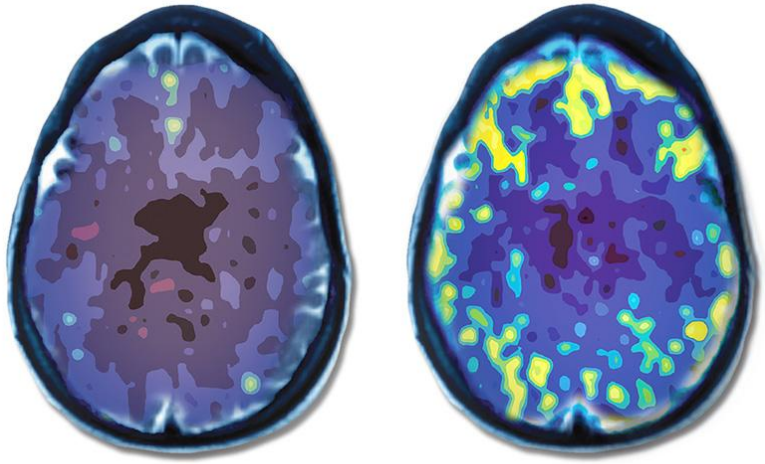
- Development of functional brain imaging in the 1990s and 2000s increased understanding of MDD pathophysiology
- Positron emission tomography (PET) and single-photon emission computed tomography (SPECT) studies showed dysfunction in both the left and right DLPFC in patients with MDD
- For MDD, the most common TMS treatment location is the left dorsolateral prefrontal cortex (DLPFC) with high-frequency stimulation.



(George et al. Depression, 1994)
(Nobler et al. American Journal of Psychiatry, 2001)

Where to Stimulate with TMS

- Research shows change in the DLPFC in MDD
  - *Regional blood flow*
    - Decreased on the left
    - Increased on the right
  - *Regional glucose metabolism*
    - Decreased on the left
    - Increased on the right



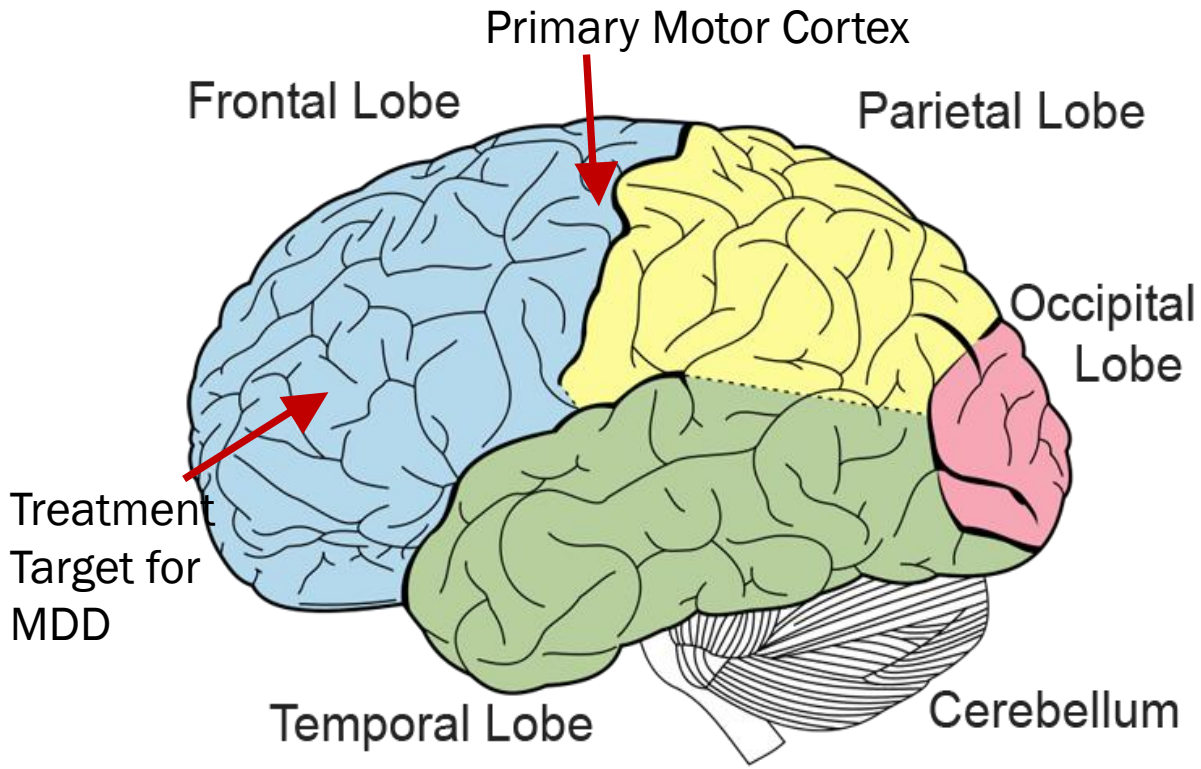
- The initial, pivotal trial was proof of concept
  - *Locate coil over the left DLPFC and stimulate with high frequency pulse protocols*
  - *This upregulates the hypo-functioning region of the brain in MDD*
- **Subsequent research has indicated the pathophysiology of MDD and effects of TMS are much more complex. Now we know**
  - **There are functional connections between different areas of the brain that work in a coordinated fashion (making up neural "circuits") - these connections are abnormal in MDD and can be changed with TMS**

(O'Reardon et al. Biological Psychiatry, 2007)

BASIC NEUROANATOMY

Basic Neurocircuitry for the Most Common TMS Treatment Targets

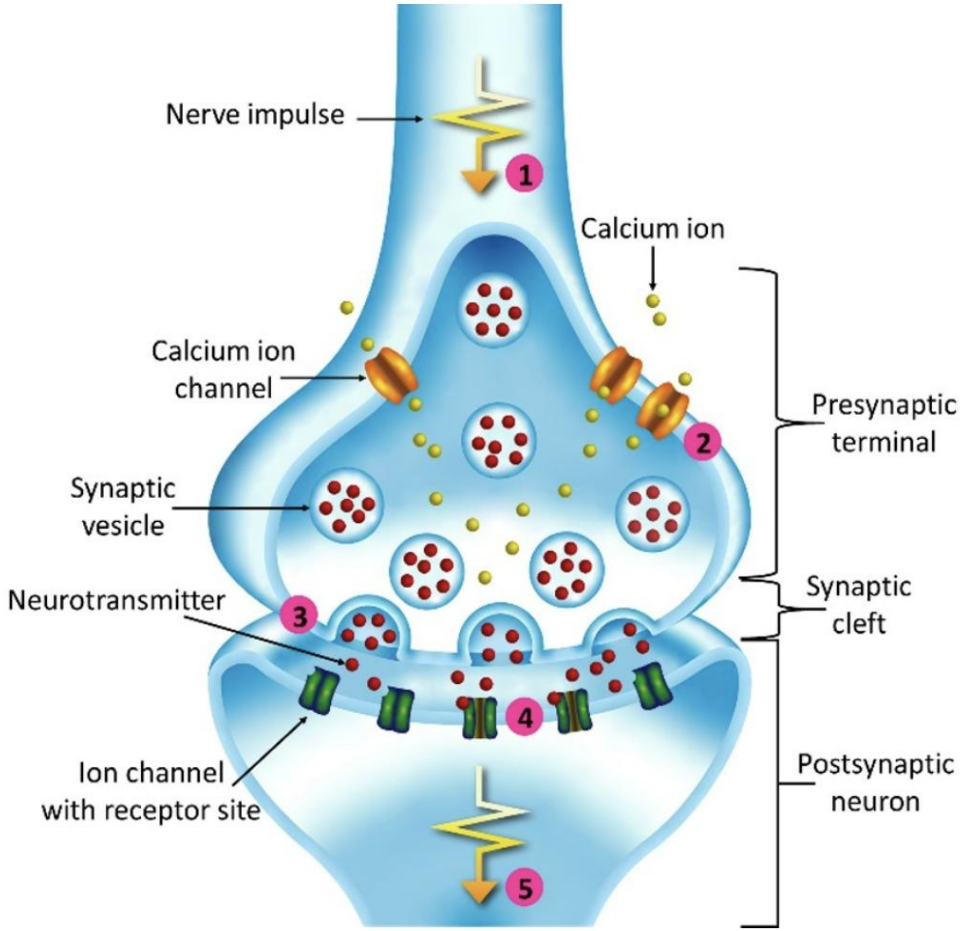
Human Cortex



- Cortex = outer layer of the brain
- Cortex is divided into four lobes:
  - *Frontal*
  - *Parietal*
  - *Temporal*
  - *Occipital*

Neurons and Synapses

- A synapse is the connection between one neuron and another.
- A nerve impulse arrives
- This causes calcium ion channels to open, resulting in an influx of calcium ions in the terminal
- This causes pre-synaptic synaptic vesicles to fuse with the terminal membrane, releasing neurotransmitters into the gap between neurons
- The neurotransmitters bind to receptor sites in the postsynaptic membrane, causing them ion channels to open
- Ions flow into the postsynaptic neuron, which generates an action potential when a threshold level is reached



https://www.oist.jp/image/diagram-synaptic-transmission

Layers of Neocortex

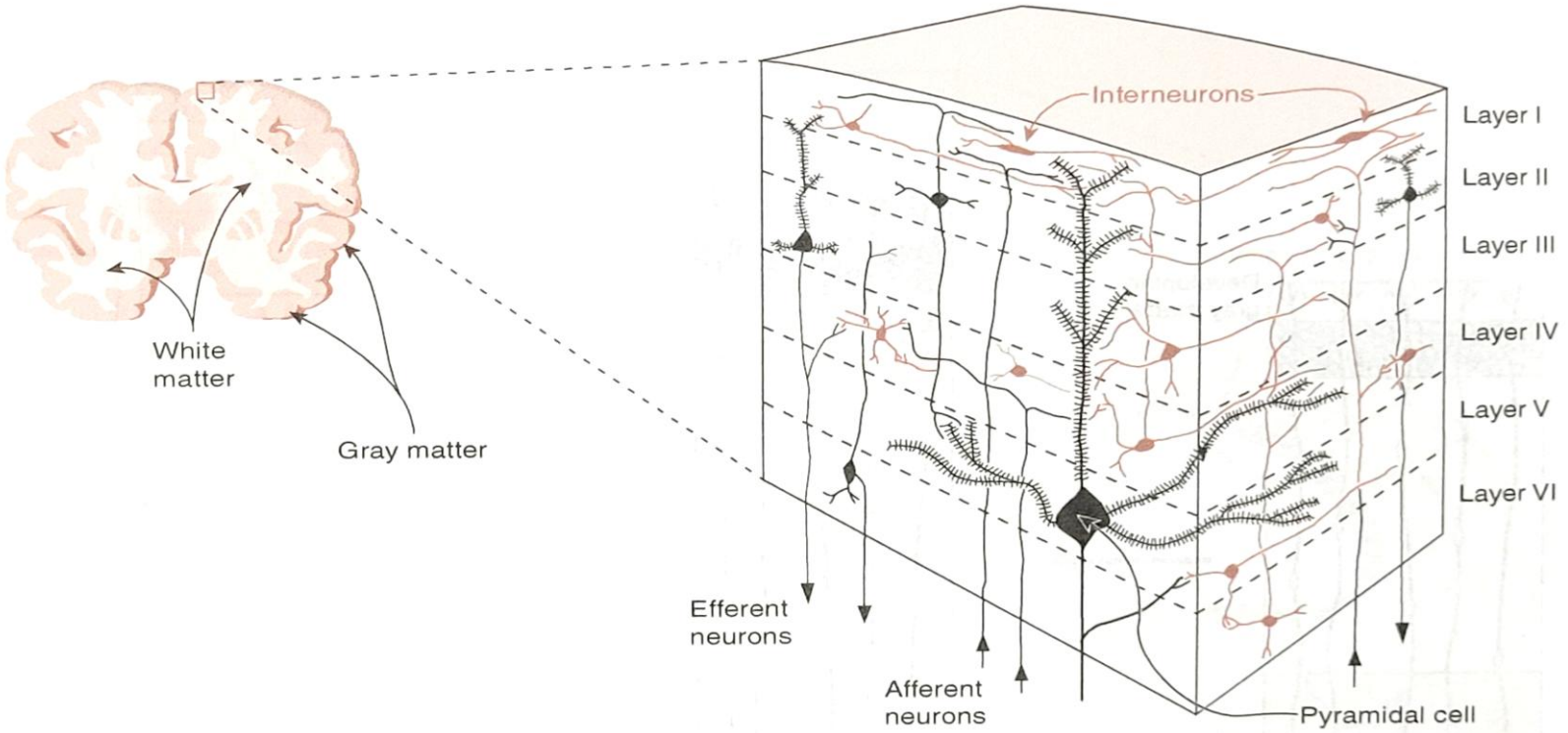
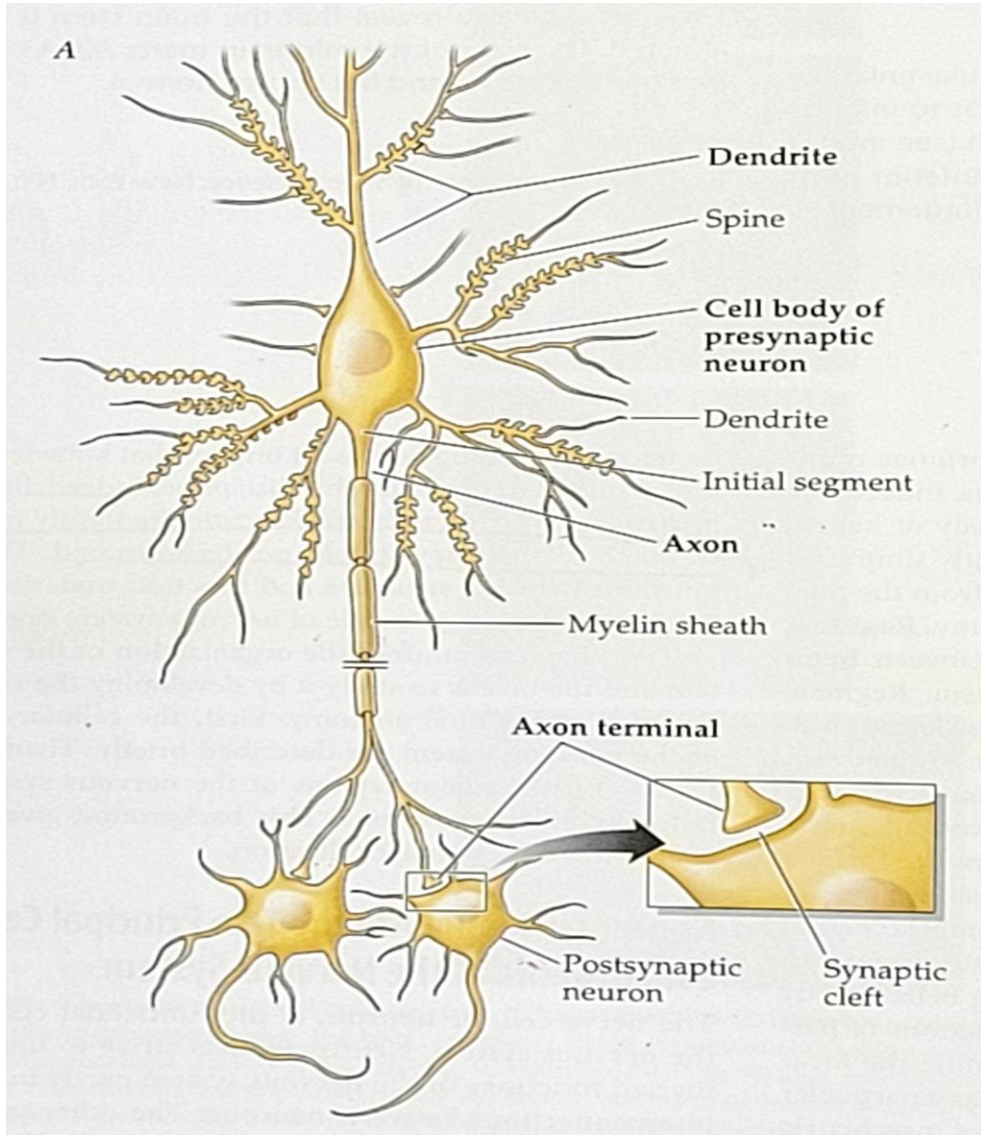


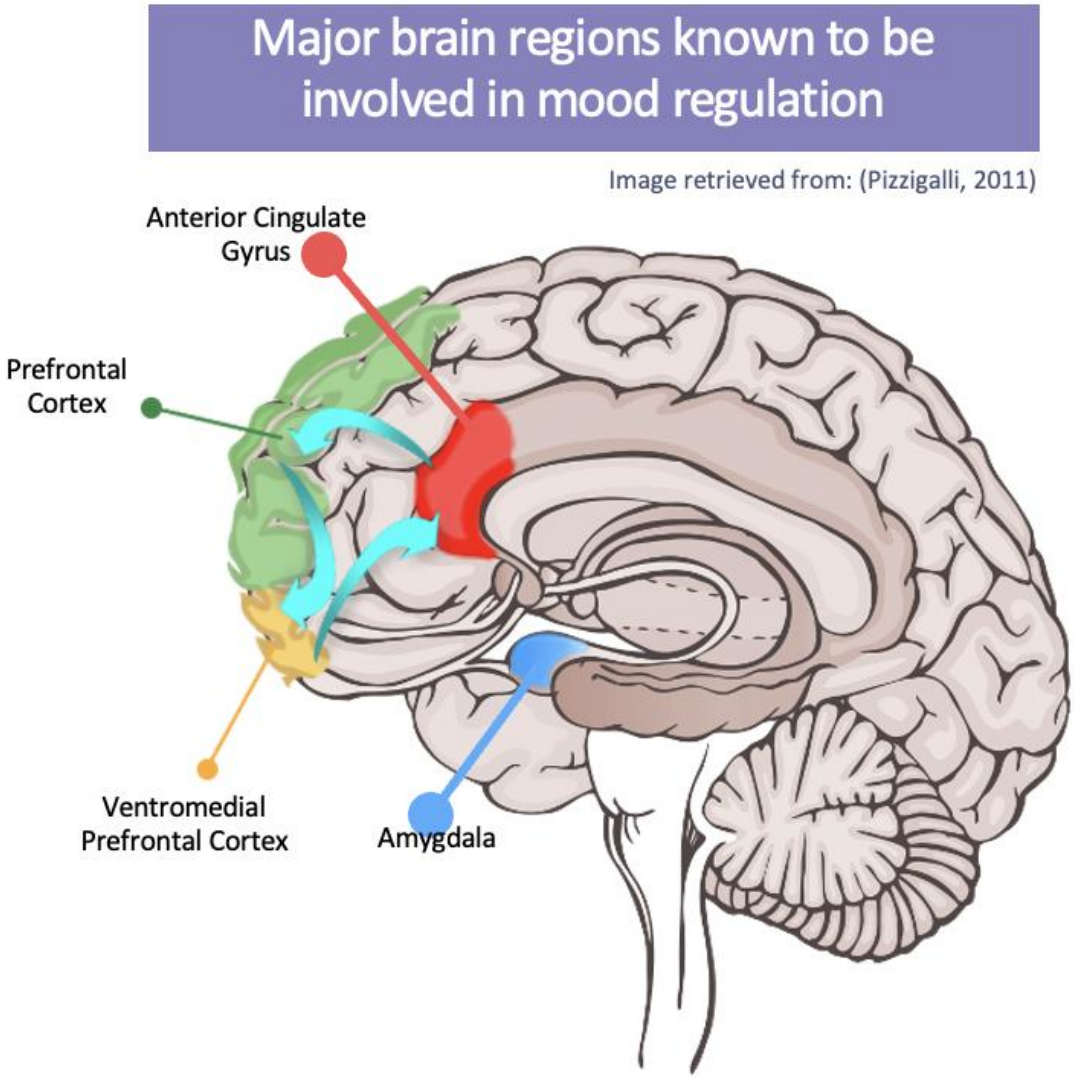
FIGURE 2.3 ● The six layers of the neocortex, from the pial surface above layer 1 to the white matter below layer 6. (Snell RS. *Clinical Neuroanatomy: A Illustrated Review with Questions and Explanations*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2001.)

TMS Action Potential Pyramidal Neurons

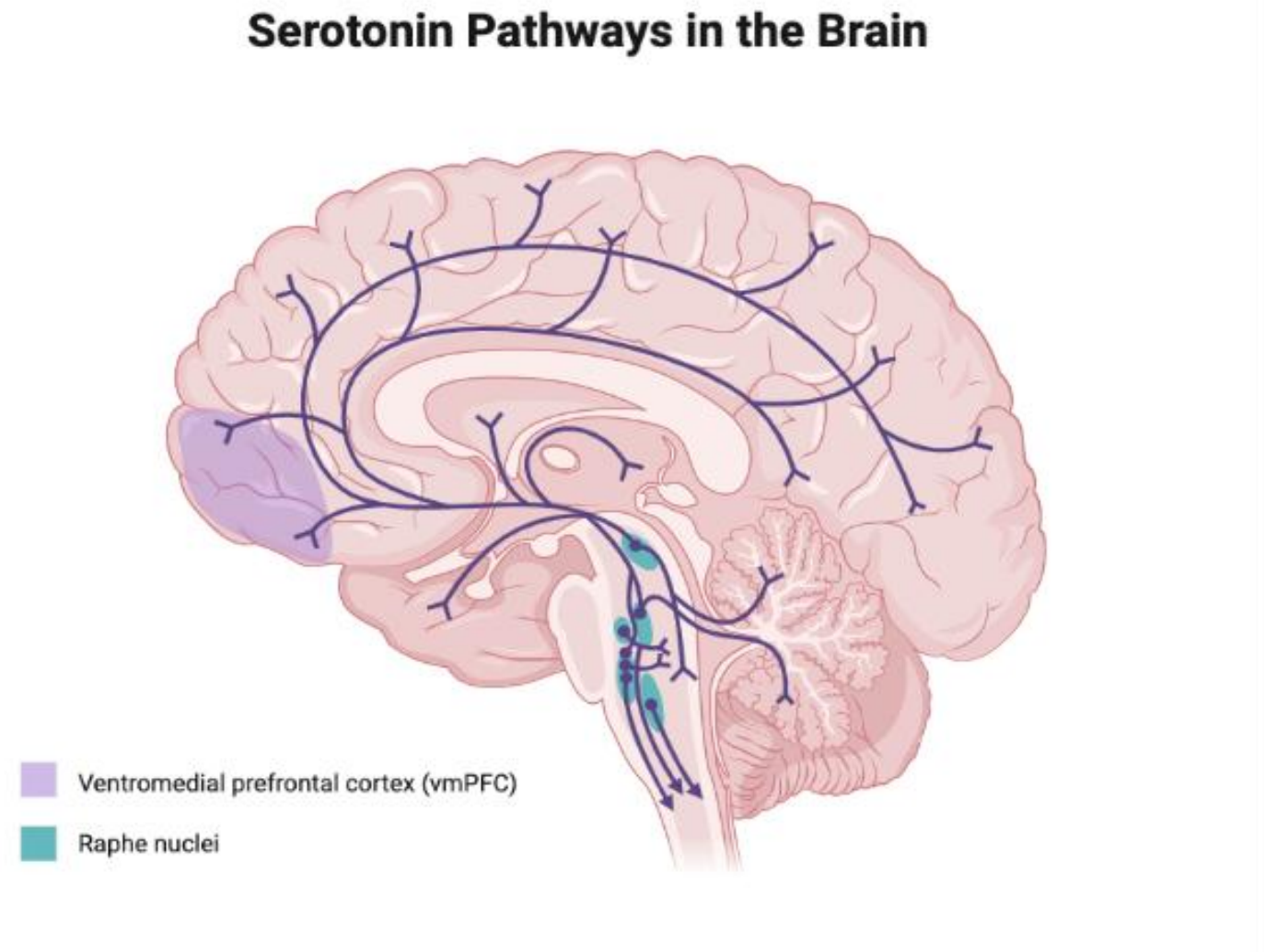
- Depolarization (change in charge) across the neuronal membrane leads to neuronal "firing" (action potential)
- When the neuron "fires", neurotransmitters (serotonin, dopamine, norepinephrine) release in the synapse
- This signal is propagated to distant neurons
- *TMS - Induced neuronal signals impact areas of brain that are both directly beneath the TMS coil and also more distant (through circuit activity)*



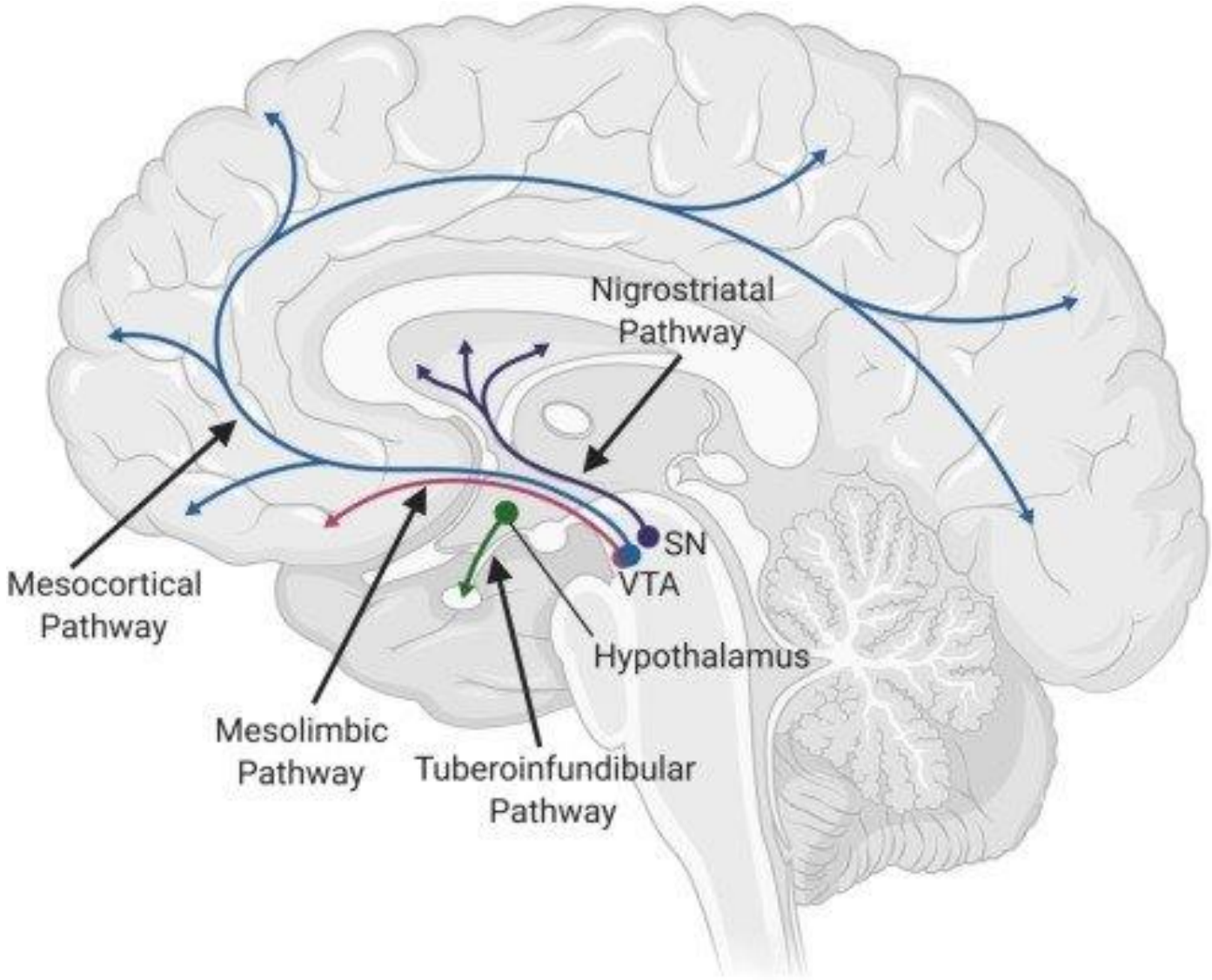
Neurocircuitry for MDD



Serotonergic System



Dopaminergic System



TMS GLOBAL APPROVALS

Regulatory Agencies and TMS Approvals Around the World

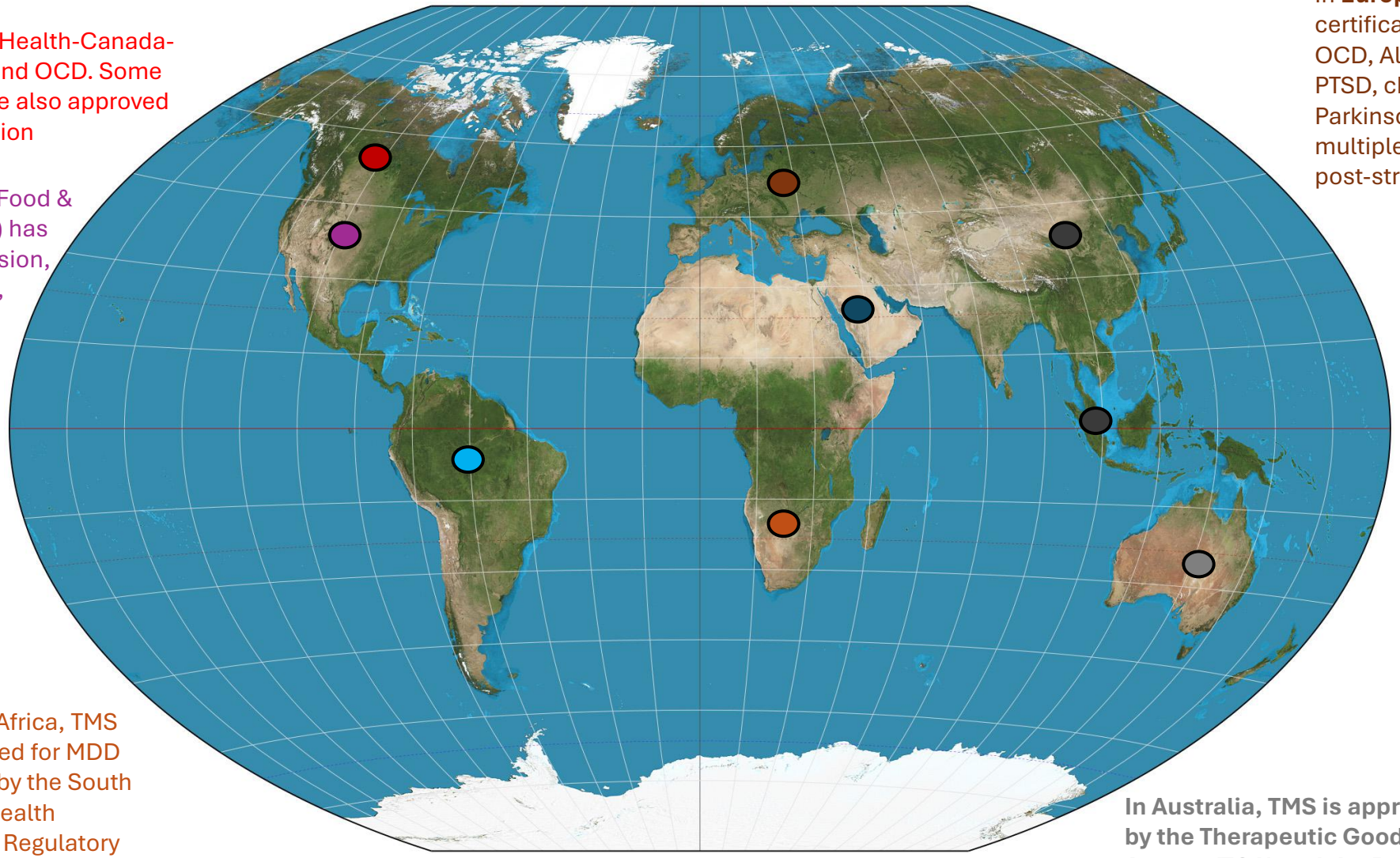
International Regulatory Agencies for TMS Approval

In **Canada,** TMS is Health-Canada-approved for TRD and OCD. Some specific devices are also approved for smoking cessation

In the **United States**, the Food & Drug Administration (FDA) has approved TMS for: depression, OCD, anxious depression, smoking cessation, PTSD

In South America, various regulatory agencies approved TMS for MDD, TRD. Approvals for other conditions vary by country.

In South Africa, TMS is approved for MDD and TRD by the South African Health Products Regulatory Authority (SAHPRA)



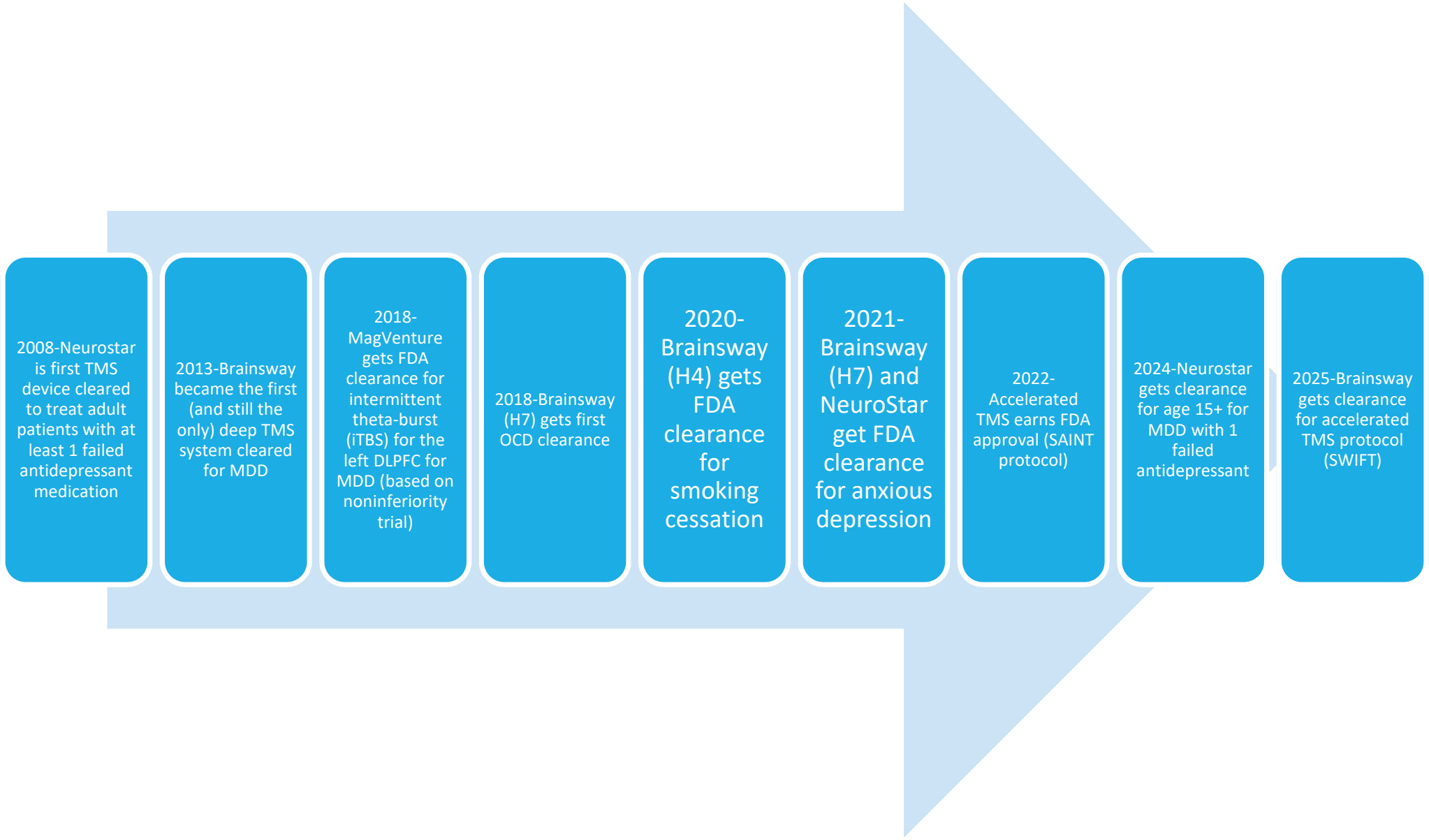
In **Europe,** TMS has CE certification for: MDD, OCD, Alzheimer's disease, PTSD, chronic pain, Parkinson's disease, multiple sclerosis, and post-stroke rehabilitation.

In Saudi Arabia, TMS is approved for TRD by the Saudi Food and Drug Authority (SFDA)

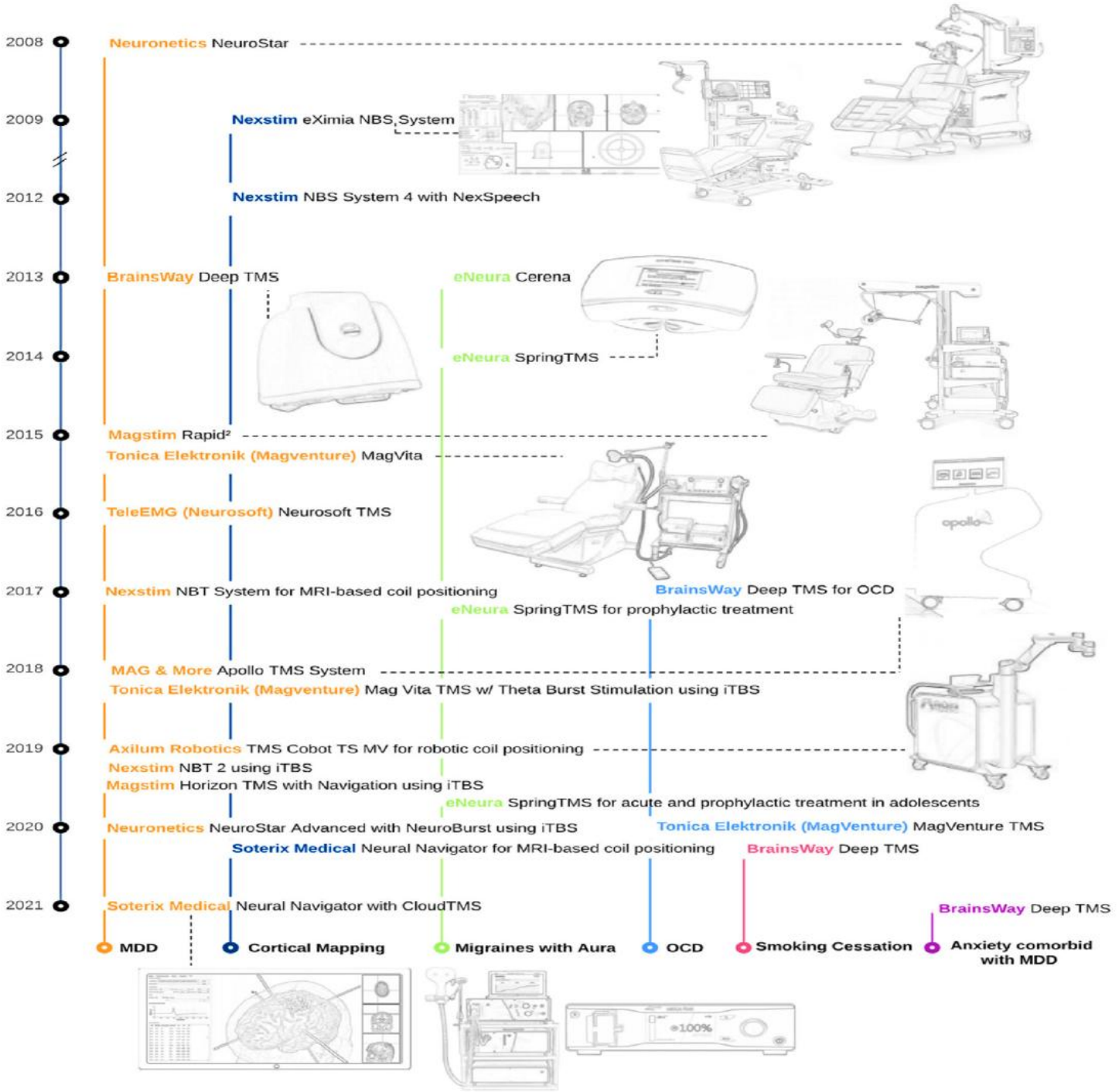
Asia: In China, TMS is approved by the National Medicine Products Administration (NMPA) for MDD. In Singapore, TMS is approved for MDD and OCD by the Health Sciences Authority.

In Australia, TMS is approved by the Therapeutic Goods Agency (TGA) and the Royal Academy College of Physicians (RANZP) for TRD

United States: TMS FDA-Clearance Timeline



TMS FDA-Clearance Timeline: 2008-2021



(Cohen et al. Brain Stimulation, 2022)

RESEARCH ADVANCEMENTS

Major TMS Research Studies that Have Advanced the Field

Historical Studies that Moved the Field of TMS Forward

1985: Anthony Barker, PhD makes use of the first TMS device

1995: Mark George, MD shows potential therapeutic utility in depression

2008: First TMS device FDA cleared for use in TRD

2013: First dTMS device FDA cleared for use in TRD

2018: FDA clearance of first TMS device for OCD

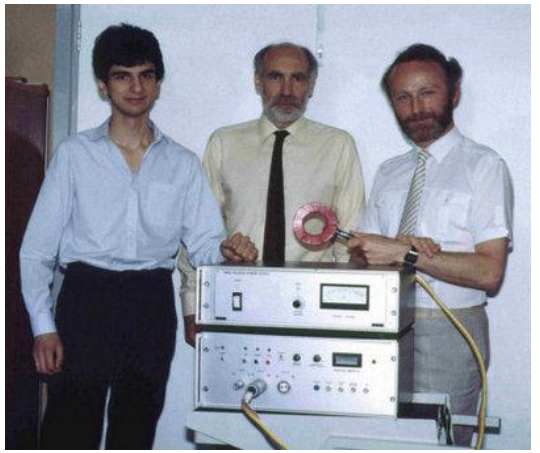
2018: First FDA clearance of device with iTBS capability

2022: FDA clearance of the SAINT protocol and system

2024: BrainsWay gets first FDA clearance for “late life depression”

2024: Neuronetics gets first FDA clearance for “adolescent depression”

2025: BrainsWay gets clearance for accelerated TMS (SWIFT) protocol



http://www.scholarpedia.org/article/Transcranial_magnetic_stimulation

TMS TREATMENT PARAMETERS

Basics of TMS Operation and Common Protocols

Protocol Terminology

- **Intensity:** pulse amplitude, noted as percentage of total machine output (0-100%)
- **Motor threshold (MT):** minimum intensity required to create visible contralateral uscle twitch (or motor evoked potential on EMG) at least 50% of the time when stimulating over the motor cortex with single TMS pulses
- **Treatment intensity:** goal for intensity of magnetic stimulation delivered during treatment
  - *Typically a percentage (120%) relative to the patient's MT level*
- **Treatment target:** brain region identified for stimulation
  - ***DLPFC:*** *the dorsolateral prefrontal cortex is a common target for depression*
  - ***MPFC :*** *the medial prefrontal cortex is a stimulation common target for OCD*
- **Frequency:** pulse frequency, number of pulses per second
  - *Pulse frequency is typically reported in Hz or pulses per second*

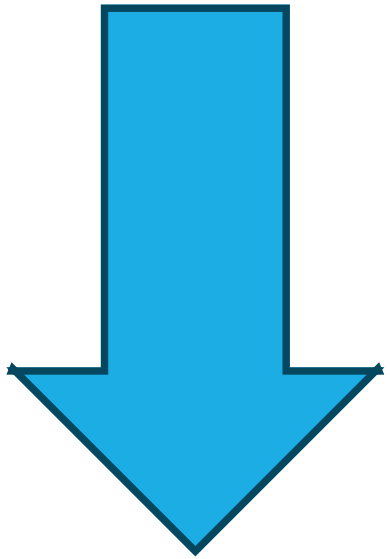
Protocol Terminology

- **Pulse pattern:** pattern type for magetic pulses
  - *Standard (repetitive trains; all pulses delivered at a fixed pulse frequency)*
  - *Bursting (bursts are "bundles" of rapid pulses; theta burst protocols use several different pulse frequencies – one between pulses, another between bursts)*
- **Train:** group of individual or patterned pulses grouped together before a rest period
- **Intertrain interval (ITI): Rest time (no stimulation)** between individual pulse trains or burst trains
- **Intersession interval (ISI):** time between stimulation sessions when patient is not under coil, can rest or do other things
  - *Typically 24 hours for once/day protocols*
  - *15-50 minutes for protocols with accelerated schedules (more than one session per day)*
- **Duration/Course:**
  - ***Session duration:*** *typically defined by the number of pulses, trains or time (min)*
  - ***Treatment duration:*** *typically defined by total pulses, sessions or time (days)*
  - ***Intersession Interval:*** *The time interval between each TMS session*

Treatment Localization Methods

- Scalp-Based Measurement Methods:
  - 5-6 cm Rules
    - *Locates the DLPFC by measuring from the motor hotspot along a parasagittal line on the scalp*
  - Beam F3
    - *Locates the DLPFC by using several simple measurements to find the scalp area corresponding to the EEG F3 electrode*
  - Scalp Geometry-based Parameter (SGP) Method
    - *Uses scalp-based measurements and calculations based on MNI space*
- Neuronavigation:
  - *Precisely locates the desired target using stereotactic software and coordinates*
    - Structural
    - Functional
- Consensus guidelines note clinical equipoise of 5.5 cm and Beam F3 methods and recommend them for general clinical use
  - *Neuronavigation **may** provide additional benefit and treatment individualization and is within standard of care as well*

Increasing Personalization

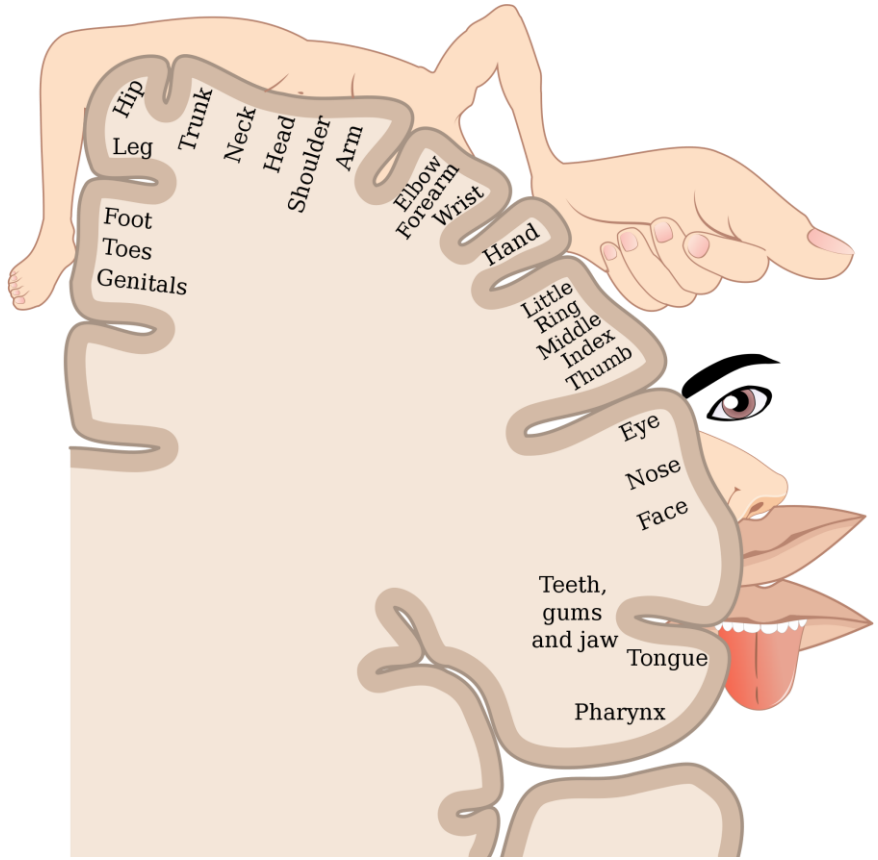


(O'Reardon et al. Biological Psychiatry, 2007)
(Beam et al. Brain Stimulation, 2009)
(Jiang et al. Brain Stimulation, 2022)
(Trapp et al. Clinical Neurophysiology, 2025)

Determining Motor Threshold

- Resting (rMT) vs. Active (aMT)
- Single pulse TMS over the primary motor cortex
  - *Motor hotspot = area of the primary motor cortex that produces maximal movement in the muscle group of interest*
    - Depression/DLPFC: contralateral thumb
    - OCD/DMPFC: either foot
- Lowest intensity that produces contralateral muscle movement (or threshold MEPs) 50% of the time

Motor Homunculus



https://humanbiology.pressbooks.tru.ca/chapter/10-5-central-nervous-system

(Fig-8 coil) Standard 10 Hz MDD Protocol

- Treatment intensity: 120% rMT
- Number of pulses: 3,000
- Trains: 75
- Stimulation train: 10 pulses per second (10Hz) x 4 seconds
- Pattern: standard rTMS pulses
- Intertrain interval: 26 seconds
- Session duration: 37.5 minutes
- Typical treatment location: left DLPFC
- FDA cleared: yes CE marked: yes

(O'Reardon et al. Biological Psychiatry, 2007)

(Fig-8 Coil) "Dash" (10 Hz, Shortened ITI) MDD Protocol

- Treatment intensity: 120% rMT
- Number of pulses: 3,000
- Trains: 75
- Stimulation train: 10 pulses per second (10Hz) x 4 seconds
- Pattern: standard rTMS
- Intertrain interval: 11-25 seconds
- Session duration: 18.75 minutes-36.25 minutes
- Typical treatment location: left DLPFC
- FDA cleared: yes CE marked: yes

(Carpenter et al. Brain Stimulation, 2021)

(H-Coil) Standard 18 Hz MDD Protocol

- Treatment intensity: 120% rMT
- Number of pulses: 1,980
- Trains: 55
- Stimulation train: 18 pulses per second (18Hz) x 2 seconds
- Pattern: individual pulses
- Intertrain interval: 20 seconds
- Session duration: 20 minutes
- Typical treatment location: left DLPFC (H1), mPFC, ACC (H7)
- FDA cleared: yes CE marked: yes

(Levkovitz et al. World Psychiatry, 2015)

1 Hz Stimulation Protocol (MDD)

- Treatment intensity: 80-110% rMT
- Number of pulses: 1,200-3,600
- Trains: 1
- Stimulation train: 1 pulse per second (1Hz)
- Pattern: individual pulses
- Intertrain interval: N/A
- Session duration: 20 minutes-60 minutes
- Typical treatment location: right DLPFC
- FDA cleared: no CE marked: yes

(Cao et al. Frontiers in Psychiatry, 2018)

(all coils) Intermittent Theta Burst Stimulation (iTBS) MDD Protocol

- Treatment intensity: 120% rMT
- Number of pulses/session: 600
- Trains: 20
- Stimulation train: 5 bursts per second (5Hz) x 2 seconds
- Pattern: bursts comprised of 50Hz triplet pulses
- Intertrain interval: 8 seconds
- Session duration: 3.33 minutes
- Typical treatment location: left DLPFC
- FDA cleared: yes CE marked: yes

(Blumberger et al. The Lancet, 2018)

Continuous Theta Burst Stimulation (cTBS) Protocol

- Treatment intensity: varies
- Number of pulses: 600
- Trains: 1
- Stimulation train: 5 bursts per second (5Hz)
- Pattern: bursts comprised of 50Hz triplet pulses
- Intertrain interval: N/A
- Session duration: 40 seconds
- Typical treatment location: right DLPFC
- FDA cleared: no CE marked: yes

(Huang et al. Neuron, 2005)

OCD Stimulation Protocol

- Treatment intensity: 100% rMT
- Number of pulses: 2,000
- Trains: 50
- Stimulation train: 20 pulses per second (20Hz) x 2 seconds
- Pattern: individual pulses
- Intertrain interval: 20 seconds
- Session duration: 18.33 minutes
- Typical treatment location: mPFC, ACC
- Provocation: pre-treatment
- FDA cleared: yes CE marked: yes

(Carmi et al. American Journal of Psychiatry, 2019)

Smoking Cessation Stimulation Protocol

- Treatment intensity: 120% rMT
- Number of pulses: 1,800
- Trains: 60
- Stimulation train: 10 pulses per second (10Hz) x 3 seconds
- Pattern: individual pulses
- Intertrain interval: 15 seconds
- Session duration: 18 minutes
- Typical treatment location: PFC, Insula
- Provocation: pre-treatment
- FDA cleared: yes CE marked: yes

(Zangen et al. World Psychiatry, 2021)

Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT/SNT)

- Treatment intensity: 90% rMT
- Number of pulses: 1,800
- Trains: 60
- Stimulation train: 5 bursts per second (5Hz) x 2 seconds
- Pattern: bursts comprised of 50Hz triplet pulses
- Intertrain interval: 8 seconds
- Session duration: 10 minutes
- Typical treatment location: functional-connectivity MR guided DLPFC coordinate most anti-correlated with the subgenual ACC
- Special considerations: 10 treatments daily (50 minute intersession interval) for five days (50 treatments)
- FDA cleared: yes CE marked: yes

(Cole et al. American Journal of Psychiatry, 2020)
(Cole et al. American Journal of Psychiatry, 2022)

General Protocol Considerations for Depression Treatment

- Most studied and validated protocol: standard 10 Hz high frequency stimulation of the left DLPFC*
- General tolerability: 1 Hz protocols > 10 Hz protocols > iTBS protocols
- General effectiveness: 10 Hz protocols ≈ iTBS protocols ≈ 1 Hz protocols
- Sequential treatment protocols using these specific targets/frequency exist but **generally** are not superior to unilateral treatment protocols in depression
- Protocols may vary on individual parameters based on clinical indication or equipment limitation
- Insurance limitations regarding coverage for a particular protocol may exist

* see slide 32

(Trapp et al. Clinical Neurophysiology, 2025)

Other Protocol Considerations

- Accelerated protocols
  - *Current FDA cleared accelerated protocols*
    - SAINT/SNT
    - BrainsWay accelerated protocol (SWIFT TMS)

- Preservation protocols
  - *Maintenance*
  - *Retreatment*
  - *Limited consensus regarding preservation protocols*
    - Currently no FDA cleared protocols
  - *CTMSS Clinical Standards Committee Preservation TMS Statement (2023)*

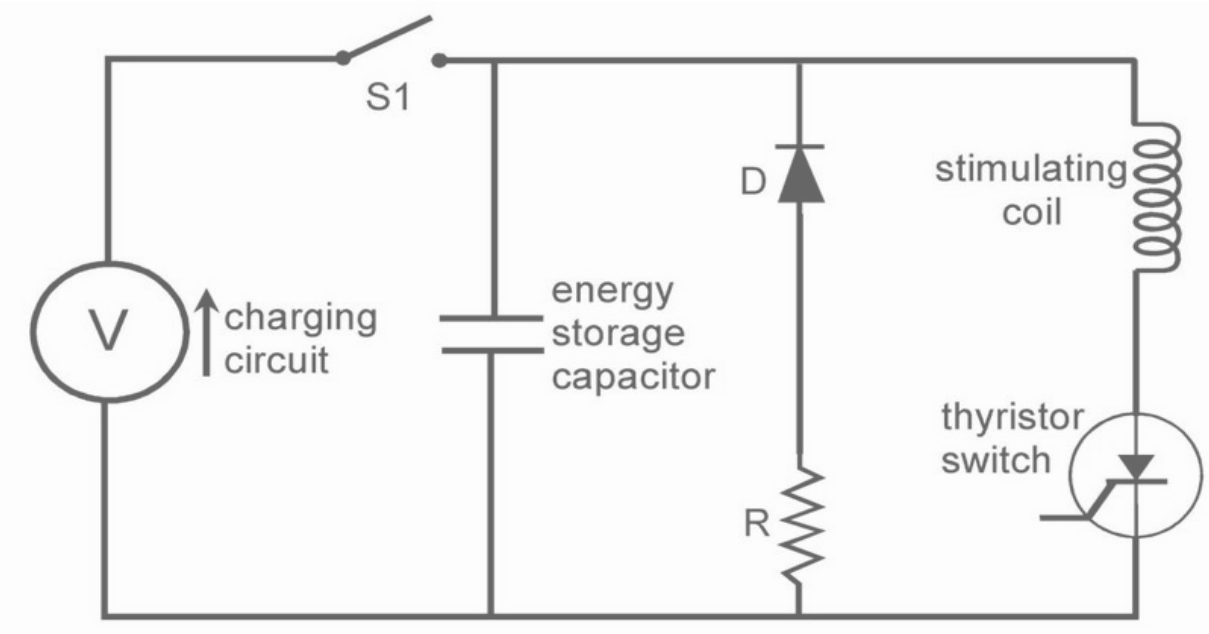
(Wilson et al. Journal of Affective Disorders, 2022)

TMS DEVICES

Basics of TMS Device Design and Common, Commercially Available Devices

TMS Devices – Basic Design

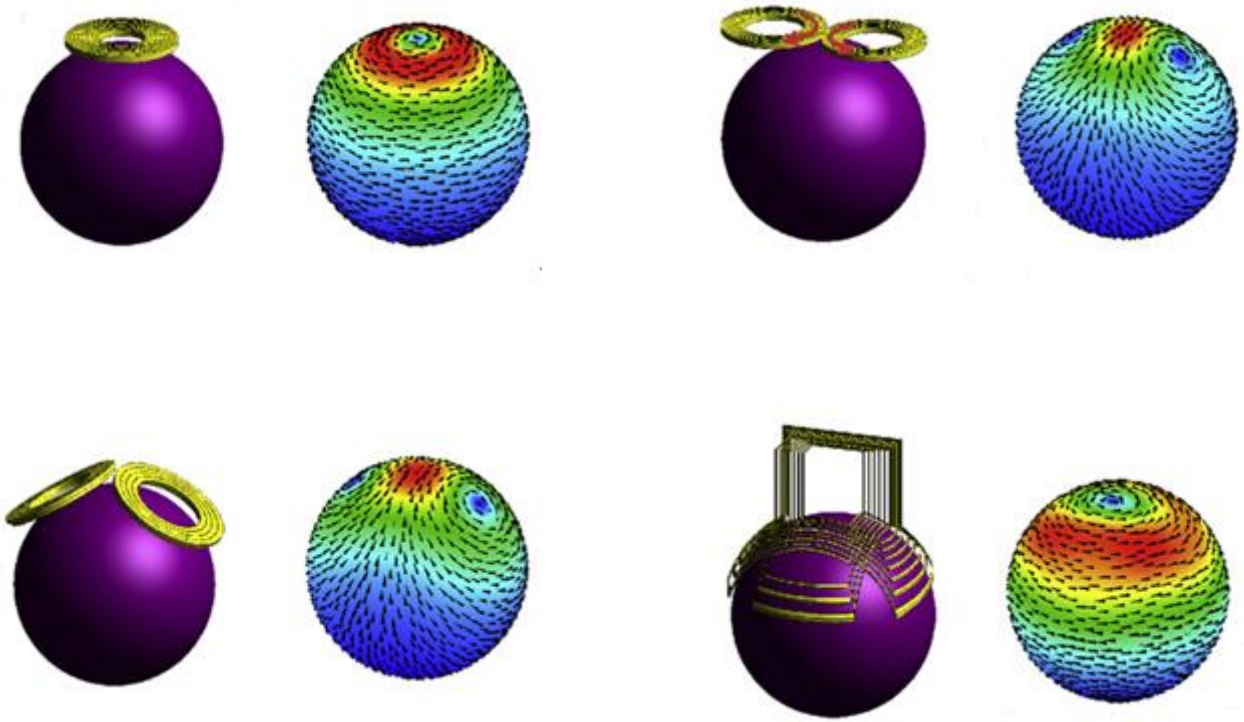
- Capacitor – stores electricity
- Thyristor switch – controls flow of current
- Coil – directs magnetic field



http://www.scholarpedia.org/article/Transcranial_magnetic_stimulation

TMS Devices – Coils

- Circle
- Figure eight or butterfly
- Double cone
- Hesed or H coil

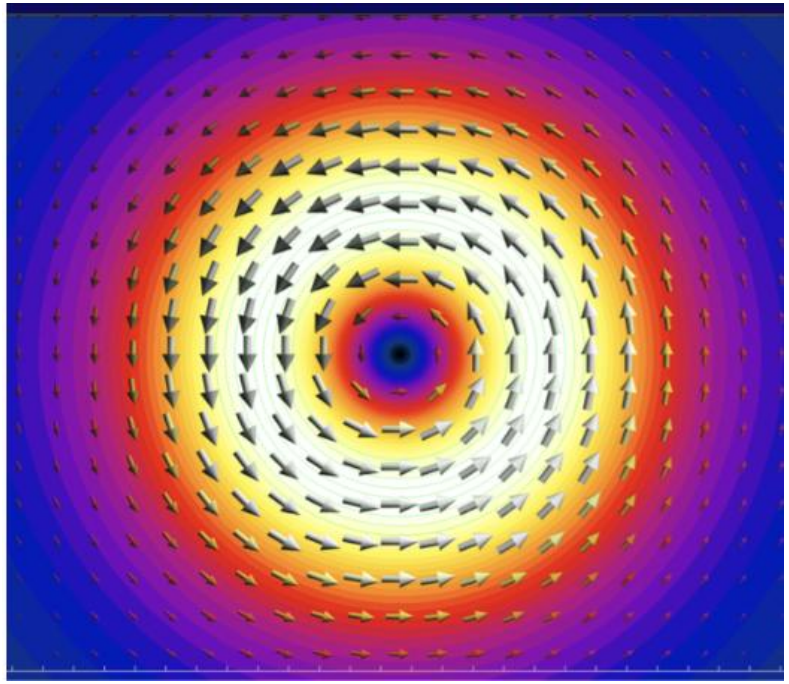


(Deng et al. Brain Stimulation, 2013)

Evolution of TMS Coils: Circular Coil



1985 Barker Circular Coil



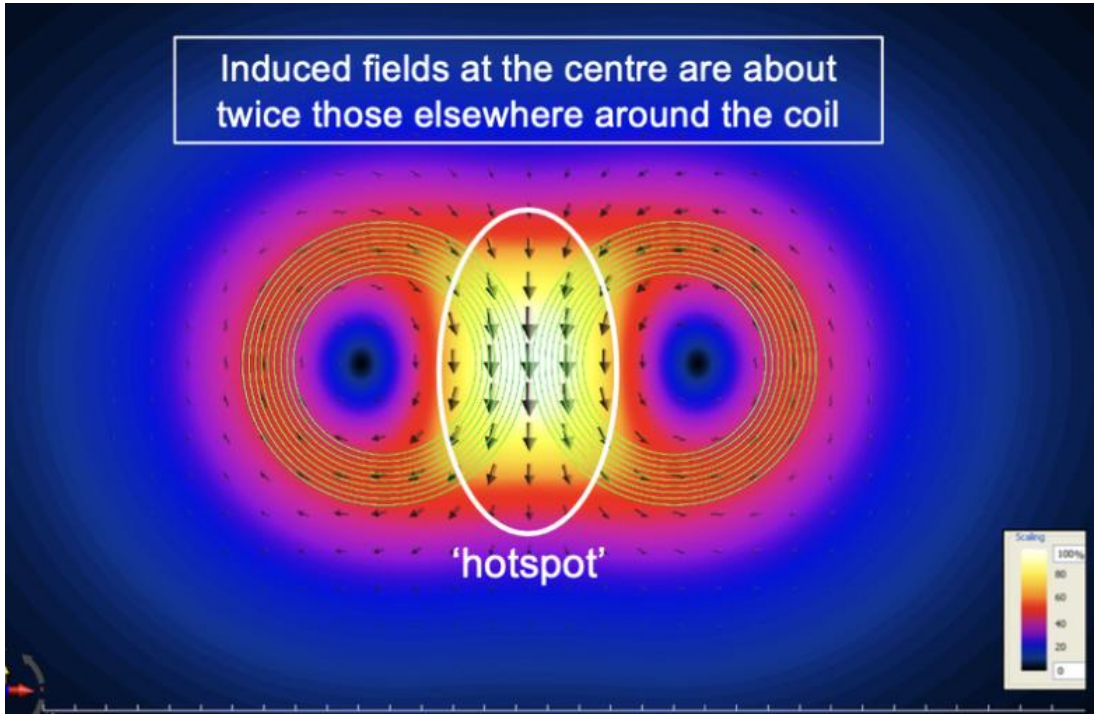
Induced electric field from a 90mm circular coil 14mm below the coil housing in a uniform ‘tissue’ slab

(Barker, CTMSS PULSES: TMS History)

Evolution of TMS Coils: Figure-8 Coil



2008 Figure 8 Coil



Induced electric fields from a 70mm figure-of-eight coil, 14mm below the coil housing in a uniform 'tissue' slab

(Barker, CTMSS PULSES: TMS History)

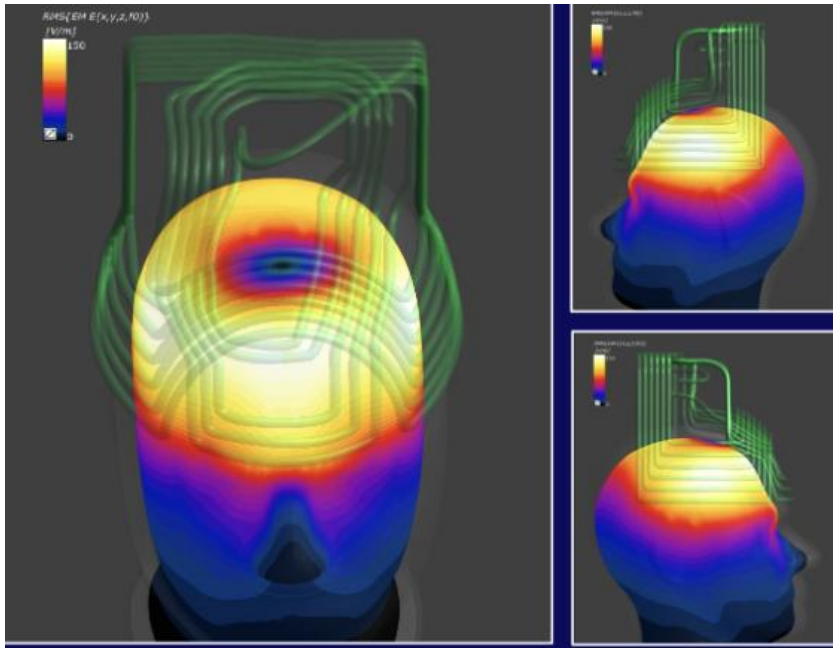
Evolution of TMS Coils: Hesed Coil



BrainsWay H1 coil



BrainsWay H4 coil



H coil induces high electric fields over large areas of the cortex, both frontally and laterally

(Barker, CTMSS PULSES: TMS History)
(Tendler et al. Expert Review of Medical Devices, 2016)

TMS Device Considerations

- Device design
  - *All in one*
  - *Modular*
  - *Mobile*
  - *Chair*
- Coils
  - *Types available*
  - *Design*
- Cost
  - *Up front*
  - *Per treatment*
  - *Subscription*
- Use
  - *Treatment*
  - *Research*
- Peripheral/accessory availability
  - *Patient management system*
  - *Neuronavigation*
  - *EMG*
  - *EEG*
  - *Robot assisted*

TMS Devices

- Please see the appendix, at the end of the presentation, for a non-comprehensive list of commercially available TMS devices for therapeutic use
- Please see device manufacturer websites for additional device specific information
- The Clinical TMS Society **does not** endorse any specific device
- The Clinical TMS Society does maintain a list of device manufacturers that have asked to be included on the society website: www.clinicaltmssociety.org/tms-devices

TMS Devices

- The CTMSS recommends:
- All TMS treaters undergo device specific (manufacturer) training on the individual device(s) they operate
- All TMS treaters undergo annual clinic/program specific re-certification of device safety and technical skills

SAFETY AND TOLERABILITY OF TMS

What Treaters Need to Know

TMS Safety and Tolerability

- Most TMS side effects are mild, expected, and temporary
- Serious adverse events are rare
- Treaters are often the first to notice changes
- Early recognition improves safety and outcomes

The Treater's Role in Safety

- Observe patients before, during, and after treatment
- Ask and document usage of caffeine, alcohol, drug use, medication changes, sleep changes
- Listen carefully to patient-reported experiences
- Document clearly and consistently
- Communicate concerns promptly

You are not diagnosing — you are observing, documenting, and communicating

Common Side Effects (Overview)

Common and expected:

- *Scalp discomfort or pressure*
- *Headache*
- *Facial muscle twitching*
- *Eyelid or jaw movements*
- *Neck discomfort*
- *Fatigue*

Key point: These effects tend to be transient and usually improve over time

Scalp Discomfort and Local Pain

- Feels like tapping, pressure, or soreness
- Often strongest during early sessions
- Typically decreases after the first 1–2 weeks

Treater actions:

- Check coil contact and angle
- Ensure proper cap placement
- Offer brief pauses if needed
- Reassure patient
- Gradually increase stimulation intensity

Headaches

- Usually tension-type headaches
- May occur during or after treatment
- Often improve as treatment continues

Helpful strategies:

- Optimize coil positioning
- Encourage hydration
- OTC analgesics if clinician-approved

Escalate if:

- Severe or worsening headaches
- Headache with neurological symptoms

Fatigue and Cognitive Effects

- Mild fatigue after sessions
- Temporary “foggy” feeling
- Brief difficulty concentrating

Important notes:

- Usually short-lived
- Can occur even as mood improves

Treater role:

- Normalize the experience
- Document severity and patterns

Hearing-Related Effects

- Ear discomfort
- Ringing in ears (rare with protection)

Prevention:

- Hearing protection is always required
- Check comfort and fit before starting

Escalate if:

- Persistent ringing
- Hearing changes after sessions

Rare Adverse Events

Very uncommon but important:

- Seizure
- Syncope (fainting)
- Activation/insomnia/agitation/irritability

Key message:

- Rare events, but treaters must recognize early signs

Seizure and Syncope Awareness

Possible warning signs:

- Sudden confusion
- Jerking movements
- Loss of consciousness

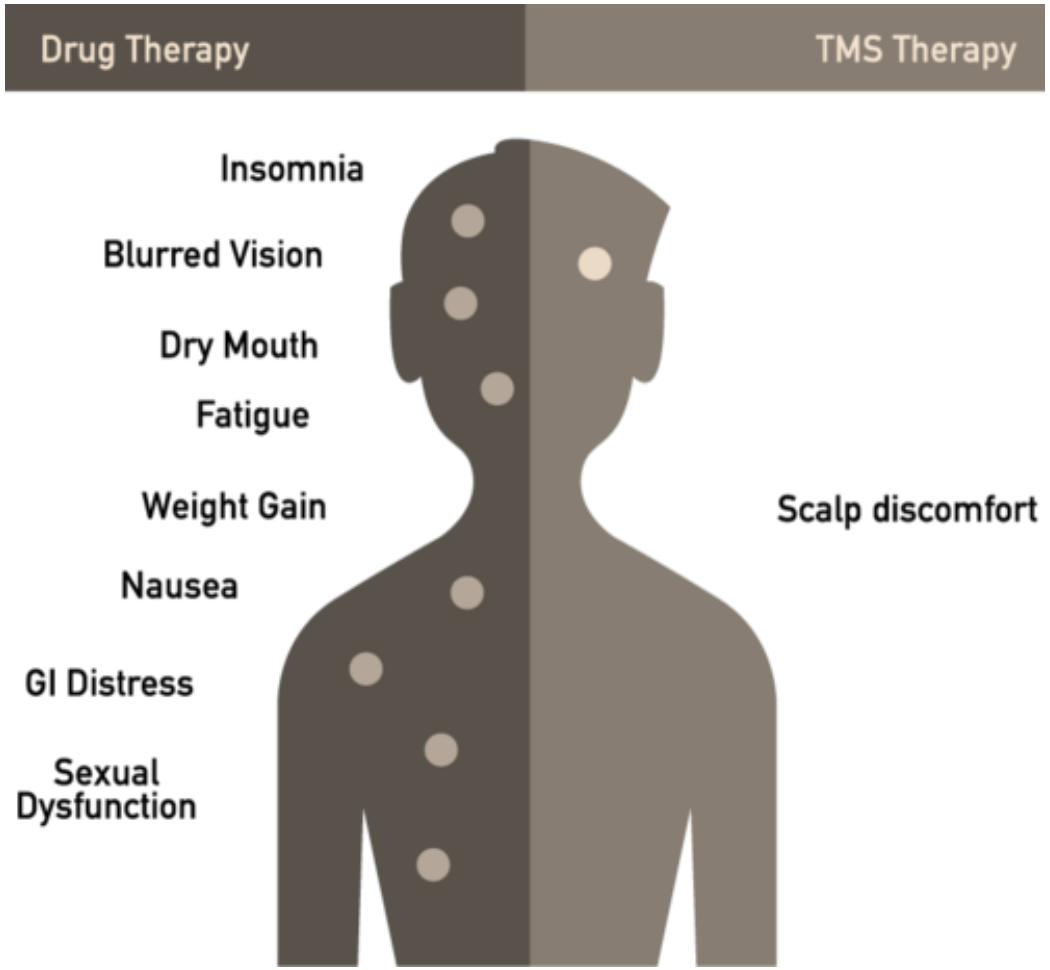
Treater response:

- Stop stimulation immediately
- Follow clinic emergency protocol
- Ensure patient safety
- Notify clinician immediately
- Document thoroughly

Key Takeaways for Treaters

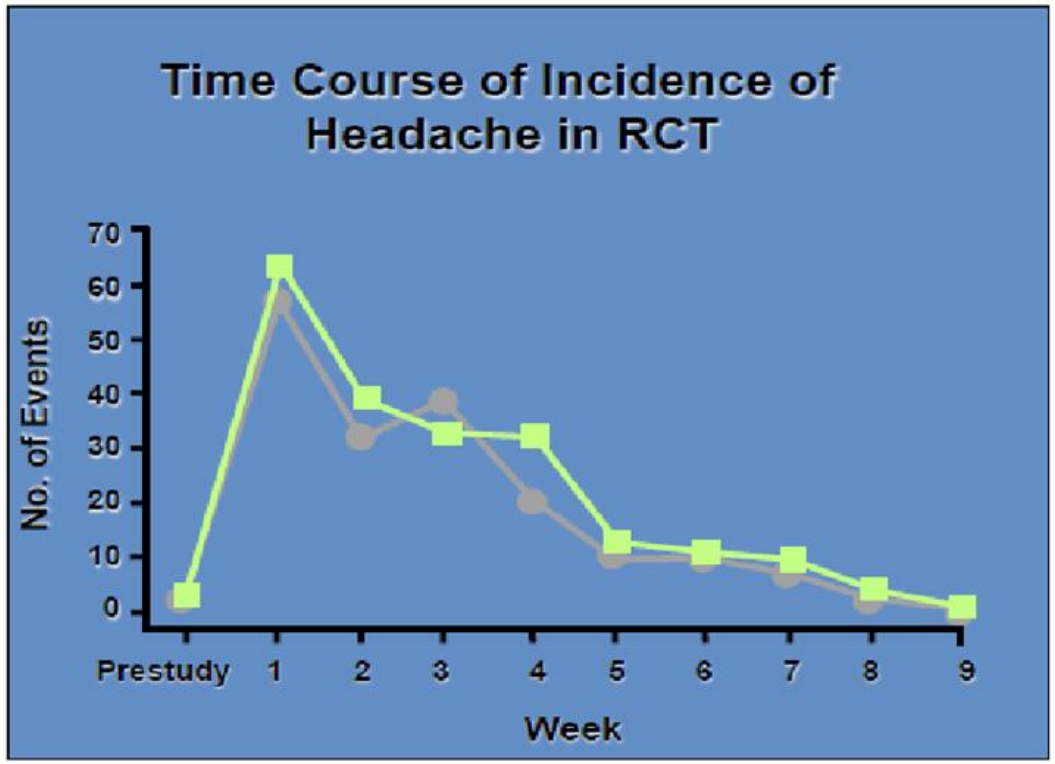
- Most TMS side effects are manageable
- Calm reassurance matters
- Consistent documentation matters
- Early communication matters
- Treaters are a critical part of patient safety

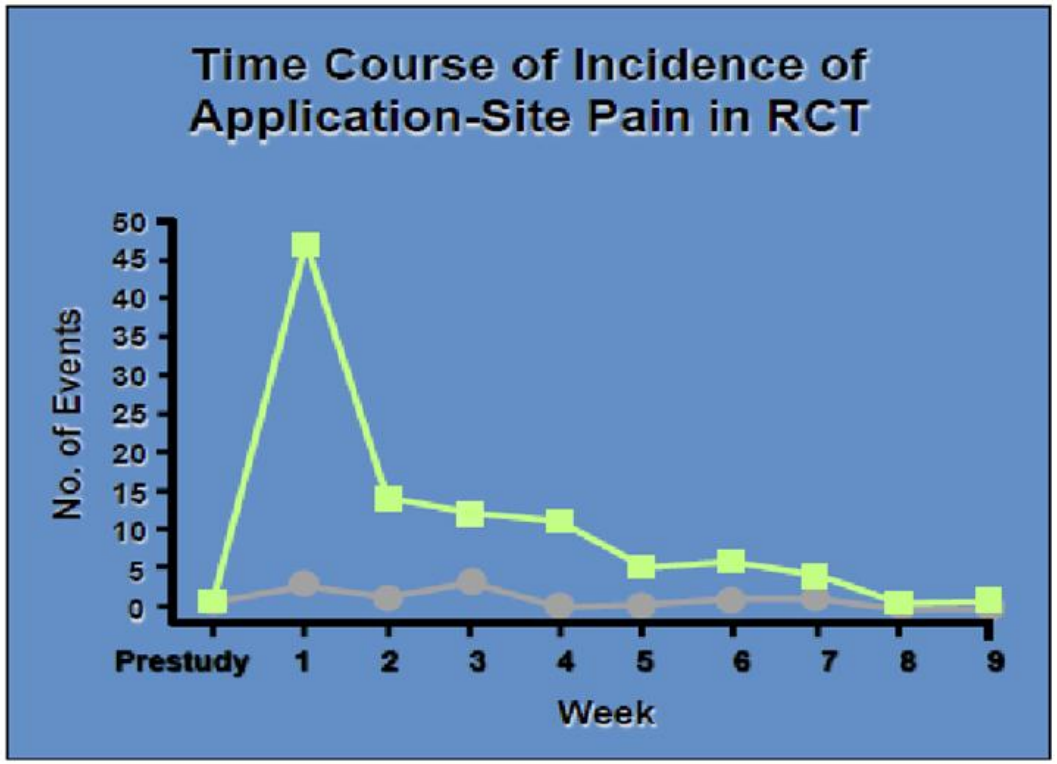
Side effects? What side effects?



(Kalu et al. Psychological Medicine, 2012)
(Blumberger et al. Current Psychiatry Reports, 2013)

Time Course for Most Common Adverse Events with Figure-8 TMS Coil







(Janicak et al. The Journal of Clinical Psychiatry, 2008)

TMS Seizures

- Seizure most serious adverse event associated with TMS
- The risk of seizures **is 0.071%** per patient
- Figure-of Eight Coil: 0.014%
- BrainsWay H-Coil: 0.56%

- Comparison of seizure incidence with medication titration during FDA trials:
  - bupropion IR- 0.4%
  - citalopram-0.3%
  - fluoxetine 0.2%
  - *venlafaxine 0.1%*

(Taylor et al. Brain Stimulation, 2021)
(Alper et al. Biological Psychiatry, 2007)

TMS: Seizures

- Most cases associated with TMS were prior to the publication of safety guidelines in 1998
- The risk is less than or comparable to that associated with antidepressant medications
- All reported TMS induced seizures have occurred during the treatment session itself and have stopped with no sequelae and no progression to epilepsy

(Wassermann. Electroencephalography and Clinical Neurophysiology, 1998)
(George et al. Current Opinion in Psychiatry, 2013)

TMS: Hearing Loss

- Small proportion of adult humans have experienced transient increases in auditory thresholds
- Permanent threshold shift in a single patient who did not wear ear plugs and was stimulated with H1 coil
- Majority of studies in which hearing protection was used report no changes in hearing
- Recent study examining the sound of 7 different TMS coils found airborne sound exceeded some exposure limits for TMS subjects and, in some cases, for treaters

(Loo et al. Biological Psychiatry, 2001)
(Zangen et al. Clinical Neurophysiology, 2005)
(Folmer et al. Acta Otolaryngology, 2006)
(Rossi et al. Journal of Neurology, Neurosurgery & Psychiatry, 2007)
(Janicak et al. The Journal of Clinical Psychiatry, 2008)
(Koponen et al. Brain Stimulation, 2020)

TMS: Hearing Recommendations

- Patients and TMS treaters are encouraged to use earplugs that meet a minimum standard of 30dB of protection

- Consider hearing protections for visitors (including babies and pets) or clinicians that stay in the room during treatments, especially with higher stimulation intensities







TMS: Treatment Emergent Mania (TEM)

Review of 10 TMS studies involving both depressed and bipolar patients reported:

- TEM was 0.84% for active treatment group and 0.73% for sham group
- The switch rate for unipolar patients was 0.34%
- The switch rate for bipolar patients was 3.1%

Review of 19 TMS studies involving bipolar patients reported:

- TEM was 0.9% for active treatment group and 1.3% for sham group

(Xia et al. International Journal of Neuropsychopharmacology, 2008)
(McGirr et al. World Psychiatry, 2016)

SCOPE OF PRACTICE

Role and Responsibilities of the TMS Treater

TMS Treater – Scope of Practice

- Core responsibilities include both clinical and administrative tasks
  - ***Clinical:*** *delivering treatment, assessing tolerability, response, and risk, collaborating with internal and external clinicians*
  - ***Administrative:*** *clinical documentation, device maintenance, supply ordering, office maintenance*
- Scope of practice may differ depending on the treater's background, role, environment, regulatory factors etc.
- As such, this slide deck assumes a therapeutically oriented role in a general clinical environment

TMS Treater – Recommended Core Competencies

- **Core Knowledge**
  - *Basic mechanisms of TMS*
  - *Fundamentals in TMS device design*
  - *Basic neuroanatomy and neurophysiology*
  - *TMS safety and risk*
  - *Clinical documentation*

- **Safety and Ethics**
  - *Common side effects and adverse effects of TMS*
  - *Diagnosis and management of seizure and syncope*
  - *Hearing protection*

(Fried et al. Clinical Neurophysiology, 2021)

TMS Treater – Recommended Core Competencies

- **Technical Applications and Hands-On Training**
  - *Device operation and troubleshooting*
  - *Scalp measurements*
  - *Basic neurophysiology methods and techniques*
  - *Targeting TMS*
  - *Basic applications of TMS*
  - *TMS protocols and clinical indications with emphasis on those cleared by relevant regulatory bodies*

(Fried et al. Clinical Neurophysiology, 2021)

TMS Treater – Scope of Practice

- The treater is the main daily contact point for patients
- Should have strong interpersonal and patient facing skills
- Needs to understand the operational aspects of all daily TMS tasks
  - *Main daily contact for patients and to collaborate care with providers*
  - *Cap and coil placement*
  - *Neuronavigation registration (if used in clinic)*
  - *Selecting parameters per the treatment "prescription"*
  - *Running the treatment*
  - *Troubleshooting*
  - *Maintaining safety and monitoring for adverse effects*
  - *Cleaning up*

ETHICAL GUIDELINES FOR TMS TREATERS

TMS Treater Code of Ethics

- Every TMS clinic should establish their own code of ethics
- We recommend that this code of ethics should have specific foundational principles
- These principles should describe the purpose and scope of practice for the TMS treater
- They should also include the responsibilities of the TMS treater and ethical guidelines for treating patients

TMS Treater Code of Ethics (Cont.)

- Preamble: The *Professional Standards of Ethics* is applicable to an individual participating in the procedural administration of Transcranial Magnetic Stimulation (TMS) therapy. This includes any person that has received clinical training or certification through an organization responsible for the safe administration of TMS therapy

- Purpose: provides proactive guidance on what it means to be qualified and to motivate and promote a culture of ethical behavior within the profession and to act in the best interest of patients

- The Code of Ethics shall serve as a guide by which current and future TMS treaters may evaluate their professional conduct as it relates to patients, healthcare consumers, employers, colleagues, and other members of the healthcare team

The Code of Ethics

1. A TMS treater shall continually present professionalism through modeled behavior
2. A TMS treater shall create and maintain appropriate professional boundaries with patients, peers, and staff
3. A TMS treater will avoid developing physical relationships with patients, which includes excessive physical contact
4. A TMS treater will maintain cultural competency, and will avoid disclosing personal racial, spiritual, political, gender, sexuality, substance use beliefs within the conversational scope of TMS therapy
5. A TMS treater will practice within their scope of practice as defined by their organizational policy

Establishing Boundaries for TMS Treaters

- TMS treaters should maintain a friendly but professional relationship with patients
- TMS treaters should avoid crossing boundaries, sharing too much personal information. Examples of what counts as too personal: religious or political beliefs, deeply personal experiences
- TMS treaters should be observant of kinds of body language, tones and phrases may indicate a patient does not wish to engage in conversation
- TMS treaters should be active listeners and not try to lead the conversation
- TMS treater role is to be a support and source of encouragement and motivation but not to counsel and give advice
- If someone is complaining, the TMS treater should be a listening ear and show sympathy before trying to encourage, so they feel heard and not dismissed
- TMS treaters should limit attempts to help patients reframe their negative thought processes, as this should be done by a licensed therapist. Instead encourage them to speak to their therapists about these challenges

Communication and Motivational Interviewing for TMS Treaters

- Motivational interviewing is a patient-centered communication style that helps patients articulate their own reasons for change and stay engaged in treatment

TMS treaters should approach patients with:

  - Unconditional positive regard – valuing patients without judgment
  - Acceptance without correction – avoiding fixing or labeling
  - Respect for autonomy – empowering patient choice
  - Empathy and compassion – warmth, curiosity, and presence
  - Non-directive support – creating space rather than giving advice

- Encourage healthy lifestyle: nutrition, exercise, sleep, medication adherence, stress management

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Appendix

- Commercially available devices
- CTMSS bibliography

Ampa One



www.ampahealth.com

- **Website:** ampahealth.com
- **Coils:** L coil, M coil
- **Cooling:** passive
- **FDA clearances:** MDD
- **CE Marked:** no
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

Apollo TMS Therapy



- **Website:** neurocaregroup.com
- **Coils:** aCool, pCool, others available
- **Cooling:** air
- **FDA clearances:** MDD
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

Blossom TMS Therapy System



www.sebersmedical.com

- **Website:** sebersmedical.com
- **Coils:** figure 8
- **Cooling:** liquid
- **FDA clearances:** MDD
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** no
- **Patient management system:** yes

Brain Ultimate TMS



www.brainultimate.com

- **Website:** brainultimate.com
- **Coils:** figure 8, double cone
- **Cooling:** liquid
- **FDA clearances:** MDD, OCD
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

BrainsWay Deep TMS System



www.brainsway.com

- **Website:** brainsway.com
- **Coils:** H1, H4, H7
- **Cooling:** air
- **FDA clearances:** MDD, OCD, anxious depression, adolescent depression, late life depression, smoking addiction, accelerated dTMS (SWIFT)
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** no
- **Patient management system:** yes

CloudTMS



www.mycloudtms.com

- **Website:** mycloudtms.com
- **Coils:** figure 8
- **Cooling:** liquid
- **FDA clearances:** MDD, OCD
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** no
- **Patient management system:** yes

Magstim Horizon TMS



- **Website:** magstim.com
- **Coils:** figure 8, double cone, others
- **Cooling:** air
- **FDA clearances:** MDD, OCD, anxious depression, adolescent depression, peripheral pain
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

MagVenture MagVita TMS Therapy System



- **Website:** magventure.com
- **Coils:** figure 8, double cone, others
- **Cooling:** liquid
- **FDA clearances:** MDD, OCD, anxious depression, adolescent depression, accelerated TMS, peripheral pain
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

NeuroStar Advanced Therapy



www.neurostar.com

- **Website:** neurostar.com
- **Coils:** figure 8
- **Cooling:** passive
- **FDA clearances:** MDD, OCD, anxious depression, adolescent depression
- **CE Marked:** yes
- **Theta burst:** no
- **Neuronavigation:** no
- **Patient management system:** yes

Nexstim



- **Website:** nexstim.com
- **Coils:** figure 8
- **Cooling:** liquid
- **FDA clearances:** MDD
- **CE Marked:** yes
- **Theta burst:** yes
- **Neuronavigation:** yes
- **Patient management system:** yes

Additional Important Research Studies that Have Advanced TMS

Recommended Bibliography for TMS Providers (Edition 3-12-25)

DOI	#	Year	Title	Column 1
https://doi.org/10.1016/j.biopsych.2007.01.018		2007	Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial	O'Reardon et al 2007
https://doi.org/10.1001/archgenpsychiatry.2010.46		2010	Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder	George et al 2010
https://doi.org/10.1002/da.21969		2012	Transcranial Magnetic Stimulation (TMS) for Major Depression: A Multisite, Naturalistic, Observational Study of Acute Treatment Outcomes in Clinical Practice	Carpenter et al 2012
https://doi.org/10.1001/jamapsychiatry.2018.1483		2018	Effect of Repetitive Transcranial Magnetic Stimulation on Treatment-Resistant Major Depression in US Veterans	Yesavage et al 2018 "The Veteran Study"
https://doi.org/10.1016/S0140-6736(18)30295-2		2018	Effectiveness of theta burst versus high-frequency repetitive transcranial magnetic stimulation in patients with depression (THREE-D): a randomised non-inferiority trial	Blumberger et al 2018 "THREE-D"
https://doi.org/10.1056/nejmra1706158		2018	Mapping Symptoms to Brain Networks with the Human Connectome	Fox 2018
https://doi.org/10.1176/appi.ajp.2019.18101180		2019	Efficacy and Safety of Deep Transcranial Magnetic Stimulation for Obsessive-Compulsive Disorder: A Prospective Multicenter Randomized Double-Blind Placebo-Controlled Trial	Carmi et al 2019
https://doi.org/10.1176/appi.ajp.2019.19090957		2019	Whither TMS: A One-Trick Pony or the Beginning of a Neuroscientific Revolution?	George 2019
https://doi.org/10.1016/j.clinph.2019.11.002		2020	Clinical outcomes in a large registry of patients with major depressive disorder treated with Transcranial Magnetic Stimulation	Sackeim et al 2020
https://doi.org/10.1016/j.clinph.2019.11.002		2020	Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation (rTMS): An update (2014-2018)	Lefacucheur et al 2020
https://doi.org/10.1016/j.clinph.2020.10.003		2020	Safety and recommendations for TMS use in healthy subjects and patient populations, with updates on training, ethical and regulatory issues: Expert Guidelines	Rossi et al 2020
https://doi.org/10.1001/jamapsychiatry.2020.3794		2020	Functional Magnetic Resonance Imaging–Guided Personalization of Transcranial Magnetic Stimulation Treatment for Depression	Cash et al 2020
https://doi.org/10.1016/j.brs.2021.08.021		2021	Neuromodulatory treatments for psychiatric disease: A comprehensive survey of the clinical trial landscape	Elias et al 2021
https://doi.org/10.1016/j.neurom.2021.09.003		2021	Synaptic Plasticity 101: The Story of the AMPA Receptor for the Brain Stimulation Practitioner	Brown et al 2021
https://doi.org/10.1176/appi.ajp.2021.20101429		2021	Stanford Neuromodulation Therapy (SNT): A Double-Blind Randomized Controlled Trial	Cole et al 2021 "SNT Protocol"
https://doi.org/10.3389/fpsyt.2022.867091		2022	The Problem and Potential of TMS' Infinite Parameter Space: A Targeted Review and Road Map Forward	Caulfield et al 2022
https://doi.org/10.1097/hrp.0000000000000364		2023	Accelerated Repetitive Transcranial Magnetic Stimulation to Treat Major Depression: The Past, Present, and Future	Chen et al 2023
https://doi.org/10.1016/j.clinph.2024.12.015		2024	Consensus review and considerations on TMS to treat depression: A comprehensive update endorsed by the National Network of Depression Centers, the Clinical TMS Society, and the International Federation of Clinical Neurophysiology	Trapp et al 2024
pending			Assessment and Management of Concurrent Substance Use in Patients Receiving rTMS for Depression, OCD, Psychotic and Trauma Related Disorders	
pending			Treating Depression with rTMS, a Clinician's Guide	
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