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Review

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

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ABSTRACT

This article updates the prior 2018 consensus statement by the National Network of Depression Centers (NNDC) on the use of transcranial magnetic stimulation (TMS) in the treatment of depression, incorporating recent research and clinical developments.

Publications on TMS and depression between September 2016 and April 2024 were identified using methods informed by PRISMA guidelines. The NNDC Neuromodulation Work Group met monthly between October 2022

Abbreviations: NNDC, National Network of Depressive Centers; (r)TMS, (repetitive) transcranial magnetic stimulation; DLPFC, dorsolateral prefrontal cortex; RCT, randomized controlled trial; iTBS, intermittent theta burst stimulation; (TR-)MDD, (treatment-resistant-) major depressive disorder; FDA, Food and Drug Administration; NNT, number needed to treat.

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and April 2024 to define important clinical topics and review pertinent literature. A modified Delphi method was used to achieve consensus.

2,396 abstracts and manuscripts met inclusion criteria for review. The work group generated consensus statements which include an updated narrative review of TMS safety, efficacy, and clinical features of use for depression. Considerations related to training, roles/responsibilities of providers, and documentation are also discussed.

TMS continues to demonstrate broad evidence for safety and efficacy in treating depression. Newer forms of TMS are faster and potentially more effective than conventional repetitive TMS. Further exploration of targeting methods, use in special populations, and accelerated protocols is encouraged.

This article provides an updated overview of topics relevant to the administration of TMS for depression and summarizes expert, consensus opinion on the practice of TMS in the United States.

1. Introduction

Transcranial magnetic stimulation (TMS) is a treatment for major depressive disorder (MDD) in adults that was cleared by the United States Food and Drug Administration (FDA) in 2008. Since the approval of the initial TMS device at that time, multiple TMS systems have received 510 k clearances. The treatment involves applying repeated, noninvasive, targeted stimulation to the prefrontal cortex of the brain over several days. Various reviews, recommendation documents, and *meta*-analyses have been published over the past 15 years summarizing the literature on the use of TMS for depression, including a consensus recommendations document from the National Network of Depression Centers (NNDC) rTMS Task Group (now the Neuromodulation Task Group) and American Psychiatric Association (APA) Council on Research Task Force on Novel Biomarkers and Treatments in 2018 (McClintock et al., 2018a). TMS use continues to rapidly expand, with new clinical indications and treatment protocols being studied that are changing how TMS is administered and the associated standard of care. For example, new forms of TMS have been pioneered, including the use of intermittent theta burst stimulation (iTBS) to shorten the total stimulation and treatment time. Other accelerated protocols attempt to push the boundaries of total pulses delivered to the brain and time to treatment response. The FDA has recently extended the label for a specific TMS device and protocol down to age 15. The rapidly changing treatment landscape prompted our group to write an updated consensus document aimed at reviewing new literature on the use of TMS in depressive disorders. In addition to reviewing this new literature, we offer consensus statements on key topics surrounding the practice of TMS for depressive disorders.

2. Methods

2.1. Participants and process for the consensus statements

The National Network of Depression Centers (NNDC) Neuromodulation Task Group convened a subgroup of 18 expert clinicians and researchers on the use of TMS for depressive disorders. The credentials for members of the task group are reviewed in **Appendix 1**. The experts met virtually via video conference on a monthly basis between October 2022 and April 2024, and a workshop focused on this process was convened as a pre-meeting event prior to the annual NNDC conference in October 2023 in Houston, Texas. Each meeting consisted of a pre-specified topic leader or leaders reviewing the evidence for a topic of clinical interest identified by the task group, followed by discussion amongst the group of experts related to practical aspects of TMS and differing practices. A modified Delphi method (Trevelyan et al., 2015) was used to achieve consensus on topics addressed at the monthly meetings, including an iterative process of blinded voting followed by providing anonymized feedback from each voter justifying their vote to the rest of the group. This process was continued until majority consensus was achieved. All members of the group then had the opportunity to provide additional edits to the drafted consensus statement. The drafted consensus statement was then submitted for review by the executive committees of the International Federation of Clinical Neurophysiology and the Clinical TMS Society for review and endorsement by both organizations.

2.2. Evidence to support the consensus statements

The NNDC Neuromodulation Task Group collected evidence via systematic literature review and expert opinion. The literature search included a search of Medline/PubMed, Cochrane, PsycINFO, and Embase between the dates of September 1, 2016 (the end date of the prior review for the 2018 publication) and September 12, 2022. References of included studies were not systematically searched for additional eligible studies, although additional articles identified by expert recommendation were also included from before September 2016 and up to October 1, 2024. Search terms included *transcranial magnetic stimulation* and seven similar terms within its MeSH designation, as well as *depression, postpartum depression, major depressive disorder, treatment-resistant depressive disorder, dysthymic disorder, premenstrual dysphoric disorder, vascular depression,* and 33 additional terms within their MeSH designations including *bipolar depression* (see **Appendix 2** for full list). Title and abstract review were conducted by authors NTT, AP, and JRR. Inclusion criteria were primary data articles, review articles, or *meta*-analyses on mood disorders and TMS. Exclusion criteria were non-English language articles, commentaries, duplicate articles, non-data articles, articles with no mood outcomes or TMS, and preclinical studies. In total, 4,238 abstracts were reviewed, identifying 2,396 unique articles meeting inclusion criteria. A PRISMA-like flow diagram is shown in Fig. 1. Each topic leader reviewed a subset of these articles relevant to the topic of interest based on a keyword search amongst the article titles and abstracts (see details in Fig. 1 and **Appendix 3**). As this number of articles was beyond the scope of a systematic review, discretion for reference to relevant articles lay with the topic leader(s) informed by input from the task group as a whole. Table 1 highlights the primary considerations from the document for reference throughout.

3. Literature review and consensus statements

3.1. Efficacy of TMS in depression

3.1.1. Major depressive disorder

The acute antidepressant effects of left dorsolateral prefrontal cortex (DLPFC) repetitive transcranial magnetic stimulation (rTMS) for major depressive disorder (MDD) have been extensively studied and reproduced, as discussed in McClintock et al. (McClintock et al., 2018a). The evidence includes three pivotal randomized controlled trials (RCTs) (George et al., 2010b, Levkovitz et al., 2015, O'Reardon et al., 2007), a large multisite non-inferiority study of intermittent theta burst stimulation (iTBS) versus high frequency (10 Hz) rTMS (Blumberger et al., 2018), and numerous *meta*-analyses (Dalhuisen et al., 2022, Kedzior et al., 2015, Mutz et al., 2017, Mutz et al., 2018, Razza et al., 2021, Wei et al., 2017). In contrast, one recent large-scale (n = 164) clinical trial in the VA health system failed to demonstrate superiority of active TMS compared to sham, due in part to high sham responder rates (Yesavage

et al., 2018). Recent developments in the clinical application of TMS have confirmed and solidified the evidence for antidepressant efficacy. For example, one *meta*-analysis of RCTs that incorporated 65 rTMS studies (n = 2,982 participants) demonstrated a large antidepressant effect size (Hedge's *g* 0.79, 95 % confidence interval 0.61 to 0.98) with high frequency rTMS applied to the left DLPFC (Dalhuisen et al., 2022). Analysis of response and remission rates in this *meta*-analysis similarly revealed odds ratios favoring active treatment over sham (ratios of 2.38:1 and 2.45:1, respectively). One large, retrospective study (n = 5,010) of "real-world" patients receiving rTMS for depression reported response rates of 58–83 % and remission rates of 28–62 % (Sackeim et al., 2020) across both self-report and clinician-administered outcome scales. Furthermore, two recent studies suggest rTMS be considered earlier in antidepressant treatment algorithms, demonstrating rTMS may be more effective than medication in patients with treatment resistance. In one study, rTMS augmentation was superior to switching pharmacologic agents in patients with TRD who had failed 2 or more medications (Papakostas et al., 2024). In the other, TRD patients randomized to rTMS had greater reductions in depressive symptoms, specifically anhedonia and anxiety, compared to those randomized to an evidence-based antidepressant medication switch or pharmacologic augmentation (Dalhuisen et al., 2024).

Although acute clinical benefits of rTMS for major depression have been well established, the durability of the antidepressant effect has been less well characterized. One systematic review and *meta*-analysis of 18 studies on this topic (n = 247 to 732 depending on timepoint of interest) suggested that sustained response rates at 3, 6, and 12 months post-treatment were 66.5 %, 52.9 % and 46.3 %, respectively (Senova

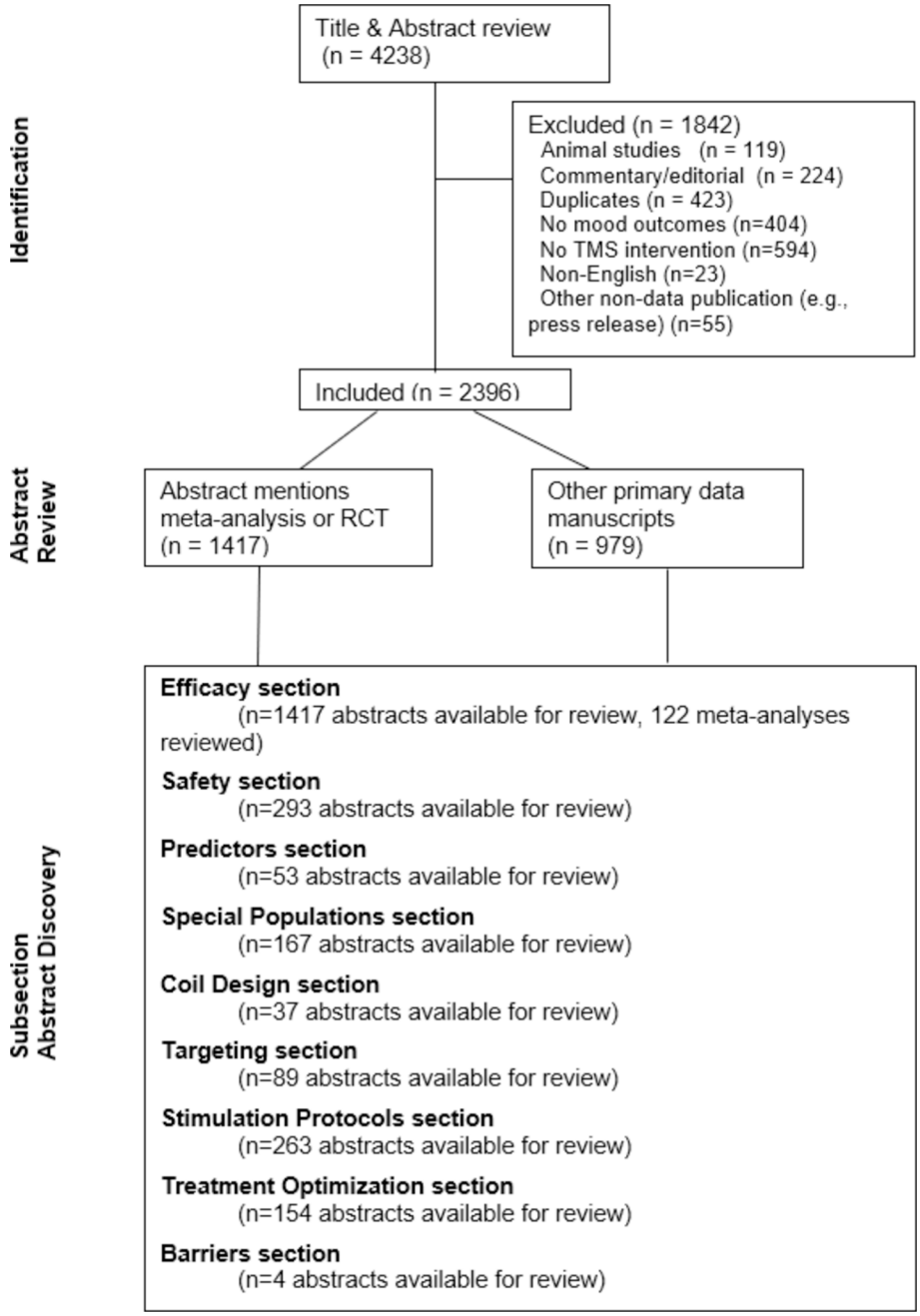

Fig. 1. Flow diagram of systematic article identification, screening, and inclusion for review. Systematic search was conducted for publications from September 1, 2016 to September 12, 2022. Additional articles from before September 1, 2016, or between September 12, 2022 and up to April 17, 2024 were added based on expert knowledge and recommendations.

Table 1
Literature Summary and Consensus Recommendations.

Topic	Summary & Recommendations
Efficacy of TMS in Depressive Disorders	• A robust evidence base supports the efficacy of left DLPFC rTMS for MDD with a large effect size, including evidence for efficacy in treatment-resistant depression. • The available data for bipolar depression demonstrate a smaller magnitude of antidepressant effect. Some protocols raise concern for an increased risk of induction of manic symptoms. • rTMS has a modest effect in reducing anxiety symptoms and depression associated with Parkinson's Disease. It has a strong antidepressant effect in post-stroke depression. There is insufficient evidence to provide guidance on rTMS • for other mood disorders, suicidal ideation, depression with psychotic features, and depression secondary to TBI or SUD.
Safety and Pre-TMS Evaluation	• rTMS is generally well tolerated, with mild side effects of scalp pain, tension-type headaches, dizziness/lightheadedness, fatigue, and insomnia. Serious adverse effects, including seizure, syncope, tinnitus, and retinal detachment are rare. Treatment-emergent mania is also rare. • A pre-TMS assessment should include a thorough history and assessment of risk factors for seizure and other contraindications. • The motor threshold should be checked at baseline and either weekly or any time there is a change in the patient's clinical status or medications. We recommend follow-up at least every other week during • a treatment course to assess for response and monitor for side effects.
Predictors of Antidepressant Response	• No demographic factors consistently predict response. • rTMS has a greater antidepressant response when combined with antidepressant medication. • Benzodiazepine use is associated with worse clinical outcomes while psychostimulant use is associated with improved clinical outcomes in retrospective studies. There is insufficient evidence to guide prescribing. • Data on the influence of comorbidities, degree of treatment resistance, and depressive symptomatology on treatment response are conflicting. • We continue to recommend that patients with depression with psychotic features be considered for ECT.
Use in Special Populations	• rTMS appears to be safe in adolescent, peripartum, and geriatric populations, but more studies are needed. • Trials generally support the safety of rTMS in these populations, though the evidence base on efficacy varies by condition. • rTMS is FDA-cleared as adjunctive therapy for adolescents ages 15 and up, but not for use in children or younger adolescents at the time of this writing. • More research is needed to further evaluate the efficacy of rTMS in these special populations, as there are distinct clinical advantages of this treatment modality in these groups.
Coil Design	• Figure-of-8 (F8) coils induce more focal and superficial electrical fields. • H coils induce electrical fields that are thought to penetrate more deeply and broadly (less focal). • F8 and H coils are both FDA-cleared and demonstrate significant evidence of efficacy and safety in treating depression.
Targeting Methods	• We recommend using the 5.5 cm method or Beam F3 method for scalp-based targeting of the DLPFC for daily rTMS. • The incorporation of structural and functional imaging in rTMS targeting is useful for treatment individualization. The extent of its potential advantage in effectiveness is still an active area of investigation.
Stimulation Protocols	• Traditional and "dash/rapid" high-frequency rTMS protocols are FDA-cleared and broadly recommended. • Intermittent theta burst stimulation is an FDA-cleared protocol of short duration and is non-inferior to standard high-frequency protocols. We equally recommend iTBS and standard high-frequency rTMS as initial antidepressant protocols. • Low-frequency only protocols have a weaker evidence basis and are not FDA-cleared for depression. • Bilateral rTMS does not appear to be superior to unilateral rTMS. • Various accelerated protocols are being investigated, and there is some evidence that increased dose (either by number of pulses or number of sessions) is associated with greater antidepressant effect. • A novel and FDA-cleared highly accelerated protocol that also incorporates individualized targeting based on functional connectivity has shown high remission rates in an outpatient setting. Larger trials in other settings are underway, and this on-brand protocol only recently became commercially available in April 2024. • Various other protocols, including synchronized TMS, are • being investigated but are not recommended in routine clinical use at this time. • Magnetic seizure therapy (MST) utilizes TMS to induce a seizure to treat depression. Early data for this modality are promising and report reduced cognitive side effects compared to ECT. Larger trials are underway.
Treatment Optimization	• We generally recommend that patients receive the full treatment course of 30–36 sessions. There is conflicting evidence about prediction of response after a portion of sessions. • Combining psychotherapy with rTMS may have additional benefits, though further research is needed before this is broadly recommended. • Maintenance TMS is promising although the frequency of • maintenance treatments needed to sustain benefit is unclear. • No medication augmentation strategies have enough • evidence to be broadly applied, although use of stimulants and glutamate receptor modulators is promising.
Training, Privileging, and Treatment Roles and Responsibilities	• TMS for depression can be prescribed by clinicians with appropriate training and licensing, including knowledge of mood disorders and safe TMS use, as well as demonstration of technical skill with the device • TMS technicians should be trained to operate and appropriately target the TMS device, in

(continued on next page)

Table 1 (*continued*)

Topic	Summary & Recommendations
	addition to receiving training on monitoring for and identifying adverse events from TMS
Barriers to Treatment	• We recommend an emphasis be placed on TMS teaching and exposure in residency training programs, as well as ongoing TMS advocacy by physicians and physicians' groups, to address key barriers to the use of TMS including lack of access to experienced providers and lack of understanding of the procedure
Documentation	• A pre-treatment assessment note should document the indication for TMS, potential risks and benefits, as well as confirmation of consent to treatment • Procedure notes should document treatment protocols, • clinical progression, and treatment-related side effects • We recommend the use of rating scales to establish baseline symptom severity and monitor clinical response • At minimum, a mood rating scale should be obtained pre- and post-treatment

et al., 2019). However, this analysis included 11 studies in which participants were provided maintenance rTMS, which is not widely available in the United States. Subgroup analyses suggested maintenance treatment and female sex are predictive of increased durability of response. For example, 6-month sustained response rates were 61.1 % in studies with a maintenance protocol compared to 38.5 % in studies without one. Further study on optimal maintenance protocols is underway and is discussed in *Section 3.8. Treatment Optimization.* In addition to further supporting acute antidepressant efficacy of rTMS for major depressive disorder and exploring durability, recent research efforts have also focused on generating a more nuanced understanding of optimal rTMS parameters and "dose;" special mood disorder populations in which rTMS has shown promising therapeutic effect; and comparison of different treatment coils, stimulus protocols, or augmenting strategies for rTMS. All these topics are discussed in detail in other sections.

3.1.2. Bipolar depression

Since the original National Network of Depression Centers and American Psychiatric Association consensus statement was published, three *meta*-analyses have been published evaluating the effects of rTMS on bipolar disorder (Nguyen et al., 2021, Noda and Kito, 2020, Tee and Au, 2020). The largest of these contained 11 studies (n = 345 adult participants) (Tee and Au, 2020). In that report, the authors reviewed studies evaluating the effects of right and left prefrontal rTMS in depressive, mixed, and manic episodes of bipolar disorder. They identified a small but significant improvement in depressive symptoms with rTMS (effect size 0.31), with a number needed to treat (NNT) of 10 for remission as the outcome. Only one case of treatment-emergent mania was reported across 135 participants with bipolar depression treated with concomitant mood stabilizers or antipsychotics; this occurred in the context of left-sided high-frequency stimulation. Other studies have demonstrated mixed and inconclusive findings related to rTMS for bipolar depression, including concern for higher rates of treatment-emergent mania with iTBS and unclear efficacy (Konstantinou et al., 2022, McGirr et al., 2021b). A more detailed discussion of risk for mania and hypomania can be found in the Safety of rTMS section (3.2.1.). Furthermore, data for treating manic symptoms with rTMS is even less promising and less well-studied. Nonetheless, rTMS for bipolar disorder remains an area of active investigation and clinical promise; for example, the FDA has granted breakthrough status to one TMS device company for treating bipolar depression (Neuronetics, 2020).

3.1.3. Other depressive disorders and comorbid conditions

Other work has focused on depression with various comorbidities. The FDA cleared the H1 coil for anxious symptoms comorbid with depression in 2021 (Pell et al., 2022) based on retrospective data from anxiety symptoms measured during three RCTs (n = 442) that found a modest effect size favoring active relative to sham treatment ($g = 0.34$, sustained at 16 weeks). FDA clearance for this indication followed for some figure-8 coil manufacturers as well (Hutton, 2021, Hutton et al., 2023b). Another focus of research over the past six years has been depressive symptoms comorbid with Parkinson's disease (Chen J. et al., 2021, Hai-Jiao et al., 2020, Li et al., 2020b, Qin et al., 2018, Zhang et al., 2022). Several *meta*-analyses found moderate effect sizes (range 0.33 to 0.80), demonstrating antidepressant effect primarily with high frequency left DLPFC rTMS (Chen J. et al., 2021, Hai-Jiao et al., 2020, Zhang et al., 2022).

One of the conditions with accumulating evidence for efficacy is post-stroke depression, with seven *meta*-analyses of large sample size (five with > 1,000 participants) published within the past six years (Deng et al., 2017, Li et al., 2017, Liang et al., 2022, Liu et al., 2019, Shao et al., 2021, Shen et al., 2017, Shen et al., 2022). These datasets have all suggested a strong antidepressant effect of high frequency left DLPFC rTMS, and in several cases low frequency right DLPFC rTMS, with homogeneously large effect sizes, often surpassing 1.0 (standardized mean differences ranging from 1.01 to 4.92).

Use of rTMS for suicidality has shown some promise in *meta*-analyses, with one *meta*-analysis of 8 randomized, controlled trials (n = 566 participants) calculating an effect size of 0.415 for treating suicidal ideation with rTMS in patients with depression (Cui et al., 2021). Other *meta*-analyses have found similar effect sizes (Chen et al., 2022), although interpretation is complicated by inclusion of uncontrolled data, multiple stimulation modalities, or multiple mental disorders, and have demonstrated high heterogeneity in outcomes reported (Chen et al., 2022, Cui et al., 2021, Mehta et al., 2022). Accelerated rTMS protocols may have robust, rapid-acting anti-suicide effects, although large, randomized, controlled trials are needed to confirm early findings (Li et al., 2024).

The role of rTMS for other mood disorders (e.g., persistent depressive disorder) remains under investigation. Other mood conditions for which patients may present to an interventional psychiatrist, such as post-traumatic stress disorder or anxiety-associated dysphoria, depression secondary to traumatic brain injury, or depression in the context of substance use disorders, remain under investigation. Although some studies have shown promising efficacy, effectiveness, and safety (Cirillo et al., 2019, Cox et al., 2022, McGirr et al., 2021a, Oberman et al., 2020, Parikh et al., 2022, Pellegrini et al., 2022, Rao et al., 2019, Siddiqi et al., 2019, Tang et al., 2022, Thatikonda et al., 2022, Tsai et al., 2021, Wu et al., 2022, Yan et al., 2017), the evidence remains mixed and limited, with no definitive conclusions or consensus recommendations at this juncture.

Notably, TMS is FDA-cleared for other psychiatric disorders, such as obsessive–compulsive disorder (OCD) and tobacco use disorder (smoking cessation). Often TMS protocols for different clinical indications use distinct brain targets and treatment parameters. However, some evidence suggests that certain medial prefrontal cortex targets and stimulation protocols may improve both depression and anxiety symptoms concomitantly (Li et al., 2020a; Siddiqi et al., 2020; Taylor et al., 2024; Trapp et al., 2023b), paving the way for future studies examining transdiagnostic effects of specific treatment targets and protocols. Indeed, one deep TMS coil (H7) is FDA-cleared for both MDD and OCD and warrants further investigation. Additional discussion of other psychiatric indications is beyond the scope of this consensus statement. Studies investigating the efficacy of combining antidepressive TMS protocols with those used for other indications is limited and worthy of future pursuit.

3.2. Safety and Pre-TMS evaluation

3.2.1. Safety of rTMS

Repetitive transcranial magnetic stimulation (rTMS) for the treatment of MDD has a generally favorable safety and tolerability profile. The most common side effects are significant scalp or stimulation site pain/discomfort (incidence 39 %), tension-type headaches (28–65 %), nausea (7–11 %), dizziness or lightheadedness (4–9 %), fatigue (7–8 %), and insomnia (5–7 %). Less common side effects (<5%) include anxiety, irritability, back or neck pain, and precipitation of migraine headache. All these side effects are acute and time-limited effects of treatment. Very rare side effects (incidence likely well below 0.1 %, difficult to quantify, and with unclear causal relationship to TMS) include syncope, posterior vitreous detachment, retinal tear, and tinnitus (Blumberger et al., 2018, Kung et al., 2011, Loo et al., 2008, Marafon et al., 2020).

Among the most concerning known TMS-induced side effects is that of a seizure. Seizures reported to date with rTMS have been self-limited, occurred at the time of stimulation, and have not resulted in a seizure disorder. Most prior literature agrees that the seizure incidence with standard clinical rTMS protocols is less than 0.1 %, with some studies suggesting rates as low as 1 in 33,000 treatments (0.003 %) (Rossi et al., 2009). Some evidence suggests that different TMS coil designs may have different risk profiles for side effects, including seizure. For example, the seizure risk of the H1 TMS coil, which is delivered at a higher stimulation frequency and is thought to stimulate a deeper and greater volume of brain tissue, appears to be roughly 1 in 2,000 treatments, (incidence 0.043 % to 0.087 % depending on the study) (Lerner et al., 2019, Tendler et al., 2018). This incidence is generally higher than reports for figure-8 coil designs (1 in 12,500 treatments, or 0.008 %) (Lerner et al., 2019, Lisanby et al., 2003, Taylor et al., 2021). On this point, it is important to note that motor threshold (MT) checks recommended by manufacturers of each coil design vary (e.g., weekly MT checks with the H1 coil and a single MT check with some figure-8 coils), and there are few randomized, controlled trials that have evaluated differences between coil designs and their unique FDA-cleared protocols from which to draw firm safety comparisons. The largest randomized, controlled trial known to the authors that compared a figure-8 TMS coil to an H1 coil (n = 143) did not report any seizures in either treatment group (Filipčić et al., 2018). Seizure incidence is so infrequent with TMS that vasovagal syncope, which has also occurred with TMS especially early in a treatment course, should be high on the differential for any loss of consciousness episode that may occur.

Despite the theoretical increased risk of seizure in patients taking medications that can lower the seizure threshold, the practical impact on seizure risk is very low for patients taking prescribed medications in standard dose ranges (Dobek et al., 2015) and who lack other seizure risk factors. Overall, the incidence of seizure with rTMS as applied for the treatment of MDD is exceedingly low, with rates lower than those reported for a seizure threshold-lowering medication such as bupropion (incidence 0.35–0.44 %) (Davidson, 1989). Indeed, the only TMS-related seizure reported in a multisite trial occurred in a patient after heavy alcohol use the night prior to treatment (Levkovitz et al., 2015, Taylor et al., 2021). Even in patients with diagnosed epilepsy, the seizure risk is < 3 % (Stultz et al., 2020). Our understanding of TMS-induced seizure risk factors continues to grow, and adjustments to stimulation parameters and targeting may further reduce seizure risk in future clinical use and research trials.

As with many antidepressant treatments, induction of hypomanic or manic symptoms is a potential concern with rTMS, typically in patients with a history of bipolar disorder (Xia et al., 2008). Associated symptoms have included psychomotor activation, pressured speech, irritability, racing thoughts, flight of ideas, grandiosity, decreased need for sleep/insomnia, euphoria, and psychosis (Dolberg et al., 2001, Mahapatra et al., 2017, Rachid, 2017). Studies vary as to the incidence of this side effect profile, but it appears to be low (0.84 % per year), similar to the development of manic symptoms with sham TMS (0.73 %) and comparable to the reported baseline risk in this population. A more recent randomized, controlled trial of intermittent theta burst (iTBS) showed that two of 37 participants with bipolar depression developed treatment-emergent hypomanic symptoms (one blinded active, one open-label active) and was terminated early based on the results of a futility analysis, suggesting the need for further investigation of the association between iTBS, antidepressant response, and hypomanic/manic symptom propagation in bipolar disorder (McGirr et al., 2021b).

Emergent suicidal ideation with rTMS, when present, is thought to be a consequence of lack of rTMS efficacy as opposed to a direct side effect of the treatment. Indeed, there appears to be some evidence for anti-suicidal effects of rTMS as mentioned above (*Section 3.1.3. Efficacy: Other Depressive Disorders and Comorbid Conditions*).

3.2.2. Pre-TMS evaluation

Much of the initial evaluation for a TMS candidate is focused on safety. Based on case reports, TMS-induced seizures are typically provoked by independent risk factors, such as sleep deprivation, substance abuse or withdrawal, or use of TMS stimulation parameters that are outside standard dosing ranges.

A pre-TMS evaluation needs to include a comprehensive review of the patient's health status (including historical and current medical, surgical, neurologic, and psychiatric conditions) and a comprehensive review of current medications and prior medications trials, including treatment dose, duration, and outcome (safety, tolerability, efficacy). Although TMS was initially FDA-cleared for MDD in patients who had failed one antidepressant medication trial, it is now approved for adults who have not responded to prior antidepressant medications more generally. Detailed documentation of prior treatment trials is crucial, as insurance companies often require demonstration of failed medication or therapy trials prior to TMS approval in many cases.

As reviewed in detail in the prior NNDC-APA consensus publication, the pre-TMS evaluation should focus on identifying risk factors associated with seizure induction including: 1) personal/family history of epilepsy/seizure, 2) past stroke or head injury with neurologic sequelae, 3) concurrent use of medications/substances that alter seizure threshold (e.g., anticonvulsants, amphetamines, or benzodiazepines), and 4) the presence of medical and/or neurologic conditions that might be associated with a lower seizure threshold (e.g., sleep deprivation, increased intracranial pressure, electrolyte imbalances, and substance use or withdrawal). An absolute contraindication to rTMS is any ferromagnetic material within 10 cm of the coil (Rossi et al., 2021), which is based on updated safety data after device companies initially recommended a minimum distance of 30 cm. The evidence for the safety of rTMS in adults with implanted devices such as deep brain stimulators, vagus nerve stimulators, cochlear implants, intracranial stents, hypoglossal nerve stimulators, or intracranial electrodes has not been definitively assessed, although there is evidence that stimulation close to programmable devices (within 10 cm) can cause them temporary (2–10 cm distance) or permanent (<2 cm distance) malfunction (Rossi et al., 2021). Much implantable hardware is now non-ferromagnetic (e.g., titanium) and MRI-compatible, but this should be confirmed for each individual patient. The safety of rTMS in adolescents, pregnant women, and those with neurologic disorders is discussed in further detail in *Section 3.4. Use in Special Populations*. A more in-depth review of the safety of TMS in special populations and in populations beyond mood disorders is discussed in detail elsewhere (Lefaucheur et al., 2020, Rossi et al., 2021, Rossi et al., 2009).

Other clinical features, such as heavy alcohol or recreational drug use during treatment or a diagnosis of epilepsy, may be better considered as relative contraindications, and the decision to pursue rTMS requires a risk and benefit assessment on the part of the clinical team, as well as a discussion with the patient to fully inform them of their personalized risk-to-benefit ratio to the extent possible. Substances can have unpredictable and variable effects on cortical excitability, and adverse events associated with concurrent substance use during an rTMS

course have been described (DePamphilis et al., 2024, Stultz et al., 2020). However, this discussion can be complicated by limited data available on the antidepressant effectiveness and safety of TMS in patient populations with active substance use, and TMS is actively being studied as a treatment for substance use disorders in research contexts.

Although previous recommendations proposed a comprehensive physical exam be performed on all patients prior to the start of rTMS, our updated consensus states that a focused physical exam is usually sufficient, as guided by patient demographics, identified risk factors, and medical history. This may be as extensive as a full physical and neurologic exam or as minimal as a focused neurologic exam based on neurological history and clinical suspicion, as is common for many psychiatric evaluations. The ultimate responsibility for the safety of the TMS procedure lies with the prescribing clinician, and thus the nature and extent of the physical exam is at their professional discretion. In certain circumstances, the prescribing clinician may request consultation with or documentation from another healthcare provider to address a suspected or diagnosed condition of concern (such as a neurologic evaluation in a patient with history of prior stroke or multiple sclerosis).

3.2.3. Improving treatment tolerability and safety

During a treatment course, methods to enhance tolerability and safety may be applied. Considerations to improve tolerability include a "ramp-up" of stimulation, where the clinician may start at a lower stimulus and gradually increase the dose during the first several stimulation trains or days to gradually acclimate the patient to the stimulation. An extended "ramp-up" may theoretically risk underdosing a patient, however. Patients who develop headaches with treatment may benefit from use of over-the-counter analgesics (such as acetaminophen, ibuprofen, or topical lidocaine cream) before or immediately following treatment to minimize future headaches. For hearing safety, patients and providers in the treatment room should wear ear protection (e.g., ear plugs) that provides at least 30 dB of noise reduction to minimize the risk of tinnitus or other auditory effects (Costello, 2011, Koponen et al., 2020).

3.2.4. Monitoring during treatment course

To minimize seizure risk, adequate training on identifying motor thresholds is crucial to ensuring that the stimulation dose administered is the intended dose, which is typically 120 % of the motor threshold for standard high frequency rTMS courses for depression. Although baseline testing is imperative, the frequency of repeat motor threshold testing during a treatment course is less standardized. Data suggest that the motor threshold varies throughout a typical treatment course (42 % of sessions had $>$ 5 % difference from baseline motor threshold in one study) (Cotovio et al., 2021), resulting in higher or lower intensity than initially planned. Although this variance poses theoretical concerns for under-dosing (ineffectiveness of treatment) or over-dosing (higher seizure risk), systematic evidence linking this variance to differences in safety or clinical benefit is limited. Thus, our consensus recommends checking the motor threshold at baseline and then consider weekly checks or re-checking on days when there may have been a change that is thought to influence cortical excitability. For example, this recheck may be especially important when patients have a change in medications that may alter the seizure threshold, experience a change in sleep pattern from baseline or have a comorbid sleep disorder, or use recreational substances such as alcohol or caffeine around the time of treatment.

If prefrontal stimulation results in any motor activity in the contralateral hand or face, this movement could represent stimulation extension into motor regions of the cortex and that potentially place the patient at a higher risk for developing seizure activity. Especially concerning features of motor activity during treatment include unexpected, involuntary movement of large magnitude and movement that persists, even briefly, beyond the last stimulation pulse in each pulse-train. Providers observing such movements should pause treatment and notify the supervising clinician to confirm the coil targeting and consider rechecking the dose and the motor threshold.

Regular visits with the prescribing or supervising clinician during the rTMS treatment course are important to monitor for any emergent hypomanic/manic symptoms, suicidal ideation, or other side effects, as well as to assess for changes in clinical status and provide psychoeducation. Our consensus recommends that follow-up occurs approximately every other week, as this offers the opportunity to make recommendations on medication adjustment or treatment optimization as described in *Section 3.8. Treatment Optimization*. In patients considered to be especially high-risk or those with significant comorbidities or side effects, more frequent follow-up visits may be indicated. In addition to clinician visits, self-report rating scales should be administered to monitor the trajectory of clinical outcome and offer additional opportunities to detect non-response or worsening of status early. These self-report scales can be self-administered or administered by trained technicians. When scales or trained technicians identify concerning features of a patient presentation, these concerns should be brought to the attention of the clinician. More details regarding documentation of such features are included in *Section 3.12. Documentation.*

3.2.5. Long-term safety effects

High frequency TMS has been cleared by the U.S. FDA since 2008, and more than 20 million treatments with the figure-8 (F8) coil have been delivered to date without any identified pattern of long-term side effects (Carpenter and Philip, 2020). The H1 coil (FDA cleared in 2013) has similarly been accumulating a record of safe and effective clinical use. However, newer forms of TMS have become commonplace since the publication of the prior NNDC-APA guidance, namely, intermittent theta burst stimulation (FDA cleared in 2018), right prefrontal low frequency rTMS (not FDA cleared), and one form of accelerated stimulation (FDA cleared in 2022). These treatments have demonstrated neuroplastic changes in the brain that appear to further enhance the therapeutic effects of rTMS. Although no acute adverse effects on cognition or neurologic status have been detected (Blumberger et al., 2019, Levkovitz et al., 2015, Li et al., 2014, Sonmez et al., 2019), the long-term safety of delivering TMS treatment repeatedly over extended periods of time remains largely unknown.

3.3. Predictors of antidepressant response

In the 2018 NNDC and APA consensus article, it was suggested that shorter duration of illness, younger age, and less treatment resistance were associated with positive antidepressant treatment outcome of rTMS (McClintock et al., 2018a). Numerous articles have since been published regarding the antidepressant efficacy of rTMS, and although very few studies were designed with the main purpose of assessing predictors of antidepressant response, additional data from these studies are helpful to further explore potential predictors of treatment response. We limited the scope of this section to variables that can be obtained by clinical interview so that they can have immediate relevance to broad clinical settings. These predictors are summarized in Table 2. Other factors that could predict treatment response, such as stimulation protocols or parameters and neurophysiological variables, are discussed elsewhere (*Sections 3.6. Targeting Methods* and *3.7. Stimulation Protocols*). A full review of neurophysiological and neuroimaging biomarkers of treatment response is beyond the scope of this manuscript and reviewed elsewhere (Jin et al., 2024).

3.3.1. Demographic factors

Regarding patient demographic factors, age was the most frequently reported predictor of response. Younger age has been correlated with better outcome in rTMS (McClintock et al., 2018a), and though relatively newer studies confirm previous findings (Qiao et al., 2020, Rostami et al., 2017, Sigrist et al., 2022), others did not (Conelea et al., 2017, Cotovio et al., 2022, Feffer et al., 2017), or even found the

Table 2
Predictors of response to rTMS in patients with major depressive disorder.

Positive Predictors	Negative Predictors	No Effect	Mixed Findings
Demographic			
- Female[#]			- Age[*]
Medications			
- Concomitant use of:	- Benzodiazepine	- Mood stabilizer (in unipolar depression)	- Antipsychotic
o Antidepressant[#]			
o Psychostimulant			
o Non-lithium mood stabilizer (in bipolar depression)			
o D-cycloserine			
Comorbid conditions			
		- OCD[#]	- Chronic pain
		- Borderline personality disorder	- PTSD
		- Autism spectrum disorder	
		- Anxiety disorders	
Disease characteristic & treatment history			
	- Longer duration of illness		- History of ECT
			- Baseline severity[**]
			- Subtypes of depression
			- Bipolar depression
			- Degree of treatment resistance

[#] At least one *meta*-analysis supports this finding.
[*] One *meta*-analysis reported younger age was associated with better outcome.
[**] One *meta*-analysis reported lower baseline severity was associated with better outcome.

opposite, that is, a correlation between older age and positive outcome (Desbeaumes Jodoin et al., 2019, Kaster et al., 2018, Sackeim et al., 2020, Trevizol et al., 2020). Female sex has been consistently correlated with positive outcome (Clarke et al., 2019, Cotovio et al., 2022, Senova et al., 2019).

3.3.2. Concomitant medication use

Three *meta*-analyses suggest that rTMS has greater antidepressant benefit when used as an adjunctive treatment to psychotropic medications (Hung et al., 2020, Sehatzadeh et al., 2019, Zaidi et al., 2024). Zaidi et al. specifically identified that concurrent SSRI use was associated with better outcomes when combined with rTMS. While benzodiazepine-class medications have been associated with worse clinical outcome (Deppe et al., 2021, Hunter et al., 2019), psychostimulants have been associated with positive outcome (Hunter et al., 2019, Wilke et al., 2022). Data on concomitant antipsychotic use is mixed (Hebel et al., 2020, Schulze et al., 2017), while mood stabilizers appear to have no influence on outcome (Hebel et al., 2021). In patients with bipolar disorder, however, use of non-lithium mood stabilizer medications was associated with better outcome (Gama-Chonlon et al., 2022). Although early evidence suggested that medications that modulate synaptic plasticity such as D-cycloserine may enhance clinical response of rTMS, replication studies are needed (Cole J. et al., 2022). The varying, and sometimes opposing, effects of the same medication on different areas of the brain, as well as the effects of different medication types and doses on clinical outcomes, warrant further investigation (Li et al., 2010).

3.3.3. Comorbid conditions

Several studies have investigated the efficacy of rTMS for the treatment of depression in the presence of comorbid conditions. In patients diagnosed with comorbid chronic pain, the evidence was conflicting on whether higher baseline pain predicted better (Phillips et al., 2018) or worse (Corlier et al., 2023) outcome. Findings were also mixed regarding depression comorbid with PTSD (Hernandez et al., 2020, Madore et al., 2022, Wilkes et al., 2020, Yesavage et al., 2018). Comorbid OCD (Thatikonda et al., 2023) and borderline personality disorder (Ward et al., 2021) have been found to be unrelated to treatment outcome. Finally, a systematic literature review found that rTMS was useful in treating depression in the presence of autism spectrum disorder and anxiety disorders (Thompson, 2020).

3.3.4. Treatment resistance

A higher degree of treatment resistance was previously reported to be associated with worse outcome (Lisanby et al., 2009), though there is inconsistency in relatively newer research (Clarke et al., 2019, Feffer et al., 2017, Fitzgerald P. B. et al., 2020, Kaster et al., 2018, Schulze et al., 2017, van Eijndhoven et al., 2020, Voigt et al., 2019). One study found that history of electroconvulsive therapy (ECT) was associated with worse outcome regardless of ECT treatment outcome (Poleszczyk et al., 2018), while others found no correlation (Clarke et al., 2019, Yuan et al., 2020).

3.3.5. Depressive symptomatology

Regarding depression symptom severity, some studies found higher severity correlated with worse outcome (Carpenter et al., 2018, Cotovio et al., 2022, Donse et al., 2018, Feffer et al., 2017, Gellersen and Kedzior, 2018, Kaster et al., 2018), while others suggested that it was either correlated with better outcome (Philip et al., 2019b, Sigrist et al., 2022) or found no correlation (May and Pridmore, 2019, Mirman et al., 2022, Schulze et al., 2017). Similarly, different depressive subtypes or characteristics, such as depression with anxiety (Clarke et al., 2019, Fitzgerald P. B. et al., 2020, May and Pridmore, 2019, Pell et al., 2022, Philip et al., 2019b, Yuan et al., 2020) or anhedonia (Fukuda et al., 2021, Rostami et al., 2017, Spano et al., 2019) have no reliable predictive value, although some studies have identified improvement predominantly in these subscales of depression symptomatology compared to pharmacologic agents (Dalhuisen et al., 2024). Longer depressive illness duration was consistently associated with worse outcome (Fitzgerald P. B. et al., 2020, Lacroix et al., 2021, Poleszczyk et al., 2018, Qiao et al., 2020). Studies suggest that the presence of psychotic features also portends lower odds of treatment response, although this has rarely been systematically studied (Konstantinou et al., 2021, Rachid and Bertschy, 2006).

3.3.6. Conclusions and considerations

Overall, the mixed and varying levels of evidence presented above highlights the continued challenges in finding conclusive predictors of antidepressant treatment response to rTMS, especially since most findings were derived from retrospective chart review or secondary analysis of RCTs. Available evidence suggests that it may be prudent to consider rTMS earlier in the treatment algorithm for treatment-resistant depression, given the consistent correlation between length of illness duration and poorer outcome, as well as evidence suggesting rTMS may be superior to some pharmacologic strategies for TRD (Dalhuisen et al., 2024, Papakostas et al., 2024). However, as rTMS is a safe and well-tolerated treatment, patients with severe, chronic, and refractory depression should not be precluded from receiving rTMS. For patients who are already taking psychotropic medications, it is reasonable to use rTMS as an adjunct to such medications. Although concurrent use of benzodiazepines was found to be correlated with worse outcome, it is unclear if the correlation is due to the medication itself or other confounding factors. Clinicians should consider discussion of minimizing benzodiazepine use when consenting patients for rTMS treatment or early in a

treatment course if a patient is not showing signs of improvement, as lack of early relief portends a less favorable prognosis (Feffer et al., 2018, Spitz et al., 2022a).The current level of evidence is insufficient to broadly recommend addition of medications or switching to a different medication to improve outcomes. Finally, there has been little progress in assessing outcomes of rTMS for depression with psychotic features. We continue to recommend that such patients instead be considered for ECT due to higher response rates from the available data (Grunhaus et al., 2000). Further investigation of the predictors of treatment response of rTMS and of the moderating effects of medications and depression subtypes on rTMS efficacy will be critical in order to better advise patients and enhance their outcomes.

3.4. Use in special populations

Research on the safety and clinical efficacy of rTMS has been largely limited to adults, and clinical use of rTMS often excludes protected populations such as adolescents and pregnant patients. Despite high prevalence rates and limited evidence-based therapeutic options for TR-MDD, the data supporting the efficacy of rTMS in adolescents or older individuals with TR-MDD or those with perinatal depression are limited. In addition, at the time of the prior consensus recommendations paper, experts concluded that there was insufficient evidence to support routine clinical rTMS use in these special populations (McClintock et al., 2018a).

One potential reason for the dearth of studies in these populations is their protected status. Federal Regulation 45 CFR 46 Subparts B (pregnant persons) and D (children) declare these populations as protected and require attention to additional regulatory requirements to safeguard the conduct of research with these individuals. Minors and older individuals with limited decision making are considered vulnerable classes that require additional consideration.

Evidence for and unique considerations associated with rTMS as an antidepressant in adolescents, older individuals, and pregnant or postpartum individuals thus represents an important topic for discussion. Although rTMS has been safely and effectively applied in other unique populations, such as those with post-stroke depression or depression in the context of a neurodegenerative condition such as Parkinson's disease, this data is reviewed in detail elsewhere and is beyond the scope of this paper (Lefaucheur et al., 2020, Rossi et al., 2021).

3.4.1. Adolescent depression

Despite the burden associated with depressive illness in these populations, there is a limited body of literature for rTMS in adolescent, older adult, or peripartum depression. In adolescent populations, the rTMS literature is composed of 16 unique datasets (N=~400 individuals) described in a recent systematic review (Majumder et al., 2021).

There is a wide reported range of response and remission rates in adolescents (Majumder et al., 2021). Youth also have known higher placebo response rates in depression treatment trials compared to adults, making efficacy difficult to quantify accurately in this age group. For example, the largest double-blind, randomized, sham-controlled trial of left prefrontal rTMS for TR-MDD in adolescents (n = 103) showed similar antidepressant effects in both the active and sham groups after 30 rTMS treatments (29 % remission in both groups), with a safety and tolerability profile similar to adults (Croarkin et al., 2021). Notably, this trial showed no differences in suicidality between the active and sham groups as measured by the Columbia Suicide Severity Rating Scale, with one case of emergent suicidal ideation in each treatment arm after starting treatment and one suicide attempt in the active treatment arm determined to be "definitely not related to the study device." A review of 6 rTMS studies in adolescents (n = 165) identified only one participant who withdrew due to worsening suicidal ideation (Qiu et al., 2023).

Based on unpublished real-world data collected by one of the TMS manufacturers and clinical data available in the published literature, TMS was FDA-cleared as a first-line add-on treatment for adolescent depression in ages 15 and up as of March 2024 [510(k) premarket notification K231926]. Unlike pharmacologic antidepressants in this age group, rTMS does not carry a black box warning for increased suicidal thoughts or behaviors.

3.4.2. Geriatric depression

In older adult populations, there is an increased potential for adverse medication interactions, making rTMS a well-tolerated alternative to consider (Knochel et al., 2015, Tedeschini et al., 2011). Only 7 RCTs (N = 148) and 8 open-label (N = 407) rTMS trials, including one RCT and one open label study of H1 coil "deep TMS" (Kaster et al., 2018, Roth et al., 2024), have focused on older adults with depression to date; these have also been recently evaluated in a systematic review (Cappon et al., 2022).

Results from these studies with older adults have found variable efficacy that ranges from 6.7 % to 54.3 % for response and 8.2 % to 40.0 % for remission (Cappon et al., 2022), although more recent large-scale clinical trials and *meta*-analyses suggest meaningful response and remission rates (Blumberger et al., 2022, Roth et al., 2024, Zhang et al., 2023). TMS is considered FDA-cleared for geriatric depression, up to age 86 for one device as of May 2024 [510(k) premarket notification K222196]. The evidence for rTMS in this population should be interpreted in light of the sample and stimulation characteristics. Older adults have a higher prevalence of medical comorbidities, concomitant medication use, and neurodegenerative disorders, in addition to larger scalp to cortex distances in the prefrontal region due to age-related brain volume changes (Lee and Kim, 2022). Indeed, trial inclusion criteria have varied but often exclude conditions that would be common in clinical practice, including the use of multiple concomitant drug combinations or the presence of co-occurring neurological or general medical conditions. Few studies have been conducted in individuals with major cognitive impairment (e.g., dementia) or other neurodegenerative disorders, which could impact both the safety and efficacy of rTMS as well as decision-making capacity for participation in clinical trials. Finally, most of the studies to date have used lower stimulation intensities (less than 120 % motor threshold) than typically used for adult antidepressant rTMS trials, which could influence efficacy.

3.4.3. Peripartum depression

Despite limited evidence, rTMS is occasionally considered for peripartum depression as some antidepressant medications are contraindicated in pregnant or lactating patients (Dubovicky et al., 2017). Sixteen studies, all small-scale, have been published on the use of rTMS during pregnancy (N = 85) and five have been published on the use of rTMS during the initial postpartum period (N = 49) (Pacheco et al., 2021).

In peripartum populations, efficacy is comparable to that of the general population, with 58 % response rate across the limited (open-label) literature (Damar et al., 2020). Although the side effect rate is also similar to the general population, there are concerns about risks to the fetus or breastfeeding infant associated with any intervention. Studies to date do not support these concerns. A recent record review of 67 births over 20 years to mothers who received rTMS during pregnancy noted that no mother or baby experienced a serious adverse event (Pridmore et al., 2021). Modeling studies have found that a F8 TMS coil held adjacent to the pregnant mother's head at the DLPFC would lead to peak electric field surrounding the fetal tissue far below established safety thresholds (Damar et al., 2020). A long-term follow up study on 26 children who were born to mothers treated with rTMS for depression during pregnancy found that they did not present with increased perinatal complications and were within normal limits in both cognitive and motor development through age 5 years, comparable to infants who were born to mothers with untreated depression (Eryilmaz et al., 2015).

While rTMS may have risks, there are also risks to not pursuing

treatment. For example, compared to mothers who received treatment for their depression during pregnancy, mothers with untreated depression were at risk for suboptimal antenatal care, poor nutrition, substance abuse, subsequent postpartum depression, and lower likelihood of breastfeeding. Maternal depression during pregnancy has been associated with a greater risk of prematurity, poor fetal growth, negative child developmental outcomes, and poor maternal-infant attachment (Grigoriadis et al., 2013). Finally, many antidepressant medications are contraindicated during pregnancy and breastfeeding due to concerns about the chemicals in the shared bloodstream and in the breastmilk. This concern does not exist for rTMS. Although ECT remains an effective treatment option for mothers experiencing depression in the peripartum period (Rose et al., 2020), TMS represents a viable alternative for non-psychotic major depressive disorder, with limited available evidence suggesting a similar, if not superior, safety profile compared to ECT.

3.4.4. Conclusions and considerations

In conclusion, our consensus is that more research of rTMS in these special populations is needed, as there is a great clinical need and a limited evidence base. Less than 1,000 individuals are represented in the combined literature for these groups, making accurate and reasonable safety or efficacy determinations difficult. Nonetheless, there may be some benefits of rTMS over pharmacological interventions in these populations in which side effects may be more common (in older populations) or medications contraindicated for safety concerns (pregnant and lactating patients). Regarding rTMS safety, existing data suggest a similar profile in children/adolescents, pregnant, postpartum, or older adults as compared to young adults, with adverse event rates ranging from 3.4 % to 15 % (Allen et al., 2017, Cappon et al., 2022, Lee et al., 2021), despite potential theoretical concerns related to neurodevelopment, neurodegeneration, and hormonal fluctuations. Regarding tolerability, the most common side effects are transient headache and neck pain, with more serious adverse events only occurring in 1–2 % of patients (Cappon et al., 2022, Zewdie et al., 2020), again mirroring the young adult literature.

As these populations are part of a federally protected class, researchers and clinicians studying and treating youth, pregnant or postpartum patients, or older adults are subject to regulations put forth by regulatory bodies such as the FDA and their local institutional ethics boards. Given this protected status, it is especially critical to carefully consider risks, benefits, and alternatives to rTMS. However, patients in these special populations may be considered for rTMS treatment with careful screening for co-occurring conditions and concomitant medications that may impact safety, tolerability, or efficacy (e.g., stroke, diabetes, hypotension, neurodegenerative disorders) and close monitoring throughout and after treatment for emergent side effects, as is standard of care for all patients receiving rTMS. Finally, it is important to inform the patient (as well as partners and/or guardians, as needed) of the nascent state of the literature and, in the case of children and adolescents under age 15, the off-label nature of the treatment at the time of this writing (i.e., not consistent with the device manual or FDA determined indication) and risk of insurance coverage denial. The limited extant literature provides reassurance regarding safety and promise regarding efficacy and highlights the importance of further research on these populations to inform whether future label expansions may be scientifically justified.

3.5. Coil design

3.5.1. Fda-cleared coils

A variety of coils have been developed for the application of TMS, each differing distinctly in design and thereby spatial distribution of induced electrical field (e-field). To date, four kinds of coils have received FDA clearance for the treatment of depression – iron core coils, figure-8 (F8) coils, and two "H coils" called H1 and H7. The iron core, F8, and H1 coils were cleared by the FDA based on results of separate multicenter randomized controlled trials (RCTs) comparing active treatment with sham TMS (George et al., 2010b, Levkovitz et al., 2015, O'Reardon et al., 2007). The H7 coil was cleared by the FDA based on data showing substantial equivalence to the H1 coil for the treatment of depression (FDA, 2022, Zangen et al., 2023).

3.5.2. Electric fields of different coils

F8 coils induce more focal and superficial e-fields than H coils. The F8 coil consists of two adjacent wings arranged to induce relatively focal stimulation underneath the central segment in superficial cortical regions (Zibman et al., 2021). The angle between the wings affects focality, efficiency, and modeled depth of the induced e-field. H1 and H7 coils are thought to offer improved e-field depth at the cost of focality (Deng et al., 2013) and are sometimes called "deep TMS" coils. The H1 coil consists of a flexible base that follows the curvature of the scalp. It broadly stimulates bilateral prefrontal cortex. A head-to-head comparison of the H1 and F8 coils examining the depth below the cortical surface for which the e-field intensity remained supra-threshold showed a depth of penetration of 1.8 cm for the H1 coil compared to 1.1 cm for the F8 coil (Guadagnin et al., 2016), although depth of stimulation modeling results vary (Deng et al., 2013). The H7 coil produces a broad e-field and was designed to target the medial prefrontal cortex and anterior cingulate cortex (Carmi et al., 2019, Roth and Zangen, 2014).

Observable clinical effects of TMS may depend on engagement of cortical-subcortical brain networks or brain regions with distributed connectivity (Dowdle et al., 2018, Kimbrell et al., 2002, Li et al., 2004). Coil orientation is also an important factor to consider, as e-field modeling suggests this variable can affect the region of neural tissue engaged by the TMS coil (Opitz et al., 2016, Siebner et al., 2022, Thielscher et al., 2011) and may have therapeutic implications (Tzabazis et al., 2013). The standard approach with the F8 coil applied to the left dorsolateral prefrontal cortex involves angling the coil towards the tip of the nose or at a 45-degree angle to the *para*-sagittal plane, angled towards the midline with the coil handle angled posteriorly and away from the head (Chen L. et al., 2021, George et al., 1997, O'Reardon et al., 2007). Little research exists comparing this coil angle to other potential coil orientations. E-field modeling software has been incorporated into some TMS devices to approximate the focality of stimulation. Some new coils attempt to increase recruitment of neural populations within a stimulated region using a rotational field, although this technology is not yet available clinically and has limited evidence (Roth et al., 2020).

3.5.3. Efficacy of different coils

The relative efficacy of treatment with F8 versus H coils remains uncertain due to differences in trial design and stimulation parameters. A systematic review and *meta*-analysis that compared the effects of the two coils after 10 sessions showed a larger reduction in depression severity in H1-coil versus F8-coil studies, and a trend towards higher remission rates in F8-coil versus H1-coil studies (Gellersen and Kedzior, 2019). However, the authors cautioned that these effects were based on studies with small sample sizes, no placebo controls, and results after 10 session (33 % of a standard treatment course), all which may limit their clinical application (Gellersen and Kedzior, 2019). A first RCT comparing F8 and H1 coils and their FDA-approved protocols found clinical superiority of the H1 standard protocol over the F8 conventional TMS protocol in terms of response rate but notably, not in terms of remission rate, which was the primary outcome (Filipcic et al., 2019). It is also important to note that this trial used the outdated 5 cm rule for F8 stimulation and examined outcomes after 20 sessions, which is short of a typical antidepressant treatment course. Other emerging data from a large naturalist study suggest that F8 coil treatment is superior to H-coil treatment (Pritham Raj, 2022), but these data have not yet been peer reviewed. It is our consensus view that the FDA-cleared coils demonstrate significant evidence of clinical efficacy for treating depression. We contend that TMS clinicians and technicians should be fully trained in the targeting and operation of the type of coil used at their site of

practice.

3.5.4. Other coils

Many other TMS coils have been created including the double-cone coil (Kreuzer et al., 2019, Monteiro and Cantilino, 2019), circular, crown, B-shaped, cloverleaf, halo-coils and coil arrays, and about 20 other H coils (Deng et al., 2013, Roth et al., 2013). These coils have been used in research settings and have informed safety considerations such as seizure risk. From this research, the risk for seizure induction is generally thought to increase with stronger e-fields and broader field distribution (Lisanby et al., 2003). Accordingly, the relative risk of a TMS-related seizure may be higher with the H1 coil compared to the F8 coil, but the absolute risk is low, and seizure remains a rare occurrence (Taylor et al., 2021). See also *Section 3.2.1. Safety of rTMS.*

3.6. Targeting methods

TMS targeting for depression has evolved over time (Cash et al., 2021b). Early targeting strategies were guided by the hypothesis that frontal lobe hypometabolism was the "final common pathway" for primary depression and secondary depression following brain lesions (Belyi, 1987, George et al., 1993, 1994, George et al., 1995, Robinson et al., 1988, Robinson et al., 1984, Robinson and Price, 1982, Wellisch et al., 2002). Over time, this hypothesis narrowed to the dorsolateral prefrontal cortex (DLPFC) (Koenigs et al., 2008, Padmanabhan et al., 2019), an area anatomically defined by Brodmann Areas 9 and 46 (Rajkowska and Goldman-Rakic, 1995a, 1995b, Rusjan et al., 2010). Of note, this section focuses exclusively on studies using figure-8 coils, which produce more focal magnetic fields than H-coils and are thus the subject of significant interest related to targeting optimization. H-coils are often referred to as "deep TMS" coils because they deliver deeper and broader stimulation, so that targeting covers wider areas of cortex. See *Section 3.5. Coil Design* for additional details about coil differences.

3.6.1. 5 cm rule

The earliest TMS trials for depression typically employed the "5 cm rule," an empiric scalp-based measurement method that emerged from the observation that left DLPFC is roughly 5 cm anterior to the "motor hotspot" of the motor strip along a parasagittal line (George et al., 2000, George et al., 1997, George et al., 1995, Pascual-Leone et al., 1996). The "motor hotspot" refers to a region of the motor cortex functionally responsible for movements of the hand or fingers, often defined by the abductor pollicis brevis or first dorsal interosseous muscle of the thumb. Indeed, the multisite FDA pivotal trial published by O'Reardon et al. 2007 (O'Reardon et al., 2007), as well as the open-label extension study in 2008 by Avery et al. (Avery et al., 2008), used this targeting method as a probabilistic approximation of the left DLPFC. The follow-up multisite OPT-TMS trial (George et al., 2010a) advanced TMS targeting by allowing investigators to adjust coil placement when the "5 cm rule" yielded a target that was too posterior (i.e., premotor area) on an anatomical MRI scan. Alternatives to standard targeting may be particularly relevant for special populations, such as children, adolescents, or elderly patients, in whom neuroanatomical variability may be more extensive (Oberman et al., 2021). Nonetheless, most FDA labels and many TMS clinics continue to use this method for targeting, and some device manufacturers continue to recommend this target in their device manual and trainings.

3.6.2. 5.5 cm Rule, Beam F3 Method, and other Scalp-Based targeting approaches

Follow-up studies continued to refine targeting based on neuroanatomy. These studies highlighted precision and accuracy limitations of the "5 cm rule" (Ahdab et al., 2010, Herwig et al., 2001) and revealed that more anterior and lateral stimulation yields better clinical outcomes (Herbsman et al., 2009). As a result, treatment sites began to shift 5.5 to 6 cm anterior to the motor hotspot (Brunoni et al., 2017, Cash et al., 2021b). Other studies used the 10–20 electroencephalography system (EEG) system to enhance precision and reproducibility (Fitzgerald et al., 2009b, Herwig et al., 2003b, Rusjan et al., 2010) by incorporating a patient's own unique scalp measurements. This work inspired a shortcut method of approximating the F3 site with just a few scalp measurements (Beam et al., 2009, Mir-Moghtadaei et al., 2015). This shortcut, known as the "Beam F3" method, has been widely adopted because of its relative efficiency, precision, accuracy, and accessibility (McClintock et al., 2018b, Trapp et al., 2020). Although more personalized, some evidence suggests that the Beam F3 method may have similar antidepressant effectiveness to the 5.5 cm method in clinical practice (Trapp et al., 2023).

3.6.3. Neuronavigation: Targeting based on structural MRI

Technological advances have further refined TMS targeting and delivery. For example, neuronavigation systems that leverage individual anatomical MRI data can be used to identify and target specific brain locations using 3-dimensional coordinates. These systems can also be used retrospectively to mark the specific brain target coordinates initially located with scalp-based measurements. The use of neuronavigation significantly reduces targeting errors or inaccuracies that emerge from unique individual brain morphologies and variations in inter-operator and inter-session coil placement (Caulfield et al., 2022a), but it has not yet been shown to significantly improve treatment outcomes when used only based on structural brain anatomy (Blumberger et al., 2016, Cash et al., 2020, Fitzgerald et al., 2009a, Li C. T. et al., 2020) or metabolism (Cash et al., 2020, Herwig et al., 2003a, Paillere Martinot et al., 2010).

3.6.4. Neuronavigation: Targeting based on functional MRI

Neuronavigation has been combined with functional neuroimaging to refine targeting. Using resting state functional connectivity (RSFC) MRI data, pertinent brain networks can be targeted at the group level or at the individual level (Fox and Greicius, 2010, Siddiqi et al., 2023b, Siddiqi et al., 2023c). The predominant hypothesis in the literature is that stimulating the region of the left DLPFC most anticorrelated to the subgenual cingulate yields the best treatment outcomes (Cash et al., 2019, Fox et al., 2012, Oathes, 2023, Weigand et al., 2018). The average coordinates of this spot are known at the group level (i.e., MNI coordinates x = -42, y = 44, z = 30), but a pivotal trial showing that this targeting approach yields better treatment outcomes than probabilistic scalp-based measurements has not been conducted (Cash et al., 2020).

There is tremendous interest in moving beyond this group RSFC average to stimulate individualized RSFC targets based on each patient's RSFC data, with numerous studies trying to tackle the reproducibility problem with various techniques (Cash et al., 2021a, Fox et al., 2013, Siddiqi et al., 2023a, Siddiqi et al., 2021b). A few clinical trials that have stimulated individualized targets have shown high response rates, but these results are difficult to collectively interpret because of small sample sizes, methodological heterogeneity, and limited head-to-head comparator targets (Cash et al., 2021b, Cole et al., 2021, Cole et al., 2020, Siddiqi et al., 2019, Williams et al., 2018). For example, the FDA-cleared Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT or SNT) uses individualized RSFC targeting with a proprietary algorithm that requires support from the device company to access. Similarly, this algorithm is only one of several differences between SAINT and traditional TMS – see *Section 3.7.6. Stanford Accelerated Intelligent Neuromodulation Therapy* for additional details.

Alternative RSFC targeting strategies are currently being explored. In a prospective, randomized, controlled trial, RSFC targeting based on individualized anterior insula connectivity showed similar effectiveness to structural MRI targeting methods (Morriss et al., 2024). Other targeting approaches have been proposed based on retrospective imaging data, from those that target the DLPFC spot most correlated with the convergent depression network (Siddiqi et al., 2021a, 2021b) to those that seek to modulate specific symptoms of depression (Downar and

Daskalakis, 2013, Siddiqi et al., 2020). These latter strategies are being studied in prospective clinical trials (Taylor et al., 2024). The extent to which individualized RSFC targeting matters remains unclear, with one retrospective study providing strong evidence for a small effect of anti-subgenual cingulate targeting on treatment response prediction (Elbau et al., 2023), and other RSFC targeting strategies showing limited benefit (Morriss et al., 2024) or remaining to be directly tested. To date, use of neuronavigation-based approaches in practice is limited, as this technology has only recently become commercially available.

3.6.5. Conclusions and considerations

In summary, the consensus of this group is that the current standard of care involves the use of the 5.5 cm method or Beam F3 method, with these targeting methods holding clinical equipoise based on current evidence in adults. Evidence suggests that targeting based on structural or functional MRI may enhance treatment effects. When available, it would be within standard of care to use this technology. However, evidence for MRI-based targeting benefits is largely based on retrospective data analysis, and the feasibility and accessibility of use and magnitude of such effects needs to be demonstrated prospectively before widespread adoption is likely. Additional research is needed to also explore in which clinical scenarios these personalized RSFC-targeted approaches offer a clinically meaningful advantage over the current standard of care.

3.7. Stimulation protocols

The effects of rTMS pulses on the brain can vary widely based on the stimulation protocol. Many aspects make up the stimulation protocol, each with significance for the safety, physiologic consequences, and potential therapeutic effects of rTMS when applied to the brain. Variables in an rTMS protocol include the frequency of stimulation (quantified in number of pulses per second) and associated nested frequencies (bursting, dynamic vs. static parameters, etc.), the pulse width, the pulse shape, the intensity of stimulation (usually defined as a percentage of the "motor threshold"), the number of pulses delivered continuously before a break (the "pulse train"), the number of trains in a treatment session, the intertrain interval (rest period between pulse trains), the number of pulses delivered in a session (a product of the number of "trains" and pulses in a train) or a full treatment course, and the number of sessions delivered in a day or in a treatment course. Numerous treatment protocols have been trialed in the treatment of depressive disorders since the 1990 s and a few have gained FDA clearance. Some of the most widely studied and commonly used protocols are outlined in this section.

3.7.1. High-frequency rTMS

High-frequency rTMS is typically defined as stimulation frequencies of > 1 Hz (>1 pulse per second), with protocols involving 10 Hz and 20 Hz stimulation generally having "excitatory" (i.e., potentiating) effects, as demonstrated on motor cortex physiology in group samples (Miron et al., 2021). High-frequency rTMS delivered with a F8 coil, targeting the left DLPFC, at 10 Hz in trains of 40 pulses with intertrain intervals (ITIs) of 26 s, and a total of 3000 pulses per session delivered at 120 % motor threshold (See *Section 3.2.4. Monitoring During Treatment Course*) was the initial US FDA-approved antidepressant protocol in 2008 (George et al., 2010b, O'Reardon et al., 2007). In 2016, the FDA cleared a substantially similar protocol with intertrain intervals decreased to 11 s while holding other parameters constant (Carpenter L. et al., 2021). This protocol, known as the "Dash" or "Rapid" protocol, shortened total treatment time from 38 min to 18.75 min. Large registry studies found that this protocol provided similar efficacy without apparent increased risk of adverse events (Carpenter Lindal. et al., 2021, Mina et al., 2018). In 2022, both the traditional and Dash/Rapid protocols were US FDA-cleared for decreasing anxiety symptoms in MDD patients with comorbid anxiety symptoms.

Deep TMS H-coil devices also employ a high-frequency TMS protocol with slightly different stimulation parameters. The H1 coil, designed to target the DLPFC, is US FDA-cleared for MDD and anxiety that is comorbid with MDD and utilizes a stimulation protocol that consists of 18 Hz in trains of 36 pulses (2 s) with ITIs of 20 s, for a total of 1980 pulses per session delivered at 120 % motor threshold (Levkovitz et al., 2015). The H7 coil, designed to target the medial prefrontal cortex bilaterally, is also FDA-cleared for MDD using identical stimulation parameters as the H1 coil (Zangen et al., 2023).

3.7.2. Low-frequency rTMS

Low-frequency rTMS, typically defined as a stimulation frequency of 1 Hz or less, is generally considered to have "inhibitory" (i.e., depotentiating) effects on cortical excitability (Miron et al., 2021). For depression treatment protocols, it is most often delivered to the right DLPFC. 1 Hz rTMS has less supporting evidence of antidepressant efficacy compared to high-frequency TMS, and no low-frequency protocols are US FDA-cleared for depression. However, *meta*-analyses show that 1 Hz right DLPFC stimulation protocols have similar efficacy to left sided high-frequency rTMS (Berlow et al., 2020, Cao et al., 2018). There is some evidence that higher number of pulses delivered at low frequency is associated with better outcomes, with 1200 or more pulses having better study outcomes than fewer pulses in double-blind sham controlled trials (Berlim et al., 2013), and 3600 pulses having better outcomes than 1200 in a recent head-to-head trial (Fitzgerald Paul B. et al., 2020b). Low-frequency rTMS has the potential for lower risk of side effects (e.g., pain at the site of stimulation, seizure) and less expensive device requirements than other protocols (Miron et al., 2020), although sessions are often longer (i.e., 20 min for 1200 pulses and 1 h for 3600 pulses). It has been postulated that right-sided low frequency treatment may be better for those patients with greater anxiety severity, but evidence does not bear this out (Chen et al., 2019). There is sparse evidence to suggest that 1 Hz rTMS may have a lower seizure risk than high-frequency protocols (Reti et al., 2015), although the exact risk has been challenging to quantify.

3.7.3. Theta-burst stimulation

Theta-burst stimulation (TBS), which mimics endogenous neuronal firing patterns associated with long-term potentiation in the hippocampus (Huang et al., 2005, Huang and Rothwell, 2004, Suppa et al., 2016), allows for the delivery of a smaller number of TMS pulses while achieving similar modulation in cortical excitability compared to the high-frequency rTMS protocols described above (Di Lazzaro et al., 2011). This discovery led to the development of significantly shorter TMS protocols, with *meta*-analyses of sham-controlled trials demonstrating effectiveness (Berlim et al., 2017, Brunoni et al., 2017). Implementation requires additional expenses including an rTMS device with additional theta burst functionality and a suitable coil cooling system.

The intermittent theta burst stimulation (iTBS) protocol that can trigger an antidepressant response consists of 600 pulses, which can be administered in 3 min per session and may enhance cortical excitability similar to high-frequency protocols (Huang et al., 2005, Huang and Rothwell, 2004). In 2018, the THREE-D trial showed that iTBS was non-inferior to high-frequency rTMS with no differences in adverse effect profile between groups (Blumberger et al., 2018). This study led to US FDA clearance of iTBS for MDD. Notably, the original trial used image-guided neuronavigation and a larger B70 F8 coil, both of which are not standard clinical practice in the United States and not required to comply with the US FDA-cleared iTBS once-daily protocol. The antidepressant efficacy of iTBS has now been replicated with protocols that do not utilize neuronavigation guidance (Bulteau et al., 2022, Spitz et al., 2022b) and confirmed by *meta*-analyses of sham-controlled trials (Berlim et al., 2017, Brunoni et al., 2017).

Another brief TBS protocol in use is continuous TBS (cTBS), which can be administered in approximately 1 min. cTBS may have inhibitory

effects on cortical physiology, although evidence suggests significant individual heterogeneity in excitability change with this and other rTMS protocols (McCalley et al., 2021). Relatively few studies of cTBS for depression exist outside of "bilateral TBS" studies (Berlim et al., 2017, Li et al., 2018, Voigt et al., 2021), so at this time, evidence supporting the independent efficacy of cTBS protocols for depression is inadequate.

Based on the available evidence, the consensus of the authors is that iTBS is a non-inferior treatment for MDD compared to standard high-frequency rTMS when delivered to the left DLPFC. Both are appropriate initial antidepressant treatment protocols to consider for a new patient seeking TMS for MDD. Additional research is needed to better understand if a non-responder to one protocol may respond to an alternate protocol. TMS providers should consider prior TMS history, such as whether patients have had a prior response to one protocol or intolerable side effects with a specific protocol, when deciding on which protocol to choose. Logistics may also play a role in medical decision-making; for example, iTBS is not covered by all insurance plans, although its use may increase convenience for patients with time restrictions due to other daytime obligations or employment, or patients with musculoskeletal issues or chronic pain making prolonged sitting uncomfortable.

3.7.4. Bilateral TMS

Bilateral TMS or TBS protocols are those involving stimulation delivered, typically sequentially, to multiple stimulation sites. The most studied protocol for antidepressant efficacy includes high-frequency TMS of the left DLPFC and low-frequency TMS of the right DLPFC delivered in the same treatment session. Although some studies have suggested that sequential bilateral TMS protocols may be more effective than protocols that stimulate a single site (Brunoni et al., 2017), a large retrospective registry study with more than 3,000 patients showed that sequential bilateral protocols were not superior to unilateral high-frequency left DLPFC protocols (Aaronson et al., 2022). This study also suggested that the order of the sequence seems to be important. In that analysis, performing low-frequency right DLPFC stimulation first had *reduced* efficacy compared to performing left DLPFC high-frequency stimulation first (Aaronson et al., 2022). However, several randomized controlled trials suggest right-to-left sequential bilateral TMS may be efficacious, so further prospective, controlled studies may be needed (Blumberger et al., 2016, Blumberger et al., 2012, Fitzgerald et al., 2006).

3.7.5. Accelerated TMS

Accelerated TMS refers to protocols that deliver multiple TMS sessions in a day, designed with the intention to achieve more rapid antidepressant treatment effects (George et al., 2014, Holtzheimer et al., 2010, Van Rooij et al., 2023) or reduce logistical challenges associated with a 30-day treatment course. There are many methods of delivering accelerated TMS, with trials delivering anywhere from 2 to 10 sessions per day, combining different treatment targets, different targeting methods, different total number of pulses and sessions, and different stimulation paradigms.

In general, research suggests that accelerated TMS protocols are efficacious, although it is unclear if they lead to a more rapid response or achieve higher efficacy than standard, once-daily treatment protocols (Caulfield et al., 2022b, Chen et al., 2020, Chen et al., 2023, Chen L. et al., 2021, Fitzgerald Paul B. et al., 2020a, Fitzgerald et al., 2018, Kaster et al., 2020, Sonmez et al., 2019, Yu et al., 2023). For example, the CARTBIND study compared two active TMS sessions per day, separated by 54 min, to one extended active and one sham session per day, and showed that the overall outcomes and trajectory of response were similar for both groups (Blumberger et al., 2021). In a *meta*-analysis of accelerated rTMS protocols applied to the left DLPFC, Yu et al. suggested that there is a dose–response effect associating more TMS sessions per day and total pulses per day with higher efficacy, although this relationship was *absent* for the total number of pulses in a session or the total number of overall sessions. Indeed, evidence suggests that changing the number of pulses delivered in a treatment session can significantly alter cortical excitability, with significant individual heterogeneity (McCalley et al., 2021).

Nonetheless, retrospective studies of TMS registry data with large samples ($N > 5{,}000$) found that patients who received more pulses per TMS session had superior clinical outcomes (Sackeim et al., 2020) and extending treatment courses past the typical 30–36 sessions showed additional benefit (Hutton et al., 2023a). Taken together, these studies suggest that adding additional pulses to a treatment course could improve outcomes, although the most effective way to do this remains to be worked out. Comparative, prospective trials are challenging, and published *meta*-analyses often suffer from confounds such as the parameters via which the pulses were delivered (i.e., 600 pulses of iTBS are not equivalent to 600 pulses of 10 Hz rTMS). Most of the studies for accelerated TMS protocols have focused on use of relatively focal F8 TMS coils; accelerated deep TMS studies are limited but show impressive depression response and remission rates around day 3–4 of accelerated treatment, irrespective of the total number of daily sessions delivered to the prefrontal cortex (Roth et al., 2023). A review of the efficacy and safety of accelerated theta burst protocols is provided by (Cole et al., 2024) and highlights the variability in protocol parameters and response rates. The most effective published protocol to date has been the Stanford Accelerated Intelligent Neuromodulation Therapy, with most other protocols achieving efficacy similar to standard daily rTMS or iTBS treatment.

3.7.6. Stanford accelerated Intelligent neuromodulation therapy

The Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT/SNT, referred to as SAINT throughout) protocol, discussed previously, is one promising implementation of accelerated TMS. This protocol employs 90,000 TMS pulses delivered in 10 sessions of iTBS per day, 1800 pulses per session, with a 50-minute interval between sessions. This protocol was delivered for 5 consecutive days in the initial studies and resulted in high remission rates (approximately 80–90 %) in both an open label and a randomized controlled trial (Cole Eleanor J. et al., 2022, Cole et al., 2020) with minimal side effects and no seizures. The SAINT neuromodulation system, which delivers the SAINT protocol, was subsequently FDA cleared in 2022. Notably, in addition to the use of more sessions and more total TMS pulses than other TMS protocols at the time, the SAINT protocol included other unique features such as functional-connectivity MRI targeting to identify a DLPFC coordinate anti-correlated with the subgenual anterior cingulate cortex (see *Section 3.6. Targeting* for additional details)) and stimulation at 90 % of motor threshold with a depth correction for scalp-to-cortex distance at the DLPFC target. The numerous parameters that constitute SAINT have not been systematically tested against other potential parameters, a general challenge for TMS devices and protocols due to the wide parameter space. Thus, the safety and efficacy of SAINT are only known for the comprehensive and unified delivery of the SAINT protocol using the SAINT neuromodulation system per its FDA clearance. At the time of this publication, additional studies are needed, with some underway, to provide additional independent replication of the currently published SAINT clinical trials, to evaluate the reproducibility of the MRI targeting algorithm, to assess long-term durability of response, and to test the performance in additional settings (e.g., inpatient units). Studies comparing the SAINT protocol to other US FDA-cleared rTMS devices and protocols, or to modified accelerated protocols (e.g., without fMRI targeting or with different dosing schedules) are needed to improve the knowledge base of the relative weight of contribution of specific TMS treatment parameters on overall safety and antidepressant efficacy. As SAINT was FDA cleared in 2022 and only became commercially available in 2024, additional time is needed to see how this new technology will be utilized by clinicians.

3.7.7. Other protocols

Various other protocols have been developed in recent years and warrant brief mentioning here. Priming TMS refers to the use of high frequency TMS to enhance plasticity in or "prime" a subsequent protocol (e.g., low frequency TMS (Cheng et al., 2021, Fitzgerald et al., 2008, Iyer et al., 2003) or ECT (Rothärmel et al., 2021)). Early evidence for this approach is positive, but larger clinical trials are needed to confirm these findings (Brunoni et al., 2017).

Quadripulse TMS, a technique for delivering bursts of four TMS pulses in rapid succession, is capable of rapidly and robustly enhancing cortical excitability, although its antidepressant efficacy remains to be thoroughly investigated (Matsumoto and Ugawa, 2020).

Synchronized TMS (sTMS) refers to the use of TMS pulses synchronized to specific EEG frequencies, often the alpha frequency (Corlier et al., 2019, George et al., 2023, Leuchter et al., 2015, Philip et al., 2019a, Zrenner et al., 2020). Some evidence exists to suggest that alpha-synchronized TMS can alter the alpha frequency with unclear clinical benefit (Zrenner et al., 2020), with some studies suggesting improved treatment response (Corlier et al., 2019) and others suggesting equivocal or potentially worse response than non-synchronized TMS (George et al., 2023). Advertised forms of sTMS include magnetic resonance therapy (MeRT) and low-field synchronized TMS, the latter of which involves use of rotating spherical neodymium magnets along the midline of the scalp to deliver low-field sinusoidal waveform stimulation synchronized to alpha EEG frequency. Although low-field sTMS protocols may be better tolerated than standard rTMS (Leuchter et al., 2015), data on antidepressant efficacy is absent for MeRT and mixed for low-field sTMS (Cook et al., 2019, Leuchter et al., 2015, Philip et al., 2019a, Philip et al., 2019b), with sham treatment or non-synchronized TMS performing as well as active sTMS treatment (additional unpublished data available on clinicaltrials.gov, NCT03288714). Additional benefit from using EEG to synchronize TMS pulses is thus not supported by the available literature, and MeRT and sTMS protocols are not recommended at this time.

3.7.8. Magnetic seizure therapy

Magnetic seizure therapy (MST) refers to the use of TMS to induce a seizure, inducing antidepressant effects through a mechanism similar to that of ECT. Evidence to date suggests that MST can induce a more focal seizure than ECT, with potentially less side effects (Daskalakis et al., 2020, Deng et al., 2023, El-Deeb et al., 2020, Lisanby, 2002, Sun et al., 2018). Furthermore, recent data from a randomized clinical trial suggests similar efficacy to ECT (Deng et al., 2023, El-Deeb et al., 2020), and a double-blind non-inferiority trial comparing MST and ECT in adults with MDD has recently completed enrollment and will provide additional information on antidepressant and cognitive outcomes (Daskalakis et al., 2021). MST is currently unavailable outside of research clinical trials in the United States.

3.7.9. Conclusion and considerations

Despite the wide parameter space, enhancements to TMS stimulation protocols have resulted in significant advances related to the efficacy and efficiency of TMS for depressive disorders. A summary of considerations for TMS protocols can be found in Table 1.

3.8. Treatment optimization

In addition to adjustments to targeting techniques and stimulation protocols, other methods have been studied in attempts to augment or optimize the TMS antidepressant response. Here we will focus on four frequently studied areas: 1) optimizing dosing, 2) combining TMS with psychotherapy; 3) combining TMS with medications; and 4) performing maintenance TMS treatments to sustain benefit.

3.8.1. Optimizing dosing

As discussed in *Section 3.7.5 and 3.7.6.*, the dose (i.e., number of treatments) of TMS needed to produce an optimal antidepressant response is under investigation. A recent analysis of a large clinical dataset of depressed patients treated with rTMS concluded that those who received fewer than 30 sessions had inferior responses and that patients whose treatment was extended beyond the FDA-cleared 36 sessions continued to derive additional antidepressant benefit (Hutton et al., 2023a). In a similar study, a larger number of pulses per session was significantly associated with higher response and remission rates (Sackeim et al., 2020). These findings are in line with similar results for accelerated protocols (Yu et al., 2023), and the considerable dose increase employed in SAINT. Trials are underway to further optimize rTMS dosing.

A practical limitation in clinical practice is insurance coverage, which typically limits the maximum number of treatments to 36. The above data suggest that patients should be advised to receive the entire treatment course. However, some studies have found that poor response after 10 treatments was predictive of nonresponse overall (Feffer et al., 2018, Spitz et al., 2022a). Others have contested this finding, highlighting that there is a subset of patients who do not exhibit a response until after 20 treatments (Beck et al., 2020). It is therefore our consensus that patients should generally be encouraged to receive all 36 treatment sessions unless clinical worsening or intolerance necessitates transition to a different therapy. In cases of lack of response after four weeks of treatment, a risk–benefit discussion with the patient that addresses the possibilities of delayed response and non-response should guide the decision regarding continuing treatment.

3.8.2. Combining TMS with psychotherapy

Evidence suggests that TMS can have state-dependent effects (Sack et al., 2024). Thus, there is a growing interest in efforts to develop new protocols for combining TMS with various forms of evidence-based psychotherapy (Xu, 2023), based in part on the premise that TMS may promote synaptic plasticity, which in turn may support therapeutic changes in cognition and behavior. However, few studies have directly tested this hypothesis in depression. In one such study (Donse et al., 2018), 10 sessions of rTMS targeting the dorsolateral prefrontal cortex (DLFPC) were combined with a structured psychotherapy informed by cognitive behavioral therapy principles. 66 % of participants showed a significant treatment response, but there was no control group that would allow the investigators to assess whether the combined treatment was superior to rTMS alone. Other pilot studies lend tentative support to a synergistic effect of combining TMS and psychotherapy (José et al., 2021, Neacsiu et al., 2018), but there is a need for larger scale, randomized controlled trials testing this approach. Future studies should evaluate whether different types of evidence-based psychotherapy are better suited for TMS augmentation, and when in relation to the TMS treatment concomitant psychotherapy may best improve outcomes (e.g., before, during, or after treatment sessions, or between sessions in accelerated, spaced stimulation protocols). For example, one study demonstrated the challenges of providing mindfulness-based therapy during TMS sessions (Cavallero et al., 2021). Another area of interest related to treatment optimization which requires further exploration relates to enhancing the therapeutic potential of state-dependent TMS effects using cue induction (as is used successfully in TMS for OCD or tobacco use disorder), closed-loop TMS-EEG protocols, cognitive tasks, or neuromodulation protocols combining TMS with other therapeutic modalities.

3.8.3. Augmentation with medications

Another augmentation strategy involves optimizing a patient's existing medication regimen or combining TMS with plasticity-promoting psychopharmacological agents. As discussed in *Section 3.3.2. Predictors of Antidepressant Response: Concomitant Medication Use*, rTMS is effective with concomitant use of antidepressant medications (Hung et al., 2020, Sehatzadeh et al., 2019), specifically SSRIs (Zaidi et al., 2024), and is associated with better outcomes than

antidepressants alone. Regarding other classes of medications, retrospective observational studies suggest that benzodiazepine use may be associated with suboptimal outcomes (Blumberger et al., 2018, Hunter et al., 2019, Kaster et al., 2019), while stimulant use may accelerate and enhance treatment response (Hunter et al., 2019, Wilke et al., 2022). Prospective randomized trials are needed to address these questions.

Another approach is co-treatment with plasticity-promoting agents, based on the observation that TMS acts in part through mechanisms that involve synaptic plasticity (Hallett, 2000, 2007, Huang et al., 2007, Wankerl et al., 2010), an N-methyl-D-aspartate (NMDA)-dependent process which may be deficient in depression (Duman and Aghajanian, 2012, Dwivedi et al., 2003, Labonté et al., 2017). In support of this hypothesis, a randomized controlled trial (Cole J. et al., 2022) showed that combining left DLPFC iTBS with 100 mg D-cycloserine, an NMDA-receptor partial agonist that enhances NMDA-receptor signaling, administered before treatment resulted in higher response rates compared to iTBS alone (74 % vs. 29 %). Further study of this and other agents that may enhance synaptic plasticity is needed before definitive statements can be made about their routine use as adjuncts to rTMS.

3.8.4. Maintenance TMS

Maintenance or "preservation" TMS refers to the use of TMS treatments to maintain benefits from an acute course of antidepressant treatment. Maintenance TMS protocols have typically been studied in and applied to patients who respond in the acute phase to a conventional course of rTMS but are at high risk of relapse. However, maintenance TMS has also been applied as a method for sustaining the benefits of ECT and pharmacotherapy as well. A recent systematic review highlighted the lack of controlled trials studying maintenance TMS and the heterogeneity of available study designs (Wilson et al., 2022). Open questions relate to when to deliver TMS (fixed vs. symptom-triggered schedule), how to schedule maintenance TMS (e.g., once monthly vs. clustered treatments), how to assess response, and when to stop maintenance TMS (i.e., how many treatments to administer after it is reintroduced). Another common practice – gradually tapering TMS treatment frequency at the end of an acute TMS treatment series – has little empirical support and requires further investigation of antidepressant durability compared to abrupt cessation of treatment.

"Clustered maintenance" rTMS is one such strategy in which patients receive monthly maintenance rTMS sessions comprised of five rTMS treatments delivered over a two-day period on a regular basis. In an open-label study (Fitzgerald et al., 2013), rTMS responders received clustered maintenance, yielding a mean duration of remission of 10.5 months. Relatively few randomized controlled trials have evaluated maintenance TMS protocols (Wilson et al., 2022), with two studies reporting statistically significant benefits (Benadhira et al., 2017, Rapinesi et al., 2015). However, in a third study involving single TMS maintenance sessions delivered monthly (Philip et al., 2016), there was no significant benefit over observation alone. Together, these studies suggest that clustered maintenance protocols have the potential for prolonging remission, but monthly single-session maintenance protocols may not be useful. Our consensus view is that larger scale randomized controlled trials examining efficacy as a function of treatment interval will be needed to establish the utility of maintenance protocols.

3.9. Training, Privileging, and treatment roles and responsibilities

Training and privileging in the use of transcranial magnetic stimulation for clinical use has varied among institutions, states, and countries. Many stakeholders are involved in the process, including a spectrum of clinical providers, insurance companies, device manufacturers, and hospital systems. The goal of training and privileging in TMS should center on ensuring the competency of the treatment team and the safety of the patient while also maintaining access to care for those suffering from disorders responsive to TMS. This process should therefore include competencies for both the supervising clinician and the TMS technicians working under that supervision.

3.9.1. Definition of roles

The "prescribing TMS clinician" is the clinician who prescribes TMS treatment for a patient after reviewing their history and examining the patient. The "covering" (or "attending") TMS clinician is the clinician directly responsible for TMS treatment of a patient on any given day. The covering clinician on any given treatment day may or may not be the same person as the prescribing clinician. The TMS "technician" or "operator" is the clinician or non-clinician who directly administers TMS to a patient who has been prescribed TMS and is under the direct supervision of the covering clinician. The "medical director" is the medically licensed TMS clinician overseeing administrative aspects of the service, often in addition to providing patient care.

3.9.2. Who can prescribe TMS?

In the US, the decision regarding who has the legal authority to prescribe TMS has largely been rendered at the level of the state, as state legislation often defines scope of practice. As of December 2023, the national Medicare policy states that the order for TMS treatment or retreatment for major depressive disorder should be written by a psychiatrist (M.D. or D.O.) who has examined the patient and reviewed the record. The physician should have experience administering TMS therapy.

The Medicare policy goes on to state that "non-physician practitioners" including physician assistants, advanced practice registered nurses, nurse practitioners, and other advanced practice providers may order TMS treatment if it is within their scope of practice in the state in which they are licensed, with the same training requirements as noted for physicians above.

The consensus view of the authors is that clinically licensed practitioners of TMS for the treatment of depression should receive specific training in the administration of TMS, demonstrate competency in the safe and effective use of TMS, and have extensive training and expertise in the diagnosis and treatment of depressive disorders, especially treatment-resistant cases. This aligns with the prior guidelines that state a prescriber should be a clinician "with prescriptive privileges who is knowledgeable about, trained, and credentialed in rTMS" (McClintock et al., 2018a). Examples of how to operationalize the above considerations regarding the necessary knowledge, training, and certification for prescribing TMS are outlined in Section 3.9.4. and Table 3.

3.9.3. Who can administer TMS?

The national Medicare policy as of December 2023 states that TMS treatment should be given under direct supervision of the physician (or non-physician practitioner), although the physician does not need to personally provide the treatment. The clinician should be "present in the area" per this policy and have experience with TMS. It is the consensus of the authors that a TMS clinician, if not the same person as the prescribing clinician, should nevertheless have the same qualifications, described above, as a prescribing clinician.

3.9.4. Certification process for clinicians to prescribe and administer TMS

Currently, TMS proficiency is monitored and certified in various ways. Certification occurs at the level of the individual institution, hospital system, and clinic. Usually, this process involves new trainees completing a certain amount of observed and supervised treatment sessions, with a focus on demonstrating proficiency with motor threshold determination, targeting and coil placement (stimulation site determination), parameter determination and settings, and knowledge on safely using the equipment and managing emergencies. A prior publication on TMS training by Fried et al. suggested that training should include "substantial emphasis on theoretical, didactic competencies and, safety and ethics, in addition to practical skills"(Fried et al., 2021). These competencies include domains of core knowledge, safety, ethics, and technical/hands-on training. The details of these

Table 3
Example competency table for TMS, adapted with edits from (Fried, et al., 2021).

Domain	Competency	Clinician	Technician
Core Knowledge	Basic Mechanisms of TMS	X	X
	Design Fundamentals	X	X
	Basic Neuroanatomy and Physiology	X	X
	Safety and Risk	X	X
	Regulatory Landscape	X	(X)
	Clinical Training and Experience in the Assessment and Management of the Underlying Condition for Which TMS is Being Used (e.g., treatment-resistant mood disorders, psychiatric disorders)	X	(X)
	Knowledge of a Typical Treatment Course and Standard Operating Procedures at Local Site	X	X
	Knowledge of Literature including Landmark Trials, Safety and Clinical Standard Documents	X	(X)
Safety and Ethics	Adverse Effects of TMS	X	X
	Screening and Risk Stratification	X	(X)
	Recognizing and Managing Seizure or Syncope	X	X
	Hearing Protection	X	X
	Recognizing and Addressing Needs of Special Populations	X	(X)
	Recognizing and Addressing Acute Mental Health Concerns	X	X
Technical & Hands-on	Device Operation, Basic Maintenance, and Troubleshooting	X	X
	Scalp Measurement Procedures	X	X
	Basic Neurophysiology (e.g., EMG vs. visible twitch)	X	X
	Targeting TMS (Coil location, orientation, angle; neuronavigation; scalp-based targeting)	X	X
	Basic Applications of TMS (Finding motor hotspot, assessing motor threshold)	X	(X)
	Basics of Different Clinical Protocols (high frequency, low frequency, theta burst stimulation)	X	X

X = recommended competency; (X) = desirable but not required.

Rccceferences.
Fried, P. J., Santarnecchi, E., Antal, A., Bartres-Faz, D., Bestmann, S., Carpenter, L. L., Celnik, P., Edwards, D., Farzan, F., Fecteau, S., George, M. S., He, B., Kim, Y. H., Leocani, L., Lisanby, S. H., Loo, C., Luber, B., Nitsche, M. A., Paulus, W., Rossi, S., Rossini, P. M., Rothwell, J., Sack, A. T., Thut, G., Ugawa, Y., Ziemann, U., Hallett, M., & Pascual-Leone, A. (2021). Training in the practice of noninvasive brain stimulation: Recommendations from an IFCN committee. *Clin Neurophysiol, 132*, 819–37.

competencies are reviewed in Fried et al. and are beyond the scope of this document. However, certification in TMS for the treatment of mood disorders should be conditional with demonstrating achievement of such core competencies. Examples of such core competencies are shown in Table 3, which can serve as a common framework for constructing a program of training and assessment of new clinicians and device operators (referred to going forward as "technicians"). However, no single universal program or set of competencies has been established, as the needs of individual clinical systems may vary. Formal training courses are currently offered by academic institutions and professional societies, and additional training content is freely available online (Lisanby, 2020). Some professionals have proposed the development of standardized, subspecialty fellowship training programs for TMS, such as those offered through the American College of Graduate Medical Education or the United Council for Neurologic Subspecialties, as the treatment procedure becomes more complex and indications expand (Trapp et al., 2023a, Trapp and Williams, 2021). To date, this is not a requirement.

Although device operation basic skills are frequently taught by the device manufacturer due to nuances of each TMS device, this is typically considered insufficient training in isolation. Prior consensus guidelines have suggested that TMS providers complete this formal training or obtain additional training via peer-to-peer direct supervision (Perera et al., 2016), and that all members of the treatment team (staff and clinical providers) receive appropriate product training. Written documentation of training completion should be obtained and archived for each treatment team member. Each clinic should have a procedure for maintaining skills and continuing education in the field, as it continues to rapidly evolve.

3.9.5. Minimum qualifications for TMS technicians

Minimum qualifications for a TMS technician are outlined elsewhere (Fried et al., 2021, Rossi et al., 2021). At a minimum, TMS technicians should be trained and certified to deliver TMS, including device operation training, TMS coil targeting, and recognition and management of side effects. Technicians should monitor the patient throughout the treatment administration, watch for adverse events, ensure contact between the patient's scalp and the coil, and adjust coil position to ensure the target remains consistent with patient's head movements. Technicians should be trained to monitor for motor cortex excitation and to follow specific guidelines for notifying the supervising clinician about concerns, such as for motor activation, seizure-like or syncopal activity, or concerning comments/behaviors related to suicidal ideation, mania, psychosis, panic attack, or other behavioral concerns. Technician qualifications and responsibilities, beyond the above minimum qualifications, may vary across TMS practices based on the level of comfort of the TMS provider and the level of training and experience of the TMS technician. For example, technicians may or may not be trained in assessing the motor threshold and initial targeting of the TMS treatment, based on the supervision structure implemented by the prescribing or supervising clinician.

3.9.6. Responsibilities

The medical director, prescribing clinician, or supervising clinician must ensure the competency and adequate supervision of TMS technicians performing the TMS procedure. The covering TMS clinician (may or may not be the medical director or prescribing clinician) is at all times responsible for the management of the TMS treatment team, including ensuring the safety and appropriate clinical management of the patient during the TMS procedure. In the context of this responsibility, the covering clinician should be available to provide assistance to the technician, including assessing safety concerns and responding to clinical emergencies.

The procedure for calculating the TMS "dose" intensity is the motor threshold determination, which involves delivering stimuli to the primary motor cortex and monitoring for motor movement (either visually or with electromyography) to determine the minimum TMS stimulus intensity necessary to induce a motor evoked potential in the muscle group of interest, often the abductor pollicis brevis or first dorsal interosseous in the hand. Motor threshold determination is typically performed by the prescribing clinician or another clinician certified in the use of TMS. Conduct and oversight of initial and subsequent motor thresholds or daily treatment sessions may be delegated by the covering clinician to another appropriately certified and experienced member of the clinical team but should be supervised by a medically licensed clinician. All clinical staff should maintain appropriate training (including basic life support) to support their role as first responders to potential clinical emergencies including, but not limited to, seizure, syncope, and acute suicidal ideation. How this training is obtained and verified should be the responsibility of the medical director of the TMS program.

3.10. Barriers to treatment

The literature describing barriers to access for antidepressant treatment with neuromodulation technologies is limited. Most of the published literature has focused on ECT (Philpot et al., 2002, Wilkinson et al., 2021), and the studies were based either on small, qualitative surveys or practitioners' viewpoints. A recent paper that highlighted perceived barriers and ethical concerns about neuromodulation, including TMS, was an interview study by Cabrera et al. that was followed by a survey study (Cabrera et al., 2022, Cortright et al., 2024).

Among available antidepressant strategies, rTMS has practical advantages for patients. Indeed, it is easily administered on an outpatient basis, allows patients to transport themselves to and from clinic, can take less than an hour for the total procedure, and tends to be well tolerated. Nonetheless, important practical barriers to its uptake and implementation remain. Lack of access to TMS is a key barrier (Cabrera et al., 2022, Health, 2021), which reduces the opportunity for eligible patients who might benefit from the treatment, or at best delays care and can limit the total treatment regimen (Health, 2021). Access barriers include financial barriers, geographical availability of TMS providers, racial disparities in depression diagnosis and access to neuromodulation treatments (Black Parker et al., 2021), space or scheduling limitations, lack of awareness amongst referring providers, lack of healthcare providers with available TMS devices, and limited training and expertise amongst providers for performing particular TMS protocols (Cabrera et al., 2022, Cortright et al., 2024). Other related barriers may include the inability of patients to obtain appointments with TMS providers, transportation limitations, and the need to be released from work or to arrange childcare for treatment (Cabrera et al., 2022, Cortright et al., 2024).

Key barriers to rTMS adoption across patients, caregivers and members of the general public were the perception of limited evidence of treatment effectiveness and lack of understanding about the intervention (Cabrera LY, 2022, Cortright et al., 2024). Another common barrier for patients seeking rTMS treatment is cost and variability in insurance coverage. While TMS is generally more expensive than first-line treatments, a recent cost-effectiveness analysis that compared TMS to antidepressant medications after a first treatment failure for depression in newly diagnosed patients found that rTMS can be a cost-saving and clinically effective therapy when considered over the entire life of the patient (Voigt et al., 2017). More work remains to be done to systematically compare the cost-effectiveness of different TMS protocols with other first line treatments and other neuromodulation modalities. An additional area in need of further exploration relates to the cost-effectiveness of maintenance TMS protocols; little data exists on the use of TMS as a maintenance treatment following an acute series of TMS or ECT, or on the use of pharmacologic agents to maintain the benefits of an acute TMS course. Thus, these strategies are not currently covered by most insurers, and practitioners resort to the common practice of providing acute treatment and monitoring for patient relapse before re-treating.

In terms of insurance coverage, while rTMS is covered by most major insurance plans, there remain problems with the administrative burden and associated requirements for patients to realize this benefit, such as with off-label use in individuals under the age of 21 (Cabrera et al., 2022, Weissman et al., 2023) Another example is the requirement by many Medicare carriers and private insurers that various trials of medication therapy must be attempted before treatment with rTMS despite the lack of evidence to support this policy (Weissman et al., 2023). Insurance criteria can also vary by state and insurance carrier, and these criteria can often fall victim to outdated interpretations of the scientific literature as insurance providers struggle to keep pace with the advancements in the field of TMS, especially in an environment where they are not incentivized to do so. Data from a national survey of four different stakeholders found that across all surveyed groups, those assigned to rTMS were more likely to report out-of-pocket costs and lack of insurance coverage among their primary perceived barriers (Cabrera LY, 2022, Cortright et al., 2024).

Time constraints were a commonly mentioned barrier in a recent study that examined different neuromodulation therapeutics (Cabrera et al., 2022. Findings from a survey highlight rTMS frequency of treatment among the top three barriers selected by psychiatrists (Cabrera LY, 2022, Cortright et al., 2024). Even in the case of new accelerated TMS protocols, other logistical challenges to implementing such protocols were reported (e.g., time commitment by patient needed for long visits, space limitations, and limitation on the TMS operator time to deliver longer daily protocols).

Important barriers that impact practitioners include cost of equipment, the need for space and technicians, and lack of training in administering TMS. Not all training programs offer or require training in TMS, and the degree of exposure trainees receive can vary across training institutions. These barriers lead to a lack of direct skill in the technique as well as limitations of knowledge and attitudes towards TMS amongst the broader community of mental health providers. Indeed, a pilot assessment of psychiatrists (N = 16) found knowledge gaps when it comes to the efficacy and tolerability of rTMS (Mehalick and Laje, 2020). Consequently, even though rTMS was first cleared by the FDA for depression in 2008, this study and others suggest that it remains unfamiliar to many healthcare professionals, patients, and families (Cabrera et al., 2022, Goldbloom and Gratzer, 2020). This highlights the need for more education and training for patients and healthcare providers, with a specific focus on TMS (see *Section 3.9. Training, Privileging, and Treatment Roles and Responsibilities*). Finally, high-expense, high-resource technological enhancements to TMS treatment, such as the use of neuronavigation equipment or MRI-based targeting procedures, may exacerbate already limited access to TMS if deemed standard of care.

Many of these barriers to care are even more pronounced in low- and middle-income countries, where equipment costs, lack of insurance coverage, lack of access to specialized facilities or expertise, lower prevalence of mental health awareness, and resource limitations such as reduced access to electricity can further complicate patient access to TMS. As TMS and other neurostimulation interventions are increasingly considered frontline, essential therapies in mental heathcare (Yam, 2024), more research on how to change policies and expand access is needed (Patel et al., 2009), with some philanthropic organizations making expansion of TMS access their global mission.

TMS is a well-tolerated and cost-effective treatment with several barriers to adequate patient access to this service. The consensus of the authors is that education and training on TMS should be emphasized in residency training programs, and ongoing TMS advocacy emphasized with insurance carriers in relation to new treatment approaches. These efforts can address current key barriers to the use of TMS, which include lack of access to experienced providers and lack of provider and patient understanding of the procedure.

3.11. Patient, Family, and Advocate education

An important factor in improving access to care involves educating not only the clinicians, but also the patients, their families, and other mental health advocates about TMS. This increases awareness of TMS amongst patients and their supporters, enabling them to make informed decisions about their care and the options available to them. Useful, free patient-oriented resources have been made available by U.S. organizations such as the Clinical TMS Society (https://www.clinicaltmssociety.org/patients) and the National Institutes of Mental Health (https://www.nimh.nih.gov/news/media), among others.

3.12. Documentation

Regarding best practices for documentation, we formulated our current considerations based on what we previously reported (McClintock et al., 2018a). A pre-treatment assessment note (see

Table 4
Assessment Note Recommendations.

Assessment Note	
Comprehensive psychiatric assessment	- Symptomatology - Comorbid disorders - Current treatments (pharmacologic and non-pharmacologic) - Treatment history • Dose, duration, and outcome of prior medications • Prior TMS course(s), outcomes, and durability of effects
Medical and surgical history	Assessment of risk factors and contraindications for TMS
Objective	- Baseline mood rating scale(s) - Mental status exam - Focused physical exam
Diagnosis and assessment	Indication for TMS
Plan	- Discussion of risks, benefits, and alternatives - Prescription for rTMS: • Number of treatments • Frequency of treatment • Stimulation site and targeting method • Stimulation dose (e.g.: % motor threshold) • Stimulation protocol (e.g.: 10 Hz, iTBS, etc.)

Table 5
Procedure Note Recommendations.

Procedure Note	
Date of treatment	
Start & stop time of treatment	
Indication (Primary diagnosis)	
Time-out	Document time-out was performed to confirm correct patient, correct treatment protocol, and presence of consent
Patient status	Outpatient or inpatient
Session type	Acute/index or maintenance
Treatment and course number	e.g., #20, 3rd treatment course
Coil type	e.g.: H-coil, figure-of-8, etc.
Stimulation target	
Targeting method	Be specific; e.g., Beam F3, 5.5 cm anterior to motor cortex, or neuronavigated (specify neuronavigation modality)
Stimulation protocol	e.g.: 10 Hz, iTBS, aiTBS, DASH, 20 Hz with OCD provocation
Train duration	In seconds
Inter-Train Interval (ITI)	In seconds
Number of pulses per session	
Stimulation intensity	- Ideally specified as % motor threshold due to stimulus variability between machines. - Include both target intensity and actual intensity delivered - If applicable, include start & end intensity
Motor threshold (MT)	- Specify if % machine output or other - Include when it was last measured - Include method of MT determination (e.g.: visual)
Bilateral stimulation	If applicable, include the stimulation targets, protocol, train duration, ITI, stimulation intensity, and motor threshold as above
Clinical progress & observation	- Dates and results of rating scales for current course - Subjective: Patient reported changes (or lack of) in symptoms - Objective: Appearance and behavior
Patient activity during session	e.g.: resting passively, psychotherapy, reading, watching videos, etc.
Treatment-emergent adverse effects	- If present, document symptom details, duration, and intensity - If absent, document lack of adverse effects
Reason for change in treatment plan	- If applicable - Include any change in medications
Names of TMS technician and supervising clinician	If applicable, document the presence of resident (s)/trainee(s)

Table 4) should document the indication for TMS, potential risks and benefits, as well as confirmation of consent to treatment. Procedure notes (see Table 5) should document treatment protocols, clinical progression, and treatment-related side effects. The use of rating scales to establish baseline symptom severity and monitor clinical progression should be documented, which is consistent with the latest APA Practice Guideline for treatment of depression (Gelenberg et al., 2010). At minimum, a mood rating scale should be obtained pre- and post-treatment. The items included in Tables 4 and 5 should be considered as the ideal framework for documentation, and individual clinical sites may add or modify items, as necessary.

4. Conclusion

Since its initial FDA clearance in 2008, TMS has increasingly become a more frequently utilized treatment approach for depressive disorders, primarily major depressive disorder. The amount of literature on this topic has increased almost exponentially in recent years (McLean, 2019), and this rapid growth presents a challenge for clinicians hoping to synthesize and interpret the evidence to inform clinical decisions and optimize patient care. These updated consensus statements build upon the 2018 NNDC/APA consensus recommendations and highlight topical issues in TMS clinical practice for mood disorders, including brief reviews of the evidence for efficacy, safety, predictors of treatment response, considerations for special populations, targeting methods, stimulation protocols, coil design, augmentation and optimization strategies, and barriers to access. We also provide consensus statements on documentation standards, training and privileging, and roles and responsibilities for providers considering the integration of TMS into their clinical practice. Although many topics require additional research, these updated considerations attempt to consolidate expert opinion and practice in the administration of this treatment technique.

Limitations of this review include those inherent to the endeavor of a finite group of experts attempting to consolidate a large amount of data into a finite document. These include limitations on knowledge and awareness of specific literature more recent than the date of the systematic data capture; geographic and diversity limitations of having a predominantly North American consensus committee membership; and variability in method of feedback provided as not every committee member was able to attend every consensus meeting, resulting in a mix of written and oral feedback from committee members. The authors acknowledge that TMS is practiced differently in different settings based on many factors, and these statements serve primarily as suggestions for good clinical practice based on the expert opinion and consensus of the authors at the time of this writing.

Author Contributions

NTT – Conception and design, Systematic literature search & abstract review, Consensus topic presentations, meetings, and discussion, Analysis and interpretation of results, Visualization/tables, Writing – original draft, Writing – revision and editing.

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MJF – interpretation of results, Writing – Revision and editing.

TB – analysis and interpretation of results, Writing – Revision and editing.

DMB – analysis and interpretation of results, Writing – Revision and editing.

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The other authors have no financial conflicts of interest regarding this manuscript.

Declaration of competing interest

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Appendix 1. Consensus Committee Panelist Info

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Susan Conroy, MD, PhD	Assistant Professor of Psychiatry Director, Neurostimulation Program Associate Director, Mood Disorders Program Co-Chair, NNDC Treatment-Resistant Depression Task Group Member, NNDC Neuromodulation Task Group	Indiana University	Indiana, USA	TMS Clinician TMS Researcher
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(continued on next page)

(*continued*)

Name	Titles & Credentials	Institution	Location of Workplace	Self-reported Stakeholder Group
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Other Authors and Roles.

Name	Titles & Credentials	Institution	Location of Workplace	Self-reported Stakeholder Group
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(*continued on next page*)

(*continued*)

Name	Titles & Credentials	Institution	Location of Workplace	Self-reported Stakeholder Group
	Member, Research Committee, Clinical TMS Society Board of Directors, Clinical TMS Society			
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Michael J. Flood	Co-Chair, Advisory Council, NNDC	National Network of Depression Centers	Michigan, USA	Layperson with Lived Experience
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Appendix 2. Search terms for primary data capture

TMS Search Terms:

"Transcranial Magnetic Stimulation"[mesh] including: "transcranial magnetic stimulation*", "TMS", "rTMS", "iTBS", "cTBS", "TBS", "theta burst".

Depression Search Terms:

"Depression"[mesh], "Depression, Postpartum"[mesh], "Depressive Disorder, Major"[mesh], "Depressive Disorder, Treatment-Resistant"[mesh], "Dysthymic Disorder"[mesh], "Premenstrual Dysphoric Disorder"[mesh], "Vascular Depression"[mesh] including: "MDD", "depressive disorder*", "disorder, depressive", "neurosis, depressive", "depressive neuros*", "neuroses, depressive", "depression, endogenous", "depressions, endogenous", "endogenous depression*", "depressive syndrome*", "syndrome, depressive", "syndromes, depressive", "depression, neurotic", "neurotic depression", "neurotic depressions", "melancholia*", "unipolar depression", "depression, unipolar", "depressions, unipolar", "unipolar depressions", "bipolar depression", "manic depression", "bipolar disorder", "postpartum depression", "depression, postpartum", "dysthymic disorder", "premenstrual dysphoric disorder", "vascular depression", "difficult-to-treat depression", "geriatric depression", "psychotic depression", "depression with psychotic features", "melancholic depression".

Appendix 3. Search terms for sub-section abstract review (when applicable). Some categories were reviewed more broadly based on input from the topic leader or task group

Efficacy section: "efficacy", "effectiveness".
Safety section: "safety".
Predictors section: "duration", "demographic", "predictor", "medication", "comorbid", "personality", "electroconvulsive".
Special Populations section: "partum", "pregnancy", "geriatric", "elderly", "older".
Coil Design section: "coil", "coil design".
Targeting section: "target", "targeting", "localization".
Stimulation Protocols section: "priming", "accelerated", "rapid", "synchronized".
Treatment Optimization section: "bilateral".
Barriers section: "barriers".

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clinph.2024.12.015.

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