Clinical Standards Committee Statement regarding SNT

Considerable interest has been generated both in the academic community as well as the popular media regarding a novel approach to providing Transcranial Magnetic Stimulation (TMS) for treatment resistant depression (TRD). This new protocol was initially referred to as Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) but is now known as Stanford Neuromodulation Therapy (SNT). SNT has not been FDA-cleared and thus remains off-label. Nevertheless, some patients are requesting treatment with this protocol and providers are looking for guidance regarding its off-label use.

Although not FDA-cleared, the SNT protocol has demonstrated some encouraging results in an open label study (n=21) and a randomized double-blinded sham-controlled trial (active n=14, sham n=15) for TRD. Importantly, this protocol, which utilizes intermittent Theta-Burst Stimulation (iTBS), differs from the current FDA clearance of iTBS for Major Depressive Disorder (MDD) in several aspects including:

SNT Protocol	FDA-Cleared iTBS Protocol
10 sessions per day with 50-minute intersession interval for 5 days	one session per day for 36 days
1,800 pulses iTBS per session	600 pulses iTBS per session
treatment at 90% motor threshold (MT) adjusted for cortical distance difference from motor cortex to dorsolateral prefrontal cortex based on the individual's MRI image	120% MT with no adjustment for depth
location of stimulation based on individualized functional MRI with neuronavigational targeting equipment	probabilistic location based on measurements on the scalp

Importantly, the SNT protocol cannot be replicated without structural and functional MRI, neuronavigation equipment, and the expertise/software to target treatment based on fMRI connectivity.

All studies have been conducted using one specific TMS device; how this will compare with responses utilizing other devices is unknown.

While these studies have demonstrated positive early effects, durability has not yet been demonstrated equal to current FDA-cleared protocols.

In summary, TMS practitioners should be aware of the efficacy and durability of SNT and SNT-like accelerated off-label protocols. As with all non FDA-cleared protocols, TMS practitioners should inform patients of the off-label status of the protocol as well as the above limitations.