

"Members are reminded to disclose any changes in Conflict of Interest (COI) information since the most recent disclosure and follow all COI policies."

Clinical Standards Committee Roll Call | Attended ☒ | Did Not Attend ☐

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|----------------------|--|-------------------------------------|----------|---------------------------|-------------------------------------|
| Co-Chair | Joseph Taylor, MD, PhD | <input checked="" type="checkbox"/> | Co-Chair | Saydra Wilson, MD | <input checked="" type="checkbox"/> |
| Member | Scott Aaronson, MD | <input checked="" type="checkbox"/> | Member | Rebecca Allen, MD, MPH | <input checked="" type="checkbox"/> |
| Member/ VP | Tracy Barbour, MD | <input checked="" type="checkbox"/> | Member | Daniel Blumberger, MD | <input checked="" type="checkbox"/> |
| Member | Suneel Chamoli, MBBS, MD, FRANZCP | <input checked="" type="checkbox"/> | Member | Pilar Cristancho, MD | <input checked="" type="checkbox"/> |
| Member | Andrew Kozel, MD, MSCR, DFAPA, FCTMSS | <input checked="" type="checkbox"/> | Member | Dino Santoro, MD | <input checked="" type="checkbox"/> |
| Member | Subha Subramanian, MD | <input checked="" type="checkbox"/> | Member | Rick Trautner, MD, FCTMSS | <input checked="" type="checkbox"/> |
| Non-Voting Member | Linday Oberman, MD | <input checked="" type="checkbox"/> | | | |
| President | Joshua Brown, MD, PhD | <input checked="" type="checkbox"/> | | | |

Guests & Staff: None

I. Dr. Wilson called the meeting to order at 2:05 pm (ET)

II. Review October meeting minutes

The Committee reviewed the minutes.

There was a motion to approve the October 9, 2025 meeting minutes, Seconded, Approved.

III. Unfinished Business

A. Supportive statement on the evidence for TMS compared to other augmentation or switch strategies in treatment-resistant depression

- This Committee and the Executive Committee previously approved the statement. The statement is posted under the "Resources" section of the committee's webpage.
- Discussion on submitting the statement to the CTMSS journal and issuing a press release.

There was a motion to submit the statement to the CTMSS journal and issue a press release to increase visibility, Seconded, Approved.

ACTION – Dr. Barbour will find out how to submit to the journal for publication.

B. Review of statements on the website

- Reviewed statement edits.
 - RANZCP guideline related statement edited by Dr. Chamoli.
 - Statement title incorrectly references TMS guidelines; change to reference Mood Disorders guidelines.
 - Background provided regarding 2020 RANZCP decisions and subsequent statement corrections.
 - Suggested shorter introduction highlighting that the 2020 guideline is outdated and has since been corrected.
 - Recommendation to remove strong or overly critical language.

ACTION – Dr. Chamoli will continue to make revisions based on Committee feedback.

- Intermittent theta burst statement edited by Dr. Taylor.
 - Changed language to clarify that the FDA clears devices, not protocols.
 - Clarification added: *once-daily intermittent theta burst*, not accelerated protocols.
 - Avoid including overly detailed parameters that may quickly become outdated.

There was a motion to approve the revised intermittent theta burst statement, Seconded, Approved.

- Guidelines for training and monitoring of TMS treaters edited by Dr. Wilson.
 - Removed references to an ethics document not yet completed.
 - Committee confirmed alignment with Trap guidelines.

There was a motion to approve the revised guidelines for training and monitoring of TMS treaters, Seconded, Approved.

ACTION – Continue edit review at the next meeting.

IV. New Business

A. Consider statement on One-D accelerated TMS protocol

- Clinics are advertising a single-day TMS treatment based on a case series, often combined with pharmacologic enhancers.
- Concerns:
 - Insufficient evidence to advertise as effective treatment.

- Confusion between device FDA clearance and protocol approval.
- Ethical concerns regarding off-label advertising without transparency.
- Agreement that patient informed consent and transparency on evidence level are paramount.

There was a motion to draft a statement of concern regarding One-D accelerated protocols, Seconded, Approved.

- Key components agreed for the statement:
 - Clarify distinction between device clearance and protocol evidence.
 - Emphasize that off-label treatments should not be advertised as established treatment.
 - Link to Dr. Oberman's editorial on ethical TMS advertising.
 - Reinforce need for informed consent and accurate representation of evidence.
 - Agreed to address this issue with a standalone statement, inclusion in the "areas of concern" list, and publishing the statement in the CTMSS journal.

ACTION – Parthenon will send the final version of the statement on level of evidence to Dr. Wilson and Dr. Allen.

ACTION – Dr. Wilson and Dr. Allen will co-draft the statement and will aim to have the Committee review and vote on the draft before the next meeting.

V. Committee Projects and Informational Items

A. Statement on appropriate advertising and ongoing list of articles of concern for the website

- No time for a report. Deferred to next meeting.

B. Create guidelines for repeat MT's

- No time for a report. Deferred to next meeting.

C. Review of literature on treatment extension

- No time for a report. Deferred to next meeting.

D. Statement on TMS and pregnancy

- No time for a report. Deferred to next meeting.

E. Device Clearance Table Task Force

- No time for a report. Deferred to next meeting.

F. Announcement

- 2026-2027 committee term renewal notices were sent to all Committee members. Timely completion is requested.

G. Volunteer Recruitment for Awards Task Force

- Dr. Santoro and Dr. Cristancho volunteered for the task force.

VI. Adjourn Meeting at 3:01pm (ET)

VII. Next Meeting: Thursday, December 11, 2025 @ 2pm ET / 1pm CT / 12pm MT / 11am PT / Friday, December 12, 2025 @ 6am AEDT

2025-2026 Committee Goals:

- Create guidelines for repeat MT's. *In progress*
 - Consider treatment extension review of literature. *In progress*
 - Develop a procedure for rapid communication between Clinical Standards and Insurance Committees. *In progress*
 - Follow up on the TMS pregnancy registry and consider a statement. *In progress*
 - Evaluate TMS evidence for bipolar depression and consider a statement. *Tabled until more evidence is available*
 - Evaluate TMS evidence after ECT non-response and consider a statement. *Tabled until more evidence is available*
 - Revisit statement policies and processes. *In progress*
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