Position Statement 34: Electroconvulsive Therapy (ECT) and Other Electromagnetic Brain Treatments

Policy Position

This policy statement discusses electroconvulsive therapy (ECT) and several potential alternatives or supplements to ECT, including low current Cranial Electrotherapy Stimulation (“CES”), Deep Brain Stimulation (“DBS”), and Transcranial Magnetic Stimulation (“TMS”).

As confirmed by the 1999 report of the United States Surgeon General concerning mental health, electroconvulsive therapy (ECT) can be an effective treatment, primarily for individuals with severe depression, some acute psychotic states, and mania. However, there are risks of memory loss and other cognitive damage, and the administration of ECT is controversial and stigmatized. The severity and prevalence of the side effects appear to result in part from failure to ensure that ECT is administered in conformity with current clinical practice guidelines. Mental Health America (MHA) recognizes that though the risks are substantial, for some people the benefits outweigh the harms. Accordingly, MHA supports the use of ECT when the person being treated has consented to it, after a thorough appreciation of the risks and benefits.

MHA also recognizes that some people with severe depression are unable to give informed consent because they lack the judgment to adequately weigh the risks and benefits of ECT. In such circumstances, the states should ensure access to enforceable advance directives and a judicial process with adequate procedural safeguards to ensure that effective services reach people for whom ECT is appropriate while protecting their right to reasonably refuse treatment and preserving their liberties when their consent is only nominal.

MHA acknowledges that many consumers are opposed to any involuntary imposition of ECT. This is a controversial subject, since there is evidence that for some extremely depressed and catatonic individuals who are refusing food, or for persons with mania-induced, fluctuating, very high fever with no infection, involuntary ECT can be a life-saving intervention. Accordingly, MHA cannot preclude involuntary use of ECT but supports it only with appropriate procedural protections that recognize the substantial cognitive side effects of ECT, a finding of an emergency that cannot be met by any other treatment, and a high threshold of proof.

Mental Health America recommends that all use of sine wave stimulation ECT be prohibited. It is recommended that the states implement comprehensive monitoring programs to determine what types of ECT are being administered and how ECT is being administered. The states should also ensure that all administering physicians are aware of and acting in conformity with current clinical guidelines.

Additionally, this policy statement discusses several potential alternatives or supplements to ECT, including low current Cranial Electrotherapy Stimulation (“CES”), Deep Brain Stimulation (“DBS”), and Transcranial Magnetic Stimulation (“TMS”). Low current CES has shown some impressive positive results with lower risk. MHA agrees with the FDA that further research is needed in order to definitively recommend this practice. MHA is skeptical about DBS, and encourages personal research and substantial discussions with a medical professional prior to undergoing this procedure. TMS offers an FDA-approved less-invasive alternative to ECT that may prove an effective tool in combating depression and other mental illnesses.

Finally, it is important to note that the National Institutes of Health is moving toward understanding mental health conditions and their treatments as a series of circuits that influence our thoughts, feelings and behaviors. The brain circuitry conceptualization stands in contrast to previous conceptualizations based on chemical balances. Research has found that genetics,
epigenetics, and experiences and exposures throughout life reinforce or weaken different a series of cells that use electromagnetic potential to transmit signals in the brain – “circuits.” Sometimes this strengthening and weakening of circuits leads to distress, and our experience of mental health conditions.

The circuit conceptualization indicates that electromagnetic interventions may be able to strengthen or weaken certain circuits to address mental health conditions. Current research in the NIH’s BRAIN Initiative and elsewhere are mapping brain circuits that affect mental health, MHA supports this new research direction in the hope that it may yield safer, more targeted and more effective treatments.

ECT
What is ECT?
ECT is a form of electrical stimulation of the brain that has been in use since the 1930s. A psychiatrist, an anesthesiologist, and other supportive medical personnel supervise the treatment. The person being treated is anesthetized. In bilateral ECT, electrodes are placed on the scalp above each temple. In unilateral ECT, the electrodes are placed above the temple on one side of the brain and in the middle of the forehead. An electrical current is then passed through the brain, inducing a grand mal seizure similar to that experienced in epilepsy. Clinically effective seizures generally last from about 30 seconds to just over a minute. The body does not convulse, and the person being treated feels no pain. Some persons may experience headache, nausea, confusion and muscle stiffness upon awakening. A typical course of ECT treatment requires six to 12 treatments over a period of less than a month. To sustain the response to ECT, continuation treatment, often including medication, should be provided when the ECT course has been completed. It is not known how or why ECT works.

ECT does not usually provide permanent relief from depression, and like medicine, may need to be re-administered following subsequent relapses.

Different types of ECT
There are currently three different ways to administer ECT: bilateral pulse stimulation, unilateral pulse stimulation, and sine wave stimulation. Sine wave stimulation is no longer considered justifiable under American Psychiatric Association guidelines because there is a considerably greater risk of memory loss without any increased benefit. Bilateral and unilateral brief pulse stimulation are each accepted treatments. One study showed that bilateral pulse stimulation, the former “gold standard” for ECT, produces greater risks of memory loss than unilateral pulse stimulation and suggests that, while it may still be necessary to use bilateral pulse stimulation during the course of treatment as the recipient’s threshold increases, unilateral pulse stimulation should always be used first. One study demonstrates that “twice-weekly high-dose unilateral ECT for severe depression is as effective as bilateral ECT, with fewer cognitive side effects.” If unilateral pulse stimulation is not effective, the recipient should have the opportunity to reconsider consent before bilateral pulse stimulation is administered.

Tailoring ECT to individual recipients
Within each method of ECT administration, the charge dose, pulse length, and duration may be varied. Each of these variables in ECT administration may be adjusted to tailor the treatment to the needs of the person receiving ECT. The best practice is to tailor the treatment to the recipient throughout the course of treatment. Tailoring the treatment permits physicians to induce the desired seizure with the minimal amount of energy.

ECT may be appropriate for individuals over 60 years of age. A 2016 study found it to be effective with this population, concluding that the administration of ECT is “a rapidly active and
highly effective treatment option for depressed geriatric patients, with excellent safety and tolerability.\(^9\)

**ECT and Adolescents**
The available scientific literature supports the use of ECT as an effective therapy for adolescents.\(^10\) Studies have found that ECT treatment is as effective for adolescent patients as it is for adult patients.\(^11\) ECT has been shown to be effective amongst adolescents who have not responded to other forms of treatment.\(^12\) For example, ECT has been shown to be most effective amongst patients with severe psychiatric disorders who have not responded to first-line treatments.\(^13\) The side effects of ECT amongst adolescent patients are moderate and temporary; with long-term memory loss being extremely uncommon.\(^14\)

However, the use of ECT on an adolescent patient population poses unique concerns which physicians should address. First, obtaining consent from a minor is a difficult legal issue. Adolescents under the age of 18 are generally not legally capable of providing consent. Therefore, physicians should be aware of these consent issues when treating adolescent patient. State law on adolescent consent varies from state to state. Second, there are very few studies on the use of ECT on minors under the age of thirteen.\(^15\) Therefore, MHA is unable to speak to ECT’s effectiveness for children under the age of thirteen and would caution physicians and parents to consult the available literature. Third, the need for the use of most effective available treatment is particularly high for adolescents suffering from mental illness.\(^16\) Adolescents suffering from mental illness have a high risk of suicide, lowered scholastic achievement and impaired social functioning.\(^17\) Therefore, ECT should remain a powerful tool employed by physicians for the treatment of adolescent patients. Potential adolescents considering ECT, and their families, should carefully consider the risk/benefit ratio and physicians ought to provide their patients with the opportunity for truly informed consent.

**Benefits of ECT**
ECT can be the best course of treatment for some individuals with severe depression, some psychotic states, and mania.\(^18\) ECT may be particularly suitable for people who have not responded to medication, or for whom medication is not a suitable treatment. While ECT has been shown to be effective in lessening symptoms, it is not a cure, and many recipients will relapse at some point after the treatment is terminated.

The primary difficulty in measuring the efficacy of ECT is determining the rate of relapse. About 50% of people who receive ECT (without continuing ECT) relapse between 6 and 12 months after treatment, and the relapse rate 4 to 5 years after treatment is around 72%.\(^19\) Several studies have indicated that the relapse rate after 6 months, with medication, is between 30% and 50%.\(^20\) Another study indicated that after 2 years of treatment, the relapse rate was 48%, and rose to 82% at 5 years out.\(^21\) When continuing ECT is administered, studies have indicated that the relapse rate is significantly lower than without continuing ECT.\(^22\) One study showed that with continuing ECT, at two years after treatment, the treatment was 93% effective, and at five years after treatment, 72% still had not relapsed.\(^23\)

**Risks of ECT**
Memory loss and other cognitive damage are the primary reasons for the ongoing controversy over the use of ECT. There are varying degrees of memory loss and other damage, depending on the recipient. There are also varying opinions as to how memory is affected by ECT. Many people report loss of memory concerning events that occurred in the period surrounding the ECT. The 1999 report of the Surgeon General asserted that “confusion and disorientation seen upon awakening from ECT typically clear within an hour.”\(^24\) Some memory loss is common and generally affects the period from up to six months before treatment to up to two months.
afterward but may affect a longer period. Some of this memory loss may be caused by the depression that the ECT is being used to treat. In some cases, the memory loss and other cognitive damage can be significant. Recent studies show that the risks of memory loss are correlated with the type of ECT administered and how it is administered. For instance, sine wave stimulation carries the highest risk of memory loss and should not be used. Bilateral stimulation is associated with greater memory loss than unilateral stimulation. Like other medical treatments, there is no way to predict who will receive adverse effects, which for ECT can include severe memory loss and cognitive deficits following ECT.

In addition to controversy surrounding the practice of ECT, there is also a considerable stigma. Popular culture often calls ECT by another name – shock therapy. This conjures up strong images of draconian practices like those described and shown in One Flew Over the Cuckoo’s Nest. Administration of ECT has changed considerably since this depiction, yet the image remains as a primary reference in American culture. Today, advances have been made that make ECT safer and have reduced the cognitive side effects. A minority of people who have received ECT have had devastating memory loss and other cognitive damage. MHA is concerned because we now know that the risk of memory loss can be substantially reduced by adherence to current clinical practice standards, yet those standards are often ignored.

In an article published in 2007, Dr. Harold Sackeim, a nationally-recognized expert in the use of ECT, reported that “adverse cognitive effects can persist for an extended period, and that they characterize routine treatment with ECT. . . .” The administration of ECT has been refined over the years, and practice guidelines have been devised that reduce the risk of memory loss, but the danger of memory loss and other cognitive damage remains significant.

In order to reduce the adverse memory loss effects of ECT, Magaoang & Lucey (2007) propose the investigation and implementation of cognitive rehabilitation. Currently, cognitive rehabilitation, potentially including Cognitive Behavioral Therapy or memory exercises by trained clinicians, are noticeably absent from the post-ECT process. MHA supports the promise of cognitive rehabilitation having a pronounced positive effect on both the post-ECT experiences of patients and the public perception of ECT, potentially leading to more patients agreeing to undergo this effective yet stigmatized procedure.

**Monitoring treatment practices.** It is important for the states to know how ECT is being administered so that they can devise suitable regulations and ensure that practitioners are using current methods. States should implement a monitoring system that collects data concerning how much ECT is being administered, who is receiving ECT, the age of the people receiving ECT, what type of ECT is being administered, how it is being administered (dosage, duration, number of treatments, etc.), the legal basis for the administration (informed consent, judicial process, advance directive, etc.), and the number of injuries and adverse outcomes resulting from ECT.

**Regulation of treatment practices.** The states should regulate how ECT is administered to ensure that treating physicians conform to current clinical guidelines. The states should focus efforts to ensure conformity with current standards through licensing and mandatory continuing education. In some states a significant number of practitioners are still administering sine wave stimulation. Some practitioners may be over-administering bilateral stimulation when unilateral stimulation may be sufficient. Finally, many facilities administer a fixed dose of electricity to the recipients instead of tailoring the administration to create the desired effect with the minimal amount of electricity. Continuing education and licensing requirements will help insure appropriate use of ECT to avoid the evils of past practice.
Regulation of informed consent for ECT. Informed consent suggests that the recipient of treatment has both the intellectual capacity and the judgment to give consent. Most individuals who are candidates for ECT have severe depression. A mood disorder, such as depression, may cause an individual to agree to ECT while giving insufficient weight to, or not caring about, the potential harms that ECT poses.

When an individual lacks ability to give informed consent, the states must provide an adequate alternative that ensures substantial procedural safeguards. Use of advance directives will improve and enhance autonomy, and is encouraged. However, in the absence of an advance directive, states should have a judicial process that provides individuals with a hearing and an attorney. During the hearing, the fact finder should hear evidence on the risks and benefits of treatment, and if an order for treatment is granted, it should specify the treatment type to be administered, and the maximum number of treatments.

Other Electromagnetic Treatments

Low current Cranial Electrotherapy Stimulation (“CES”)

Richard P. Brown, M.D., lead author of How to Use Herbs, Nutrients & Yoga in Mental Health Care (2009), states that he has observed “overwhelmingly positive results” with CES in treatment of anxiety and depression, with response rates of 80% or better, and with respondents uniformly reporting subjective impressions of improvement. The device uses a current below four milliamps that cannot be sensed by the consumer, and serious side effects are unknown. The FDA has grandfathered CES as a Class III device for treatment of depression, anxiety and insomnia, and a proceeding is pending for Class II status, focused on its use in people with substance use conditions. MHA encourages additional research to determine whether the promise of CES can be fulfilled, without the serious side effects of large-current ECT.

Future studies should target an understanding of the mechanisms or neurophysiology of both DC and AC methods of neuromodulation, as well as results for a broad range of mental health conditions, particularly depression, in which most past studies have been small and not been double-blind. Bipolar disorder has not been studied at all, although the anecdotal evidence is positive. And Dr. Brown’s concerns about use of CES in patients with panic disorders require more scientific attention. The low incidence of side effects and the suggestive findings in small studies require additional research attention and counsel responsible consumer use as the data are being developed.

Deep Brain Stimulation (“DBS”)

DBS involves the surgical implantation of a device similar to a pacemaker in order to electrically stimulate the brain. A DBS system includes three parts: the DBS lead, an extension wire, and a stimulator. Following surgical implantation, the device “must be programmed to identify the optimal stimulation parameters that provide the most clinical benefit, the least amount of side effects, and ideally, utilize the lowest energy.”

DBS is approved by the FDA for treatment of Parkinson’s disease, essential tremor, and dystonia. Additionally, DBS has been used in the treatment of Obsessive Compulsive Disorder and Major Depressive Disorder. The FDA has approved DBS for OCD under a Humanitarian Device Exemption. While OCD is typically responsive to medication and therapy treatment, DBS has been used to treat patients that are not responding to first-line approaches.

Some research has demonstrated positive outcomes associated with DBS. Many patients with MDD are unresponsive to antidepressants, therapy, and ECT. For those patients, DBS may be a useful alternative. A 2005 study by Brian Snyder, Clement Hamani, and Andreas Lozano found that, of 25 patients, 4/6 (66%) patients met their criteria of disease response (50% or
more reduction in the patients score on the Hamilton Depression Rating Scale-17. Also, Snyder, Hamadi, and Lozano reported that their treatments “maintained a similar disease remission rate in our more recent patients as well with a mean follow-up of 2 years.” In light of the intrusive nature of DBS, the risks associated with all surgical procedures and the very limited research supporting its effectiveness, MHA urges caution in the use of DBS. Further research is warranted before the use DBS is expanded.

Transcranial Magnetic Stimulation (“TMS”)
TMS is a “noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of depression.” There are two types of TMS: Repetitive Transcranial Magnetic Stimulation (rTMS) and Deep Transcranial Magnetic Stimulation (dTMS). TMS does not cause a seizure and is also used to treat MDD. In addition, TMS does not cause memory loss and does not require anesthesia. Because the process is noninvasive and does not produce a seizure, it is perhaps an alternative to ECT. One recent study examined 42 TMS clinics and “found that 58 percent of patients showed improvement, including 37 percent who achieved full remission.” MHA supports further research on TMS, including on its viability as a possible less-invasive alternative to ECT.

The Future of Electromagnetic Interventions
While all of the interventions reviewed thus far leverage the concept of brain circuitry to improve mental health, they do not precisely target certain circuits based on the developing neuroscience. Crucial research into mapping neural circuitry, how that interacts with mental health, and how it can be modified is underway. One day this may lead to ways to minimally-invasively target individual circuits and provide new options for consumers to choose from in improving their mental health. MHA supports these research approaches for the opportunity to give individuals more options in their treatment.

Call To Action
In support of future electromagnetic interventions, MHA calls on:

- The federal government to continue to devote resources and partner with the private sector and academia to advance neural circuitry research and the opportunities for translational science it may bring; and

- Health insurer and the Centers for Medicare and Medicaid Services to provide transparency on under what circumstances they would cover new electromagnetic interventions and other interventions that may arise from neuroscience research, creating a stronger value proposition for investing in potential therapies in this area.

- Medicare< Medicaid and other third-party funders to consider withholding funding or requiring prior authorization for the use of sine wave stimulation

Each state should assume an active monitoring role concerning use of electromagnetic brain treatments. States should collect data on:

- Demographic information

- Number of recipients

- Type of electromagnetic treatment administered including type of ECT (sine wave, bilateral pulse, unilateral pulse)

- Extent and use of tailoring
• Approval process for administering electromagnetic brain treatments

• Informed consent procedures used by treating facilities, and whether recipients are giving informed consent

• Numbers of injuries and adverse outcomes arising from the use of electromagnetic brain treatments

Each state also should assume a regulatory role concerning use of electromagnetic brain treatments. States should:

• Implement continuing education programs for physicians who administer electromagnetic brain treatments to ensure awareness and conformity with current standards

• Enact legislation ensuring informed consent for the use of electromagnetic brain treatments.

• Implement special licensing requirements for physicians and facilities administering electromagnetic brain treatments.

• Prohibit the administration of sine wave stimulation.

• Each state should assume a regulatory role for obtaining informed consent to electromagnetic brain treatments. States should:

  • Require an informed consent form specifically for electromagnetic brain treatments that articulates the risks and benefits

  • Strengthen procedures to ensure that the recipient of the treatment has the judgment to give informed consent

  • Require a consent process where a person other than the treating physician evaluates the potential recipient’s capacity to give informed consent and confirms that the appropriate information has been explained and understood

  • Encourage the use of, and offer assistance in creating, advance directives

Each state should implement a judicial process for administration of electromagnetic brain treatments in instances when informed consent cannot be obtained. Judicial process for administration of electromagnetic brain treatments should contain the following procedural safeguards:

• A petition process that specifies the parameters of treatment sought

• A hearing before a neutral finder of fact

• An attorney to advocate for the individual

• Access to an independent expert
• Involvement of people (such as family members or others designated by the individual) to advocate on behalf of the individual

• Weighing of risks and benefits of treatment

Effective Period
This policy was approved by the Mental Health America Board of Directors on June 14, 2018. It is reviewed as required by the Mental Health America Public Policy Committee.

Expiration: December, 2023


2. “Much of the stigma attached to ECT is based on early treatments in which high doses of electricity were administered without anesthesia, leading to memory loss, fractured bones, and other serious side effects. ECT is much safer today.” (Mayo Clinic)


9.


13. Id.


17. For more information on issues relating to children’s mental health, see Mental Health America’s Position Statement 41: Early Identification of Mental Health Issues in Young People and Position Statement 42: Services For Children With Mental Health Conditions And Their Families


22. This is generally accepted, but there are methodological problems with these retrospective studies, and often the size of the study is very small


24. Id. at 259

25. Id.

26.

27. “One Flew Over the Cuckoo’s Nest is far from the only negative portrayal of ECT in popular culture. In a 2001 survey of 24 films featuring the technique, psychiatrists Andrew McDonald of the University of Sydney and Garry Walter of Northern Sydney Central Coast Health of New South Wales reported that the depictions of ECT are usually pejorative and inaccurate." (Scientific American)

28. Randomized-controlled trials have shown more severe short-term memory deficits with sine wave compared to brief pulse stimulation (Valentine et al., 1968; Weiner et al., 1986), bilateral (BL) compared to right unilateral (RUL) electrode placement (Lancaster et al., 1958; Sackeim et al., 1986; Sackeim et al., 1993; Sackeim et al., 2000), and higher electrical dosage (McCall et al, 2000; Ottosson, 1960; Sackeim et al., 1993).” Sackeim et al., op. cit. (2007), at 244.


31. Id.


38. Id.


40. Id.

41. Id.


44. Texas and Illinois both collect comprehensive date concerning the administration of ECT. See, 405 ILCS 5/2-110.1

45. A sample of comprehensive informed consent form may be found at: https://www.hopkinsmedicine.org/psychiatry/specialty_areas/brain_stimulation/docs/ECT%20consent_Feb2017.pdf

46. See, 405 ILCS 5/2-107.1