

## INTRODUCTION

Neurotherapies for diagnostics and treatment—such as electroencephalography (EEG) neurofeedback, single-photon emission computerized tomography (SPECT) imaging for neuropsychiatric evaluation, and off-label/experimental uses of brain stimulation—are continuously being offered to the public outside mainstream healthcare settings. Because these neurotherapies share many key features of complementary and alternative medicine (CAM) techniques—and meet the definition of complementary and alternative medicine (CAM) as set out in Kaptchuk and Eisenberg (2001)—here we refer to them as “alternative neurotherapies.”

## OBJECTIVE

By explicitly linking these alternative neurotherapy practices under a common conceptual framework, this paper draws attention to, and critically considers, the cross-cutting ethical and legal issues related to the provision of these services.

## ALTERNATIVE NEUROTHERAPIES

**SPECT Diagnostics:** In traditional health care settings, SPECT imaging is typically used to evaluate neurological diseases, such as stroke, epilepsy, neurodegenerative disorders. There are at least a dozen clinics in the U.S. offering SPECT scans for neuropsychiatric diagnostics and evaluations. At present, SPECT is not recommended by the American Psychiatric Association (APA) for neuropsychiatric diagnostic purposes.

**EEG Neurofeedback:** EEG neurofeedback is a practice in which individuals purportedly learn how to regulate their brainwaves by viewing real-time recordings of their own brain data. Although there are over a thousand studies on neurofeedback, research in this domain has been criticized for its lack of rigor, as most studies have lacked double-blinding and sham controls. Therefore, the therapy remains controversial and is not recommended by any professional physician society.

**Brain Stimulation Techniques:** Transcranial magnetic stimulation (TMS) is one brain stimulation technique that is FDA-approved to treat major depression, migraine headaches, and obsessive-compulsive disorder. In a preliminary scoping review, we found that over a hundred clinics promote the technique for off-label (i.e., unapproved) indications ranging from post-traumatic stress disorder (PTSD) to schizophrenia.

## ETHICAL ISSUES

### Truthful representation of evidence base

Neurofeedback providers and some SPECT clinics often use anecdotes and testimonials to highlight the efficacy of the services offered,<sup>2,4</sup> which may lead to misinterpretations and create an erroneous impression about the efficacy and evidence base of certain therapies.

### Vulnerable populations

These services are often promoted to individuals who may be considered vulnerable, as they may be more prone than others to be exploited or to suffer psychological harm. Clinics offering such therapies may capitalize on their desperation by making unfounded claims about the efficacy of their services.

### Potential harms

Overall, the risks of physical harms from the mentioned therapies are relatively low. Users may experience opportunity costs if they choose a non-empirically supported treatment instead of a scientifically validated one. Also, such services may come at a considerable out-of-pocket financial cost.

### Provider competency

Both relevant professional/educational background, as well as appropriate training for the specific services offered, may be required in order to ensure that providers have the skills and knowledge needed to deliver these therapies in a safe and effective manner.

### Conflicts of interest

Although concerns regarding potential conflict of interest are not uncommon in biomedical sciences more broadly, the commercial interests and lack of independent research in the neurofeedback and SPECT domains are particularly notable.

## LEGAL ISSUES

The regulation of neurotherapy *services* for medical treatment largely falls to individual states, which define and limit who (i.e., individuals with which types of licensing) can offer medical services for which indications. “Scope-of-practice” regulations set out the services that are considered to be within the limits of one’s license. The main questions regarding licensing and scope-of practice are threefold:

1. Does the provider hold a professional license?
2. Is the technique and indication treated by the provider considered to be within the scope-of-practice for that license?
3. If applicable, does the provider comply with the state’s legal requirements involving CAM and unconventional therapies?

Based on our informal scoping review of clinics offering SPECT neuropsychiatric evaluations and those promoting TMS for off-label indications, most individuals offering such services have MDs. Since providers with MDs have broad leeway to practice medicine for a wide variety of indications, there are unlikely to be significant scope-of-practice issues in these domains.

In the realm of neurofeedback, however, there appears to be far more variability in terms of licensing, with few MDs but many psychologists, mental health counselors and social workers.<sup>4</sup> Neurofeedback does appear to be within the scope-of-practice for individuals holding these licenses in the three states (California, Texas, and Florida) whose regulations we examined.

Regarding the provision of CAM, many states have regulations specifying requirements for the provision of such treatments, such as mandating patient assessment and specific informational disclosures regarding the nature of the therapy.

## CONCLUSION

We have outlined the unique characteristics of alternative neurotherapies and the distinct ethical and legal questions that arise from their provision. By drawing attention to alternative neurotherapy practices as a whole, we have attempted to recognize a larger social phenomenon that merits ethical scrutiny. Linking this phenomenon to CAM allows us to take advantage of a wide body of ethical and legal scholarship in this domain.

One potential explanation for the rise in alternative neurotherapies, particularly in recent decades, can be found by examining how regulation in the U.S. applies differentially to medical devices and pharmaceutical drugs. While the prescription of drugs is tightly regulated at the state level, there are no analogous restrictions surrounding the use of medical devices. This regulatory difference has likely contributed, at least in part, to the flourishing of alternative neurotherapies.

Future research in this domain should aim to better understand the saliency of specific ethical concerns to inform policy recommendations that encourage the ethical provision of alternative neurotherapies.

**Disclosures:** None

## REFERENCES

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