

Innovative Practice Outside of Medical Institutions

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When is it ethically appropriate to make an emerging therapeutic technique or treatment available to the public outside of a research protocol? Earl (2019) proposes a “dual deviation model” whereby clinicians engaged in “innovative practice” should be required to prospectively justify not only why they are deviating from the standard of care but also why they are deviating from the so-called research standard. This commentary highlights one main limitation of Earl’s proposal: namely, it is geared towards clinicians working in institutional contexts. Yet, as Earl (2019) notes, clinicians who work in such contexts are often already subject to some form of institutional oversight—and are therefore likely more cautious than their counterparts in private practice. It is physicians who work privately, with no institutional oversight and with little connection to research infrastructure, who may be engaging in innovative practices that most dramatically depart from the standard of care—and that may present the most harm to patients.

Take, for example, the use of transcranial direct current stimulation (tDCS), an experimental technique that provides low levels of electrical stimulation to the brain. Although tDCS is not approved by the Food and Drug Administration for any indication (Fregni et al. 2015), in clinical research it has shown promise for treating conditions such as depression and chronic pain (Lefaucheur et al. 2017). The handful of physicians working in institutional contexts who provide tDCS for non-research purposes must typically justify their use of the technique—using available scientific evidence—to an institutional oversight committee. In this example, Earl’s proposal would have little effect on patient safety, as physicians’ protocols are

already typically subject to committee oversight. Furthermore, runaway diffusion is unlikely to be a concern, because uptake will be limited so long as tDCS is not FDA-approved.

Outside the institutional context is where more serious questions arise with regard to experimental brain stimulation techniques, both in terms of direct harm to patients and runaway diffusion. My preliminary work on private “brain wellness” clinics has indicated that many practitioners utilize tDCS and other experimental brain stimulation techniques for indications for which there is little evidence. This, of course, raises the intractable question of where to draw the line between innovation and non-evidence-based medicine. It also highlights the lack of oversight, as these practitioners are not required to justify their use of brain stimulation techniques to institutional committees. Earl might argue that oversight in this case should fall to professional societies and peers. But the professional societies seem to encourage the use of these techniques: at the annual meetings that these practitioners attend (ISNR 2018; AAPB 2019) there are training sessions in brain stimulation techniques using non-FDA approved devices—thereby increasing both the chances of runaway diffusion and patient harm.

Brain stimulation is not an isolated example. Innovation flourishes more readily outside the rules and bureaucracy of institutions, in the safe harbors of private practice. Although much of the bioethics literature on medical innovation arose in the context of surgery (e.g., Agich 2001; McKneally and Daar 2003; Reitsma and Moreno 2006), which most often occurs in an institutional setting, it is time to cast a wider net. A comprehensive proposal to balance access to innovative therapeutic techniques with patient protection must consider all innovation, not only that which occurs in institutional contexts.

References

- Agich, George J. 2001. "Ethics and Innovation in Medicine." *Journal of Medical Ethics* 72 (5): 295–96. doi:10.1136/jme.27.5.295.
- Association for Applied Psychophysiology and Biofeedback, Biofeedback. 2019. "AAPB 50th Annual Scientific Meeting (2019)." *Aapb.org*.
<https://www.aapb.org/i4a/pages/index.cfm?pageID=3903>.
- Earl, Jake. 2019. Innovative Practice, Clinical Research, and the Ethical Advancement of Medicine. *American Journal of Bioethics*, in press.
- Fregni, F, M A Nitsche, C K Loo, A R Brunoni, P Marangolo, J Leite, S Carvalho, et al. 2015. "Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): Review and Recommendations From an Expert Panel.." *Clinical Research and Regulatory Affairs* 32 (1): 22–35. doi:10.3109/10601333.2015.980944.
- International Society of Neurofeedback and Research. 2018. "ISNR 26th Annual Conference." *Isnr.org*. <https://theisnr.wixsite.com/2018-conference/conferenceagenda>.
- Lefaucheur, Jean-Pascal, Andrea Antal, Samar S Ayache, David H Benninger, Jérôme Brunelin, Filippo Cogiamanian, Maria Cotelli, et al. 2017. "Evidence-Based Guidelines on the Therapeutic Use of Transcranial Direct Current Stimulation (tDCS)." *Clinical Neurophysiology* 128 (1): 56–92. doi:10.1016/j.clinph.2016.10.087.
- McKneally, Martin F, and Abdallah S Daar. 2003. "Introducing New Technologies: Protecting Subjects of Surgical Innovation and Research." *World Journal of Surgery* 27 (8): 930–34. doi:10.1007/s00268-003-7096-3.
- Reitsma, Angelique M, and Jonathan D Moreno. 2006. *Ethical Guidelines for Innovative Surgery*. Edited by Angelique M Reitsma and Jonathan D Moreno. Hagerstown, MD: University Publishing Group.