



# Buttressing regulation of cognitive enhancement devices with principles of harm reduction

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## ABSTRACT

Maslen and colleagues offer an excellent model for regulating cognitive enhancement devices (CEDs), and we largely endorse their approach of extending medical device policy to include CEDs. Maslen et al. argue that since the risks and benefits of CEDs can be identified, consumers are best placed to evaluate the impact of these effects on their own wellbeing: ‘experts are to assess what the risks are, the consumer how much they matter’. In principle, we agree: consumers should be allowed to decide what risks are worth taking, but the situation is somewhat more complicated, for the evidence that consumers are in a strong position to evaluate the many risks associated with CED use is lacking. Indeed, a glance at online forums on CEDs suggests that undue risks are already being taken. Importantly, given the ease with which devices can be built using easily obtainable parts, overly tough regulation will not effectively curtail use, but rather push it underground. For these reasons, we suggest that any regulatory framework be buttressed by principles of harm reduction, providing real-world users with expert-backed recommendations for safe use. We argue for the development of tools that facilitate this dialogue, while recognizing the challenges in so doing.

**KEYWORDS:** brain stimulation, harm reduction, regulation, transcranial direct current stimulation, cognitive enhancement devices, technology policy

## HOME USE OF CEDs IS OCCURRING IN THE ABSENCE OF REGULATION

We have previously discussed the challenges of crafting policy for cognitive enhancement devices (CEDs).<sup>1,2</sup> Our hope was that regulators, scientists, and the home-user community might offer policy proposals that improve public safety. Maslen and colleagues have done just this, providing an excellent model for regulating CEDs,<sup>3</sup> and we largely endorse the approach that they have outlined. We agree with authors' overall analysis of risk—there is indeed no relevant distinction between medical devices and CEDs—and support their recommendation to extend the medical device regulatory framework to include CEDs. Such a move would afford a standard of comprehensive, evidence-based information about risks and benefits for CEDs. Maslen et al. argue that the risks and benefits of CEDs can be identified, and that consumers are best placed to evaluate the impact of these effects on their own well-being. In their words, 'experts are to assess what the risks are, the consumer how much they matter'.<sup>3</sup>

In principle, we agree with this libertarian approach to regulating consumer use of CEDs, but the situation is somewhat more complicated, for the evidence that consumers are in a strong position to evaluate the risks associated with CED use is lacking. There are likely thousands of home users of CEDs,<sup>4</sup> but given the rapidly increasing interest in both the media and academia,<sup>5</sup> in the near future there could be substantially more. We have found that the public is surprisingly comfortable with CEDs viewing them in much the same way as they view pharmacological cognitive enhancement.<sup>6</sup> In a recent online survey, 87 per cent of respondents told us they would undergo tDCS if it could enhance their performance at school or work.<sup>7</sup>

There are two routes by which these home users currently obtain their CEDs: either by constructing devices themselves (DIY) or by purchasing a commercially available device, most prominently the foc.us device<sup>8</sup> but other sources of direct-to-consumer devices are likely to arise in the absence of regulatory oversight. These home users are by and large intelligent and practice safe use to the best of their abilities, but they appear to rely upon somewhat unreliable sources of information for using CEDs safely: the discussion forums at the websites [www.DIYtDCS.com](http://www.DIYtDCS.com) and [www.reddit.com/r/tDCS](http://www.reddit.com/r/tDCS). Notably, these are user-driven communities without professional oversight.

While we agree that CEDs should be regulated under the medical device model, it is clear that this process may take a substantial amount of time. We propose that in the

<sup>1</sup> The overall thrust of the paper is about CEDs, but because the bulk of the data to date are about tDCS, when referring the specific points of information in our arguments, we regularly refer to tDCS. That said, the issues raised with tDCS do generalize.

<sup>2</sup> Nicholas S. Fitz & Peter B. Reiner, *The Challenge of Crafting Policy for Do-It-Yourself Brain Stimulation*, J. MED. ETHICS, DOI: 10.1136/medethics-2013-101458 (last accessed February 28, 2014).

<sup>3</sup> Hannah Maslen et al., *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, <http://jlb.oxfordjournals.org/content/1/1/68.full>.

<sup>4</sup> tDCS Subreddit, *tDCS Subreddit*, <http://www.reddit.com/r/tDCS/> (last accessed June, 2014).

<sup>5</sup> Veljko Dubljevic, Victoria Saigle & Eric Racine, *The Rising Tide of tDCS in the Media and Academic Literature*, 82 NEURON 731, 736 (2014), DOI:10.1016/j.neuron.2014.05.003.

<sup>6</sup> Nicholas S. Fitz et al., *Public Attitudes Toward Cognitive Enhancement*, 7 NEUROETHICS 173, 188 (2014).

<sup>7</sup> Roy H. Hamilton & Jihad Zriek, *Should We Use Devices to Make Us Smarter?* SCIENTIFIC AMERICAN, Feb. 14, 2014. [http://www.scientificamerican.com/article/should-we-use-devices-to-make-us-smarter/?WT.mc\\_id=SA\\_MB\\_20140205](http://www.scientificamerican.com/article/should-we-use-devices-to-make-us-smarter/?WT.mc_id=SA_MB_20140205)

<sup>8</sup> <http://www.foc.us>

interim the professional community engage in active harm reduction<sup>9</sup> by developing an inclusive online forum that helps users of CEDs navigate the risks in the safest way possible. Such an initiative recognizes that home use of CEDs is a reality today and offers opportunities to improve the safety of such activities. Indeed, Maslen et al. allude to a harm reduction perspective when they say that:

it might also be argued that CEDs ought to be permitted in order to help forestall unregulated illicit use... devices can be built from off-the-shelf components: it is preferable that, if individuals choose to pursue enhancement, they purchase devices that are held to a strict level of safety, appropriate for the particular use intended.<sup>3</sup>

The focus of this commentary is in developing a harm reduction strategy in the near term.

### THE HARMS THAT CEDs POSE TO HOME USERS TODAY

Before proper regulation is implemented, what are the harms that might befall home users of CEDs? In our previous publication,<sup>2</sup> we listed some of these, but in the interim more have appeared. Therefore, we provide a more exhaustive list below.

- (i) *Changes in waveform, duration, and placement matter*: The setup of the electrodes and stimulation parameters are crucial to inducing specific effects.<sup>10</sup> The issue is succinctly summarized by Marom Bikson, a prominent practitioner and developer of CEDs who explains that, “The way to think about electrical stimulation is that you have a dose, just like with a drug. But instead of talking about what the drug is made out of in terms of chemical composition, we talk about the waveform, duration, and placement. Any alterations make it a different drug altogether”.<sup>11</sup>
- (ii) *Reversing polarity can impair function*: There is now strong evidence that at least in some instances, reversing the polarity of the electrodes may impair the mental function of the user.<sup>12,13</sup> Instances of this error by home users are legion.
- (iii) *Stimulation can interact with existing drug use*: The pharmacological status of the brain can have a meaningful effect on the outcome of CEDs,<sup>14,15</sup> and many home users may be using other brain-changing agents.

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<sup>9</sup> GORDON A. MARLATT, MARY E. LARIMER & KATIE WITKIEWITZ, HARM REDUCTION (2nd ed. 2011).

<sup>10</sup> Kathrin S. Utz et al., *Electrified Minds: Transcranial Direct Current Stimulation (tDCS) and Galvanic Vestibular Stimulation (GVS) as Methods of Non-Invasive Brain Stimulation in Neuropsychology—A Review of Current Data and Future Implications*, 48 NEUROPSYCHOLOGIA 2789 (2010), DOI: 10.1016/j.neuropsychologia.2010.06.002.

<sup>11</sup> Mary H. K. Choi, *Would TDCS Make Me Smarter?* AEON MAGAZINE, Sept. 6, 2014. <http://aeon.co/magazine/psychology/would-dabbling-in-cranial-stimulation-make-me-smarter/>

<sup>12</sup> Roi C. Kadosh et al., *Modulating Neuronal Activity Produces Specific and Long-lasting Changes in Numerical Competence*, 20 CURR. BIOL. 2016, 2020 (2010).

<sup>13</sup> Amir H. Javadi, Paul Cheng & Vincent Walsh, *Short Duration Transcranial Direct Current Stimulation (tDCS) Modulates Verbal Memory*, 5 BRAIN STIMULATION 468, 474 (2012), DOI:10.1016/j.brs.2011.08.003.

<sup>14</sup> Andre R. Brunoni et al., *Interactions Between Transcranial Direct Current Stimulation (tDCS) and Pharmacological Interventions in the Major Depressive Episode: Findings from a Naturalistic Study*, EUR. PSYCHIATRY, DOI:10.1016/j.eurpsy.2012.09.001.

<sup>15</sup> Paulo S. Boggio et al., *Modulation of Risk-Taking in Marijuana Users by Transcranial Direct Current Stimulation (tDCS) of the Dorsolateral Prefrontal Cortex (DLPFC)*, 112 DRUG & ALCOHOL DEPENDENCE 220, 225 (2010), DOI:10.1016/j.drugalcdep.2010.06.019.

- (iv) *Effects may be long lasting*: Short-term changes in brain plasticity can and often do lead to long-term changes in neural function.<sup>16</sup> Since the intent of CED use is often to increase plasticity of the brain, the long-term effects of CED use are worthy of consideration. Indeed, studies have reported effects lasting for months.<sup>12</sup> Thus, any unintended effects of CEDs by home users may be difficult to reverse.
- (v) *There may be motor and cognitive interference*: CEDs are generally used to augment neural activity induced by a specific cognitive task. Not only can unintended cognitive activity also be augmented (see below), but both motor and cognitive activity undertaken during or following CEDs can abolish the effects and even impair the user, a phenomenon that is largely underappreciated.<sup>17</sup>
- (vi) *Electrical current is influenced by many factors*: Several variables such as hair thickness, rates of perspiration, and electrode attachment methods moderate the effects of CEDs.<sup>17</sup> Perhaps the least discussed but pertinent issue is that the brains of left-handed people may be organized differently than those of right-handed people,<sup>18</sup> and most studies using CEDs are restricted to subjects who are right-handed.
- (vii) *There may be unintended effects*: CEDs that enhance mental function in one area may have a negative impact on another aspect of mental function.<sup>19</sup> This means that while CEDs might offer some benefit in one context, they might also induce impairments in another context, the duration of which is essentially unknown.
- (viii) *Users may overestimate the safety of CEDs*: While CEDs themselves are not technically non-invasive and are often described as such, we have pointed out that the electrical current itself enters the brain and therefore is invasive in some meaningful way.<sup>2</sup> Indeed, Davis and Koningsbruggen reinforce this view stating that, ‘any technique which directly affects brain tissue to generate such powerful acute and long-lasting effects should be treated with the same respect as any surgical technique’.<sup>20</sup>

At the moment, many of these concerns are relevant to the current crop of direct-to-consumer devices. For example, home users on the subreddit that discusses safety issues of the foc.us device have made the following observations: the internal electrodes exceed the general safety guidelines for current density at all stimulation levels, the voltage limits do not behave as specified in the manual, the device behaves unpredictably

<sup>16</sup> Eric R. Kandel, Yadin Dudai & Mark R. Mayford, *The Molecular and Systems Biology of Memory*, 157 CELL 163, 186 (2014), DOI:10.1016/j.cell.2014.03.001.

<sup>17</sup> Jared C. Horvath, Olivia Carter & Jason D. Forte, *Transcranial Direct Current Stimulation: Five Important Issues We Aren't Discussing (But Probably Should Be)*, 8 FRONT. SYST. NEUROSCI. (2014), DOI:10.3389/fnsys.2014.00002.

<sup>18</sup> Roel M. Willems et al., *On the Other Hand: Including Left-Handers in Cognitive Neuroscience and Neurogenetics*, 15 NAT. REV. NEUROSCI. 193, 201(2014), DOI:10.1038/nrn3679.

<sup>19</sup> Teresa Iuculano & Roi C. Kadosh, *The Mental Cost of Cognitive Enhancement*, 33 J. NEUROSCI. 4482, 4486 (2013).

<sup>20</sup> Nick J. Davis & Martijn V. Koningsbruggen, *'Non-Invasive' Brain Stimulation is not Non-Invasive*, FRONT. SYST. NEUROSCI., DOI:10.3389/fnsys.2013.00076.

when its connection to the head is lost, and under some circumstances the focus can generate small voltage or current spikes.<sup>4</sup> The list of harms noted above can no longer be considered theoretical.

### **BUILDING AN INCLUSIVE ONLINE COMMUNITY**

We do not advocate home use of CEDs given the known and unknown risks. However, we feel that it is important to support those who are going to use CEDs irrespective of these risks.<sup>21</sup> Many home users of CEDs are already trying to access expert information. The tDCS subreddit and DIYtDCS.com are filled with posts that make reference to the scientific literature, and some users have even begun to download software that clinicians use to determine appropriate montages, such as the Beam F3 locator. However, these activities are transpiring without expert guidance.

We recognize that it is challenging for scientists and clinicians to provide advice to home users of CEDs. Some experts have considered offering such guidance but the issue is complicated enough that they have not yet decided to move forward.<sup>11</sup> We suggest that the time is ripe for a coalition of professionals to join together with the home-user community to create an inclusive online community whose objectives are to reduce the likelihood of unsafe use of CEDs. This online community might offer safety guidelines, frequently asked questions, and an opportunity to ‘ask an expert’ along the lines of Reddit’s ‘ask me anything’ sessions. Other solutions to reduce the harms that may accompany home use of CEDs may exist, and we welcome any proposals about how to do this in the best way possible. The critical element is that we act, and that we do so quickly and effectively.

### **THE CHALLENGES IN CREATING AN ONLINE COMMUNITY TO SUPPORT SAFE HOME USE OF CEDs**

There are numerous challenges for creating an inclusive online community of the kind that we are proposing. Chief among these are legal liability concerns; here, we defer to the members of the legal establishment for guidance. Once liability issues are sorted out, it will be important to create a safe space for open dialogue. One common approach is to allow users to adopt pseudonyms so that they feel safe openly discussing challenges they have encountered. While creating a professional website and using the time of experts costs money, these costs might be borne by industry and government.

A common misconception about harm reduction is that it encourages illicit use. This is based on the idea that harm reduction ‘sends out the wrong signal’ and undermines primary prevention efforts, but such a view underestimates the complexity of factors that shape individual’s decisions about whether to use CEDs. Indeed, while the data suggest that harm reduction programs do not increase the use of illicit drugs,<sup>22</sup> we do not know whether implementing our proposal will increase the number of home users of CEDs. Even so, the objective of harm reduction is to improve safety in the interim while regulation such as that proposed by Maslen et al.<sup>3</sup> is pending. While we do not advocate home use of CEDs, we would suggest that it is better for society as a whole to

<sup>21</sup> We draw inspiration from the harm reduction principles that do not endorse heroin use but strive to find solutions that reduce the harm for those who will use heroin anyway.

<sup>22</sup> David Satcher, *Evidence-Based Findings on the Efficacy of Syringe Exchange Programs: An Analysis of the Scientific Research Completed Since April 1998*. Washington, DC, US Department of Health and Human Services (2000).

have more people using CEDs safely than a smaller number of people using them with greater risk.

Taken together, these arguments suggest that there are strong reasons to create an inclusive online forum to support harm reduction in home use of CEDs. We call upon our colleagues in the investigative, clinical, and legal communities to join with us in making this vision a reality.