OXFORD MARTIN POLICY BRIEF

Mind Machines: The Regulation of Cognitive Enhancement Devices

Hannah Maslen, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu

The aims of the paper

It is becoming increasingly easy for individuals to buy brain-modulating devices online that promise to make the user's brain work faster, or more effectively, or more creatively. Such devices can involve passing electronic currents through one's brain or using electromagnetic fields to penetrate the scalp and skull to make neurons fire. Yet, when purchased outside clinical settings, these devices are unregulated, with no system in place to ensure their safety.

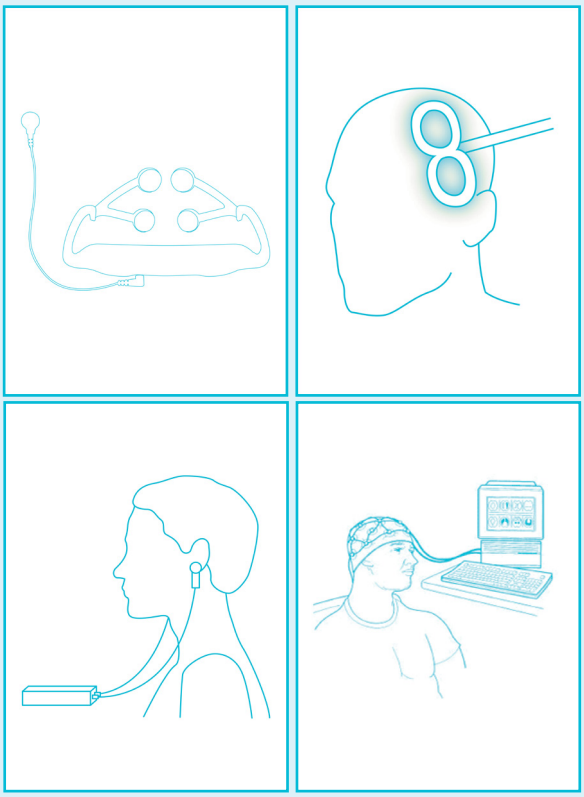
It is a confused situation given that the same kinds of devices are being trialled by scientists in clinical settings to potentially alleviate the symptoms of conditions such as depression or Parkinson's disease. Others are being developed to improve the concentration of people suffering with attention deficit hyperactivity disorder, or as a cure for insomnia. However, when sold and used outside clinical settings, these devices are considered to be cognitive enhancement devices (CEDs), as the manufacturers do not claim that they treat any recognised medical conditions. As the market for CEDs grows, it is timely to ensure that the correct regulatory mechanisms are in place to oversee this expanding industry. This paper presents a summary of the scientific literature on CEDs; provides an overview of the types of CEDs available; assesses the regulatory weaknesses as they relate to CEDs; and provides a practical path forward in designing an appropriate regulatory model for CEDs.

What are CEDs?

A CED is a piece of equipment or combination of pieces of equipment that affects the functioning of a healthy brain such that it performs better in at least one cognitive domain (e.g. memory, attention, learning, facial recognition). Possible examples include:

- ***Transcranial direct current stimulators:*** the most widely-marketed CED, which involves sending a small direct current between two or more electrodes to facilitate or inhibit spontaneous neuronal activity. They have been shown to enhance working memory, attention, language and mathematics skills.
- ***Transcranial magnetic stimulation:*** a neurostimulation and neuromodulation technique that uses electromagnetic fields to penetrate the scalp and skull. It has been shown to improve working memory and performance of complex motor learning tasks.
- ***Cranial electrotherapy stimulator:*** a non-traditional therapeutic device that applies pulsed, alternating microcurrent transcutaneously to the head via electrodes placed on the earlobes. There is evidence that CES is effective for anxiety, headaches, fibromyalgia, smoking cessation, drug withdrawal symptoms, and pain.
- ***Neurofeedback equipment:*** uses real-time displays of electrical patterns from brainwave activity to regulate or suppress different patterns of activity. In the clinical domain, neurofeedback has helped patients with epilepsy, autism and insomnia.

Examples of CEDs:



Clockwise from top left: a transcranial direct current stimulator, a transcranial magnetic stimulation device, neurofeedback equipment and a cranial electrotherapy stimulator

Our recommendations in summary:

Recommendations for regulators in the EU

- ***Regulate CEDs within the Medical Devices Directive***: CEDs have similar mechanisms and risk-profiles to some medical devices and are often essentially the same device; parsimony in legislation is desirable; and the inclusion of some non-medical (cosmetic) implantable and invasive devices sets a precedent for broadening the remit of the directive in this way.

- ***Develop a 'positive list' of 'cognition improving or facilitating devices (without a medical purpose)'***: Although this means that the legislation has to react to the emergence of hitherto unregulated devices as they come on to the market, the extension of the directive to all cognition improving or facilitating devices would generate huge difficulties for regulators in keeping the purview of the directive appropriately narrow. To be included on the list, it must be the case that the manufacturer makes cognitive enhancement claims about the device. There should be a strong presumption for inclusion of all active devices. Devices used widely in quasi-clinical settings should also be considered for inclusion.

- ***Develop a graded system of regulation***: Low, moderate and high-risk devices will undergo different assessment procedures designed to optimise consumer choice and maximise efficiency of the system.

- ***Prohibit high-risk CEDs from the market***: Where particular models of devices are likely to cause harm (e.g. some TMS-type devices may be likely to cause seizures), they should be prohibited.

- ***Err on the side of consumer choice for moderate-risk devices***: Given that there may be differences in opinion concerning how valuable enhancement is, and given that consumer decisions are not made amidst the vulnerabilities of the clinical context, an estimation of the benefits of a moderate-risk CED should not be restricted to a narrow measure of effectiveness. The assessment should therefore err towards consumer freedom. Comprehensive, objective information from the manufacturers about mechanisms, safe use and risks and benefits should be required under the MDD to allow consumers to make informed decisions and to use devices safely.

- ***Ensure regulatory efficiency by incorporating a low-risk exemption***: Where CEDs are deemed to be low risk and are unlikely to generate large indirect costs to the healthcare system, there would be a case for exempting them from continued regulatory evaluation and the need to demonstrate objective benefit. Neurofeedback devices would be an example of a low-risk CED unlikely to require ongoing evaluation.

Recommendations for regulators in the US and elsewhere

- ***Address global gaps***: The same regulatory gap exists in the US and other jurisdictions, so our model could be adopted elsewhere. A global response to the emerging CED market could involve a coordinated approach to amend analogous medical device legislation, as most CEDs will be marketed and purchased across borders.

Why are CEDs not regulated?

Despite often raising safety and effectiveness concerns comparable to those raised by medical devices, CEDs are not covered by the EU Medical Devices Directive (MDD). The current definition of a medical device specifies that the device must be intended by the manufacturer to be used for diagnostic and/or therapeutic purposes. Since CEDs are neither diagnostic nor therapeutic, they are not identified as devices for medical regulation. In our paper, we explore a number of regulatory options for CEDs, including the possible use of new and/or existing instruments. We also consider the conceptual and practical issues which will influence the different approaches, and argue that the MDD should be amended to ensure appropriate safety and regulatory oversight of CEDs.

Recommendations for protecting children

- ***Require a higher level of safety***: The exception to our proposal is where devices of any level of risk are intended for use on/by non-competent third parties such as children. These devices should be regulated to the same standard as medical devices requiring effectiveness to justify risk.

- ***Introduce criminal sanctions***: Due to the possibility that CEDs that are intended for adults could be used on children, by individuals lacking adequate training, we propose that such use should attract criminal sanctions in the same way as supplying children with alcohol attracts criminal sanctions.

Recommendations for manufacturers

- ***Exercise best practice***: In anticipation of regulatory oversight, manufacturers should begin to adhere to good practice in manufacturing consistent with the sorts of requirements that the MDD would be likely to impose. This could involve drawing up technical documentation (including clinical evaluation); setting up an internal quality management system; establishing a follow-up system to respond to incidents arising from consumer usage or from the internal testing process; and ensuring devices are sold with comprehensive, objective information about safe use, risks and effectiveness.

Benefits of our proposed regulatory model

The outcome of our model would be to filter the most dangerous enhancement technologies out of the market, leaving individuals free to choose which small-to-moderate risks they are willing to take in pursuit of their wellbeing. It also imposes requirements on manufacturers to provide enough detailed, honest information about the product to enable individuals to use the devices in the safest way possible, in full knowledge of all known risks and side effects.

This policy brief is an edited extract of an Oxford Martin Policy Paper published in April 2014. Oxford Martin Policy Papers harness the interdisciplinary, innovative research of the Oxford Martin School to address today's critical policy gaps.
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To contact the authors: Hannah Maslen hannah.maslen@philosophy.ox.ac.uk
For policy enquiries: Natalie Day natalie.day@oxfordmartin.ox.ac.uk and for media enquiries: Carole Scott carole.scott@oxfordmartin.ox.ac.uk