

# Chapter 8

Non-therapeutic  
applications

## Chapter 8 – Non-therapeutic applications

### Chapter 8 – overview

We discuss three areas in which novel neurotechnologies might be used for non-therapeutic purposes: neural enhancement, gaming and military uses.

- **Enhancement:** A number of small studies using non-invasive neurostimulation report improvements in participants' performance in laboratory tasks, for example involving memory or language skills, or in their mood that could be construed as 'enhancements'. However, there is need for great care in extrapolating from small studies conducted under laboratory conditions to lasting real-world effects; the potential use of neurostimulation for neural enhancement is still far from proven.
- **Gaming:** There are already games on the market claiming to use non-invasive electroencephalography (EEG) based brain-computer interface (BCI) technology, although whether they all actually utilise brain signals is questionable. Nevertheless, there is considerable research activity to develop commercially viable games that are genuinely BCI-controlled. These recreational neurotechnologies overlap with EEG-based neurofeedback 'games' that are already being marketed for use as treatments for attention deficit / hyperactivity disorder or that purport to improve capacities such as concentration.

Uses of non-invasive neurostimulation or BCIs either for putative 'enhancement' purposes or gaming are unlikely to pose serious health risks. Nevertheless, the large number of people targeted by these applications and the lack of any clear associated health benefits mean that it is important to attend to several ethical concerns. In particular, to minimise the pursuit of unnecessary brain interventions, there is a need to ensure the originality and rigour of research investigating non-therapeutic uses in humans (paragraph 8.39) and also to disseminate existing evidence through publically accessible registers (paragraph 8.41).

Non-therapeutic applications of neurodevices (such as BCI games and those that purport to offer enhancements) are likely to be used privately and without medical supervision. This places greater onus on the effective regulation of the devices themselves. We recommend that the European Commission considers designating neurostimulation devices as products that should be regulated under the medical devices regime irrespective of the purpose for which they are marketed (paragraph 8.52).

Those marketing neurodevices and services with unsubstantiated or misleading claims about their putative benefits may be exploiting consumers and undermining wider public trust in neurotechnologies. We recommend that there is a need for responsible self-governance by businesses operating in this sector, establishing best practice standards both for the provision of honest and accurate information and for delivering services using neurodevices within parameters of safe use (paragraph 8.59).

Given the lack of evidence of the efficacy of these neurotechnologies for enhancement, we do not examine in detail the ethics of human enhancement *per se*. However, two concerns familiar from wider bioethical debates about human enhancement may arise. The first is that pursuit of non-therapeutic innovation might represent an opportunity cost at the expense of investigating applications of greater social value. The second is that, provided some believe that enhancements using neurodevices are realisable, pressure might be exerted on individuals to use these. This latter is a particular concern in children, in whom the effects of neurostimulation or BCIs on the developing brain are not well understood. We recommend that observational research with children who are already using neurotechnologies is needed to address this (paragraph 8.40) and also that advice is issued to teachers and parents about the current evidence of the efficacy of neurofeedback as an educational enhancement tool (paragraph 8.62).

- **Military:** Novel neurotechnologies have potentially valuable applications in treating physical and psychiatric injuries caused by combat. However, in this chapter our concern is with their non-therapeutic uses, and there are indications from the US that there is considerable investment in non-therapeutic military applications. These include the use of BCIs in enhancing fighters' effectiveness by augmenting their perceptual or cognitive capacities, or by permitting neural control of remote weaponry. It is also plausible that BCIs or neurostimulation could be used for interrogation purposes. The existing international conventions outlawing the use of biological and chemical agents in war do not cover the use of neurodevices.

We recommend that advice is issued to armed forces highlighting that the use of neurodevices in interrogation would be coercive and illegal under the Geneva Conventions (paragraph 8.84). Military applications of novel neurotechnologies raise particular challenges for research ethics. We suggest that military clinicians can play an important role in protecting the wellbeing of personnel within their own forces who may be subject to professional coercion to participate in experimental uses of neurotechnologies (paragraph 8.87). We further recommend that the education of neuroscientists should include ethical training that draws attention to the dual-use applications of neurotechnologies for military as well as civilian ends (paragraph 8.89).

## Introduction

- 8.1 In this chapter, we turn from our focus upon therapeutic applications of novel neurotechnologies to consider their possible applications for non-therapeutic ends and by healthy users. Compared to the applications of novel neurotechnologies we have considered thus far – which offer respite from debilitating symptoms of illness or injury, or the opportunity to restore lost capacity to interact with the world – applications designed for enhancement or recreational purposes may seem trivial. However, the number of potential users in these fields is inevitably much greater than that for specialised medical interventions, so any ethical or social concerns that do arise warrant attention.
- 8.2 This chapter is divided into two parts, looking first at the use of novel neurotechnologies for the purposes of **neural enhancement** and **recreation**, before turning to consider **military** applications. We consider these topics separately from our discussion of therapeutic applications because several of the ethical and social issues they raise differ, in either kind or degree, from those that apply to interventions intended for use to treat brain disease or injury. This means that the ethical framework we developed in Chapter 4 may not always be applicable in non-therapeutic contexts. Though some ethical concerns may be shared between the two contexts, for example regarding uncertainties about unintended long-term effects of repeated brain stimulation.
- 8.3 A key respect in which non-therapeutic and therapeutic applications differ is in the range of actors involved in their development, regulation, and use. The size and nature of the market raises the prospect of direct to consumer (DTC) marketing of devices and services and private use of neurotechnologies unmediated by healthcare professionals. Where devices do not fall under the definition of medical devices, their regulation will not fall under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). These factors mean that oversight of the safe use of these applications may be fragmented and inadequate.
- 8.4 However, therapeutic and non-therapeutic uses may not always be easily distinguishable from each other where the line between treatment and enhancement is blurred. Nor can their development trajectories be easily separated: studies investigating therapeutic applications may deliver findings that help to inform non-therapeutic innovation trajectories (and vice versa); and unsubstantiated claims made for enhancement or recreational benefits carry the risks of undermining understanding and trust in novel neurotechnologies which may help to address profound impairment in those living with brain illness and injury.
- 8.5 Exploration of the non-therapeutic uses of novel neurotechnologies is still in its infancy, with few applications currently in use outside research settings. Yet in the areas of neural enhancement and brain-computer interface (BCI) gaming, the economic incentives of large potential markets create powerful motives to translate research findings into commercial applications. Military research concerning novel neurotechnologies is subject to quite different drivers, and receives significant funding from both military and security budgets. Examination of the ethical and social impacts raised in all three of these fast growing fields of development is therefore timely.
- 8.6 In undertaking our assessment of the ethical issues in this chapter, we seek to strike a particular balance. If there is indeed a ready market for non-therapeutic applications of neurotechnologies, we cannot afford to be overly sanguine in respect of any ethical concerns simply because real-world applications may still be some way off. Equally, we wish to avoid engaging in ethical speculation unsubstantiated by robust evidence or driven by hype. We suggest that it is incumbent upon those involved in ethical and policy scoping not to exacerbate the detrimental effects of hype by overselling speculative ethical concerns.

## Neural enhancement

- 8.7 Cognitive enhancement may be understood as the use of interventions to improve cognitive functioning and performance, where these are not impaired in clinically significant ways (see Box 8.1 below). This encompasses improvements in capacities such as attention, understanding, reasoning, learning, and memory.<sup>766</sup> Induced loss of painful memories might equally be viewed as a functional improvement.<sup>767</sup> More widely, *neural* enhancement may be understood to include improvements in wakefulness, perception, mood, and social or moral cognition.<sup>768</sup>
- 8.8 While conventional educational tools or nutrition can be regarded as means of cognitive enhancement, bioethical discussions of the methods of boosting the brain's capacities focus chiefly on pharmaceuticals and other newer neurotechnological methods. In recent years, considerable attention has been paid to the possibilities of advances in drugs, particularly the off-label use of stimulants commonly prescribed for attention- or sleep-disorders.<sup>769</sup> While pharmacological enhancement provides a useful comparator, detailed discussion lies outside the remit of this report.<sup>770</sup>
- 8.9 At present, it is not thought plausible that invasive neurotechnologies involving surgical implantation of electrodes or stem cells into the brain itself would be used to improve the capacities of healthy individuals, as the risks of brain surgery are disproportionate to non-therapeutic goals. However, perhaps given evidence of the possible psychiatric applications of deep brain stimulation (DBS), its future exploration as a means of mood enhancement cannot be ruled out. Prospects for the use of neural stem cell therapies to improve cognitive capacities such as memory beyond 'normal' function, however, remain even more speculative. Here, we focus on the prospects of non-invasive transcranial brain stimulation (TBS) (using transcranial magnetic stimulation (TMS), repetitive TMS (rTMS), and transcranial direct current stimulation (TDCS)) as means of neural enhancement.

### Box 8.1: Human enhancement: definitions and debate

Both the definition of enhancement and its ethical significance are fiercely contested. The following provides an overview of some of the central issues only.

#### Defining enhancement

Human enhancement has been defined as "the directed use of biotechnical power to alter, by direct intervention, not disease processes but the "normal" workings of the human body and psyche, to augment or improve their native capacities and performances", and in that sense is taken to be "beyond therapy".<sup>771</sup> Cognitive enhancement, the sub-category that is of particular interest in this report, has been defined as "the amplification or extension of core capacities of the mind through improvement or augmentation of internal or external information processing systems."<sup>772</sup>

<sup>766</sup> Bostrom N and Sandberg A (2009) Cognitive enhancement: methods, ethics, regulatory challenges *Science and Engineering Ethics* **15**(3): 311-41, at page 312.

<sup>767</sup> Farah MJ, Illes J, Cook-Deegan R *et al.* (2004) Neurocognitive enhancement: what can we do and what should we do? *Nature Reviews Neuroscience* **5**(5): 421-5, at page 422. Although, this might more properly be framed as treatment if it is designed to alleviate the effects of a recognised health impairments such as post-traumatic stress disorder.

<sup>768</sup> Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76**(2): 187-93.

<sup>769</sup> Farah MJ, Illes J, Cook-Deegan R *et al.* (2004) Neurocognitive enhancement: what can we do and what should we do? *Nature Reviews Neuroscience* **5**(5): 421-5; Greely H, Sahakian B, Harris J *et al.* (2008) Towards responsible use of cognitive-enhancing drugs by the healthy *Nature* **456**(7223): 702-5, at page 702; Smith ME and Farah MJ (2011) Are prescription stimulants "smart pills"? The epidemiology and cognitive neuroscience of prescription stimulant use by normal healthy individuals *Psychological Bulletin* **137**(5): 717-41; Ragan CI, Bard I and Singh I (2012) What should we do about student use of cognitive enhancers?: An analysis of current evidence *Neuropharmacology* **64**(1): 588-95.

<sup>770</sup> Low-tech or no-tech methods such as conventional educational tools or nutrition may also be regarded as means of cognitive enhancement.

<sup>771</sup> President's Council on Bioethics (2003) *Beyond therapy: biotechnology and the pursuit of happiness* (Washington DC: President's Council on Bioethics), at page 13.

<sup>772</sup> Bostrom N and Sandberg A (2009) Cognitive enhancement: methods, ethics, regulatory challenges *Science and Engineering Ethics* **15**(3): 311-41, at page 311.

### Contested distinctions

The most fundamental debate is whether it is even possible to draw a meaningful distinction between treatment and enhancement.<sup>773</sup> Some have framed this distinction in terms of a question about the legitimate scope of health care.<sup>774</sup> However, health care is often concerned with more than treating illness.<sup>775</sup> Others have objected that the concept of enhancement is premised on problematic and discriminatory presumptions about what constitutes 'normal' functioning. It has been suggested that a less problematic distinction between treatment and enhancement takes into account the level of contextual impairment to physical or mental functions. If these are not impaired at clinically significant levels in a given context, the motivation for interventions can be considered enhancement. It is certainly not possible to draw a hard line between treatment and enhancement as there are interventions that occupy a grey area between these two categories. What is considered 'normal' (and therefore 'enhanced' by comparison) is socially, contextually, and technologically fluid, and has changed within the lifetime of those who read this report. For example, one may ask whether contact lenses or a walking stick count as treatments or enhancements. In separating our discussions of the therapeutic applications of novel neurotechnologies from the non-therapeutic in this report, our intention is not to deny that some uses of novel neurotechnologies will inevitably occupy an ambiguous space between that which is therapeutic and that which is not – for example, BCI-assisted neurofeedback to improve concentration in children. Moreover, the enhancement / treatment dichotomy is not exhaustive of all possible categorisations; some applications – for example BCI games – may be enjoyed for purely recreational reasons.

### Ethical implications

Even if a line can be drawn between treatment and enhancement, this still leaves open the question of whether this demarcates any meaningful *ethical* distinction with which to guide responses to biotechnological enhancement.<sup>776</sup> Some commentators have suggested that enhancement is, by definition, 'good';<sup>777</sup> or at least that biotechnological enhancements do not differ in ethically significant ways from conventional and well-accepted methods of self-improvement, such as education.<sup>778</sup> Other commentators have taken a contrasting view that many, if not all, biotechnological enhancements are, in themselves, ethically problematic because they threaten to undermine aspects of human existence, such as dignity, achievement through effort, authenticity, humility, or solidarity, that give our lives meaning.<sup>779</sup> Between these polar positions are those that hold that the ethical status of enhancement cannot be decided *a priori*. Accordingly, it is argued that even if it were possible to differentiate treatment from enhancement this, in itself, does not determine the relevant ethical distinction – the risks and benefits of each particular means of enhancement must be assessed on the basis of empirical evidence where possible.<sup>780</sup> This broadly reflects the position we adopt in this report.

## Research evidence of the 'enhancement' effects of neurostimulation

8.10 It is common for studies using TMS (including rTMS) or TDCS to report changes in the performance of healthy adult participants in standardised laboratory tasks (or variations on these) that might be construed as evidence of improvement or 'enhancement'. Studies with the explicit aim of inducing such effects represent only a small fraction of research using non-invasive brain stimulation in healthy participants. Nevertheless, many examples may be found in

<sup>773</sup> Parens E (1998) Is better always good? The enhancement project *Hastings Center Report* **28(1)**: s1-s17, at page s1.

<sup>774</sup> See, for example, Norman Daniels' position discussed in Parens E (1998) Is better always good? The enhancement project *Hastings Center Report* **28(1)**: s1-s17, at page s2.

<sup>775</sup> Parens E (1998) Is better always good? The enhancement project *Hastings Center Report* **28(1)**: s1-s17; World Health Organization (1946) *Definition of health: preamble to the constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, at page 100) and entered into force on 7 April 1948.*

<sup>776</sup> Bostrom N and Sandberg A (2009) Cognitive enhancement: methods, ethics, regulatory challenges *Science and Engineering Ethics* **15(3)**: 311-41, at page 324.

<sup>777</sup> Harris J (2007) *Enhancing evolution: the ethical case for making people better* (Princeton: Princeton University Press); Chan S and Harris J (2008) In support of human enhancement *Studies in Ethics, Law, and Technology* **1(1)**: 1-3.

<sup>778</sup> Greely H, Sahakian B, Harris J *et al.* (2008) Towards responsible use of cognitive-enhancing drugs by the healthy *Nature* **456(7223)**: 702-5, at page 703; Bostrom N and Sandberg A (2009) Cognitive enhancement: methods, ethics, regulatory challenges *Science and Engineering Ethics* **15(3)**: 311-41.

<sup>779</sup> Parens E (1998) Is better always good? The enhancement project *Hastings Center Report* **28(1)**: s1-s17; Sandel MJ (2011) The case against perfection: what's wrong with designer children, in *Atlantic Monthly*, Jecker N (Editor) (Mississauga, ON: Jones & Bartlett Learning).

<sup>780</sup> Smith ME and Farah MJ (2011) Are prescription stimulants "smart pills"? The epidemiology and cognitive neuroscience of prescription stimulant use by normal healthy individuals *Psychological Bulletin* **137(5)**: 717-41.

the scientific literature reporting effects upon, *inter alia*, memory,<sup>781</sup> language skills,<sup>782</sup> vision,<sup>783</sup> mathematical ability,<sup>784</sup> reasoning,<sup>785</sup> emotional processing,<sup>786</sup> what is termed ‘social cognition’ (that is, the interpretation of others’ behaviour),<sup>787</sup> and mood.<sup>788</sup>

- 8.11 The methodologies of these studies vary, but generally participants receive neurostimulation to particular brain regions. ‘Enhancement’ is then measured in terms of improved performance. Some of these findings are interesting and worth further pursuit, but in the majority of cases, the effects have been obtained after a single session of brain stimulation and performance effects are small, and probably not behaviourally (even if statistically) significant. Concerns have been raised about the absence of adequate control conditions in some studies. In particular, the absence of stimulation at a control site negates any claims that can be made about the specificity of any effects.<sup>789</sup>

## Future prospects: limitations and opportunities

### Real world limitations

- 8.12 While scientifically interesting, the leap from a small effect in a single session to claims of utility in cognitive, perceptual, social, or emotional enhancement are unwarranted without further evidence. The putatively ‘enhancing’ effects of non-invasive TBS have not been demonstrated to be practically achievable or meaningful outside research laboratories. This is in marked contrast to the maturity of the science and the volume of empirical data accrued about the effectiveness of TBS in therapeutic fields – for example relating to its use in the treatment of drug-resistant depression.
- 8.13 There are several grounds for scepticism about the possibilities of extrapolating from effects observed under experimental conditions to expectations of practical applications. The cognitive improvements observed in these research studies pertain to performance in specific, and often quite artificial, experimental tasks.<sup>790</sup> That such tasks transfer to real world challenges is sometimes assumed, but rarely tested. Neural enhancement applications of practical utility must be able to contend with distractions, confounding factors and tasks that demand more multifaceted and complex cognitive (emotional or perceptual) capacities than those tested by narrow, artificial standardised laboratory exercises. Furthermore, even if changes in performance under research conditions are statistically significant, if these improvements are not observed to be large in scale, they are unlikely to be useful for most practical purposes. Effects are also often short-lived, lasting only the duration of the stimulation,<sup>791</sup> although some

<sup>781</sup> Marshall L, Mölle M, Hallschmid M and Born J (2004) Transcranial direct current stimulation during sleep improves declarative memory *The Journal of Neuroscience* **24(44)**: 9985-92.

<sup>782</sup> Flöel A, Rössler N, Michka O, Knecht S and Breitenstein C (2008) Noninvasive brain stimulation improves language learning *Journal of Cognitive Neuroscience* **20(8)**: 1415-22.

<sup>783</sup> Walsh V, Ellison A, Battelli L and Cowey A (1998) Task-specific impairments and enhancements induced by magnetic stimulation of human visual area V5 *The Royal Society* **265(1395)**: 537-43.

<sup>784</sup> Cohen Kadosh R, Soskic S, Luculano T, Kanai R and Walsh V (2010) Modulating Neuronal activity produces specific and long-lasting changes in numerical competence *Current Biology* **20(22)**: 2016-20.

<sup>785</sup> Dockery CA, Hueckel-Weng R, Birbaumer N and Plewnia C (2009) Enhancement of planning ability by transcranial direct current stimulation *The Journal of Neuroscience* **29(22)**: 7271-7.

<sup>786</sup> Harmer C, Thilo K, Rothwell J and Goodwin G (2001) Transcranial magnetic stimulation of medial-frontal cortex impairs the processing of angry facial expressions *Nature Neuroscience* **4(1)**: 17-8.

<sup>787</sup> Knoch D, Pascual-Leone A, Meyer K, Treyer V and Fehr E (2006) Diminishing reciprocal fairness by disrupting the right prefrontal cortex *Science* **314(5800)**: 829-32; Young L, Camprodon JA, Hauser M, Pascual-Leone A and Saxe R (2010) Disruption of the right temporoparietal junction with transcranial magnetic stimulation reduces the role of beliefs in moral judgments *Proceedings of the National Academy of Sciences of the United States of America* **107(15)**: 6753-8.

<sup>788</sup> Schaller G, Lenz B, Friedrich K *et al.* (2011) Repetitive transcranial magnetic stimulation influences mood in healthy male volunteers *Journal of Psychiatric Research* **45(9)**: 1178-83.

<sup>789</sup> Walsh V, Pascual-Leone A and Kosslyn SM (2003) *Transcranial magnetic stimulation: a neurochronometrics of mind*: MIT press Cambridge, MA).

<sup>790</sup> For example, being asked to recall randomly presented sequences of consonants with which they had been earlier presented: Kirschen MP, Davis-Ratner MS, Jerde TE, Schraedley-Desmond P and Desmond JE (2006) Enhancement of phonological memory following transcranial magnetic stimulation (TMS) *Behavioural Neurology* **17(3)**: 187-94.

<sup>791</sup> Thut G and Pascual-Leone A (2010) A review of combined TMS-EEG studies to characterize lasting effects of repetitive TMS and assess their usefulness in cognitive and clinical neuroscience *Brain Topography* **22(4)**: 219-32.

studies have reported improved competence in the task learned under stimulation conditions for up to six months.<sup>792</sup>

- 8.14 There is no doubt that brain stimulation can have positive therapeutic effects (see paragraphs 2.29 to 2.31). However, when considering non-therapeutic uses, it must be borne in mind that the standards for what constitutes an enhancement have not been formalised. In this emerging field of research there are likely to be methodological shortcomings that would not be acceptable in delivering a therapeutic intervention, and instances where effects are overstated. It is well established, however, that TBS can change the brain and behaviour. The challenge for those working in the field is to find the route from small laboratory changes to real world effects that merit the use of the term ‘enhancement’.

### Opportunities

- 8.15 Nevertheless, it is plausible that, were indications from early research to be translatable into practical applications, there would be a large and enthusiastic market for applications of novel neurotechnologies from a wide range of users.<sup>793</sup> One reason for this assumption is the evidence, largely from college populations in the US, of the prevalence (estimated to be 5-15%) of use of prescription drugs such as Ritalin apparently for enhancement purposes.<sup>794</sup> A 2009 report conducted on behalf of the European Parliament observed that of all possible fields of technological human enhancement, those directed at improvements in human cognition are most likely to have public appeal and gain widespread use.<sup>795</sup> The report attributes this to a number of factors including the reversibility of interventions,<sup>796</sup> and fertile cultural climates in which the ‘knowledge society’ and round-the-clock working increase demands on our cognitive capacities.<sup>797</sup> Cognitive enhancements, perhaps unlike physical enhancements, may also be seen as offering universally useful benefits rather than being limited to positional advantages in particular competitive environments such as sport.
- 8.16 Given these kinds of considerations, it is plausible that school teachers and educationalists might show interest in the potential application of neuroscience and neurotechnologies in the classroom. However, whilst neuroscientific findings about the development of the brain and cognition may indeed help formulate educational strategies tailored to particular age groups or children with specific learning disabilities,<sup>798</sup> the weak evidence for the enhancing effects of neurostimulation outside the laboratory recommends caution. The Royal Society has warned against the propagation of what they describe as educational ‘neuromyths’.<sup>799</sup> It should also be noted that the kinds of cognitive improvements (for example, in memory) supposedly achieved through neurostimulation are likely to be more effectively accomplished through conventional educational means. While education, at its best, seeks to inculcate transferable skills required for global improvements in learning, findings from these kinds of studies referred to above tend

<sup>792</sup> Cohen Kadosh R, Soskic S, Luculano T, Kanai R and Walsh V (2010) Modulating Neuronal Activity Produces Specific and Long-Lasting Changes in Numerical Competence *Current Biology* **20(22)**: 2016-20, pp. 2017-8.

<sup>793</sup> Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76(2)**: 187-93, at page 191.

<sup>794</sup> Smith ME and Farah MJ (2011) Are prescription stimulants “smart pills”? The epidemiology and cognitive neuroscience of prescription stimulant use by normal healthy individuals *Psychological Bulletin* **137(5)**: 717-41; Ragan CI, Bard I and Singh I (2012) What should we do about student use of cognitive enhancers? An analysis of current evidence *Neuropharmacology* **64(1)**: 588-95.

<sup>795</sup> European Parliament: Science and Technology Options Assessment (2009) *Human enhancement study*, available at: [http://www.europarl.europa.eu/RegData/etudes/etudes/Join/2009/417483/IPOL-JOIN\\_ET\(2009\)417483\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/Join/2009/417483/IPOL-JOIN_ET(2009)417483_EN.pdf), at page 26.

<sup>796</sup> This observation was made specifically with reference to pharmaceutical enhancement, but holds equally of the majority of neurotechnological interventions discussed below.

<sup>797</sup> European Parliament: Science and Technology Options Assessment (2009) *Human enhancement study*, available at: [http://www.europarl.europa.eu/RegData/etudes/etudes/Join/2009/417483/IPOL-JOIN\\_ET\(2009\)417483\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/Join/2009/417483/IPOL-JOIN_ET(2009)417483_EN.pdf), at page 26.

<sup>798</sup> Blakemore S-J and Frith U (2005) *The learning brain: lessons for education* (Bodmin: Blackwell).

<sup>799</sup> Royal Society (2011) *Brain waves 2: neuroscience: implications for education and lifelong learning*, available at: [http://royalsociety.org/uploadedFiles/Royal\\_Society\\_Content/policy/publications/2011/4294975733.pdf](http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/publications/2011/4294975733.pdf), at page 18.

not to represent generalised or global improvements in abilities, only transient improvements in relation to specific tasks.

## Uses of BCIs for gaming and neurofeedback

- 8.17 Research into practical applications of BCIs is a rapidly growing field.<sup>800</sup> The 2011 report of the EC-funded *Future BNCI* project predicted that, as the costs of developing BCIs fall, gaming applications are likely to be the fastest growing sector, due in large part to the number of potential users.<sup>801</sup>
- 8.18 As we observed in Chapter 2, the majority of BCI research involves non-invasive electroencephalography (EEG). BCI games also use EEG to record brain activity using electrodes that rest on the scalp or forehead. The brain activity thus recorded is converted into information that is used to control or bring about effects in computer-operated games, either on-screen or in three-dimensional toys (see Box 8.2 for examples). Although limited by the spatial resolution at which it can measure brain signals and its vulnerability to interference, EEG nevertheless has high temporal resolution, is relatively easy and cheap to use, and does not carry the surgical risks associated with implanted electrodes. There is some speculation that, in the future, some serious enthusiasts might be prepared to have implanted electrodes to enhance their gaming experience, but this is not yet a reality.<sup>802</sup>
- 8.19 Currently available commercial gaming applications of BCIs utilise brain signals in ways that fall broadly under one or more of the following three categories:
- **Passive:** the BCI automatically records brain signals associated with the affective state of the user and converts these into instructions that bring about changes in the game environment.<sup>803</sup> These signals may also be used to monitor the player's experience so that the game may adjust accordingly to sustain a desired state of absorption.<sup>804</sup>
  - **Active:** users can control activity in the game either by imagining movement – in which case the BCI records associated signals from their motor cortex,<sup>805</sup> or by trying to change their affective state, for example by shifting from feeling frustrated to calm. On this latter principle, the University of Twente in the Netherlands conducts research using a game in which changes in players' brain's alpha activity recorded over a particular brain region will transform their avatar from a bear to an elf.<sup>806</sup>
  - **Reactive:** the BCI makes use of brain signals associated with event-related potential (ERP) responses elicited through the user's reaction stimuli such as the recognition of significant information.<sup>807</sup>
- 8.20 The kinds of games included in Box 8.2 tend not to be based upon peer-reviewed scientific research. There is some scepticism that all commercially available EEG headsets sold for

<sup>800</sup> Vlek RJ, Steines D, Szibbo D *et al.* (2012) Ethical issues in brain–computer interface research, development, and dissemination *Journal of Neurologic Physical Therapy* **36**(2): 94-9.

<sup>801</sup> Future-BNCI (2012) *Future BNCI: a roadmap for future directions in brain / neuronal computer interaction research*, available at: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf), at page 95.

<sup>802</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1**(2): 85-94, at page 86.

<sup>803</sup> Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer Interaction Series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 161.

<sup>804</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1**(2): 85-94, at page 90.

<sup>805</sup> *Ibid.*, at page 90.

<sup>806</sup> Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer Interaction series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), pp. 162-3. Alpha waves are the kind of brain activity associated with being awake and in a relaxed state.

<sup>807</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1**(2): 85-94, at page 86.



recreational purposes are *genuinely* recording brain signals; the suggestion is that they might instead be responding to facial muscle movement.<sup>808</sup> If this is the case, misleading marketing could indeed have a detrimental impact on public understanding of the capabilities and limitations of non-invasive BCIs. It has been suggested that it would be to the benefit of games developers to be open about the likelihood of signal interference and make a virtue of the fact that they are not ‘pure BCI’.<sup>809</sup>

### Box 8.2: Commercially available BCI-based games

Current commercially available gaming applications are relatively limited. These include:

- A range of on-screen games based around simple challenges, such as rebuilding Stonehenge from fallen blocks, that can be downloaded onto a personal computer or mobile device for use with an EEG headset;<sup>810</sup>
- an EEG headset incorporating furry ‘cat ears’ that adopt upright, lowered or wiggling positions purportedly depending on whether the user is in a state of mind described as ‘focused’, ‘relaxed’, or ‘in the zone’;<sup>811</sup> and;
- three-dimensional games in which players can try to make a ball hover suspended in vertical tube<sup>812</sup> or to move across a board using a signal recorded from an EEG headband. In the latter, the ball’s movement apparently depends on the players maintaining a calm or relaxed state of mind.<sup>813</sup>

## Other related applications

### Neurofeedback

8.21 Bridging the categories of novel neurotechnologies designed for enhancement or recreational purposes are non-invasive EEG-based BCI devices marketed with the purported purpose of permitting users to improve their concentration, relaxation, cognitive capacities, or mood using ‘neurofeedback’.<sup>814</sup> Neurofeedback refers to the method by which a BCI-controlled device provides the user with information (usually visual) about the kind of brain signals they are producing in performing particular task, thus permitting them to adjust the way they go about this task and thereby, supposedly, ‘training’ their brain. These devices often comprise a gaming element. The ‘Mindball’ application described in Box 8.2, in which a ball is moved across a table using active BCI control, is marketed in both ‘game’ and ‘training device’ forms, with the latter apparently particularly aimed at use in children.<sup>815</sup>

8.22 Attention deficit/hyperactivity disorder (ADHD) is a recognised mental health disorder in children. However, the potential for over-diagnosis of ADHD<sup>816</sup> and the diversion of pharmacological treatments such as Ritalin to be used for cognitive enhancement suggest that ADHD diagnoses can be used to exploit the ambiguous area between treatment of impairment

<sup>808</sup> Hildt E (2010) Brain-computer interaction and medical access to the brain: individual, social and ethical implications *Studies in Ethics, Law and Technology* 4(3): 1-22, at page 12; Future-BNCI (2012) *Future BNCI: a roadmap for future directions in brain / neuronal computer interaction research*, available at: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf), at page 73.

<sup>809</sup> Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer Interaction Series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 172.

<sup>810</sup> Emotive.com (2013) *Featured applications*, available at: <http://emotiv.com/consumers/>; NeuroSky (2013) *MindWave Mobile: MyndPlay Bundle*, available at: <http://store.neurosky.com/products/mindwave-mobile>.

<sup>811</sup> Neurosky (2013) *Necomimi: brainwave cat ears*, available at: <http://www.neurosky.com/necomimi/>.

<sup>812</sup> NeuroSky (2009) *Uncle milton star wars force trainer* available at: <http://company.neurosky.com/products/force-trainer/>;

Mindball (2012) *Interactive productline*, available at: <http://www.mindball.se/product.html>.

<sup>813</sup> Mindball (2012) *Products*, available at: <http://www.mindball.se/trainer.html>.

<sup>814</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* 1(2): 85-94. Neurofeedback is a kind of ‘biofeedback’ which refers to generally to the use of tools to gain information about the effective functioning of physiological systems so that intentional efforts can be made to improve performance of these systems.

<sup>815</sup> Mindball (2012) *Products*, available at: <http://www.mindball.se/trainer.html>.

<sup>816</sup> Scituito MJ and Eisenberg M (2007) Evaluating the evidence for and against the overdiagnosis of ADHD *Journal of Attention Disorders* 11(2): 106-13.

and improvement of function beyond the normal range. As such, new treatments targeted at ADHD may be a means of neuroenhancement for some users, as well as a treatment for others.

- 8.23 EEG-based neurofeedback is growing rapidly as a form of alternative treatment for attention deficit/hyperactivity disorder (ADHD). Neurofeedback software and equipment advertised as improving the symptoms of ADHD are being marketed in the form of toys and games, such as simple video games (for example, Pac-Man)<sup>817</sup> and systems that connect to commercially-available video games using Sony PlayStation or Nintendo Xbox.<sup>818</sup> Immersive virtual reality environments are also in development.<sup>819</sup> At present, the majority of reviews are cautious about recommending neurofeedback for treatment of ADHD.<sup>820</sup> However, the practice of 'home neurofeedback' is likely to grow, given that the method combines gaming with an ostensible therapeutic function.

### **Research and training uses**

- 8.24 BCI games are still predominantly used in research environments rather than in commercial applications. This research is not only aimed at developing commercial gaming products. Basic games are used to maintain users' interest and encourage performance improvement as part of the training phase of research into the potential assistive uses of BCI technologies.<sup>822</sup> Research using games is also conducted to better understand features of human-computer interaction that would improve the experiences of anyone using a computer for work, recreation, therapeutic, or assistive purposes.<sup>823</sup>

#### **Box 8.3: Investigating the uses of invasive BCIs**

Given the disproportionate balance of the risks of surgery to anticipated benefits, using BCIs implanted directly in the *brain* for non-therapeutic purposes still lies in the realm of science fiction. However, Professor Kevin Warwick of the University of Reading has experimented with a series of technological enhancements enabled by such an implant in his own peripheral nervous system (PNS) – in his arm – over a three-month period. This permitted him to extend his sensory range by experiencing ultrasonic sensory input to give an indication of distance. It took six weeks for his brain to learn to recognise the electrical pulses injected into his nervous system. Electrodes were also inserted into his wife's PNS, permitting electronic signals to be transmitted between their nervous systems via the internet. Every time his wife closed her hand, an electrical pulse was injected into Professor Warwick's nervous system which his brain was able to recognise and *vice versa*.<sup>821</sup>

### **Creative applications**

- 8.25 Studies have been conducted into applications permitting users to make music or to 'paint' using non-invasive BCIs. These not only offer novel means of self-expression for both able-

<sup>817</sup> Fuchs T, Birbaumer N, Lutzenberger W, Grzelier JH and Kaiser J (2003) Neurofeedback treatment for attention-deficit/hyperactivity disorder in children: a comparison with methylphenidate *Applied Psychophysiology and Biofeedback* **28**(1): 1-12, at page 4.

<sup>818</sup> SmartBrain Technologies (2008) *Smartbrain technologies*, available at: <http://www.smartbraintech.com/>.

<sup>819</sup> OpenViBE (2012) *A BCI based virtual reality solution for ADHD treatment (prototype)*, available at: <http://openvibe.inria.fr/a-bci-based-virtual-reality-solution-for-adhd-treatment-prototype/>.

<sup>820</sup> Bard I and Singh I (2013) ADHD: improving performance through BCI, in *Handbook of Neuroethics*, Clausen J, and Levy N (Editors) (London: Springer).

<sup>821</sup> Warwick K, Gasson M, Hutt B *et al.* (2004) Thought communication and control: a first step using radiotelegraphy *Communications, IIE Proceedings* **151**(3): 185-9, pp. 187-8.

<sup>822</sup> Marshall D, Coyle D, Wilson S and Callaghan M (2013) Games, gameplay and BCI: the state of the art *IEEE Transactions on Computational Intelligence and AI in Games* **5**(2).

<sup>823</sup> Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer Interaction Series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 172.

bodied users, but also offer particular pleasure and even therapeutic benefits for disabled users.<sup>824</sup>

## Future prospects: limitations and opportunities

8.26 The potential customer-base for recreational BCI applications is far greater than that for assistive BCIs, and the regulatory requirements for devices not intended for medical uses will be less stringent. Recreational BCIs are therefore likely to present an attractive investment opportunity.<sup>825</sup> One company that sells a chip chiefly for use in gaming BCIs has estimated that five million devices incorporating this chip were sold in 2011.<sup>826</sup> The literature in this field reflects optimism and inventive ambition amongst BCI researchers about what might be achieved through BCI gaming in the future.<sup>827</sup> However, the real-world promise of BCI-controlled games and any corollary commercial viability remains under debate. One clear point of agreement is that these benefits will not be realised unless BCI offers improvements over traditional gaming interfaces, about which indications are mixed. On one hand, currently commercially available BCI games are primitive in what they permit players to do when compared with the sophistication of popular non-BCI games.<sup>828</sup> On the other hand, games that are able to make direct use of brain signals offer novel and potentially more direct mode of interaction than games that are reliant on conventional controls (such as joysticks and keyboards) which may assist players' sense of immersion in a game. For example, game-play could respond directly to a player's affective state,<sup>829</sup> or to brain signals that precede players' conscious awareness of which move they plan to make.<sup>830</sup> One indication of the kind of enthusiasm that might greet these kinds of capabilities may be seen in the following response to the Working Party's consultation:

"I would use technology that intervenes in the brain for many non-medical uses, think of a simulation game where it tricks your brain into believing you are working out or using your muscles vigorously, therein building actual muscle mass. Or being in such immersive virtual reality that you can actually fly or live out your dreams in a completely safe and isolated environment."<sup>831</sup>

<sup>824</sup> Muenssinger JI, Halder S, Kleih SC *et al.* (2010) Brain painting: first evaluation of a new brain-computer interface application with ALS-patients and healthy volunteers *Frontiers in Neuroscience* **4(182)**; Future-BNCI (2012) *Future BNCI: a roadmap for future directions in brain / neuronal computer interaction research*, available at: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf), at page 75.

<sup>825</sup> Nijboer F, Allison BZ, Dunne S *et al.* (2011) A preliminary survey on the perception of marketability of brain-computer interfaces (BCI) and initial development of a repository of BCI companies, in *Proceedings 5th International Brain-Computer Interface Conference* (Verlag der Technischen Universitaet Graz, Austria), pp. 344-7; Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer Interaction Series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 150.

<sup>826</sup> Wired (2011) *Meet NeuroSky's mind controller headset*, available at: <http://www.wired.co.uk/magazine/archive/2011/07/start/mind-controller>.

<sup>827</sup> Marshall D, Coyle D, Wilson S and Callaghan M (2013) Games, gameplay and BCI: the state of the art *IEEE Transactions on Computational Intelligence and AI in Games* **5(2)**.

<sup>828</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1(2)**: 85-94, at page 88.

<sup>829</sup> Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-computer interaction series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 172; Allison BZ, Dunne S, Leeb R, Millan JdR and Nijholt A (2013) Recent and upcoming BCI progress: overview, analysis, and recommendations, in *Towards practical brain-computer interfaces: bridging the gap from research to real-world applications*, Allison BZ, Dunne S, Leeb R, Millan JdR, and Nijholt A (Editors) (London: Springer), at page 2.

<sup>830</sup> Although not yet commercially realised, it has been suggested that devices which record lateralised readiness potential (LRP - signals thought to be associated with preparation for motor activity) will allow 'preconscious' game play of this kind. See: Plass-Oude Bos D, Reuderink B, van der Laar B *et al.* (2010) Brain-computer interfacing and games, in *Human-Computer Interaction Series*, Tan DS, and Nijholt A (Editors) (London: Springer-Verlag), at page 153.

<sup>831</sup> An anonymous respondent, response to Working Party's Public Consultation.

## Ethical and governance issues raised by enhancement and recreational applications

8.27 In many respects, non-invasive neurostimulation and EEG-based neurofeedback used for neural enhancement, and BCI gaming applications raise similar ethical issues. On the basis of current research evidence, a question mark hangs over whether these technologies can actually deliver *practical* applications. However, in each field, the promise of early research is subject to a degree of popular and commercial hype. We examine these shared issues below, alongside those raised more particularly by neural enhancement.

### Need

8.28 As we noted at the start of this chapter, the ethical framework we developed in Chapter 4 is designed to assess the ethical issues raised by therapeutic applications and may not always be suitable for non-therapeutic contexts. Most obviously the question of ‘need’ clearly has less obvious applicability in respect of non-therapeutic applications. The absence of need nevertheless sets a challenge to demonstrating how innovation in these fields fulfils one of the criteria we endorse for Responsible Research and Innovation ((RRI), as described in Chapter 6): that there must be a clearly identified need for a technology that fulfils a valuable social benefit and does not threaten to undermine other social values.

8.29 In the absence of a clear demonstration of need, research and development of non-therapeutic interventions does not straightforwardly instantiate the virtue of inventiveness. One respect, however, in which it *may* be present, is where innovation in these fields could also help development of therapeutic or assistive technologies. For example, there are close similarities between BCI gaming devices and EEG-based devices used in therapeutic contexts.<sup>832</sup> It is tempting to infer from this that investment and innovation in the field of gaming could give rise to valuable corollary innovations for disabled users, for example in designing assistive neurotechnologies with more user-friendly interfaces and equipment.<sup>833</sup> Caution is warranted in making this assumption, however, as devices offering genuine utility to disabled users will typically require a higher number of electrodes, to be more robust, and to have more specialised training and support available than with those used for gaming.<sup>834</sup> Crucially, while performance and reliability do not pose serious problems in gaming, they present significant barriers to ethically and legally acceptable therapeutic uses.<sup>835</sup> This notwithstanding, the benefits offered by BCI games – in terms of users’ enjoyment, relaxation and imaginative expression – should not be overlooked. This is particularly so for individuals with severe movement disorders, for whom BCI gaming offers a valuable avenue for entertainment and competition; for example, by providing a disabled parent with a new opportunity to play with their children.<sup>836</sup>

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<sup>832</sup> Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1(2)**: 85-94, at page 88.

<sup>833</sup> Hildt E (2010) Brain-computer interaction and medical access to the brain: individual, social and ethical implications *Studies in Ethics, Law and Technology* **4(3)**: 1-22, at page 11; Zander TO and Kothe C (2011) Towards passive brain-computer interfaces: applying brain-computer interface technology to human-machine systems in general *Journal of Neural Engineering* **8(2)**: 1-5.

<sup>834</sup> Coyle D, Carroll A, Stow J *et al.* (2012) Enabling Control in the minimally conscious state in a single session with a three channel BCI (Paris: 1st international DECODER workshop); Future-BNCI (2012) *Future BNCI: a roadmap for future directions in brain / neuronal computer interaction research*, available at: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf), at pages 65 and 212.

<sup>835</sup> Luna P (2011) Controlling machines with just the power of thought *Lancet Neurology* **10(9)**: 780-1, at page 781. Indeed, it has been suggested that unreliability may provide an enjoyable challenge for gamers: Nijholt A, Plass-Oude Bos D and Reuderink B (2009) Turning shortcomings into challenges: brain-computer interfaces for games *Entertainment Computing* **1(2)**: 85-94, at page 89.

<sup>836</sup> Coyle D, Carroll A, Stow J *et al.* (2012) Enabling Control in the minimally conscious state in a single session with a three channel BCI (Paris: 1st international DECODER workshop)

## Uncertainty

8.30 While the virtue of inventiveness might not be wholly absent from research and innovation in this field, the imperative to reconcile this with the virtues of responsibility and humility is even stronger than in innovation directed at therapeutic ends. Research into uses of novel neurotechnologies to improve human capacities, or for gaming, is in its infancy and the potential benefits, let alone risks, remain largely unknown. The problem of uncertainty is particularly acute outside of paradigmatic treatment contexts as it is not clear how benefits are to be assessed and what constitutes proportionate risk where an intervention is non-essential.

### *Uncertain benefits*

8.31 Uncertainty about the benefits of neural enhancement applies not only to the specific question of whether neurodevices can actually deliver improvements in cognitive abilities or mood in real world settings, but also to the broader question of whether neural enhancements constitute unequivocal advantages at all. For example, some *prima facie* enhancements, such as improved memory, may, in practice, turn out to be detrimental if they prevent someone from discarding painful memories or disregarding distracting information.<sup>837</sup> The individual benefits of neurostimulation for neural enhancement purposes remain unproven. Even if they *were* shown to be effective, the public (as opposed to individual) benefit that would be served by widespread enhancement is questionable when individual positional advantages enjoyed by those with improved capacities are, inevitably, enjoyed at the expense of others.<sup>838</sup>

### *Uncertain safety risks*

8.32 Expectations of serious health risks in respect of the kinds of non-therapeutic applications we discuss here are low. However, as we have observed in earlier chapters, our still limited knowledge of how the brain works, coupled with its central role in many aspects of a meaningful existence, means that unintended effects of intervening come at a potentially high cost.

8.33 As we observe in Chapter 2, neither TMS nor TDCS raise serious safety issues if they are used according to the appropriate parameters for treatment or research involving humans.<sup>839</sup> Nevertheless, the long-term unintended effects of *repeated* uses of non-invasive neurostimulation are not yet clear.<sup>840</sup> The uncertainty here is of particular relevance where neurostimulation may be self-administered without appropriate medical supervision. While TDCS, compared with TMS, poses even fewer safety concerns, it is also a more portable, cheap, and easily self-administered technology. This raises the prospect that it may be more widely marketed directly to consumers, widening the field for any concerns we might have about its use.

8.34 Seeking to modify brain function through neural stimulation has been likened to “adjusting the weights on a complicated mobile”, in the sense that enhancement of abilities of one kind could be accompanied by deleterious effects to other abilities.<sup>841</sup> Humility therefore requires that all parties remain mindful of how little is known about the effects of intervening in the brain in this

<sup>837</sup> Farah MJ and Wolpe PR (2004) Monitoring and manipulating brain function: new neuroscience technologies and their ethical implications *Hastings Center Report* **34(2)**: 35-45, at page 42.

<sup>838</sup> Indeed, some have suggested that cognitive enhancement only increases the likelihood of the emergence of destructive malicious powers. See: Persson I and Savulescu J (2008) The perils of cognitive enhancement and the urgent imperative to enhance the moral character of humanity *Journal of Applied Philosophy* **25(3)**: 162-77.

<sup>839</sup> Rossi S, Hallett M, Rossini PM and Pascual-Leone A (2009) Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research *Clinical Neurophysiology* **120(12)**: 2008-39, at page 2022.

<sup>840</sup> Illes J, Gallo M and Kirschen MP (2006) An ethics perspective on transcranial magnetic stimulation (TMS) and human neuromodulation *Behavioural Neurology* **17(3-4)**: 149-57, at page 151.

<sup>841</sup> Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76(2)**: 187-93, at page 190.

way. It also recommends that, in conducting research and reporting findings, researchers attend equally to unintended or disappointing findings, rather than seeking only to publicise positive findings of enhanced performance.

- 8.35 The risks of non-invasive BCIs using EEG are thought to be minimal. However, there has been no systematic research into the long-term effects of their use for recreational purposes.<sup>842</sup> The most plausible long-term risks are those relating to the brain's inherent plasticity and the potential to change connectivity and the functions of particular regions due to repeated use of the same neuronal pathways, for example, while striving to generate the motor signals required to play a game.<sup>843</sup> If we accept that non-invasive BCIs may, through exploitation of brain plasticity, be effective rehabilitation tools (for example, in assisting stroke patients to re-learn motor functions), then we cannot reasonably exclude the possibility of less desirable effects related to plasticity.<sup>844</sup>

### **Risks to children**

- 8.36 Particular attention is warranted in respect of any unintended impacts on children's brains of devices that use neurostimulation, function by influencing brain plasticity, or encourage the repeated use of particular neural pathways, as the effects of these on the developing brain are still largely unknown. This concern is particularly acute given that children are likely to be a key target group both for cognitive enhancement for educational purposes, and for BCI gaming. Several of the games referred to in Box 8.2 above are explicitly targeted at younger age groups, using images of children in their marketing materials.<sup>845</sup>
- 8.37 The use of neurodevices (and chemical agents) by children and young people for purposes of enhancement has particular social and ethical implications that require focused scrutiny and analysis. It is especially important that these analyses do not simply translate normative judgments on adult enhancement practices or intentions to children. Because children are more vulnerable to many effects of neuro-enhancers than adults and rely on proxies for their care, the barriers to use of cognitive enhancers should be much higher than those for adults.<sup>846</sup>

### **Addressing uncertainty**

- 8.38 These uncertainties appear to point to the need to gather more evidence about the efficacy of neural enhancements using novel neurotechnologies and the longer-term effects of BCI gaming. However, research into the non-therapeutic applications discussed here itself raises ethical concerns because it would involve non-essential interventions – albeit non-invasive – in the human brain. While it is still not possible to provide prospective research participants with clear information about the longer-term and unintended effects of interventions, questions arise about whether their consent to participate can yet be truly informed. Unlike therapeutic research, these concerns are not so readily offset by arguments that a small degree of risk might be proportionate and defensible in relation to the public good served by health-focused research.
- 8.39 The reasonably anticipated risks of neurostimulation and non-invasive BCI use are not so serious as to warrant prohibiting neurostimulation research directed at non-therapeutic ends in adults. Moreover, given the complex and non-linear innovation trajectories of many novel

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<sup>842</sup> Vlek RJ, Steines D, Szibbo D *et al.* (2012) Ethical issues in brain–computer interface research, development, and dissemination *Journal of Neurologic Physical Therapy* **36(2)**: 94–9, at page 97.

<sup>843</sup> Hildt E (2010) Brain-computer interaction and medical access to the brain: individual, social and ethical implications *Studies in Ethics, Law and Technology* **4(3)**: 1–22, at page 7.

<sup>844</sup> Caria A, Weber C, Brötz D *et al.* (2011) Chronic stroke recovery after combined BCI training and physiotherapy: a case report *Psychophysiology* **48(4)**: 578–82; Vlek RJ, Steines D, Szibbo D *et al.* (2012) Ethical issues in brain–computer interface research, development, and dissemination *Journal of Neurologic Physical Therapy* **36(2)**: 94–9, at page 97.

<sup>845</sup> See, for example, NeuroSky (2009) *Uncle Milton Star Wars Force Trainer* available at: <http://company.neurosky.com/products/force-trainer/>.

<sup>846</sup> Singh I and Kelleher KJ (2010) Neuroenhancement in young people: proposal for research, policy, and clinical management *AJOB Neuroscience* **1(1)**: 3–16.

technologies, it may not always be possible wholly to disentangle the generation of new knowledge in this area from that which may benefit our understanding of brain structure and functioning in way that serves therapeutic or assistive ends. Nevertheless, because of the uncertain balance between public benefits and individual risks to participants, there is a need for ethical oversight to ensure the value and quality of studies using neurotechnologies directed at non-therapeutic research questions and to avoid unnecessary interventions in the brain. **We recommend that institutional ethics committees reviewing research proposals for studies using neurostimulation directed at non-therapeutic ends ensure that these meet high standards of originality and rigour. The aim should be to prevent the use of poorly defined protocols and the unnecessary repetition of similar studies, and to make sure participants are informed about the limited knowledge of long-term unintended health effects.**

- 8.40 Given that some children currently play BCI games, and it is possible that parents and educators may be interested in using non-invasive BCIs and neurostimulation to bring putative educational benefits for children, a responsible approach requires that further research is conducted to better understand the effects of these uses on the developing brain. However, precisely this uncertainty means that an unqualified call to explore these questions through *interventional* research involving children would be in tension with the virtues of responsibility and humility. **We therefore recommend that there is a need for observational studies of children, who are already using neurodevices for gaming, or to improve their capacities for attention or learning, to assess the benefits and risks of these interventions, including their effect on the developing brain.**
- 8.41 **Recalling our recommendation from Chapter 5 for clinical experiences of experimental treatment interventions and small studies to be recorded in registers, we would further recommend that the findings – including negative or inconclusive outcomes – from research investigating non-therapeutic effects of novel neurotechnologies should also be included in these registers.** This would not only mean that current evidence of benefits and unintended effects are brought together to reach the widest audience and achieve cross-fertilisation of valuable findings from therapeutic and non-therapeutic protocols, it would also help to prevent the unnecessary repetition of similar studies and to challenge and correct some of the problems of small sample sizes and research and reporting integrity noted earlier in this chapter.

## Privacy and data protection

- 8.42 As we noted in Chapter 5, all neurodevices that use electrodes are vulnerable to interference and disruption (paragraph 5.52). Furthermore, where BCIs collect or transmit data about brain activity or brain states, this raises ethical and legal questions about how data collected by these devices can be used.<sup>847</sup> These issues do not differ significantly in this context from those we have already discussed in Chapter 5 in relation to therapeutic applications. However, as gaming applications of BCIs become more prevalent and affordable, their sheer ubiquity raises the prospect of greater quantities of data relating to users' neural activity being transmitted or collected by devices. A distinct privacy issue arises in respect of the capacity for some BCI games to respond to directly to players' affective states. This provides one of their unique selling points, but might also expose emotional states in ways for which players used to conventional games might not be prepared.<sup>848</sup> A further kind of privacy concern relating to the involuntary extraction of information has only been demonstrated through research and is not yet a realistic threat, but introduces a possible area for vigilance. One study has indicated that EEG computer-

<sup>847</sup> Future-BNCI (2012) *Future BNCI: a roadmap for future directions in brain / neuronal computer interaction research*, available at: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf), at page 106.

<sup>848</sup> Hildt E (2010) Brain-computer interaction and medical access to the brain: individual, social and ethical implications *Studies in Ethics, Law and Technology* 4(3): 1-22, at page 13.

gaming headsets could be maliciously modified in ways intended to obtain private information. Hacked headsets might permit a third party to identify when a user is viewing something important (such as their bank PIN).<sup>849</sup> These headsets would work by permitting an unauthorised party to know when the user's brain produces signals (those associated with the recognition of a stimulus of particular significance), combined with information about the stimulus that elicited this response.

- 8.43 These examples illustrate ways in which BCI-game players' expectations about who will have access to information about their brain activity or their states of mind might differ from the expectations of patients. While a person using neurodevices for therapeutic or assistive reasons might reasonably expect data collected by these devices to be shared within the team responsible for their clinical care, an online gamer might, in contrast, require more explicit advance notification if data about their neural activity were to be gathered, (for example, for consumer research purposes). As we discussed in Chapter 5, what counts as a 'reasonable expectation' of how such data will be used could make a difference to whether privacy and confidentiality concerns arise. The European Radio and Telecommunications Terminal Equipment Directive, under which computer gaming devices are regulated, empowers the European Commission to decide that certain classes of equipment must incorporate safeguards to protect privacy and personal data.<sup>850</sup> As commercially available BCI-based games become more sophisticated, it may be necessary for the European Commission to consider enhanced regulation under this provision.

### Particular ethical concerns raised by neural enhancement

- 8.44 Our analysis thus far has not yet addressed the much debated ethics of neural enhancement *per se* – that is, when might it be unacceptable, defensible, or even obligatory for people to use technologies to 'extend or amplify the core capacities of the mind' (using the definition introduced Box 8.1).<sup>851</sup> It is not obvious that the kinds of neural enhancement that might potentially be achieved using the categories of neurotechnologies we discuss in this report differ in ethically significant ways from those achieved through the use of pharmaceuticals. For example, *if* the pertinent concern is that neural enhancement could undermine the authenticity of one's actions by removing personal effort and endeavour, then it is not clear that the particular kind of technology by which the advantage is achieved is strongly relevant – although its cost and availability might be. The discussions of this report so far have been premised on the assumption that, just because novel neurotechnologies are tools external to and intervening in our brains, this does not mean that the mere fact of their use automatically undermines the autonomy or authenticity of the activities they enable (see paragraph 4.29). Moreover, in this report, we have sought to avoid speculation about the ethical implications of (as yet) unrealised technological capacities. The very early state of research and the limited evidence of the possibility of achieving meaningful neural enhancement using neurostimulation mean that detailed discussion of its harms or benefits *qua* enhancements (rather than *qua* intervention) is not yet warranted. For this reason, we limit our discussion here to ethical issues that might arise even if novel neurotechnologies were not effective in extending human capacities, but some people (either developers or users) were nevertheless sufficiently convinced that they *could* be.
- 8.45 Concerns that unequal access to the means and benefits of neural enhancement might give rise to injustice (and a consequent corrosion of solidarity between members of a community)

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<sup>849</sup> Martinovic I, Davies D, Frank M *et al.* (8-10 August 2012) On the feasibility of side-channel attacks with brain-computer interfaces *Presentation to the Usenix Security Symposium 2012*, (Bellevue, WA).

<sup>850</sup> Article 3, paragraph 3(c) of Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

<sup>851</sup> Farah MJ, Illes J, Cook-Deegan R *et al.* (2004) Neurocognitive enhancement: what can we do and what should we do? *Nature Reviews Neuroscience* **5**(5): 421-5; BMA (2007) *Boosting your brainpower: ethical aspects of cognitive enhancement* (London: BMA); Greely H, Sahakian B, Harris J *et al.* (2008) Towards responsible use of cognitive-enhancing drugs by the healthy *Nature* **456**(7223): 702-5; Bostrom N and Sandberg A (2009) Cognitive enhancement: methods, ethics, regulatory challenges *Science and Engineering Ethics* **15**(3): 311-41; Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76**(2): 187-93.



depends on there being a demonstrable benefit to healthy users at all – precisely what is yet to be demonstrated in the case of neurostimulation or neurofeedback. Nevertheless, injustice could arise even (or perhaps particularly) if the evidence of effective enhancement is doubtful, if finite resources and expertise are invested in pursuing non-essential innovations for the privileged few, or the ‘worried well’, at the expense of therapeutically-directed research. This could be seen as the hijacking of inventiveness for ends of questionable social value. However, even this might not represent an unalloyed harm, given the non-linear and intertwined nature of research and innovation trajectories of therapeutic and non-therapeutic novel neurotechnologies.

- 8.46 A further ethical concern that arises in respect of enhancement technologies is that people may be coerced into using them when they would not otherwise choose to; either by explicit pressure from employers, educators or parents,<sup>852</sup> or because the use of a (putative) enhancement becomes so widespread that individuals fear positional disadvantage if they do not join in. Each of these possibilities, but especially explicit pressure, may be seen as infringements of autonomy. Importantly, given our caveat above, this pressure could persist irrespective of actual efficacy, provided some of the parties involved believe neurotechnological interventions to be effective. Coercive pressure to improve oneself is, of course, not uncommon in educational or employment contexts. However, it is of particular concern in respect of neurotechnologies because it pertains to individuals’ choices about what is done to their brain (an organ that we have recognised has special status in people’s lives, in which the effects of intervening remain uncertain). It is not clear the extent to which coercive pressure to use neurotechnologies for enhancement purposes is yet a problem in civilian life, however it may be a particular ethical concern in military contexts, which we consider further in the second part of this chapter (see paragraph 8.86).

### Effective and proportionate oversight of neurodevices for non-medical purposes

- 8.47 One commentary on the ethics of neural enhancement has observed that, despite persistent uncertainties about safety and longer term impacts of neural enhancement technologies, these do not raise serious ethical problems because all stakeholders will be equally motivated to protect against them.<sup>853</sup> We suggest that this conclusion is too swift in the context of the technologies we are discussing here because it ignores two practical distinctions between the oversight of pharmaceuticals and neurodevices. The first of these relates to the nature of the regulatory frameworks that apply to marketing neurodevices, particularly when these are not classed as ‘medical devices’. The second relates to the likelihood that neurodevices will be used for non-therapeutic purposes outside health care settings.

#### Regulating the technologies

- 8.48 When a manufacturer wishes to place particular classes of product (including electronic and medical devices) on the market in Europe, it is necessary for that product to conform to the relevant European legislation governing its marketability.<sup>854</sup> The ‘CE-mark’ is the indication that the manufacturer has taken the necessary steps to ensure their product’s conformity. Devices intended to be marketed for non-therapeutic neurostimulation, neurofeedback or recreational purposes are unlikely to be classed as ‘medical’ under the definition of the Medical Devices Directive.<sup>855</sup> If a manufacturer seeks to market a non-invasive neurostimulation or BCI device

<sup>852</sup> The Academy of Medical Sciences, British Academy, Royal Academy of Engineering, The Royal Society (2012) *Human enhancement and the future of work*, available at: <http://www.acmedsci.ac.uk/p47prid102.html#downloads>, pp. 44-5.

<sup>853</sup> Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76(2)**: 187-93, at page 190.

<sup>854</sup> Department for Business, Innovation and Skills (2012) *CE marking*, available at: <https://www.gov.uk/ce-marking>.

<sup>855</sup> A “‘medical device’ means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human

for non-medical purposes, it is likely to be regulated under the regimes relating to generic electrical equipment or radio and communications devices.<sup>856</sup> CE-marks have been granted for the sale of BCI games and EEG neurofeedback devices (see Box 8.2). However, as far as we are aware, neither TMS nor TDCS devices have received CE-marks for non-therapeutic purposes.

- 8.49 Under the regulatory regimes covering non-medical devices, the scrutiny and oversight of health impacts on users is likely to be light touch. Non-medical electronic products must meet basic safety requirements if they are to carry a CE mark, which will take into account, for example, risks from high temperatures, or electromagnetic fields.<sup>857</sup> However, this is unlikely to encompass the kinds of obligations to provide data from clinical investigations, or from the relevant scientific literature, that fall upon manufacturers of devices seeking CE-marking for *medical* purposes.<sup>858</sup> This raises concerns about the effectiveness and proportionality of regulation of devices for non-therapeutic purposes.
- 8.50 Our discussion in Chapter 7 acknowledges that the current framework for regulating medical devices in UK and the rest of Europe is not perfect. This includes, for example, the lack of transparency and oversight of the Notified Bodies responsible for determining conformity of devices with legislative requirements; the fact that devices can receive CE-marks on the basis of equivalence data rather than specifically conducted clinical investigations; and uneven oversight and reporting of post-market surveillance activities. However, we also welcome current proposals from the European Commission that signal improvements on all these fronts.<sup>859</sup> Moreover, despite current shortcomings, the obligations upon manufacturers under the Medical Devices Directive require conformity with clinical safety and performance standards that are appropriate to devices that intervene in the human body and impact upon human health.<sup>860</sup> Furthermore, medical devices are regulated by the MHRA with the attendant oversight informed by expertise and experience in matters of human health that this entails. The MHRA is not, however, responsible for regulating devices intended for non-medical purposes. A further lacuna relates to the transparency of information, and post-market surveillance data in particular, which will not be captured on the centralised European Databank on Medical Devices (Eudamed) if a neurodevice is not regulated as a medical device.
- 8.51 It might seem both inconsistent and disproportionate that a neurostimulation device marketed for a non-medical purpose, but which nevertheless has the same capacity to intervene in the brain and impact upon its functions, should not be subject to the same level and kind of regulatory oversight as it would if marketed for a medical purpose. We suggest that this is a considerable gap in the regulation of novel neurotechnologies, one that is of particular concern in respect of TMS and TBS devices, which are classified under the Medical Devices Directive as ‘medium risk’, because they are ‘active’ in administering or exchanging energy.<sup>861</sup>

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beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; [or] control of conception.” See: Article 1, Paragraph 2(a) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

<sup>856</sup> Non-invasive BCI devices that are sold for gaming purposes in Europe are likely to receive marketing approval under either: Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity or, if powered by a voltage not exceeding 24 volts, Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 of the safety of toys (as amended). Electrical equipment with a voltage input or output of 50-1500 volts is regulated under: Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

<sup>857</sup> For example see Annex 1 of Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

<sup>858</sup> MHRA (2012) *Guidance for manufacturers on clinical investigations to be carried out in the UK*, available at: <http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007504.pdf>.

<sup>859</sup> Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (26 September 2012).

<sup>860</sup> Annex 1 to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

<sup>861</sup> MHRA (2008) *Bulletin No. 4: conformity assessment procedures*, available at: <http://www.mhra.gov.uk/home/groups/es-era/documents/publication/con007492.pdf>.

8.52 As we note in Chapter 7, the EC published proposals for reform to the regulation of medical devices in Europe in 2012 (see Box 7.1). Amongst these is the proposal that some categories of devices – which will be specified in the legislation – “shall be considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose”.<sup>862</sup> The categories of devices currently falling within the scope of this proposal include contact lenses, dermal fillers, and equipment for delivering intense pulsed light.<sup>863</sup> We suggest that non-invasive neurostimulation devices represent interventions in the human brain that could be comparable both in terms of risks to safety, and in terms of the likelihood of being marketed or administered for non-therapeutic purposes, as the devices to be classed as ‘medical’ in the proposed regulation. **We recommend, therefore – in the interests of consistency and of providing effective and proportionate oversight of devices that intervene in the brain – that the European Commission consider including neurodevices that deliver TMS and TBS amongst the categories of devices that would (irrespective of their intended purpose) be regulated as medical devices and that their marketing in the UK is overseen by the MHRA.**

### **Marketing neurodevices and services**

8.53 A CE-mark determines the purpose for which a device may be marketed, but it does not extend to restricting the kind of purpose for which it may then be used. A device may be lawfully used ‘off-label’ (that is, for purposes other than those for which it has received a CE-mark) provided it does not jeopardise customers’ safety or defraud them. The matter of ‘safe use’, however, is somewhat question-begging in this context, as there will not have been regulatory oversight of what constitutes ‘safe use’ for off-label purposes. A device may not, however, be marketed by the manufacturer for an off-label purpose.

8.54 As far as we can ascertain, neurodevices that are most likely to be sold ‘direct to consumers’ (DTC) for their private use at present are non-invasive BCIs designed for gaming or neurofeedback.<sup>864</sup> In addition to the kinds of games referred to in Box 8.2, it is possible to purchase EEG headbands to monitor the quality of one’s own sleep.<sup>865</sup> The value of the market for BCI-like personal monitoring devices is potentially considerable.<sup>866</sup> The risks to user’s health posed by such devices are low. Nevertheless if, for example, BCI games are designed to be particularly immersive, this potentially increases any discomfort or effects on brain plasticity associated with overextended periods of use.

8.55 There is some evidence of online businesses based outside the UK selling TBS<sup>867</sup> devices or ‘portable’ TMS devices online to consumers.<sup>868</sup> Non-medically qualified providers also appear to offer non-therapeutic *services* using neurostimulation devices directly to consumers in the UK.<sup>869</sup> Where non-invasive neurostimulation devices or services are marketed directly to consumers for non-therapeutic purposes, this means – almost invariably – that they are likely to be used without medically qualified supervision or advice. Even where interventions are not self-administered, there may still be risks associated with service providers who lack the necessary training or skills to determine safe parameters of use, or to recognise if a customer is otherwise

<sup>862</sup> Article 2(1)(1) to the Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (26 September 2012).

<sup>863</sup> Annex XV of the Proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (26 September 2012).

<sup>864</sup> Factfinding meeting on non-therapeutic applications, 7 September 2012.

<sup>865</sup> Zeo (2012) *Zeo sleep manager*, available at: <http://myzeo.co.uk/pages/what-is-zeo/>. There is increasing interest in recording and monitoring one’s own health and daily routine inspired by movements such as the ‘Quantified Self’. See: Quantified Self (2012) *About the quantified self*, available at: <http://quantifiedself.com/about/>.

<sup>866</sup> Mobihealthnews (4 May 2011) *NeuroVigil lands venture funding, impressive valuation*, available at: <http://mobihealthnews.com/10855/neurovigil-lands-venture-funding-impressive-valuation/>.

<sup>867</sup> Mind Alive Inc. (2012) *Oasis pro*, available at: [http://www.mindalive.com/Products\\_OASIS\\_Pro.htm](http://www.mindalive.com/Products_OASIS_Pro.htm).

<sup>868</sup> Biophysica (2013) *Transcranial magnetic stimulator*, available at: <http://shop.biophysica.com/articles/526.php>.

<sup>869</sup> Biofeedback & Neurofeedback in York (2012) *Transcranial direct current stimulation*, available at: <http://www.york-biofeedback.co.uk/neurofeedback/tcds.aspx>.

vulnerable or unwell in a way that would make neurostimulation unsafe or unsuitable for them. Furthermore, as discussed in Chapter 5, private businesses may not adequately protect customers' interests in other respects, such as in safeguarding their confidentiality or providing follow-up care (see paragraphs 5.28 to 5.29). There may also be inadequate recording or reporting of incidents in which result in adverse effects. These concerns are compounded by the fact that, outside health care settings, there is a lack of any professional bodies that might oversee services and offer guidance to practitioners or consumers.

- 8.56 The most immediate threat to consumers' interests from the direct marketing of neurodevices and services might relate not to users' physical health, but to their exploitation and the abuse of their trust from false or misleading claims about the benefits of devices or services. The uses and positive effects implied by some of the marketing materials associated with DTC marketing in this field may be seen to extrapolate beyond that which is supported by peer-reviewed evidence and contribute to hype about the capabilities of neurostimulation and neurofeedback, to provide benefits for otherwise healthy users. One business marketing TMS devices states that conditions such as "memory impairment [and] sleepiness" have been "successfully treated" using "Magnetic Deep Brain Stimulation [sic]" and that "savant like creative abilities" have been enhanced.<sup>870</sup> Another business which markets TDCS devices suggests these might be used for "mood elevation" and "increased concentration".<sup>871</sup> Yet another refers to the use of EEG for "self-improvement" and "mental conditioning".<sup>872</sup> There is also evidence of UK businesses marketing neurostimulation services by implying that these can improve cognitive performance or mood.<sup>873</sup> Those who market devices and services in this way arguably demonstrate a failure of responsibility as unsubstantiated claims of the kind illustrated here interfere with autonomous choice by preventing the informed weighing of risks and benefits by inflating or fabricating the latter.
- 8.57 The European Directives that regulate these technologies are unlikely to offer protection against misleading claims, except insofar as these pertain to the purpose for which the device has received CE-marking and basic product function. The compliance requirements for CE-marking are not concerned with questions of efficacy. So, for example, where a device makes claims for positive benefits in terms of improved concentration or mood, manufacturers would not be required to demonstrate this as a proven benefit in order to use the CE-mark.
- 8.58 This suggests that there are regulatory gaps around the provision of full and honest information to consumers about the limits of knowledge regarding the long-term effects of these devices and the benefits they actually confer. If the claimed benefits *are* sufficiently misleading, this could constitute fraud. Where there is a commercial relationship or contract with a UK business, the gap associated with misleading or fraudulent marketing claims may be partially filled by consumer protection laws including the Consumer Protection from Unfair Trading Regulations 2008, which make it an offence for businesses intentionally to make false claims about the goods or services they sell; and the Control of Misleading Advertising Regulations 1988. The Sale of Goods Act 1979 and the Supply of Goods and Services Act 1982 may also provide for a means for consumers to respond where the goods or services they receive do not conform to those they were led to expect. However, in this context, inefficacy will undoubtedly be challenging for consumers to prove, and it is preferable that users are alerted to any limitations of such technologies *before* undertaking interventions involving their brains.
- 8.59 The risks to consumers' health and well-being from non-invasive neurostimulation are unlikely to be sufficient to warrant restricting consumers' freedom to undertake interventions of questionable efficacy. Where neurodevices and services are marketed to consumers for non-

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<sup>870</sup> Biophysica (2012) *Transcranial magnetic stimulation*, available at: <http://biophysica.com/content/electromedical-devices-instruments/electromedical-devices/transcranial-magnetic-stimulator/tms/>.

<sup>871</sup> Mind Alive Inc. (2012) *Oasis pro*, available at: [http://www.mindalive.com/Products\\_OASIS\\_Pro.htm](http://www.mindalive.com/Products_OASIS_Pro.htm).

<sup>872</sup> Brain Master Technologies, Inc. (2012) *About brainmaster*, available at: <http://www.brainmaster.com/page/about-brainmaster/>.

<sup>873</sup> Biofeedback & Neurofeedback in York (2012) *Transcranial direct current stimulation*, available at: <http://www.york-biofeedback.co.uk/neurofeedback/tDCS.aspx>.

therapeutic purposes, we echo here the doubts we expressed in Chapter 5 that attempts to control this are unlikely to be effective or practical, particularly if vendors are based outside the UK. Nevertheless, given the special status of the brain and the potential for hype to distort public understanding of the capacities of neurotechnologies to offer improvements to individuals without brain disorders, businesses offering services using neurodevices for non-therapeutic purposes have a responsibility to adhere to responsible standards of practice that protect their customers' health, and equip potential consumers to make informed choices about the interventions they undertake. **We recommend therefore, that service providers should form a trade association to establish and uphold best practice standards in the sector of non-therapeutic neurostimulation and neurofeedback. These standards would encompass best practice for both the *delivery* of interventions, and the *kind* of information provided to customers.** This means ensuring that customers do not have health problems that would be contraindications were the device to be used in a health care setting; and only delivering interventions in accordance with the most up-to-date information available on safe parameters, including the maximum duration and frequency, of the devices' use. Responsibility and humility also require that service providers supply clear, accurate, and up-to-date information on the purposes for which the device has been approved to be marketed and information about current knowledge (or lack thereof) of its risks and effectiveness in relation to the services they are marketing.

## Misrepresentation and trust

- 8.60 Responsibility to represent the capabilities of neurotechnologies extends beyond those who market products and services. As we observed in our brief review of the status of current scientific evidence of the enhancement capacities of neurostimulation and neurofeedback at the beginning of this chapter, some academic researchers may overstate or misrepresent the real-world applications of their findings. The BCI research community has itself recognised that hype regarding the technological capabilities of neurotechnologies is a problem in its own field.<sup>874</sup> Innovations impacting upon the brain and promising improvements from which we all may benefit (not only when we are unwell) inevitably capture the public imagination and thus also media attention. Small neurostimulation studies, of the kind referred to earlier in this chapter, have been reported in the mainstream media in terms of devices that “unlock our inner potential” or of “morality being modified in the lab”.<sup>875</sup>
- 8.61 While there is undoubted potential in some research into the non-therapeutic utility of neurostimulation, premature claims can impede, rather than accelerate, scientific progress. Unsustainable claims about the enhancement or recreational promise of novel neurotechnologies deceive consumers and raise false expectations. This risks the kind of disenchantment that was evidenced by the backlash against neurofeedback methods in the late 1960s when the promises of (unsuitably designed) research studies were not fulfilled.<sup>876</sup> Such a backlash could potentially harm research funding.<sup>877</sup> More importantly, hype by researchers and the popular media undermines public understanding of the current state of scientific understanding of the benefits and risks of these technologies. Where unsubstantiated claims to benefits are made in a commercial context, these risk exploiting the vulnerable or credulous by marketing unproven interventions (at potentially great expense) and intervening in the brain without sound scientific reasons to do so. The ethical consequences of hype would perhaps be

<sup>874</sup> Nijboer F, Clausen J, Allison BZ and Haselager P (2011) Researchers' opinions about ethically sound dissemination of BCI research to the public media *International Journal of Bioelectromagnetism* **13**(3): 108-9.

<sup>875</sup> BBC News (30 Mar 2010) *Morality is modified in the lab*, available at: <http://news.bbc.co.uk/1/hi/8593748.stm>; Mail Online (8 February 2011) *How a zap to the brain could bring out the genius in you*, available at: <http://www.dailymail.co.uk/sciencetech/article-1353039/How-zap-brain-bring-genius-you.html>.

<sup>876</sup> Allison BZ, Dunne S, Leeb R, Millan JdR and Nijholt A (2013) Recent and upcoming BCI progress: overview, analysis, and recommendations, in *Towards practical brain-computer interfaces: bridging the gap from research to real-world applications*, Allison BZ, Dunne S, Leeb R, Millan JdR, and Nijholt A (Editors) (London: Springer), at page 10.

<sup>877</sup> *Ibid.*, at page 10.

at their most serious if disappointment relating to the capabilities of non-essential non-therapeutic applications undermines public understanding of, and trust in, related technologies that offer genuine and much needed therapeutic benefits.

- 8.62 The need to exercise humility and a responsible approach to communicating the non-therapeutic capacities of neurotechnologies, and the limits to these, extends to a wide range of actors. We return to discuss the problem of hype and the respective responsibilities of those involved in more detail in Chapter 9. In view of the priorities for ethical attention identified in this chapter, one particular area of concern that emerges is the coercive use of neurostimulation and neurofeedback interventions with children. As we have noted, the effects of these interventions on the developing brain are, as yet, unclear and children and young people may be less well equipped to resist pressures from educators or parents who wish them to use neurotechnologies to enhance their capacities for learning and educational performance. **We recommend that the departments for education in each of the governments in the UK and the Royal College of Paediatrics and Child Health should issue advice directed to both teachers and parents on the current best evidence, and the evidence gaps, of the efficacy and risks of neurofeedback and neurostimulation for cognitive enhancement in children.**

## Military applications of novel neurotechnologies

### Introduction

- 8.63 This second part of this chapter concerns the uses of novel neurotechnologies by states for either offensive or defensive military purposes in international and domestic conflicts. As with the other non-therapeutic applications discussed in this chapter, these uses are currently chiefly at a research or proof-of-concept stage. In addition, much of the research being conducted is classified. The examples we draw upon are primarily from development activities funded by the US *Defense Advanced Research Projects Agency* (DARPA), as public access to information on US defence activities is surprisingly open, meaning that it is possible to find out more about US military research than that of perhaps any other nation.<sup>878</sup>
- 8.64 As we noted in the introduction to this chapter, non-therapeutic applications raise a range of distinct ethical and social issues that do not always fit easily into our ethical framework, which was constructed with *therapeutic* neurotechnologies foremost in mind. This distinction is particularly marked when we come to consider military applications, where normative concepts such as 'need' or the duty to avoid harming others take on quite different meanings, as contrasted with those they have in medical contexts. It may, therefore, be appropriate to treat the remainder of this chapter as somewhat separate from our earlier discussions.
- 8.65 This notwithstanding, consideration of military-focused activities is pertinent to the central concerns of this report because investment in this field is considerable. War, medicine and science have long had a symbiotic relationship, and the military has a clear interest in fostering advances in science and technology to enhance the capacities of its own troops and to degrade those of the enemy. Military research and development comprises a significant part of the research and development budget of many high and middle income countries, notably the US, UK, Russia, France, and China.<sup>879</sup> Since the fall of the USSR, the US military research and development budget has dwarfed that of any other state and has grown following the events of 11 September 2001 through a huge increase in funding for 'biodefense', allocated by the US Department of Homeland Security.<sup>880</sup> There are no publicly-available statistics on the proportion

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<sup>878</sup> DARPA (2013) *Our work*, available at: [http://www.darpa.mil/our\\_work/](http://www.darpa.mil/our_work/).

<sup>879</sup> Guardian online (17 April 2012) *Military spending: how much does the military cost each country, listed*, available at: <http://www.guardian.co.uk/news/datablog/2012/apr/17/military-spending-countries-list#data>.

<sup>880</sup> Franco C and Kirk Sell T (2011) Federal agency biodefense funding, FY2011-FY2012 *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 9(2): 117-37; Moreno JD (2012) *Mind wars: brain science in the military in the 21st Century* (New York: Bellevue Literary Press). See also: National Research Council (2013) *Emerging cognitive neuroscience and related technologies* (Washington D.C: National Academies Press).

of this spend which is allocated to research on neurotechnologies, but it is likely to be only a small percentage of the total budget.<sup>881</sup>

- 8.66 Psychology was also an early recruit into military science, with an emphasis on interrogation and ‘brainwashing’, and also for the treatment of military personnel suffering from what came to be called post traumatic stress disorder (PTSD). During the 1960s, psychotropic drugs with effects on perception and behaviour such as LSD were explored in a series of clandestine and unethical experiments by the CIA and other US agencies.<sup>882</sup> DARPA has also funded research into the early development of artificial intelligence and robotics which have played an important role in the development trajectories of today’s novel neurotechnologies.<sup>883</sup> In the first decade of the 21<sup>st</sup> Century, other biological sciences, hitherto more allied to medicine than weaponry, including the neurosciences, have been added to the list of military research priorities.<sup>884</sup> There has been a steady rise in US military funding of neurobiological research in recent years, along with military and civil research interest in neuroactive agents.<sup>885</sup>
- 8.67 Potential interest in the application of the biomedical sciences to conflict settings is no longer necessary limited to wars fought between states, but may also extend to today’s asymmetric conflicts where the armed forces of technologically advanced, weaponised states may be set against groups of ‘insurgents’. In such conflicts, methods of obtaining *information* (concerning both individuals and organisations) may be of great importance, as is preventative or pre-emptive action taken before any presumed or actual threat. This has led to a convergence of interest between the military, and civil security and policing concerns.<sup>886</sup> The threat of terrorism has also raised concerns about the so called ‘dual use’ of the products of scientific research for hostile ends.<sup>887</sup>

## Defence-funded research into novel neurotechnologies

- 8.68 In addition to considerable investment by government departments in the therapeutic uses of neurotechnologies for treating physical and psychological injuries sustained during conflict (again the evidence of this investment is most apparent in the US, see Box 8.4), there is also notable interest in the *non*-therapeutic military potential of novel neurotechnologies, as we will now discuss. These applications include methods for enhancing the performance of a country’s own troops (for example, through improving surveillance and intelligence-gathering capacities),<sup>888</sup> but also using neurotechnologies to undermine the capacities of enemy forces, including through enhanced means of interrogation.<sup>889</sup>

<sup>881</sup> It is reported that, in 2011, DARPA invested \$240 million in the brain-machine interaction programme. See: Moreno JD (2012) *Mind wars: brain science and the military in the 21st century* (New York: Bellevue Literary Press), at page 53.

<sup>882</sup> *Ibid.*, pp. 89-90.

<sup>883</sup> Graubard SR (1988) *The artificial intelligence debate* (Boston: MIT Press).

<sup>884</sup> Moreno JD (2011) Brain trust: neuroscience and national security in the 21st century, in *Oxford Handbook of Neuroethics*, Illes J, and Sahakian B (Editors) (USA: Oxford University); Rose H and Rose S (2013) *Genes, cells and brains: the promethean promises of the new biology* (Croydon: Verso).

<sup>885</sup> Moreno JD (2012) *Mind wars: brain science and the military in the 21st century* (New York: Bellevue Literary Press), pp. 164-5.

<sup>886</sup> Lutterbeck D (2005) Blurring the dividing line: the convergence of internal and external security in Western Europe *European Security* **14**(2): 231-53.

<sup>887</sup> For further discussion of the issues of dual use, see: Dando M (2009) Biologists napping while work militarized *Nature* **461**(7258): 950-1; Marchant G and Gulley L (2010) National security neuroscience and the reverse dual-use dilemma *AJOB Neuroscience* **1**(2): 20-2.

<sup>888</sup> The Greenwall Foundation (2013) *Enhanced warfighters: risk, ethics, and policy* (San Luis Obispo: The Greenwall Foundation).

<sup>889</sup> Tennison MN and Moreno JD (2012) Neuroscience, ethics, and national security: the state of the art *PLoS Biology* **10**(3): e1001289.

## Enhancing effectiveness

- 8.69 In the UK, the Defence Science & Technology Laboratory (DSTL) adopts the role of maximising “the impact of science and technology for the defence and security of the UK.” An indication of DSTL’s interest of the role of neuroscience for military applications may be found in their programme supporting doctoral research on the role of cognitive neuroscience in “understanding, managing and optimising human performance”.<sup>890</sup> However, as we have already suggested, greater detail may be found in relation to US Government-funded research into enhanced military effectiveness.
- 8.70 With the increasing automation of the battlefield and the complexity of weaponry, there is continued pressure to enhance the speed and accuracy of analysis and decision-making both by combatants themselves and intelligence analysts.<sup>891</sup> For example, on the basis of proof-of-concept research, it has been hypothesised that a helmet-mounted non-invasive EEG worn by pilots could be used to detect neural indications of fatigue or cognitive overload, which would then be used by the BCI system to calibrate the kind of information and support supplied to the pilot.<sup>892</sup>
- 8.71 BrainGate, a company developing invasive BCIs for assistive technologies (as discussed in Chapter 2), received DARPA funding to enhance the speed, sensitivity and accuracy with which a combatant might analyse incoming information and respond appropriately to threats.<sup>893</sup> Similarly, in 2010, DARPA awarded a \$2.4 million contract to a company called Neuromatters to develop a prototype of a novel BCI ‘image triage’ system, termed C3Vision, under its *Cognitive technology threat warning system* research programme.<sup>894</sup> This programme includes investigation of the use of non-invasive BCIs to enhance the capacity of military personnel conducting intelligence analysis. It identifies potential signs of threat by recognising signals associated with event-related potential (ERP) responses that are triggered by recognition of significant stimuli (in ways similar to the ‘reactive’ games discussed in the first part of this chapter). These signals can be recorded in an operational environment as the analyst views photographic, binocular or video images, and are then processed in real time to select images that merit further review, thus speeding up decision making. In 2012, DARPA demonstrated a successful prototype.<sup>895</sup>
- 8.72 One further DARPA funded research programme is premised on the potential use of invasive BCIs in remote weaponry, controlled directly by operators’ brain signals.<sup>896</sup> A US patent has been granted jointly to Duke University and DARPA for “apparatus for acquiring and transmitting neural signals” for purposes including, but not limited to, “weapons or weapons systems, robots or robot systems”.<sup>897</sup>
- 8.73 Attempts to enhance the cognition of military personnel have hitherto generally employed drugs. Notably, these drugs have included the stimulant Ritalin, which is used to improve performance in some attention-related activities, and Modafinil, which was originally developed to treat

<sup>890</sup> Defence Science and Technology Laboratory (2013) *About us*, available at: <https://www.dstl.gov.uk/>.

<sup>891</sup> Kruse AA, Boyd KC and Schulman JJ (2006) Neurotechnology for intelligence analysts. In Defense and Security Symposium, (Florida, United States: International Society for Optics and Photonics).

<sup>892</sup> Schnell T, Melzerb JE and Robbins SJ (2009) The cognitive pilot helmet: enabling pilot-aware smart avionics *Proceedings of the SPIE* **7326**: 1-9.

<sup>893</sup> Moreno JD (2012) *Mind wars: brain science and the military in the 21st century* (New York: Bellevue Literary Press), at page 144.

<sup>894</sup> Neuromatters (2010) *Neuromatters awarded \$2.4M DARPA contract to develop C3Vision™ prototype* available at: <http://www.neuromatters.com/news-darpaniap3.html>.

<sup>895</sup> Kasanoff B (2012) DARPA’s new “brain-computer interface” makes you a pattern recognition machine, on at: <http://www.digitaltrends.com/cool-tech/this-is-your-brain-on-silicon/>; DARPA (2012) *Tag team threat-recognition technology incorporates mind, machine*, available at: <http://www.darpa.mil/NewsEvents/Releases/2012/09/18.aspx>.

<sup>896</sup> White SE (2008) Brave new world: neurowarfare and the limits of international humanitarian law *Cornell University Cornell International Law Journal* **41**: 177-210.

<sup>897</sup> Wolf PD, Nicoletis M, Morizio J and Chaplin J (2007) *Apparatus for acquiring and transmitting neural signals and related methods*, available at: <http://www.google.com/patents/US20050090756>



narcolepsy, but supplied to pilots on long flight missions to ensure wakefulness.<sup>898</sup> However, there has recently been increased military interest in the use of both TDCS and (r)TMS for purposes of enhancement. For example, DARPA programmes have focused on the use of such neurotechnologies to achieve accelerated learning and improved memory retention. Indeed, there are currently both in-helmet and in-vehicle TMS projects under trial.<sup>899</sup> As discussed in the first part of this chapter, however, the efficacy of such methods outside the controlled conditions of a research environment remains in doubt (see paragraph 8.12 to 8.14).

8.74 Although the focus of this chapter is upon non-therapeutic applications of novel neurotechnologies, any discussion of the role of military research and development programmes involving these technologies would be incomplete without reference to the considerable investment in therapeutic or assistive technologies, the aim of which is to address the grave physical and psychiatric damage suffered by military personnel. Some examples of these research programmes are provided in Box 8.4.

#### Box 8.4: Military research into therapeutic applications of novel neurotechnologies

Advances in frontline medical intervention have dramatically reduced the deaths of US and NATO troops in recent conflicts, notably in Iraq and Afghanistan. Concomitant with the increased survival rate, however, has been a great increase in the number of service personnel who lose limbs. Although vehicle armour and protective helmets aid in survival from roadside explosives, there is increasing evidence of long-term brain damage resulting from the blast. In addition, large numbers of army veterans suffer mental health disturbance and are diagnosed with PTSD (32% of those who had been physically injured, 14% of those who had never been injured).<sup>900</sup> This has provided a powerful spur to research on improving prosthetics and treating brain and psychiatric damage, including PTSD.

The hippocampus is a brain region essential for the encoding of new memories. The emotional salience of those memories engages another deep brain region, the amygdala. Animal research over the past decade has shown that if a memory is evoked, it becomes labile and can potentially be erased by pharmacological or neurophysiological intervention.<sup>901</sup> As PTSD is often associated with such painful memories, there have been suggestions that applying TMS directed towards such deep brain structures whilst evoking the memory might help erase it, or at least modulate its painful aspects.<sup>902</sup>

US military-funded research in these fields includes:

- **BrainGate** is a research programme that uses invasive BCIs to investigate the use of assistive devices by people with spinal cord injury, brainstem stroke, and motor neurone disease. People with these conditions are trained to control a computer cursor simply by thinking about the movement of their own paralysed hand. This research is funded, in part, by the US Department for Veterans Affairs.<sup>903</sup>
- DARPA '**Revolutionizing Prosthetics**' is a DARPA programme that has developed prosthetic arm systems including promising initial results with "brain control of an advanced arm system" in tetraplegic volunteers at the Johns Hopkins University Applied Physics Lab worked.<sup>904</sup>
- **REMIND (Restorative encoding memory integration neural device)** is a DARPA programme looking at memory loss and the inability to acquire new memories. They suggest that "A biomimetic model of the hippocampus could serve as a neural prosthesis for lost cognitive function and memory impairment."<sup>905</sup>
- **REPAIR (Reorganisation and Plasticity to Accelerate Injury Recovery)** is a DARPA programme that aims to better understand "neural computation and reorganisation to improve brain modelling and our ability to interface with

<sup>898</sup> Moreno JD (2012) *Mind wars: brain science and the military in the 21st century* (New York: Bellevue Literary Press), at page 136-7.

<sup>899</sup> National Research Council (2013) *Emerging cognitive neuroscience and related technologies* (Washington D.C: National Academies Press).

<sup>900</sup> Kean S (2012) From soldiers to veterans, good health to bad *Science* **336(6086)**: 1226-7.

<sup>901</sup> Sara SJ (2000) Retrieval and reconsolidation: toward a neurobiology of remembering *Learning & Memory* **7(2)**: 73-84.

<sup>902</sup> Osuch EA, Benson BE, Luckenbaugh DA *et al.* (2009) Repetitive TMS combined with exposure therapy for PTSD: a preliminary study *Journal of Anxiety Disorders* **23(1)**: 54-9.

<sup>903</sup> Department of Veterans Affairs (2012) *BrainGate research*, available at: [http://www.providence.va.gov/features/BrainGate\\_Research.asp](http://www.providence.va.gov/features/BrainGate_Research.asp); BrainGate (2012) *About Us*, available at: <http://www.braingate2.org/aboutUs.asp>.

<sup>904</sup> DARPA (2012) *Revolutionizing prosthetics*, available at: [http://www.darpa.mil/our\\_work/dso/programs/revolutionizing\\_prosthetics.aspx](http://www.darpa.mil/our_work/dso/programs/revolutionizing_prosthetics.aspx).

<sup>905</sup> DARPA (2012) *Restorative encoding memory intergration neural device (REMIND)*, available at: [http://www.darpa.mil/Our\\_Work/DSO/Programs/Restorative\\_Encoding\\_Memory\\_Integration\\_Neural\\_Device\\_\(REMIND\).aspx](http://www.darpa.mil/Our_Work/DSO/Programs/Restorative_Encoding_Memory_Integration_Neural_Device_(REMIND).aspx)

it.” The Agency’s aim is that these approaches could lead to new classes of devices to help rehabilitation following brain injury, restore impaired sensory function, and manipulate external devices.<sup>906</sup>

- **Regenerative medicine:** DARPA also provides large amounts of funding to research in regenerative medicine, although not specifically neural regeneration.<sup>907</sup>

## Degradation of enemy personnel

8.75 DARPA has funded studies on the possible long range uses of microwave radiation or magnetic fluxes to disorient enemy forces or insurgents at a distance,<sup>908</sup> although no realistic weapons system has yet been developed.<sup>909</sup> Similar mass-disruption applications using TMS (or other neurostimulation technologies) are currently beyond the bounds of practicability as these can only be administered at close proximity and on an individual level. More foreseeable applications of such technologies are in the interrogation of prisoners of war.

## Interrogation

8.76 As we have seen in the first part of this chapter, there are early suggestions in research environments that neurostimulation could have an effect on some kinds of brain activity associated with cognitive processes. For example, one study has reported an association between non-invasive neurostimulation and the slowing of participants’ generation of deceptive, but not truthful, responses.<sup>910</sup> It is therefore *hypothetically* possible to envisage the future employment of neurostimulation as a coercive interrogation technique, either to disorient an individual under interrogation, or to acquire information. However, as we have noted, the nature of research studies in which such effects have been recorded means that speculation as to their practical real-world application should be treated with caution.

8.77 Similarly, BCIs that identify brain signals associated with particular affective states, or ERP signals associated with the user’s recognition of significant images or information – for example, those relating to a crime scene – could potentially be used for interrogation. There have been proposals to employ technologies that measure ERP using EEG-based BCIs in this way, either pre-emptively to identify criminal, psychopathic or terrorist intent, or retrospectively to determine guilt or innocence. Indeed, there are commercial companies claiming to be able to identify terrorists on this basis.<sup>911</sup> It has been questioned whether such techniques would actually be effective or ethically defensible, particularly as they may be susceptible to false positive readings and to countermeasures adopted by those undergoing questioning.<sup>912</sup> Nevertheless, the company NoLieMRI, which makes similar claims, though based on the use of functional magnetic resonance imaging (fMRI), estimates its own market as \$3.6 billion.<sup>913</sup>

<sup>906</sup> DARPA (2012) *Reorganization and plasticity to accelerate injury recovery (REPAIR)*, available at: [http://www.darpa.mil/Our\\_Work/DSO/Programs/Reorganization\\_and\\_Plasticity\\_to\\_Accelerate\\_Injury\\_Recovery\\_%28REPAIR%29.aspx](http://www.darpa.mil/Our_Work/DSO/Programs/Reorganization_and_Plasticity_to_Accelerate_Injury_Recovery_%28REPAIR%29.aspx).

<sup>907</sup> Mason C (2007) Regenerative medicine 2.0 *Regenerative Medicine* **2**(1): 11-8, at page 15.

<sup>908</sup> Rose S (2005) *The 21st-century brain: explaining, mending and manipulating the mind* (Reading: Jonathan Cape), at page 292.

<sup>909</sup> Weinberger SS (2012) Microwave weapons: wasted energy *Nature* **489**(7415): 198-200.

<sup>910</sup> Lo Y, Fook-Chong S and Tan E (2003) Increased cortical excitability in human deception *NeuroReport* **14**(7): 1021-4; Hamilton R, Messing S and Chatterjee A (2011) Rethinking the thinking cap: ethics of neural enhancement using noninvasive brain stimulation *Neurology* **76**(2): 187-93.

<sup>911</sup> BBC Online (17 February 2004) *Brain fingerprints under scrutiny*, available at:

<http://news.bbc.co.uk/1/hi/sci/tech/3495433.stm>; Rosenfeld JP (2005) Brain fingerprinting: a critical analysis *Scientific Review of Mental Health Practice* **4**(1): 20-37.

<sup>912</sup> Canli T, Brandon S, Casebeer W *et al.* (2007) Neuroethics and national security *The American Journal of Bioethics* **7**(5): 3-13, at page 6.

<sup>913</sup> No Lie MRI (2006) *Investors overview*, available at: <http://www.noliemri.com/investors/Overview.htm>.

## Ethical and regulatory issues raised by military applications

8.78 In this report, we recognise that engagement in armed conflict, the conduct of armed forces in war and in the treatment of captured enemy combatants, raise vast and contested ethical questions. Some would argue that war is itself unethical, irrespective of how it is conducted.<sup>914</sup> Even if it is conceded that some wars may be fought for just causes, there remain unresolved debates about what constitutes defensible grounds for going to war or ethical conduct in war. Philosophical and theological debates about what constitutes a ‘just war’ date at least as far back as ancient Greece.<sup>915</sup> We do not enter into these wider debates here. That being said, it is clear that ethical and legal concerns and constraints *do* apply to military applications of novel neurotechnologies.

8.79 A network of rules of engagement, international treaties and conventions that attempt to govern military activities and the treatment of combatants, non-combatants and prisoners in ways broadly considered ethical have their origins in ‘just war’ debates and in international humanitarian law. For example, the treaties and additional protocols that make up the Geneva Conventions establish standards for the humane treatment of people during war.<sup>916</sup> The Hague Convention, meanwhile, concerns the use of weapons in war.<sup>917</sup> The specific threats of chemical and biological weapons, meanwhile, have led to international conventions forbidding the use of both of these categories of weapons, though not the research, development or even stockpiling of such agents. Subsequent revisions of the Biological Weapons Convention and the Chemical Weapons Convention banned these kinds of preparatory activities too. However, research into means of defending against the potential use of these kinds of weapons is, permitted.<sup>918</sup> This has arguably served several nations with a useful ‘get-out’ clause to continue studying potential agents under the rubric of developing defences. Although neuroactive chemicals or biological agents are covered by these conventions, it is notable that there are no instruments of international law which specifically address the fusion of physical sciences, informatics, and neuroscience that underpin the categories of neurotechnologies with which this report is concerned.

8.80 In the paragraphs below, we consider what we take to be the three main areas in which ethical questions arise in respect of the least speculative military applications of the neurotechnologies outlined above. These concern:

- the use of neurodevices in interrogation;
- the involvement of serving military personnel as participants in research; and
- the dual-use of neurotechnologies developed for therapeutic applications, but used for military purposes.

8.81 We have not included amongst these issues the possibility of using neurodevices for the direct injury or degradation of enemy combatants as we consider such applications still to be too speculative to warrant further attention. Some have suggested that special ethical issues are raised by the use of BCIs (as opposed to conventional controls) to operate weapons (for example, drones) from remote locations, on the grounds that neural responses may be too swift or non-conscious to be appropriately weighed or considered, thus raising doubts about moral

<sup>914</sup> See, for example, Russell B (1915) The ethics of war *International Journal of Ethics* **25(2)**: 127-42, at page 127.

<sup>915</sup> Orend B (2008) *War*. In, Zalta EN, ed. (The Stanford Encyclopedia of Philosophy).

<sup>916</sup> International Committee of the Red Cross (1949) *The Geneva conventions of 12 August 1949* (Geneva, Switzerland: ICRC).

<sup>917</sup> Carnegie Endowment for International Peace (1915) *The Hague conventions and declarations of 1899 and 1907* (New York: Press OU).

<sup>918</sup> Petro JB, Plasse TR and McNulty JA (2003) Biotechnology: impact on biological warfare and biodefense *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* **1(3)**: 161-8, at page 166.

and legal responsibility for any consequences.<sup>919</sup> However, in our view, the ethical issues associated with remote weaponry – which are very serious – relate not primarily to the use of neurotechnology in this context but to the context in which drones are employed in the first place.

## Interrogation

8.82 There are no specific treaties or conventions relating to the use of these neurotechnologies on prisoners of war as either methods of interrogation or torture. However, the use of neurostimulation or BCIs as interrogation devices may be seen as coercive. Their use to interrogate or disorient prisoners is therefore of dubious legality under Article 17 of the third Geneva Convention, which states, *inter alia*, that:

“No physical or mental torture, nor any other form of coercion, may be inflicted on prisoners of war to secure from them information of any kind whatever. Prisoners of war who refuse to answer may not be threatened, insulted, or exposed to any unpleasant or disadvantageous treatment of any kind.”<sup>920</sup>

8.83 In recent conflicts arising from the ‘War on Terror’, both actual and suspected fighters who were captured were deemed to fall outside international humanitarian law by the Bush administration. As a result these fighters were subject to varying forms of interrogation under physical and psychological pressure<sup>921</sup> (the Obama administration has since changed this policy).<sup>922</sup> Even parties who are not strictly classed as prisoners of war (for example, those who have laid down arms or have been taken prisoner in internal armed conflicts or civil unrest) are still covered by Article 3 of the Geneva Conventions, the Additional Protocol II to these Conventions: the Convention against Torture, and by international human rights law, including Article 3 of the European Convention on Human Rights that prohibits torture and inhuman or degrading treatment.<sup>923</sup>

8.84 The involvement of doctors in cruel, inhuman or degrading treatment of detainees is also prohibited under the Declaration of Tokyo.<sup>924</sup> However, as we have already noted in this report, non-invasive neurostimulation devices do not necessarily require operation by a medical professional. **We recommend that the armed forces and intelligence services consider issuing advice to their personnel that the use of neurodevices in interrogation is coercive and as such is prohibited under international humanitarian law.**

## Research and development

8.85 While the military use of a novel neurotechnology demonstrated to be safe and effective (as a means, for example, of enhancing perception or attention) would not raise ethical issues distinct from those we have considered in respect of civilian populations, their experimental use in military contexts prior to their safety and efficacy having been established does raise some different concerns. As we have observed, the long-term unintended effects of enhancement uses of even non-invasive neurotechnologies on otherwise healthy individuals have not been systematically investigated and are still uncertain. These are still experimental technologies and, as such, their research uses are governed by the Declaration of Helsinki. This requires that in all

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<sup>919</sup> White SE (2008) Brave new world: neurowarfare and the limits of international humanitarian law *Cornell University Cornell International Law Journal* 41: 177-210, at page 196.

<sup>920</sup> International Committee of the Red Cross (ICRC) (1949) *Geneva convention relative to the treatment of prisoners of war (third Geneva convention)*, available at: <http://www.unhcr.org/refworld/docid/3ae6b36c8.html>.

<sup>921</sup> Cobain I (2012) *Cruel Britannia: a secret history of torture* (London: Portobello Books).

<sup>922</sup> The Washington Post (23 January 2009) *Obama reverses Bush policies on detention and interrogation*, available at: [http://articles.washingtonpost.com/2009-01-23/news/36920354\\_1\\_executive-orders-detention-and-interrogation-task-force](http://articles.washingtonpost.com/2009-01-23/news/36920354_1_executive-orders-detention-and-interrogation-task-force).

<sup>923</sup> Article 3 of the European Court of Human Rights (1950) *Convention for the protection of human rights and fundamental freedoms*, available at: [http://www.echr.coe.int/NR/ronlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/Convention\\_ENG.pdf](http://www.echr.coe.int/NR/ronlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/Convention_ENG.pdf).

<sup>924</sup> World Medical Association (1975) *Declaration of Tokyo: guidelines for medical doctors concerning torture and other cruel, inhuman or degrading treatment or punishment in relation to detention and imprisonment* (Tokyo: WMA).

research with human participants, the well-being of the individual research subject must take precedence, that the research protocol must be reviewed by a research ethics committee. The Declaration also requires free and informed consent by the participant.<sup>925</sup>

- 8.86 Military personnel, however, are subject to a disciplined regime in which the concept of freely given consent becomes problematic. It is questionable what role, if any, informed consent has in some military contexts, because those serving in the armed forces have to obey reasonable orders from their commanding officers.<sup>926</sup> This raises the question of what counts as a ‘reasonable order’ and whether this would include instructions to undertake unproven neurological interventions in the interest of improving – or increasing the understanding of how to improve – combat effectiveness. In the context of the administration of an unproven prophylactic drug during the first Gulf War, a US federal appeals court held that it was possible that “legitimate government interests” could counterbalance an individual soldier’s interest in only taking part experimental treatment if they have given their informed consent.<sup>927</sup>
- 8.87 Clinicians and researchers conducting clinical investigations, in which military personnel are participants, are bound by professional ethical codes of conduct. In the UK, studies involving human participants that are undertaken, funded, or sponsored by the MOD must undergo scrutiny by its Research Ethics Committees (MODREC) and meet internationally recognised ethical standards.<sup>928</sup> However, in situations where the use of neurotechnologies constitutes experimental use rather than a formal research study, the position regarding ethical guidelines and informed consent may be more ambiguous. **We suggest that clinicians working with the armed forces may play a crucial role by exercising their duty of care to protect the welfare of personnel who may feel under pressure to participate in experimental military applications of novel neurotechnologies that carry uncertain risks and benefits.**
- 8.88 The question also arises as to whether military authorities would be legally liable for any harm experienced by military personnel required to make use of such devices in research contexts, or potentially, in the future, as part of their combat training. In the US the Feres doctrine – according to which members of the armed forces are barred from collecting damages from the US Government for injuries sustained while performing their duties – might seem to preempt such claims.<sup>929</sup> However, in the UK, the MOD long contested veterans’ claims relating to their experiences of ‘Gulf War syndrome’, before conceding that veterans suffering long term illnesses could be provided with “appropriate support” and financial assistance.<sup>930</sup>

## Dual use and opportunity costs

- 8.89 Concerns about ‘dual use’ technologies and products have been raised amongst those engaged in updating and revising conventions on chemical and biological warfare; that is, the use of these products for hostile as well as peaceful purposes without significant modifications being required.<sup>931</sup> The potential for the kinds of neurotechnologies we have discussed in this report to

<sup>925</sup> World Medical Association (2008) *WMA declaration of Helsinki - ethical principles for medical research involving human subjects*, available at: <http://www.wma.net/en/30publications/10policies/b3/>.

<sup>926</sup> Moreno JD (2012) *Mind wars: brain science and the military in the 21st century* (New York: Bellevue Literary Press), at page 156; The Greenwall Foundation (2013) *Enhanced warfighters: risk, ethics, and policy* (San Luis Obispo: The Greenwall Foundation), at page 72.

<sup>927</sup> *John Doe et al. vs Louis W. Sullivan, Secretary of Health and Human Services et al.* 938 F.2d 1370 291 U.S. App.D.C. July 16 1991, discussed in Miles SH (2013) The new military medical ethics: legacies of the Gulf wars and the war on terror *Bioethics* **27(3)**: 117-23. The drug was pyridostigmine and was administered to soldiers with the aim of protecting them from the effects of exposure to some chemical or biological weapons.

<sup>928</sup> Defence Science and Technology (2012) *Research ethics committees (MODREC)*, available at: <http://www.science.mod.uk/engagement/modrec/modrec.aspx>.

<sup>929</sup> *Feres v. United States*, 340 U.S. 135 (1950).

<sup>930</sup> Ministry of Defence (2012) *Gulf veterans’ illnesses*, available at: <https://www.gov.uk/gulf-veterans-illnesses>.

<sup>931</sup> Miller S and Selgelid MJ (2007) Ethical and philosophical consideration of the dual-use dilemma in the biological sciences *Science and Engineering Ethics* **13(4)**: 523-80, pp. 527-9.

be put to dual use has been raised by some commentators.<sup>932</sup> It has been argued that special ethical responsibilities are associated with technologies amenable to dual use and that it is important that scientists working in fields of research associated with these technologies are aware of the hostile uses to which they might be put – even if it is not possible to be specific about particular dual-use applications. Here the concern is not specifically with scientists who are already work on defence or security programmes (and who would, therefore, be aware of the military applications of their work), but with education and awareness-raising amongst the wider disciplines from which these researchers are drawn. We have suggested that continuous reflexive evaluation of innovation pathways is an important element of responsible research and innovation in neurotechnologies. We therefore welcome initiatives such as the Wellcome Trust-funded collaborative project on dual-use bioethics, one strand of which has investigated the current provision of ethical training in undergraduate and postgraduate neuroscience curricula in the UK.<sup>933</sup> This investigation reported that at the time it was conducted, only one neuroscience course had a dedicated ethics module and only a very small proportion of courses addressed the ethics of dual-use.<sup>934</sup> **We recommend that, as part of their ethical training, those studying for a higher degree in neuroscience should be alerted to the possible dual-use implications of neurotechnologies.**<sup>935</sup>

- 8.90 Even when neuroscientists *are* adequately informed of the possible applications for which innovations in neurotechnology could be directed, concerns may still arise as to the opportunity costs and cooption of inventiveness for military (as opposed to therapeutic) ends. This may be seen as a particular ethical concern where research is resource-intensive, ties up limited facilities and expertise, or risks participation fatigue amongst a small population of eligible participants. One response to this is that, not infrequently, research conducted for military purposes – such as research in the fields of regenerative and rehabilitative medicine – could have significant ‘reverse dual-use’ applications for wider therapeutic applications in civilian populations. Nevertheless, it might be argued that rather than rely on the hope of spin-offs that are of benefit to civilian populations, it would be a more efficient use of research resources to channel these *directly* towards unmet therapeutic needs of the population in general.

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<sup>932</sup> Tennison MN and Moreno JD (2012) Neuroscience, ethics, and national security: the state of the art *PLoS Biology* **10(3)**: e1001289.

<sup>933</sup> University of Bradford (2012) *About the project on building a sustainable capacity in dual-use bioethics*, available at: <http://www.brad.ac.uk/bioethics/about/>.

<sup>934</sup> University of Bradford: Bradford Disarmament Research Centre (2011) *Where is the ethics? ethical training in neuroscience curricula in UK universities*, available at: <http://www.brad.ac.uk/bioethics/monographs/>.

<sup>935</sup> Dando M (2009) Biologists napping while work militarized *Nature* **461(7258)**: 950-1.