

This response was submitted to the consultation held by the Nuffield Council on Bioethics on *Novel neurotechnologies: intervening in the brain* between 1 March 2012 and 23 April 2012. The views expressed are solely those of the respondent(s) and not those of the Council.

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Nuffield Council on Bioethics Consultation

Novel Neurotechnologies: intervening in the brain

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In this response to the Nuffield Council on Bioethics' consultation we have identified a number of issues that cut across all three areas (brain-computer interfaces [BCIs], neurostimulation, neural implants), and we have therefore considered these together. Where points are more relevant to one or more technology than to others we indicate this in brackets. We start with some general comments on the question of neuroexceptionalism, then consider specific ethical issues, and end with some comments focusing on BCI applications.

Our comments focus less on the specifics of what the technologies are capable of doing, and more on how the social, cultural, ethical and political contexts in which they will operate will play an important role in what results from their use. Such contexts should therefore be considered important aspects of evaluating potential social and ethical implications and, from what we know has happened with previous 'novel' technologies, should also make us aware that unanticipated consequences will be at least as significant as anything we can expect and plan for.

Neuroexceptionalism: is intervening in the brain either new or different?

The Introduction to the consultation document points out that interventions targeting the brain are not in themselves new. There are historical precedents of trepanning, ECT and so on which, as the document notes, eventually "came to be seen as treatments that were often inappropriate and sometimes harmful". There is a broad expectation that the interventions being developed today are more scientifically credible, and are being introduced in a more responsible way. Social science does not attempt any evaluation of the scientific validity of these technologies; what we *can* note, however, is that the earlier interventions were, in their time, also considered valid and effective. So the possibility that the current generation of novel neurotechnologies may also prove ultimately problematic, or simply disappointing, cannot be ruled out.

Many of the broad ethical issues raised are also neither new nor specific to neurotechnologies but have parallels and precedents in biomedical innovation as a whole, although certain dilemmas may present particularly strongly with these technologies (see discussion of consent, below).

Aside from the question of whether these technologies represent something *new* is whether they are something *different*: that is, whether possible manipulation of brain activity is exceptional or whether it simply represents another aspect of the progressive capacity to extend and improve human life via new technologies. Again, if we focus exclusively on the technology itself and the science behind it,

then the argument that neurotechnologies offer nothing significantly different from what is already done to the human body, and so requires no particularly stringent consideration of its ethical and social implications, seems convincing.

However, possible sources of exceptionalism do not lie solely with the technologies or their potential uses. What also needs to be considered, and which are salient here, are the social factors that provide the background against which ethical and social implications are to be evaluated. The first of these is the distinctive history of interventions in the brain – particularly in the field of mental health. This history means that any current anxieties expressed about possible damaging side effects, or the misuse of neurotechnologies as tools of social control, cannot be dismissed as ‘irrational’. Such a response not only disregards the significance of these concerns to people’s approaches to contemporary medicine (particularly people who feel especially vulnerable to the forcible imposition of these or similar technologies), but also overstates the ability of medicine to anticipate precisely how new forms of intervention will really be used in practice, and to predict possible side effects or risks.

A second reason is given by the socially and culturally embedded meaning given to the brain as a source of human identity and selfhood. Professional ethical debate as well as more popular unease both pick up on the fear that interventions in the brain, even if effective and without obviously adverse side effects, will have profound and potentially undesirable consequences on fundamental aspects of personality, personhood, ‘human nature’, free will and self-determination. While it is true that the same sorts of questions have been raised about other biomedical areas it is also the case that the link between interventions in the brain and human behaviour or consciousness is, or appears to be, much more direct than the effects of genetic manipulation, for example. Moreover, ‘the genes’ still do not have the same cultural resonance as the site of selfhood as ‘the brain’.

This significance goes beyond scientific knowledge of the physiology of the brain. For example, just as people who receive organ transplants sometimes claim to feel that some aspect of their selfhood has changed, it may be that brain interventions will similarly produce narratives of shifts in the way people relate to their identity. And while these perspectives are not scientifically plausible, it would be a mistake to dismiss them as irrational, emotional responses with no reality. They emerge from the interplay of technological intervention and the status given to the brain as the source of selfhood and identity, and so do have reality for those living within that interplay.

Therefore, we would argue that neurotechnologies warrant particular ethical and social scrutiny not because they necessarily *are* a new and different kind of intervention, but rather because they emerge within a unique and complex context of intersection between the history of intervention in, and contemporary cultural values placed on, the brain.

Consent in research, development, and treatment

Device prototypes are likely to be tested on non-human animals, most likely mammals and possibly apes, raising the ethics of animal experimentation at a time when such forms of testing are under increasing scrutiny. Eventually, human research subjects will be required. The existing legal, regulatory and moral frameworks for the use of human subjects in research may need adapting for invasive neurotechnologies. For instance, although new pharmaceutical agents are routinely tested on healthy volunteers, this is less appropriate for a device which may require being left in situ for extended periods and which has the potential to influence fundamental aspects of consciousness and behaviour. The potential gain of developing a major medical application of such devices would need to be carefully evaluated against the risk, and standardised protocols developed and applied.

The extension of research to patient populations introduces other levels of ethical and social concern, as the most appropriate research subjects are likely to be those at the more severe

end of the disease spectrum (compare early phase cancer drug research in patient populations). Some patients with conditions to which neurotechnologies may be applicable are also likely to raise issues of their mental capacity to consent to research. Although there are legal provisions in Scotland, and more recently in England and Wales, to allow for research involving adults who lack the capacity to consent, it is nevertheless recognised that such research remains ethically complex and requires careful review by expert research ethics committees. The safeguards enshrined within the law may need amendment in the light of developments in neurotechnology, and it may be advisable to establish a higher threshold for involvement -- as currently applies to an investigatory medicinal product (drug trials) as set out within the Clinical Trials Directive

One issue that raises ethical concerns in all areas of medicine is that of consent for interventions into children, in stages of research and development, and in treatment. This is likely to be of particular concern in the neurotechnological arena where some interventions may need to be put in place early in development, well before a person has capacity for consent, in order to be effective or to prevent longer-term damage. A long-standing criticism of medicinal products (drugs) research is that few drugs in the pharmacopeia have been developed for use in children. This may mean that novel neurotechnologies may have to be denied to children, or else tested on children, with all of the accompanying ethical sensitivities.

Cochlear implants, the earliest neuroprosthetic in routine use, provide a precedent. Cochlear implants are claimed to be only or most effective if given before the age of two or less, although it should be noted this claim has been contested. Similar claims and time constraints might hold for other neuroprosthetics/BCIs or for TMS given with the aim of cognitive enhancement. Here, the ethical problems of parents consenting for interventions on behalf of their children will obviously be exacerbated by the lack of knowledge (by anyone) about medium to long-term risks.

Regulation

Some neurotechnologies, particular BCIs and neurostimulation, are likely to fall within the remit of the Medicines and Healthcare Products Regulatory Agency (MHRA). However, at the time of writing, controversies over breast implants and metal hip replacements are raising difficult questions about the effectiveness of the MHRA, indicating that something more rigorous is needed to ensure patient safety and public confidence, and to apply reasonable controls to the market. Therefore it will be necessary to consider whether the current regulatory processes are 'fit for purpose' for neurotechnologies, and whether the relatively light touch scrutiny the MHRA has traditionally provided for products in comparison to the regulation of new drug treatments is still appropriate. Given the scope and potential of neurotechnologies a more robust approach is likely to be needed to ensure control (possibly through licensing) and quality control as these technologies are developed. This may prove problematic when the technologies are applied to social, entertainment, or military applications rather than purely medical/ care uses. The gaming industry, for example, might well feel it has or should have greater freedom to develop technologies outside of the strict controls usually applied to medical technology.

Novelty, hype and investment

In recent years a growing amount of concern has been expressed about overheated claims and artificially raised patient hopes, often but not solely media-driven, for new biomedicine and biotechnologies. In the case of neurotechnologies this habit is likely to be exacerbated by their novelty, by the apparent authority of very sophisticated and complex science, and by the awe

that direct intervention in the brain is likely to inspire. It is therefore important to remain sensitive to the risk that the excitement and enthusiasm about potentially powerful new therapies will divert attention, and more concretely money and other resources, from less high-tech solutions that could conceivably be just as effective, cheaper, and less invasive.

Security and dual use issues

An issue of particular concern for BCIs and neurostimulation is that of dual use – the potential for equipment, technology, or scientific findings which are meant to bring benefit, to be deliberately misused or inadvertently misapplied, with resulting societal harm. In many ways, the dual use dilemma provides a new angle on an old question: if a researcher's intentions are good – to contribute to scientific progress, to save lives or to improve the quality of life – then where does responsibility lie for the unintended and unforeseen malevolent use of such discoveries, and how can they be prevented? At present, much of the effort to regulate the sciences in terms of dual use focus on proposals for a protective oversight system designed to block projects and publications which pose a security risk.

However, there is very little research on whether or not many neuroscientists are aware of these efforts or their implications for scientific responsibility, although we know from previous studies that the majority of bioscientists have little or no knowledge of their ethical or legal obligations under related Conventions. This is true not only in the UK and EU but across many developing countries in Asia and the former Soviet Union. For example, one study found that neuroscience students 'received formal neuroethics teaching in less than 8 of the 20 major research-intensive universities in the UK and that neuroethics is mentioned on the neuroscience- or psychology-related websites of only five of the same 20 universities'. (Morein-Zamir and Sahakian, 2009).

Morein-Zamir, S. and Sahakian, B. J. (2009) Neuroethics and public engagement training needed for neuroscientists. *Trends in Cognitive Sciences*, **14** (2), 49-51.

Comments specific to brain-computer interfaces

BCIs that require invasive procedures to establish direct neural connections are particularly troubling for the reasons outlined above in relation to consent during research and development. Establishing a direct and possibly permanent connection to the brain, for example, carries the risk of infection and brain damage following insertion of a device, quite apart from any less foreseeable medium or long-term risks. A further specific concern arises from the known plasticity of the brain: could extended use of BCIs result in inadvertent permanent changes to the brain, with resulting effects on personality and behaviour?

BCIs are promising means of providing technological support to people with extremely limited physical ability to interact with the world through 'standard' body movements, and who currently are dependent on the work of personal care assistants. These technologies thus add to the existing repertoire of assistive technologies to improve the quality of life of people living with a variety of physical limitations, providing an enhanced level of control and agency over how they choose to live.

However, there are also some concerns drawn from our knowledge of other assistive technologies, such as forms of telemedicine. Electronic and remote devices like alarms, medication reminders, aids to memory and support with domestic activities such as bathing, cleaning, cooking, are increasingly held up as a solution to the problems of an ageing society, because they replace the need for human care with technological support. Replacing family or care assistants with technologies may be more efficient, and in some cases and for readily understandable emotional reasons may be welcome; but at the same time it may neglect the broader aspects of care that are provided by human interaction. Therefore, it is important to approach such technologies, including BCIs,

as a supplement to, rather than replacement for, human care that, because it can ideally be based on intimate knowledge of the person, can be flexibly responsive to their needs and wishes in a way that technological solutions may not be.

Further questions are raised by the potential for extended or dual uses of BCI technology. It is not hard to imagine the potential for abuse here, by the criminal justice system, within military discipline, or by oppressive regimes against political dissidents, for example. More banal but equally concerning is the extension of BCI and related technology to virtual gaming. Current gaming technologies seek to achieve ever greater realism in the gaming experience, and many critics have voiced concerns about the level of violence and sexual exploitation possible using such technologies (to say nothing of the politically biased worldviews implicit in many contemporary ‘combat’ games). BCI technologies may conceivably offer further routes for individuals to live out violent, anti-social or extremist activities in virtual worlds. And although at the moment it seems implausible that BCIs would ever be available in an unregulated way for gaming uses, if relatively cheap and less invasive platforms were developed, then control of access is likely to be very difficult (as is currently true of supposedly age-restricted computer games).

Summary and recommendations

We do not see the need for extreme concern in the development of these technologies for medical and other uses. What we do see is a need for regulatory processes to be robust and flexible enough (i) to engage with the social and technical complexity of their pathways into use, and (ii) to respond to the emergence of unforeseen uses and social concerns associated with their implementation.

We recommend that the Working Party should:

1. endorse further research into the dual-use possibilities of novel neurotechnologies;
2. support the development of methods for engaging, raising awareness, and training neuroscientists and neurotechnologists on their ethical and legal obligations.
3. conduct an early scoping exercise on the possibilities for regulation of novel neurotechnologies across all the sectors in which they are likely to be developed and used;
4. encourage funding bodies to support research into the social and ethical aspects of neurotechnologies running in parallel with the support given to research into the technologies themselves.