

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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General questions

1. Have you ever used a technology that intervenes in the brain, and with what consequences? Please describe your experience.

As a researcher, I was involved in the BRAIN research project (www.brian-project.org) where a multidisciplinary consortium investigated BCI technology over a 3 year period Sept 2008-Dec 2011.

2. If you have not used a technology that intervenes in the brain before, would you do so if you were ill? Why / why not?

Possibly, but this very much dependent upon circumstance and the performance and maturity of the technology.

3. Would you use a technology that intervenes in the brain for non-medical purposes, such as gaming or improving your cognitive skills? Why / why not?

Yes. Non invasive BCI is appropriate to such applications. As these applications are not safety critical, then some users may adopt them, if they provide some advantage. The analogy is with Nintendo Wii and Xbox Kinect. Accuracy is not paramount but usability is a key aspect. The main priority is safety and ensuring infection could not be passed. Thus technical advances in dry and disposable wet electrodes are important.

4. What are the most important ethical challenges raised by novel neurotechnologies that intervene in the brain?

Safety. Providing a benefit to research domain, and ensuring that no harm is done. Ensuring that expectations are managed appropriately for vulnerable people, while the science and technology improves over time.

5. In what ways, if at all, should the development and use of these technologies be promoted, restricted and/or regulated? Please explain your reasons.

There are two domains in BCI:

(i) Vulnerable people and scientific studies, where regulation is important. Highest ethical standards and governance apply.

(ii) Entertainment/ games, where regulation should be lightweight; although safety/hygiene considerations should always be adhered to. If the head-set uses muscle signals as well as brain signals to improve performance, then in this case it is fine.

Questions

Please be specific with regards to the type of BCI you are referring to in your answer

6. Have you used a BCI, and if so, with what consequences? Please describe your experience.

As a researcher, I have been involved in a research project (www.brian-project.org) where a multidisciplinary consortium investigated BCI technology over a 3 year period Sept 2008-Dec 2011. The aims of the project were: to move BCI out of the laboratory to the community; and that the technology could be used by non-experts. The project investigated BCI with healthy volunteers and people with brain injury using visual evoked potential and intended movement paradigms. In this study the healthy volunteers were generally more able to use the technology, whereas performance was poorer in people with brain injury.

7. If you have not used a BCI before, under what circumstances would you do so?

Inexpensive gaming headsets will probably lead any widespread uptake in BCI technology.

8. What are your expectations and concerns for BCIs?

BCI attracts significant media attention, e.g. <http://brown.edu/academics/brain-science/news/2012-05/people-paralysis-control-robotic-arms-using-brain-computer-interface>, was given prime time news slots on BBC/SKY in May 2012.

This exposure is important for the discipline and to be welcomed. However these advances take place in leading research institutions, involving many experts, many disciplines, investing significant research time with a very small number of vulnerable people, often with surgically implanted sensors. There is a danger that public expectation may be unduly raised, as to what the more generally available BCI technology (non invasive EEG based) can deliver.

However some BCI technology/applications are becoming available to the public. A speller called Intendix was released in 2011 by g.tec, followed in 2012 by SOCI, which provides screen overlay control for a computer (www.intendix.com) and this has shown promise for wider deployment. Games related devices have also been released, along with application development toolkits. It could be that either spelling for communication or alternatively computer gaming becomes the 'killer app', forcing BCI technology further into the mainstream.

Finding the right balance between appropriate publicity and undue optimism is a concern. However the discipline could well see more widespread scientific and user deployment in the next 5 years.

9. Are there any particular ethical or social issues associated with BCIs?

The BNCI Roadmap (Allison, 2011) highlights some of the key ethical, legal and social issues identified by stakeholders in December 2011. Below lists some of these aspects.

Responsibility and liability. When the BCI approach is unsuccessful, it may not be clear as to where a failing might have occurred; within the technology or with the user?

Managing User expectation. Expectation often is compromised by representation of BCI by the media (Nijboer et al, 2011).

Shared responsibility of BCI teams. Hasselager et al (2009) comment on team responsibility, discussing the understanding of BCI across research groups due to the heterogeneous skill-set, 'with a fragmented understanding of the overall picture'.

Side effects and Risks. Nijboer et al (2011) discusses the research communities' lack of agreement of potential side effects, and notes that little study has been done to determine negative side effects within the 'person'.

The additional ethical issues I have been involved with were:

Consent to participate for Vulnerable Adults. This issues has been addressed by Haselager et. al. 2009, who have made useful recommendations for BCI recording.

Safety and comfort of recording procedure. Flashing visual stimuli for 'visual evoked potential' protocol (need to exclude certain participants) and long recording times for 'Intended Movement' (concentration, tiredness, active involvement, motivation of participant)

Privacy of participants. A compromise was needed, as the research also required a rich description of the Brain Computer Interaction. Indeed some of the participants with brain injury were keen to assist dissemination activity, waiving rights to anonymity in photographs for example.

Ensuring Data Security. This is a standard issue for research projects, ensuring that the data is appropriated documented and securely stored.

Managing the development / testing cycle. The need to ensure deployment of robust software, when recording with vulnerable adults; in a study where technical development is ongoing.

The objective was to include user involvement throughout the project lifecycle to provide user informed development (Lightbody et al, 2010). Indeed it was important to treat users as 'partners' informing the development process. However, early involvement of the user raised ethical issues due to the stability of the hardware/software development. Yet, user involvement is

essential to fully understand the complexity of issues to be solved. At what point within a project is it ethical to include a vulnerable user group? This issue need to be a team responsibility, which can pose a challenge in creating an understanding for the need for caution when there is also a real enthusiasm to deploy the technology under development to the user for which it is aimed.

The risks revolved around managing user expectations. As part of the consent process such discussions took place, but in retrospect it was difficult to portray the complexity of the development process required for BCI to the non-technical user. Furthermore, this was initially compounded by the unrealistic expectations of the researchers themselves. The pace of such developments could have a negative effect on the user, as it might have been their belief that such a technology might have become accessible to them. There should be some responsibility post-project to keep interested users informed of the status of the continued progress.

A cause for concern in BCI is the effect of a negative trial result on the user. Recordings demonstrated that the user with brain injury had a lower accuracy than the healthy volunteer. Thus the people for whom the technology was intended were less likely to successfully apply it. With negative recording sessions it could be a concern that this would negatively impact the user. Personalisation is key to successful deployment, reflecting on protocols and signals that can be effectively utilised. However, this is time consuming (and hence costly).

10. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.

If BCI technology was deployed to the home setting then the risk factors need to be assessed, as with all assistive technologies. Although the technology was not aimed at control of prosthetic devices for example, it could be used within a smart home setting. Grübler (2011) discusses the importance of minimum reliability depending on application; as such the system would need to categorise the applications that could be supported by the user depending on their ability.

In 2009, Hildz (University of Mainz, Section of Neuroethics) proposed a European network with the following remit. She stated:

“The network is designed to the raising of awareness; the systematization of ethical issues; the prescription of ways and approaches to deal with them; the addressing of the social, cultural and anthropological impact of BCI technology; the documentation and comparison of legal regulations within Europe; the sharing and reflecting on the experiences with ethical committees made by the different teams and projects; and the establishment of general guidelines for good practice in BCI research and use.”

The network was not realised, but the ethical and regulation issues raised are still relevant today. A more detailed and standardised set of guidelines is

needed, when deploying BCI technology within vulnerable user groups that goes beyond data protection, session guidelines and informed consent. If standard guidelines in policy and practice were available then this could help to assist in such issues within interdisciplinary teams and provide a more objective viewpoint.

References

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