

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

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1. Please briefly describe the neurotechnology or neurotechnologies you are working with and the nature of your research. Please also describe whether you do basic/translational/clinical research.

Brain-computer interfaces. BCI's can be defined as systems that acquire brain signals, extract certain features and translate those features into commands for devices or software. I don't know how you guys define BCI's but there is a lot of difference between communities on what a BCI is.

I worked for 6 years to test BCI's with locked-in patients in their homes (using non-invasive EEG as well as invasive ECoG recordings). Currently I work in a dept whi develops BCI applications for the general population.

I've recently been awarded a Veni grant from the Netherlands Organisation for Scientific Research ([http://www.nwo.nl/nwohome.nsf/pages/NWOP\\_5TTCVA\\_Eng](http://www.nwo.nl/nwohome.nsf/pages/NWOP_5TTCVA_Eng)) to investigate the ethical, legal and social issues related to brain-computer interfacing. I aim to bridge the gap between the neuroengineers, neuro-ethicists and general public through finding a common 'terminology' on neurotechnologies, empirical studies and translational activities such as theatre performances for the public.

Finally, for the Dutch research consortium BrainGain ([www.braingain.nl](http://www.braingain.nl); budget: 24 million Euro) I am the public relations coordinator. I organize lectures from scientists to patient organizations, museum exhibits, demo's at public events, media attention and so on. BrainGain focuses on 3 topics: brain-computer interfaces, neurofeedback and neurostimulation. We are the largest neurotechnology consortium in Europe (apart from the Human Brain Project)

2. What, if any, are currently the main clinical applications of this technology?

Brain-Computer Interfaces: there are 2 companies selling BCI as an assistive technology based on EEG. They hardly sell any products for various reasons. There are many companies selling BCI's as gadgets and toys. They don't work so well but sell many products. Neurosky for example has already sold more than a million headsets.

Clinically, trials with BCI's and locked-in patients have been done and are still underway. No commercial implanted BCI is available though.

Overview of companies for BCI: [http://prezi.com/nnuig5ke\\_aia/the-marketability-of-brain-computer-interfaces/](http://prezi.com/nnuig5ke_aia/the-marketability-of-brain-computer-interfaces/)

3. What clinical applications of the technology do you envisage *in the future*? (Please try to specify a timeframe for these developments)

- between now and 5 years: more gadgets and toys based on EEG/EMG  
- > 10 years: implanted sensors that record ongoing brain activity. This will first be used for medical applications such control of robot limbs. Also, passive brain-computer interfacing is increasingly being studied in computer science right now.. Using the passive info (involuntary rather than the traditional voluntary signals) from users to enhance human-computer interaction. For example, when you make a

mistake when typing, your brain gives an error detection signal. If that signal would be fed back to the computer the typo might be automatically deleted. Some computer scientists believe that this will make our interaction with technologies more intuitive and smooth.

We also believe that implanted BCI's will be used for gaming, serious gaming and learning environments. Imagine a tool that can help detect which learning state a student is in and automatically optimally support when the next chunk of learning material should be presented to the student. And, if it detects the student is confused, it could alarm the teacher or something.

We've developed several scenarios for the roadmap on future brain-computer interfacing which has recently been send to the European Commission: [http://future-bnci.org/images/stories/Future\\_BNCI\\_Roadmap.pdf](http://future-bnci.org/images/stories/Future_BNCI_Roadmap.pdf)

4. What are, or were, the main barriers to overcome in translating your research into the clinical application(s)?

The main problem is not technology but the lack of knowledge. Everyone will first start about sensors and so on, but we don't really know much about the brain. There is a lack of theory development. Even if we can detect and classify mental states, we cannot transfer that knowledge from 1 person to the next person, or even from 1 day to the next day!

BCI's are currently unreliable, inefficient and very unusable.

Hardware problems are there of course: implanted electrodes that don't damage the cortex or build up scar tissue are needed; everything should be miniaturized; BCI's should be robust.

Biggest problem between neuroethicists and neuroengineers: definitional ambiguity of what a BCI is. See above.

5. How could the technology you work with help address unmet needs of neurologists and psychiatrists?

Until so far brain-computer interfaces have not helped neurologist and psychiatrists.

However, this questions leads me to mention another future use of BCI's. BCI's could be used to make a more sensitive diagnosis of coma, vegetative state and complete locked-in syndrome. See EU projects like DECODER: <http://www.decoderproject.eu/>

6. What do the technologies currently cost, and will it be possible to include them as part of regular service in the NHS? If not, what are the likely markets or funders?

I think g.Tec sells a BCI as assistive technology for a couple of thousands Euros (they've sold 30 to 40 systems, so no much). When I was working in Tuebingen (with prof. Niels Birbaumer) we did manage to get health insurances reimburse some of the systems we put together for patients. But it is not standard yet of course.

7. Are there currently any non-medical applications of this technology? How far have these been researched and developed and commercialised? Are devices you work with available on the internet/direct-to-consumer?

Games, gadgets (see prezi presentation, link above). They costs between 2 dollars (for an app) to 18.000 euros (product from a company in Sweden!).

8. What non-medical applications of the technology do you envisage *in the future*? (Please try to specify a timeframe for these developments)

gaming with your brain, enhancement of human-computer interaction. Technologies and ambient intelligences will become context-aware and user-aware thus allowing more intuitive interaction between humans and their world.

9. Are there any unexpected or unintended effects of the technology, and if so, how frequent and serious are they? (Where applicable, please include clinical and non-medical applications)

Side effects of BCI's are not empirically investigated. Researchers disagree on what side effects are.

Nijboer, F., Clausen, J., Allison, B., & Haselager, P. (2011). The Asilomar Survey: Stakeholders' Opinions on Ethical Issues Related to Brain-Computer Interfacing. *Neuroethics*, 1-38.

10. Is there anything in your area of research and development that you find particularly problematic? Where do you feel you need more guidance? What is there in the way of guidance for these problems already?

Media hype about brain-computer interfaces. Some researchers are really saying that thought reading is possible when it is not. Nijboer, F., Clausen, J., Allison, B. Z., & Haselager, P. (2011). Researchers' opinions about ethically sound dissemination of BCI research to the public media. *International Journal of Bioelectromagnetism*, 13(3), 108-109. Great problem: you get more money from Brussel the more you seem to brag in the media.

BCI's are being developed for locked-in patients, but no one is considering the fact that there are not so many of these patients, which in turn makes sure that no company wants to make products for such a small market. Thus... creating lots of hope and no benefit for patients.

Informed consent process with locked-in patients is not carefully executed by physicians. The patients are often treated as coma patients. BCI research actually created some awareness about this. We created some first guidelines on how to obtain informed consent: Haselager, P., Vlek, R., Hill, J., & Nijboer, F. (2009). A note on ethical aspects of BCI. *Neural Netw*, 22(9), 1352-1357.

## Questions if you work with patients

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11. In your experience, what do patients and/or users expect from the technology?

The locked-in patients I worked hoped to maintain communication through this technology.

12. What risks are patients and/or users willing to take, and why?

Some patients which I have seen were willing to risk even their lives (with an implanted ECoG operation) because they had no alternative. They could not imagine living without being able to communicate. This makes them very vulnerable.

13. How well-informed are patients and/or users about the technology, and how helpful is the notion of informed consent in your experience? What happens if patients lack the capacity to consent?

Depends how well informed they are. When BCI researchers come to their house it depends on BCI researcher what story he/she tells the patient. Haselager et al, 2009 mentioned this as the problem of shared responsibility.

Informed consent is obviously important, but there are many problems with this (see above). No one takes the time to test the validity, reliability and objectivity of yes/no signals of patients.

14. After an intervention: are expectations of patients and/or users regularly met?

In tuebingen we always made sure that expectations were tempered. Patients often still have too high expectations. But since in reality BCI's work so poorly of course some patients are going to be disappointed. Sometimes you can also see that BCIs can bring more quality of life than we researchers even expected. See for example the nice application from Munssinger, J. I., Halder, S., Kleih, S. C., Furdea, A., Raco, V., Hosle, A., et al. (2010). Brain Painting: First Evaluation of a New Brain-Computer Interface Application with ALS-Patients and Healthy Volunteers. *Front Neurosci*, 4, 182.

## Broader questions about the field of novel neurotechnologies

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15. If you consider the whole field of novel neurotechnology development, what advances do you believe are possible over the next ten years? What aspects (e.g. material technologies, theories of underlying mechanisms and pathways, treatment targets) of today's novel neurotechnologies will be with us in ten years' time?

chronic implanted micro-electrodes

16. Looking at the whole field, what are the main challenges/barriers in the innovation trajectory from idea to bedside/ market for novel neurotechnologies, and how could these be tackled?

Legal barriers: liability

Social barriers: public understanding and acceptance; researchers don't translate their research.

17. Recently concerns have been raised about the regulatory regime for medical devices both in the US and in Europe. What are your views on the current regulatory regime for novel neurotechnologies in your region, and in what ways, if at all, do you think it needs to be improved?

18. Could there be a need for more regulation of novel neurotechnologies *in the future*; and if so, what should this permit, prevent, and inspire?

19. Advances in neurotechnologies raise a lot of interest and many hopes. Do you believe that there is 'hype' surrounding these technologies? If so, how can we distinguish between the 'hype' and the reality? And who is responsible for creating the hope and for managing the hype?

Yes there is too much hype. Ethicists generally worry about the futuristic scenarios presented to them by neuro-engineers. Ethicist should first check the feasibility of the claims of the scientists. The scientist are often biased and give strategic answers.

20. What do you think are the main social and ethical concerns raised by novel neurotechnologies and their applications?

21. Who do you think should be the target audience for a report on the ethics of novel neurotechnologies that intervene in the brain? If the Working Party developed direct recommendations to any particular groups or institutions, who should they be in your view? What would you like the Working Party to recommend?

target audience: general public, health insurances