

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.

## **European Brain Council**

### **General questions**

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

Members of the European Brain Council, which represent a wide range of stakeholders involved in brain research and treatments, include patients, their families and carers, scientific societies and through them researchers, health care professionals and industry both pharmaceutical and device.

Our members have therefore got broad and wide experience of the use of such technologies, from many individual and varying viewpoints. This response encapsulates all the varied stakeholders. Overwhelmingly the experience is positive. With appropriate selection of patients, careful and long term monitoring, together with the intention of continued to monitoring the longer term impacts both beneficial and potentially harmful, we believe that these technologies are extremely useful additions to the therapeutic armamentarium for healthcare professionals and bring real benefits to patients

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?

In line with our previous response, without doubt we would use and have used upon us in the appropriate circumstances. Whilst the potential long term effects are to an extent unknown, they represent a life changing benefit for appropriately selected patients for patients now and most patients accept the potential for risk as a risk well worth taking. In fact the broader and more equitable use of such technologies is a much larger ethical issue than the potential long-term risk per se. Many patients have little alternative therapeutic options and have grossly impaired quality of life, these therapies can make a significant difference to lives of patients and those that care for them. A paternalistic approach from society is to be avoided, accepting that detailed consent will be necessary, including the potentially unknown long-term consequences. At this stage we are not aware of any such long term effects that are likely to alter the very real benefits seen and therefore the harm:benefit equation is strongly in favour of use in our opinion.

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?

This is more a question for individual opinion as opposed to the view of an organisation such as ours whose mission is to increase research funding for brain disorders and to improve the quality of life of patients of those that suffer from them

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

Appropriately consenting patients to their use, including communicating later side effects that may come to light.

As discussed earlier, in our view the ethical imperative of ensuring equitable access to these and other proven therapies for those who are most likely to benefit is a bigger issue than their introduction as such.

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.

UK and European regulatory processes are already considerable for health care interventions and should remain. Appropriate regulation which ensures that high quality scientific data remains the basis for approval of new technologies, together with clear safety and quality standards should apply to these products as much as any other. Promotion to health care professionals should follow similar lines. There should be no promotion to the public, however the provision of high quality non-promotional medical information should be able to be provided as part of the process of determining a patients suitability for these therapies

## 1) Brain computer interfaces (BCIs)

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### 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.

Some of our members have experience of these in a limited way in the medical setting where there are some very real potential uses and benefits. Although this is limited potentially helpful uses have been established without major side effects. The current invasive nature of this technology means that it should be restricted to those for whom the potential benefits clearly outweigh the risks, of at the very least the procedure related potential side effects.

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

8. What are your expectations and concerns for BCIs?

As technology evolves it could be possible to extend use way beyond that which has currently been considered.

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

As with all new technologies overuse in certain areas or in certain types of more addictive personalities could cause problems but this could be managed, awareness of the possibility is key

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

It is probably unrealistic to expect that such technology would only be used in the medical setting. In such circumstances a clearer regulatory framework would probably be necessary to include robust restriction to adults where this was possible, to avoid disturbing the developing brain. How this could be done is difficult to determine given the inability of society to restrict much adult only computer content

## 2) Neurostimulation

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### Questions

***Please indicate which technology (TMS, DBS) you are referring to in your answer***

11. Have you used neurostimulation and if so, with what consequences? Please describe your experience.

DBS has been widely experienced by our members, either as neurosurgeons implanting, clinicians prescribing or patients using, with extremely good results clinically.

Overwhelmingly the experience is positive. With appropriate selection of patients, careful and long term monitoring, together with the intention of continued to monitoring the longer term impacts both beneficial and potentially harmful, we believe that DBS is an extremely useful addition to the therapeutic armamentarium for healthcare professionals and bring real benefits to patients

12. If you have not used neurostimulation before, under what circumstances would you do so?

13. Under what circumstances do you think it might be acceptable to use neurostimulation in non-medical context (that is to say, not for the treatment of a disease or disability)?

We do not think this is appropriate, it would undermine the real value of use in the clinical setting, potentially undermine a valuable therapy.

14. Are there any particular ethical or social issues associated with neurostimulation?

Appropriately consenting patients to their use, including communicating later side effects that may come to light.

As discussed earlier, in our view the ethical imperative of ensuring equitable access to these and other proven therapies for those who are most likely to benefit is a bigger issue than their introduction as such.

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

We believe the current regulatory framework is appropriate, though given the time taken for new therapies to get to the patient, that a broader ethical issue of how to speed innovative new medicines and technologies to those most in need should be explored

### 3) Neural stem cell therapy

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#### Questions

16. Under what circumstances would you use neural stem cell therapy?

Many of our members believe that this is the next important frontier as they search for a cure for their current incurable disease. Others see this as an interesting potential research avenue to be explored and only if the key clinical questions answered appropriately should this be considered.

17. What do you think of the risks and benefits of neural stem cell therapy?

Benefits are potentially huge for sections of the population with long term neurodegenerative disease, side effects apart from the known ones associated with surgery are poorly studied and will require time to elucidate

18. Are there any particular ethical or social issues associated with neural stem cell therapy?

In our view no more than many other therapy interventions

19. How do you feel about neural stem cell therapy being used for non-medical purposes one day, for example for human enhancement?

We are not in favour of this, at this time

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

We believe the current regulatory framework is appropriate, though given the time taken for new therapies to get to the patient, that a broader ethical issue of how to speed innovative new medicines and technologies to those most in need should be explored