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.

Non-invasive brain-computer interface (BCI) technology. Clinical groups worked with include stroke (BCI enhanced neurorehabilitation therapy), spinal cord injury (BCI for alternative communication and control and entertainment) and minimally conscious state or disorders of consciousness (BCI for detection of awareness and alternative communication and control). I also work on BCI controlled games for entertainment and BCI training. Brain controlled video games can be used in training users to intentionally modulate their brainwaves for 1) gamers, to augment and improve the game playing experience; 2) in rehabilitation and therapy (post stroke rehab and ADHD treatment); and 3) for communication and assistive technology (to augment BCI training for those with severe movement problems).. I do basic research in terms of the signal processing and technology development along with clinical research involving trials of the technology with the above groups. We are currently translating our research in to commercially viable products and trying to focus on spinning-out the technology for clinical groups that can really benefit from the technology in its current state.

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

Alternative communication and control for the severely physically impaired.
Detection of awareness in disorders of consciousness
Neurofeedback therapy for stroke rehabilitation.

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

Stroke and neurorehabilitation : Motor imagery based neurofeedback therapy to improve outcomes after stroke.
robotics and robotics rehabilitation
BCI controlled functional electrical stimulation
neuroprosthetics
Clinical assessment of awareness in disorder of consciousness

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

Limitations of the technology, funding and time, finding the appropriate clinical partners. Extensive technology trials are required for the applications listed in 3 above. In 2 above, if the application works for a particular user and improves their quality of life then it can be used however there are barriers including cost, training requirements, technology and hardware limitations.

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

Up to 43% of patients diagnosed as vegetative are reclassified as (at the least) minimally conscious after

further assessment by clinical experts however there is a lot of evidence suggesting that a subset of patients diagnosed as vegetative actually have some level of awareness and are perhaps capable of controlling a BCI (see attached submitted but unpublished work). Clinicians are interested in using BCI for bedside detection of awareness and possibly offering people diagnosed MCS to communicate from a completely locked in state.
As outlined allowing the completely locked-in and severely disabled to communicate would improve the quality of life of these people but also help neurologists and clinicians to learn more about their conditions.
In stroke rehab motor imagery based BCIs can help clinicians device a better more advanced rehabilitation therapy schedules for in-patient care as well as in home rehab programs.

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?

Currently technologies range form £200 to £10000 for mobile recording of EEG. Some are approved for clinical use, some are not. Along with the BCI and proprietary hardware and software, training and specialist assistance in using the technology are still barriers to providing the technology long term at a cost effective price. We are working on this to ensure that health services can consider funding the technologies where there is a clear cost/benefit for the patient/client and their families. Obviously, if we can prove that the technology can enable someone who has not communicated with their family for 12 years and was assumed to have a severe disorder of consciousness to communicate then there is a good case to ask health services to fund the use of the technology for that person even if the technology is expensive.

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?

BCI based gaming and entertainment and executive toys have become popular over the past few years. Although these technologies have not be fully proven or tested they have attracted consumer sales. Companies include Neurosky, Emotiv and Mattel.

Anecdotal Evidence for Commercialisation: BNCI Games company Neurosky : shipped over 1 million ICs for EEG processing

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

BCIs have been linked with applications such as cognitive load monitoring, military applications, human enhancement, car control, control in hazardous environments, art, neuroeconomics, marketing etc.

many of these have been tested and some applications may be realised with the next 5-10 years

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)

1. side-effects (e.g. neurofeedback of sensorimotor rhythm training is reported to affect sleep quality)
2. sore head due to stimuli / flashing stimuli in games (no reports)
3. personal responsibility and its possible constraints (e.g. who is responsible for erroneous

actions with a BCI controlled prosthesis)
4. Long term use not yet significantly tested
5. Fatigue
6. gels and electrode may cause skin irritation

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?

Efforts are being made to standardize technology but at this stage it would be difficult to regulate the technology. No real issues have been identified. Regulation at this stage may unnecessarily inhibit development but may be needed for non-clinical applications.

Questions if you work with patients

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

Most patients (those who can provide feedback) understand what is possible. Spinal cord injury users know that there are many technologies that are more appropriate for them. They are still very keen to partake in trials.

- SCI patients want BCI for entertainment : 35 year spinal cord injury playing computer game for the first time
- 4 months SCI want to have even playing field to enable gameplay between him and sons. Both use a BCI to challenge or play against each other.
- MCS families are eager to carry our more trials as this is the only technology that has provided an indication of their sons awareness and may enable him to communicate
- Users are generally excited about the technologies prospects but aware of the limitations: Excited/motivated/something to do/interested in cutting edge technology

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

With non-invasive BCI there are minimal risks (side effects mentioned above)
Not many people would be willing to have surgery for invasive technologies

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?

Informed consent is necessary to comply with ethical standards. If there is an issue during the trials then informed consent is important. It is important that patients are explained the protocol before they partake in trials, any risks are highlighted and they are aware of the limitations.

Informed assent from medical teams and family members is important. Family members and clinical teams should be present during trials with those who cannot communicate needs. Family members and

clinical staff are normally able to identify when a patient/client is uncomfortable and/or becomes agitated. The participants willingness to participate needs to be assessed on an ongoing basis.

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

Expectations are never raised too high. Some who are able to control the BCI are happy with the outcome whereas others who are not able are less satisfied (30% of motor imagery based BCI users cannot reach an acceptable level of performance).

There are differing perception of an acceptable/meaningful level of accuracy by user, family/carers and the experimenter.

Patients and their families can sometimes misinterpret what is actually possible. In such cases it is necessary to explain. In the context of spinal cord injury motor imagery will ~~now~~ not improve hand function whereas stroke rehabilitation there is that possibility.

Conducting trials with MCS can be problematic: Families can consent but the client/user may not consent or may want more. Technology may be withdrawn without consent from the user.

Broader questions about the field of novel neurotechnologies

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?

BCI for alternative communication and control and assistive technology will be useable by more and more groups as the technology becomes more accurate.

If randomized controlled trials with BCI assisted rehabilitation therapy show clear improvements in outcomes after stroke rehab they will be integrated in rehabilitation programs.

BCI games are already in the market place for consumers.

BCIs are tipped as one of 7 technologies to disrupt this decade (http://www.newscientist.com/special/seven-technologies-to-disrupt-the-decade) and IBM predicts BCI technology will change our lives in 5 years (http://mashable.com/2011/12/21/ibm-kevin-brown-mind-reading/).

It is expected that more and more user groups will adopt BCI technology as the performance improves and cost is reduced.

Survey of BCI researchers indicate strong expectations for the next five years

Short term : specific patient groups (small market)

Stroke rehab, games and neuromodulation therapy have large market potentials

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?

Cost, clinically proven, trials, funding, commercialization issues, nascency of the technology?

- identifying the most appropriate mental tasks/EEG signals;
- enhancing training - better feedback, reduced training times
- developing hardware for ambulatory EEG – unobtrusive, practical, low power consumption and cost effective;
- developing biosignal processing algorithms
- enabling long-term and short-term autonomous system adaptability
- developing BCI-specific intelligent applications
- design and validation principles in HCI and AT need to be considered a lot more
- safety critical issues – risk/benefit analysis
- creating ethical standards and policies
- assessing user acceptance and the service and care required at the initial stages

More clinical support for trials, more funding for technology and fundamental 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?

Efforts are being made to standardise technology but at this stage it would be difficult to regulate the technology. No real issues have been identified for non-invasive technologies with the current user groups however this is likely to change~~s~~ as more users use the technology for longer periods. Regulation at this stage may unnecessarily limit the technology and could inhibit progress.

There is a need to consider standards and standard terminology.

Patients/disabled individuals/physically impaired/able-bodied/
customers/clients/subjects/participants/users

BCI terms : BC illiteracy/proficiency and technical terms

Referring to participants as Minimally Conscious is considered inappropriate terminology by family members who believe their family member to have good levels of consciousness but are total locked in.

Standards/certifications may be needed around terminology/technology

Companies, insurers and regulatory entities may need to establish if a device should heed existing regulations or guidelines

Terminology will matter to many groups in the long term

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?

See above response

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?

There is a lot of hype around BCIs. I think it is necessary to look at the research, clinical trials, RCT, large group studies, long term studies to determine the true state of the technology. Case studies with e.g. MCS, can show where the technology is at and provide evidence of clear applications in severe cases but normally one off non-peer reviewed studies and media commentary need to be taken with a pinch of salt, particularly if they are not supported by experienced researchers or published evidence.

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

1) obtaining informed consent from people who have difficulty communicating
2) risk/benefit analysis
3) shared responsibility of BCI teams (e.g. how to ensure that responsible group decisions can be made)
4) the consequences of BCI technology for the quality of life of patients and their families
5) side-effects (e.g. neurofeedback of sensorimotor rhythm training is reported to affect sleep quality)
6) personal responsibility and its possible constraints (e.g. who is responsible for erroneous actions with a BCI controlled prosthesis)
7) issues concerning personality and personhood and its possible alteration,
8) therapeutic applications and their possible exceedance
9) questions of research ethics that arise when progressing from animal experimentation to application in human subjects,
10) mind-reading and privacy
11) mind-control
12) selective enhancement and social stratification
13) communication to the media.
14) involuntary or 3rd party control of prosthesis/wheelchairs

Personal experience with BCI and issue that need consideration

- No participant remuneration : physically impaired users in trials
- Indemnity cover for negligent and **non-negligent** harm : Some patients are very sick : Should researchers be covered for non-negligent harm?
- Misinterpretation by users/families
  - Some participants in trials may never benefit from the technology
  - Confused about the outcomes
- Time involved in trials (accommodating schedules)
- Long term training /long training durations: how do we deal with that? Months/years. What affect does long term use have? (there is gap)
- SSVEP : continuous flashing frequency : sore head after an hour but one of the best BCIs : Risk of seizure/epilepsy
- Informed consent/assent for the locked-in/minimally conscious

- short trials / false hope : a participants inability to say they don't want **OR** want the technology
- differing perception of an acceptable/meaningful level of accuracy by user, family/carers and experimenter

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?

Health services and consultants, researchers, media, families and medical teams, funding bodies

Emphasize the importance of the technology and the imminent application that may be change lives.

Emphasize the need for large scale long term studies, Recommend funding.

- There is need to focus on ethical issues
- Lots of areas : focus on BCIs for AT (communication control(prosthesis, wheelchair, environment), stroke rehab/therapy and games
- Stroke rehab to induce plasticity needs to consideration
- Long terms use of the technology : what are the side affects?
- Do gamers develop mental or physical problems during long gaming sessions or long term use? Sleep issues? Headaches/seizures form VEP?
- Terminology/regulation/standards
- Consider users in research (partners) and in life/society (clients/consumers)
- What are the specific needs and is the technology tailored enough to needs?
- Games are used for training – once trained - moved to fill a function or application need
- **FBNCI project** emphasizes the lack of ethical consideration in funded projects, in a survey 86% of BNCI researchers said they would like ethical guidelines for BNCI in 5 years/ 57% said 2 years
- Nuffield Council on Bioethics could play an important role in this field (Ethical, legal and social issues (ELSI))