

NUFFIELD COUNCIL ON BIOETHICS

NOVEL NEUROTECHNOLOGIES: INTERVENING IN THE BRAIN CONSULTATION SUMMARY

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Introduction

In February 2012, the Working Party on *Novel neurotechnologies: intervening in the brain* launched a call for evidence in order to seek the views of the wider public about the issues raised by the project.

Respondents were provided with a background paper that gave a summary of the different novel neurotechnologies covered by the remit of the report (neurostimulation, brain-computer interfaces and neural stem cell treatment). Respondents were asked to answer 20 questions which can be found in Appendix 1. Forty individuals and 20 organisations submitted responses to the consultation.

This summary gives an overview of the responses received and summarises the issues raised by respondents in their answers. It does not, however, aim to evaluate the views expressed. Where there are footnotes in this document they include information submitted by respondents to the consultation.

This summary does not represent the views of the Working Party or the Nuffield Council on Bioethics.

1. Experience of a neurotechnology

Question 1 asked respondents whether they had ever used a technology that intervenes in the brain, and with what consequences. Expanding on this, questions 6 and 11 asked respondents if they had experience of using a brain-computer interface (BCI) or a neurostimulation device respectively. Those who responded to these questions included clinicians, researchers and people who had personal experience as patients or carers.

a) Positive experiences of technologies

Respondents who had experience of using a technology that intervenes in the brain (question 1) reported largely positive experiences. With regard to deep brain stimulation (DBS) and on behalf of its members, which include neurosurgeons, neurologists and patients, the European Brain Council reported “extremely good results clinically” and said that “overwhelmingly the experience is positive.” Another respondent reported witnessing positive effects despite initial incredulity:

“[M]any people describe the effects as ‘being themselves again’ after being ‘alive but dead inside’ and disabled for a number of years.”

Dr Andrea L Malizia, psychiatrist and clinical psychopharmacologist, responding to the Working Party’s consultation

b) Hope and disappointment

For those who had experience of using neurostimulation to address a medical condition there was some discussion about balancing the hope offered by the treatment, with any subsequent disappointment. In answer to question 11, one respondent reported that she had used DBS with the hope that it would improve her treatment-resistant depression that had affected her for over 30 years. Another respondent who had used DBS said that it gave her the feeling “that there was a light at the end of the tunnel” but that ultimately she was disappointed that the treatment had not worked. In the example below the respondent recognises some of the negative side effects and limitations of DBS but prioritises the feeling of hope:

“I have been pulled up by the DBS...My mood has improved from base-line but I think I have a way to go yet, I experience a lot more anxiety (usually over silly little things) now than before. I usually only get about 3 hours sleep a night, my short term memory is bad and I lack concentration which makes reading very difficult... I am not sure whether these were totally pre-existing but I am sure there are ways around them... DBS has given me the most important thing – HOPE.”

Anonymous respondent, responding to the Working Party’s consultation

c) Efficacy

In response to question 11 the Association of British Neurologists reported the results of an audit of their DBS patients:

“[P]atients experience a 56% improvement in their underlying illness severity...[there was] no occurrence of symptomatic haemorrhage in over 300 patients receiving operations in our hospital...”

Association of British Neurologists, responding to the Working Party's consultation

Another perspective was provided by a researcher participating in his own transcranial magnetic stimulation (TMS) research as part of his own research and reported that TMS was effective in improving mood:

“It was, in fact, effective in producing an altered (i.e.- improved) mood, and to some extent, heightened sense of clarity and intensity of the visual scenes presented, both acutely, and with increasing regularity and durability over the course of trial.”

Prof. James Giordano PhD, responding to the Working Party's consultation

On balance, reported experiences were positive. However, some limitations were noted. For example, in response to question 11 the Association of British Neurologists listed some side effects associated with DBS such as impaired clarity of speech and fluency of word production.

2. Attitudes towards novel neurotechnologies

a) Neurotechnologies for therapeutic uses

Question 2 asked respondents if they would use a technology that intervenes in the brain if they were ill. A number of respondents expressed interest in using neurotechnologies for a therapeutic purpose, including: to treat a neurodegenerative disease or severe depression; to regain function lost through disease; and for pain relief. One respondent acknowledged the potential unknown long-term effects but asserted that neurotechnologies represented a life altering opportunity.

b) Conditions for use

Some respondents said that they would use a neurotechnology that intervenes in the brain but provided qualifications for this use. A few of the qualifications related to the severity of the illness and the prognosis of the condition.

One respondent asserted that, given the risk of the intervention bringing about changes to personality, she would only use the neurotechnology if diagnosed with a life-threatening illness with no other treatment options. The same respondent said that the inevitability of death due to the illness would also prompt the use of such a technology, even if there was only a very slight chance of recovery.

Another respondent acknowledged unease about technologies that intervene in the brain and stated that they would have to be “quite ill” before they permitted the use of a neurotechnology on themselves.

Some qualifications related to the safety and/or efficacy of the intervention. For example, respondents cited improvement in quality of life, favourable risk-benefit ratio, and sufficient knowledge about the risks and benefits. One respondent wrote:

“Yes [I would use a technology that intervenes in the brain] ...provided I was convinced of the safety and efficacy of the procedure in remedying the illness... If the situation were desperate however, I might relax this requirement.”

Anonymous respondent, responding to the Working Party’s consultation

A few respondents felt that the decision about whether to use such a technology would depend on the context. For example, one respondent stated that it “entirely depends [on] what illness and what intervention” and another said that it would be “very much dependent upon...the performance and maturity of the technology.”

Brain-computer interfaces for therapeutic purposes

As well as answering a general question about the use of novel neurotechnologies, respondents were also asked to consider the technologies individually. Question 7 asked respondents if they had not used a BCI before, under what circumstances they would do so. A number of

respondents suggested that they would use a BCI if they had an illness or an injury that impeded normal neurological function such as the ability to move or communicate. The Royal College of Physicians reported that they would consider using a BCI “[w]here there is reasonable evidence that the results of previous neurological injury (of whatever sort) could be obviated.”

Neurostimulation for therapeutic purposes

Question 12 asked participants who had not used neurostimulation before, under what circumstances they would do so. A number of respondents suggested that they would consider using neurostimulation in response to a medical problem such as a “neurological illness” or “mental illness”.

Another perspective was provided by Chijioke G. Ogbuka, of the Albert Gnaegi Center for Health Care Ethics, who suggested that neurostimulation might be used to help people forget harmful and damaging memories:

“...certain kinds of traumatic events are better if out of the human memory system. Physical abuse, genocide and massacre, rape, war-related images etc. are examples of these traumatic events. Psycho-therapy for these kinds of traumatic events (post-trauma) seeks to reduce painful memories, and to enable the individual dissociate from these memories.”

Chijioke G Ogbuka, Albert Gnaegi Center for Health Care Ethics, responding to the Working Party's consultation

Other respondents were cautious in their assessment of neurostimulation and one participant said that while they might try non-invasive stimulation if they were “severely traumatized and hallucinating” they clarified that “...under no circumstances, including suicidal depression would I give DBS a try.”

Neural stem cell therapy for therapeutic purposes

Question 16 asked under what circumstances respondents would use neural stem cell therapy. Some respondents reported that they would use neural stem cell therapy if they had a “neurological condition”, “dementia” or a “brain lesion”. Others made the provision that the treatment would have to be proven to be safe or that they would be willing to use neural stem cell therapy if it was the last available option for treatment.

c) Neurotechnologies for non-medical use

Positive responses and reasons

Question 3 asked respondents whether they would use a technology that intervenes in the brain for non-medical purposes, such as gaming or improving cognitive skills.

Some respondents said that would use a neurotechnology for non-medical purposes. For example, Chijioke G Ogbuka of the Albert Gnaegi Center for Health Care Ethics highlighted the

importance, and also the history, of scientific advances improving human experience, whilst acknowledging that neurotechnologies raised specific issues due to targeting the brain:

“Throughout the history of science, scientific inventions have transformed human experience in aviation, telecommunication, electric energy, transportation, agriculture etc. Despite shortcomings and unfortunate accidents, all of these have greatly improved human existence. The difficulty with novel neuro-technologies is that they directly affect the fundamental human organ in a manner unlike before, and most of their reach as well as long-term potential risks remain relatively unknown.”

Chijioke G Ogbuka, Albert Gnaegi Center for Health Care Ethics, responding to the Working Party’s consultation

One respondent asserted that there was no distinction between enhancement achieved through use of neurotechnologies and that obtained through other means, such as education, transport and electronic communication.

A couple of respondents noted the potential use of neurotechnologies for new virtual experiences such as gaming:

“I would use technology that intervenes in the brain for many non-medical uses, think of a simulation game where it tricks your brain into believing you are working out or using your muscles vigorously, therein building actual muscle mass. Or being in such immersive virtual reality that you can actually fly or live out your dreams in a completely safe and isolated environment.”

Ryan Carlow, responding to the Working Party’s consultation

A few respondents gave conditional affirmations. For example, one respondent noted that he would use a neurotechnology for a non-therapeutic purpose “on the condition that I believed, on reasonable scientific grounds, that it were safe and effective.”

Negative response and reasons

A significant number of respondents said that they would not use a technology that intervenes in the brain for a non-medical purpose.

Some respondents reported concerns relating to safety while others queried the need for such interventions. For example, Professor David Stanley, School of Health, Community & Education Studies at Northumbria University, saw novel neurotechnologies for non-therapeutic purposes as “an unnecessary intervention”. Patrick Degenaar, School of EEE, Newcastle University highlighted the abilities that were already afforded by existing technologies: “Sensory enhancement devices such as night vision sensors, and mobile phones are in daily use – allowing us to do things that were not previously possible [and] without any need for neuroprosthetic intervention... As such, I would not recommend any invasive procedure for a long time for non medical purposes.” Alma Linkeviciute observed: “...I am also quite happy with my cognitive abilities for now.”

Other negative responses centred on the effectiveness of using neurotechnologies for non-medical purposes. Patrick Degenaar, School of EEE, Newcastle University expressed doubts on account of the capabilities of the technology and the limitations posed by the brain:

“My belief is that it will be a very long time before neuroprosthetic technologies have sufficient bandwidth to truly give additional benefit over non prosthetic interfaces...Deep Brain Stimulation technologically has yet to come out of the dark ages. Additionally, there are fundamental limitations to the brains architecture which could probably not be improved upon.”

Patrick Degenaar, School of EEE, Newcastle University, responding to the Working Party's consultation

Deng Zhuo highlighted the benefit of using other means to improve one's cognitive skills:

“As for [using neurotechnologies to enhance] cognitive skills, there are many more methods to improve them, including prodigious reading, writing and taking classes. These basic ways of bettering cognitive skills may take a longer time but give people time to think, enjoy the process and afford more comprehensive understanding for everything.”

Deng Zhuo, responding to the Working Party's consultation

Deng Zhuo also highlighted the potential harmful impacts on individuals, as well as a risk of addiction and dependence:

“With BCI, everything would be too easy and direct [and would] deprive people's natural abilities of meditation. The more ease the technology offers to us, the more lazy, simple and silly people's brains will be. Finally, people would be addicted to and dependent on the technology...”

Deng Zhuo, responding to the Working Party's consultation

With regard to invasive neurotechnologies, Patrick Degenaar, School of EEE, Newcastle University highlighted privacy and security concerns:

“...we have many hurdles in terms of security – the potential for hackers to eavesdrop or command destructive illusions, cause epilepsy or other negative consequences.”

Patrick Degenaar, School of EEE, Newcastle University, responding to the Working Party's consultation

A few respondents did not comment on whether they themselves would use neurotechnologies for non-therapeutic interventions, but set out some conditions for any such use. For instance, Fernando Lolas, MD, University of Chile, Interdisciplinary Center for Studies on Bioethics wrote: “I believe that any technique that affects the human body should be thoroughly tested before any medical or non-medical use is envisioned.”

Brain-computer interface for non-medical purposes

Question 7 asked respondents who had not used a BCI before, under what circumstances they would do so. Two respondents said they would be willing to use BCIs for non-medical purposes. One said they would use a BCI “[t]o enable new experiences, such as fully immersive virtual reality settings, consciousness expansion, and creativity exploration.”

Neurostimulation for non-medical purposes

Question 13 asked under what circumstances it might be acceptable to use neurostimulation in a non-medical context. One respondent thought that the use of neurostimulation would be acceptable for the development of new communication platforms, while another said that they would be willing to use non-invasive stimulation for the purpose of “enhancement or exploration”.

The Addiction Neuroethics Unit, The University of Queensland, differentiated between invasive and non-invasive neurostimulation emphasising that as the risks of TMS were far less than those for DBS “TMS for non-therapeutic purposes, especially scientific purposes, would be appropriate.”

A significant number of respondents felt that neurostimulation in a non-medical context would not be acceptable due to potential physical and psychological risks.

“Due to the surgical risks that go along with DBS and the stress of a brain surgery lasting several hours, I do not see any need and/or any motivation for someone to undergo such a procedure for non-therapeutic purposes.”

Markus Christen, Institute of Biomedical Ethics, University of Zurich, responding to the Working Party’s consultation

“Balanced against the significant risks associated with the technology, the use and trialling of DBS for cognitive enhancement is not warranted.” *Addiction Neuroethics, UQCCR, The University of Queensland, responding to the Working Party*

Neural stem cell treatment for non-medical purposes

Question 19 asked respondents how they felt about neural stem cell therapy being used for non-medical purposes in the future. A number of respondents raised concerns about the use of neural stem cells for non-medical purposes related to safety and potential risks.

3. Ethical issues raised by neurotechnologies

The ethical issues identified by respondents are detailed in the following sections. Specifically, question 4 asked respondents to identify the most important ethical challenges raised by novel neurotechnologies that intervene in the brain; questions 9, 14, 17, and 18 asked about ethical challenges raised in relation to the different technologies. In addition, some respondents outlined measures for addressing these issues. These are included at the foot of the relevant section.

a) Issues of uncertainty, safety and risk-benefit profiles

i) Uncertainty and safety

Respondents expressed concern relating to the uncertainty associated with neurotechnologies. For example, the following comments were made in answer to question 4, raising concerns about the risks (both short and long-term), the scientific basis of the intervention and efficacy:

“A partial understanding of the full scope of potential burdens, risks and harms that may arise from nascent technology... “Incomplete” science, viz. an incipient and/or partial understanding of neural mechanisms involved in/subserving processes of cognition, emotion and behaviors”

Prof. James Giordano PhD, responding to the Working Party’s consultation

“Efficacy may be difficult to assure, given that many variables are involved in the application of novel technologies...”

Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation

Such concerns were also identified in relation to specific neurotechnologies. For neural stem cell therapies, the European Brain Council observed that the side effects are poorly understood and will require time to elucidate. Prof Lewis Wolpert reinforced this sentiment noting “there is little understanding of the true nature of the stem cells and what they may do. There is still much research to be done.” A number of respondents also raised safety concerns relating to installation, replacement and any potential brain damage as a pertinent ethical issue relating to invasive neurotechnologies.

Brain–computer interfaces

Dr Paul McCullagh felt there was a lack of consensus and research regarding the safety risks of BCIs:

“Nijboer et al (2011) discuss the research communities’ lack of agreement of potential side effects, and note that little... has been done to determine negative side effects within the ‘person’.”

Dr Paul McCullagh, responding to the Working Party’s consultation

Policy, Ethics and Life Sciences Research Centre, at Newcastle University highlighted the operative risks associated with invasive BCIs:

“BCIs that require invasive procedures to establish direct neural connections are particularly troubling... 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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

Foresight took a more favourable view of this operative risk but still advocated the use of invasive BCIs only in severely disabled individuals:

“The surgery needed to implant electrodes against the motor cortex is minor (as brain surgery goes) and experience with cochlear implants and other devices using electrodes chronically implanted in the head suggests that issues related to infection and long-term performance of electrodes in the brain can be managed... However, for the foreseeable future, BCIs would appear best suited to enhance communication in severely disabled individuals.”

Foresight, Government Office for Science, responding to the Working Party's consultation

Neurostimulation

Respondents described safety concerns with regard to neurostimulation, specifically TMS and DBS. In its response, Addiction Neuroethics, at the University of Queensland wrote: “TMS raises fewer health and safety concerns than neurosurgery or DBS because it does not involve physical penetration of neural tissue¹” However, it continued: “... it has been reported to cause psychotic and epileptic symptoms in a minority of patients.²”

Neural stem cell therapy

The safety of neural stem cell therapy drew several comments. Somatic risks detailed included:

¹Anand S, Hotson J. Transcranial magnetic stimulation: neurophysiological applications and safety. *Brain and Cognition* 2002; 50:366-86.

² Machii K, Cohen D, Ramos-Estebanez C, Pascual-Leone A. Safety of rTMS to non-motor cortical areas in healthy participants and patients. *Clinical Neurophysiology* 2006; 117:455-71; Wassermann EM. Risk and safety of repetitive transcranial magnetic stimulation: report and suggested guidelines from the International Workshop on the Safety of Repetitive Transcranial Magnetic Stimulation, June 5-7, 1996. *Electroencephalography and Clinical Neurophysiology - Evoked Potentials* 1998; 108:1-16.

“...risks associated with the origin of the cell to be administered. Further the implantation procedure which...may itself be the cause of severe impairment or could pose a potential life threat to the patient.”

European Medicines Agency (EMA), responding to the Working Party's consultation

“...immune rejection of the implant, the acquisition of genetic disorders or viral diseases (e.g. HIV), uncontrolled proliferation of the transplanted stem cells (e.g. tumorigenesis), and migration of cells from the site of implantation to produce seizures, neurogenic pain, and dyskinesias.”

Addiction Neuroethics, UQCCR, The University of Queensland, responding to the Working Party

There was some consensus amongst respondents regarding these risks. The Association of British Neurologists, however, felt that the potential risks should not be overstated and characterised the risks as being:

- “(a) From the surgery itself (which is very minor)
- (b) Overgrowth of the cells, which I think is unlikely given what we can do with the derivation of these cells nowadays
- (c) Infection which again I think is minimal
- (d) Migration and integration into “normal” circuits which is unknown and could be a problem
- (e) Immune rejection
- (f) Hype around what can be achieved in the first into man trials
- (g) The occurrence of the disease in the grafted cells especially in case of iPS cell derived cells.”

Association of British Neurologists, responding to the Working Party's consultation

Psychological risks were also mentioned. The European Medicines Agency cautioned that: “A further aspect to be considered is how the implantation of stem cells (autologous and allogenic) in a human brain will impact the patients' neurological functions and eventually behaviour.”

Addiction Neuroethics, UQCCR at the University of Queensland were concerned that the safety focus was on “speculative risks”, such as unintended modulation of neural networks, compared with the “more plausible immediate risks”. They wrote:

“All of these putative risks [e.g. modulating neural networks] presuppose that the progeny of transplanted stem cells are able to make functional connections with other neural cells or a network of cells in the adult brain in ways that will change brain function. We do not believe that this presumption is supported by evidence from animal studies. Analysis of such speculative risks may distract attention from

the more plausible immediate risks of implanting foreign material into the human brain.”

Addiction Neuroethics, UQCCR, The University of Queensland, responding to the Working Party

iv) Suggestions for addressing issues

The Mission and Public Affairs Council, Church of England, recommended robust regulation in view of the somatic and psychological risks. It wrote:

“Because of the potential risks to mental and physical health associated with the introduction of novel neurotechnologies, it is essential that robust regulation is introduced to maximise their safe application.”

Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation

b) Autonomy and agency

i) Agency

Christians Against Mental Slavery articulated their anxiety with regard to this potential for external control and highlighted several likely candidates for such misuse:

“Christians Against Mental Slavery members would be especially concerned about any application of neurostimulation that was inflicted without continuing informed consent, and which was intended or likely to influence human thought. One suspects that the following industries are amongst those most likely to wish to inflict the technological influence of human thought without consent: the military, intelligence, security, anti-terrorist, law enforcement, counter-insurgency, mental health, social control, political repression and advertising.”

Christians Against Mental Slavery, responding to the Working Party’s consultation

ii) Autonomy

Ethical issues relating to autonomy were divided between therapeutic and non-therapeutic uses of the technologies. With regard to therapeutic uses, one respondent highlighted the tension between allowing patients to act autonomously, for example by taking risks in almost futile situations, whilst also protecting vulnerable patients from exploitation:

“We must respect an individual’s right to take risks when circumstances dictate e.g. DBS for a debilitating, function losing tremor in MS, whilst protecting vulnerable people from untested treatments eg untested neural stem cell implantation.”

Anonymous, responding to the Working Party’s consultation

Dr Andrea L Malizia, psychiatrist and clinical psychopathologist, identified the possible restriction of individual freedom by regulation, as being one of the most important ethical

challenges arising. With regard to autonomy issues relating to non-therapeutic uses, concerns were raised about potential uses for enhancement. For example, Alma Linkeviciute speculated how individuals might be coerced into such uses:

“There might be pressure from parents to use it on children, teachers on students, employers on employees; in military it might become obligatory if it enhances performance. Even for professions [where] human factor mistakes are undesirable[,] like pilots, traffic controllers, public transport drivers, medical staff [they] might be forced by the society to be cognitively enhanced for the sake of everybody.”

Alma Linkeviciute, responding to the Working Party’s consultation

Cesagen relayed comments from a workshop, which highlighted how use for enhancement could further entrench societal and environmental problems:

“Some [of the workshop attendees] also remarked that we might choose enhancements that cannot change our societies, only deepen already entrenched societal and environmental problems, thus leave us with less rather than more choice. In that sense we make collectively informed choices with collective rather than individual consequences.”

Cesagen – the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party’s consultation

c) Informed consent

i) Issues

In response to question 4 some respondents highlighted issues relating to informed consent. One of the most frequently raised concerns was whether a person with diminished mental or physical capacity due to a neurological condition or brain injury would be able to give truly informed consent. For example, the Association of British Neurologists questioned the “ability of the patient with a neurological condition to give informed consent for experimental invasive trials of this nature”. This concern was also extended to people in persistent vegetative or minimally conscious state:

“[In the context of DBS for persistent vegetative or minimally conscious state] can one therefore offer any treatment without patient consent that may prolong life or heighten awareness of what must be an intolerable existence?”

Professor Tipu Z Aziz, F.Med.Sci, Professor of Neurosurgery, University of Oxford and Mr Alexander L Green FRCS(SN) MD

Concern was also raised about informed consent procedures with children when technologies are still in development and research stages:

“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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party’s consultation

Scully et al. went on to highlight how children could effectively miss out on such technologies:

“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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party’s consultation

Other responses acknowledged the difficult situation faced by patients who had exhausted all other therapeutic options, leaving neurotechnologies as their last resort or last best hope:

“Severe illness can render people extremely vulnerable. When faced with the prospect of death or serious illness, the offer of hope can also be coercive.”

British Medical Association, responding to the Working Party’s consultation

“...we recognize how desperate some of the families and individuals with dementia are, and we can see that they might be tempted to undertake risky or dangerous interventions to escape from the horror of their situation.”

Dementia Services Development Centre, University of Stirling, responding to the Working Party’s consultation

“Since DBS is often used as a last resort procedure, expectations and desperation may create substantial challenges for free and informed consent.”

Markus Christen, Institute of Biomedical Ethics, University of Zurich, responding to the Working Party’s consultation

ii) Suggestions for addressing issues

Various respondents provided suggestions for improving informed consent practices. For example, in acknowledgement that seeking informed consent from locked-in patients for invasive BCIs could be problematic, Dr Paul McCullagh asserted:

“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.”

Dr Paul McCullagh, responding to the Working Party’s consultation

With regard to decision making by individuals with diminished capacity, the Wellcome Trust highlighted the pertinence of the Mental Capacity Act in research involving humans:

“Given that some neurointerventions may be specifically targeted at treating those with reduced capacity to make decisions about their own care, it is important to note that the application of the Mental Capacity Act (2005) in research already requires a balancing of the risks with the benefits in order for those who lack capacity to be enrolled in research. The potential benefit to the individual must outweigh the risks and be in proportion to the burden of risk undertaken, or there must be a benefit to society and negligible risk for the individual [Section 30-34 of the Mental Capacity Act (2005).]”

The Wellcome Trust, responding to the Working Party’s consultation

In relation to the use of DBS to treat addiction, Addiction Neuroethics, UQCCR at the University of Queensland, called for:

“...independent oversight of the consent process to ensure that patients have the capacity to provide free and un-coerced consent that is based on a realistic appreciation of the potential benefits and risks of DBS...” In addition, they emphasised that: “DBS should not be trialled in patients who lack the capacity to provide free and informed consent either because of their illness or because of external pressure that may indirectly arise as a result of their illness, such as social or legal coercion to be treated for addiction.”

Addiction Neuroethics, UQCCR at the University of Queensland, responding to the Working Party’s consultation

There were also general suggestions with regard to consent. Markus Christen, Institute of Biomedical Ethics, University of Zurich, proposed for the purpose of enhancing informed consent:

“...the development of a “living database” that contains the consecutive, standardized outcomes of all DBS treatments of a multitude of neurosurgical centers. This database should be available online and be continuously updated. An independent organization, optimally a patient organization, should organize the database; it should be supported scientifically and financed by public resources.”

Markus Christen, Institute of Biomedical Ethics, University of Zurich, responding to the Working Party’s consultation

d) Security and privacy

i) Security

Some respondents voiced concerns about the possibility of external parties being able to exert some kind of harm, or control an individual, using an invasive neurotechnology, raising challenges to autonomy, as previously described.

“An attacker of sorts could short-circuit the chip and kill you, control or persuade your thoughts and actions, or even completely control your motor functions and play you like a sims character.”

Ryan Carlow, responding to the Working Party's consultation

Cesagen, the ESRC Centre for Economic and Social Aspects of Genomics, raised the prospect of human brains 'going online':

"It is not far-fetched to envision applications that, for one or another purpose, read neuro-signals. If such implants find currency, whether that is for medical, non-medical, even recreational purposes, they will take bodies and minds online and thereby integrate them directly in what appears to be indefinite expansion of cyberspace. We observe here a whole host of social-cultural, health, safety and security implications which blur the boundaries between cyber- and biosecurity."

Cesagen - the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party's consultation

ii) Privacy

Several responses cited or alluded to issues of privacy. David Coe described the issue of one's immediate privacy being invaded:

"The ability of governments or corporations to 'read' thoughts, without your knowledge would be a huge invasion of individual liberty."

David Coe, responding to the Working Party's consultation

The Christian Medical Fellowship described their concerns about BCIS and the invasion of immediate privacy, and how this would ultimately restrict an individual's autonomy:

"BCI's also generate concerns with civil liberties and privacy, including ownership of data, access to data, recording conversations, surveillance, monitoring devices that will enable the surreptitious collection of human subject data, chips and sophisticated databases, including genetic databases.

Ironically, all would serve to restrict individual autonomy. Personal autonomy would be reduced to the extent that individuals would have less control over what people knew about them, which would make individuals more vulnerable to government and employer control."

Christian Medical Fellowship, responding to the Working Party's consultation

iii) Suggestions for addressing issues

Recommendations for security and privacy were similar or overlapping. Below is an example of the suggestions made:

"Some mechanism should be established for encryption or other barriers to transfer across the standard Brain Machine Interfaces."

Bob Whitcombe, responding to the Working Party's consultation

e) Identity

i) Individual identity

Several respondents discussed the potential impact of neurotechnology use on the identity of the individual. For example, some concerns were raised about authenticity and concepts of self:

“...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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

With regard to neurostimulation, Prof James Giordano PhD queried how identity changes should be balanced against any beneficial effects:

“What should be done if and when an intervention such as neurostimulation (or any other neurotechnology) both mitigates pathologic signs and symptoms, and also induces changes in personality traits and personal identity?”

Prof. James Giordano PhD, responding to the Working Party's consultation

He further considered:

“...important ethical questions might be whether neurotechnologic interventions such as transcranial or deep brain stimulation threaten, diminish or augment certain personality traits and personal identity, and how such alterations affect the patient, as well as her personal and professional relationships. How will these effects be judged – and by whom?”

Prof. James Giordano PhD, responding to the Working Party's consultation

Neural stem cell therapy also raised the issue of identity through the potential transplantation of material that was not one's own; for example, there were the following comments:

“...concerns about “identity” given the extent of implanted “non-self” (i.e. xenotransplanted) tissue, shifting constructs of personal and community ontologies, and definitions of normality.”

Prof. James Giordano PhD, responding to the Working Party's consultation

Further to this, Cesagen recommended ethnographic research into the public understanding of brain tissue:

“It would be of value to conduct systematic ethnographic research on the understandings of tissue donors and potential patients as to any recognition of a special status accorded to tissue engineered brain tissue as opposed to other tissue types -- e.g. liver, kidney, skin etc in notions of identity and selfhood.”

Cesagen – the ESRC Centre for Economic and Social Aspects of Genomic, responding to the Working Party's consultation

ii) Human identity

Respondents also discussed the impact of neurotechnology use on *human* identity more broadly (i.e. what it is to be a human being), and what are the implications of changes to this notion. For example, the National Bioethics Committee of Jamaica thought that there could be an “impact on our current concept of ‘human’ resulting in a lessening of respect for the person”. Other comments regarding the impact on notions of *human* identity arose in the context of enhancement. For instance, there were the following comments:

“If I am my brain, am I still fully human if I employ the use of brain-intervening technologies perhaps to improve and enhance my cognitive skills?”

Chijioke G Ogbuka, Albert Gnaegi Center for Health Care Ethics, responding to the Working Party’s consultation

“The integration of silicon or carbon chips into our systems to enhance our health and other abilities is simply an extension of the applications of tools.” He continued at a later point, highlighting young people as early adopters...Adoption will drive a wedge between technology luddites on one side (“Fleshies” – in support of the “pure” human) and today’s youth who think nothing of body paint, tattoos and piercings as vehicles for differentiation. They will love the idea of an integrated iPhone”

Bob Whitcombe, responding to the Working Party’s consultation

“Whilst some advocates can see no reason to remain fully human if we can evolve into, or create, creatures ‘better’ than ourselves, the deepest fear that most people express about new technologies and enhancement is that they will cause us in some way to lose our humanity – the essential quality that has always underpinned our sense of who we are and where we are going.”

Christian Medical Fellowship, responding to the Working Party’s consultation

iii) Suggestions for addressing issues

The British Medical Association highlighted the possibility of the need for regulation:

“Given that the seat of these defining human qualities is understood as residing in the biochemistry of the brain, and that neurotechnologies hold out the prospect of altering this chemistry, it is not surprising these technologies are giving rise to concerns about the loss or transformation of fundamental human characteristics. Should it become clear that neuroscience and the technologies [...] have a direct impact on these fundamental human concepts and [are] opening them up for re-fashioning, then the case for ethical oversight and, possibly, regulation is likely to be strong.”

British Medical Association, responding to the Working Party’s consultation

f) Responsibility

i) Issues

Some respondents described issues concerning responsibility (i.e. responsibility of the neurotechnology user). For example, would using BCIs to control devices have an effect on the individual's behaviour and their *perception* of responsibility?

“How would behaviour change if our physical bodies were no longer the principal, local agents of action? Would it become riskier? More irresponsible?”

Anonymous respondent, responding to the Working Party's consultation

In the context of neurostimulation, there was similar consideration as to whether deep brain stimulation for treatment of abnormal behaviour (e.g. aggression) would actually decrease the individual's feelings of personal responsibility for their behaviour. Professor Aziz and Mr Green of Oxford University wrote:

“Does DBS effectively reduce the individuals' responsibility towards their behaviour rather than encouraging them to accept the responsibility?”

Professor Tipu Z Aziz, F.Med.Sci, Professor of Neurosurgery, University of Oxford and Mr Alexander L Green FRCS(SN) MD, responding to the Working Party's consultation

Michael Madray questioned whether individuals would apportion moral responsibility differently when a BCI was in use.

“In our relationships with others, we have what Peter Strawson called “reactive attitudes” to the acts of others (Strawson 1962)... there are conditions which must be met in order for someone to be considered morally responsible for an act... an agent must know what she is doing and she must be in control of her acts (McKenna 2012). When one of these conditions is not met, we may be inclined to suspend our reactive attitudes. What kind of reactive attitudes will we have towards acts mediated by a BCI?...The issue of moral responsibility for acts performed using a BCI is most pressing in military applications, but it is relevant in medical and entertainment applications as well. Even acts performed in virtual environments can stir up strong reactive attitudes. Perhaps the most notorious example of such an act would be the “virtual rape” in the online community of LambdaMOO.”

Michael Madary, responding to the Working Party's consultation

g) Distributive justice and equity

i) Issues

Respondents voiced concerns relating to equity which largely centred around who should have access to the technologies and how; plus would the distribution of neurotechnologies create further societal division?

“...our primary concern with their use is whether they will undermine the equality and value of all humans, and whether they will value and uphold the common good.”

Christian Medical Fellowship, responding to the Working Party's consultation

“Simply put, even in countries in which there medicine is fully subsidized by the government, it is probable – based upon recent trends in allocation of biomedical resources and services – that everyone will not be able to get such high-tech medical interventions, as these are often only partially covered, and in some cases, not covered at all by the majority of health provision (and/or insurance) plans. So, who will receive state-of-the-art neurotechnological interventions? Will these approaches become part of a new ‘boutique neurology and/or psychiatry’? Or, will there be active assertion and effort(s) to increase the utility and use of these interventions, so as to make them more affordable and more widely accessible within the general population of those patients who might require them?”

Prof. James Giordano PhD, responding to the Working Party's consultation

Access to neurotechnologies for non-therapeutic applications was also singled out, with one anonymous respondent writing with regard to BCIs and neurostimulation: “Where applications are non-medical, I worry about the inequality of opportunity these technologies could aggravate.” Use for enhancement also raised discussion about equity. In its submission, the British Medical Association discussed access:

“The use of neurotechnologies for non-therapeutic purposes such as cognitive enhancement can raise questions of social equity... the question of who gets access to enhancement will become important. Should the market be allowed to govern distribution, therefore potentially giving further advantages to the wealthy or should the equity costs mean that they are distributed equally through state subsidy?”

British Medical Association, responding to the Working Party's consultation

One respondent highlighted the likely significance of money in determining access for non-therapeutic applications:

“In our society the difference between access to these technologies for medical reasons and for other reasons is often down to money – the parallel with cosmetic surgery is interesting”

Anonymous respondent, responding to the Working Party's consultation

In its response the British Medical Association also highlighted the potentially detrimental impact of inequitable access to applications for enhancement on solidarity and social cohesion:

“If the potential benefits of neurotechnologies are inequitably distributed, they could put pressure on solidarity. Where an already advantaged minority can afford access to neuro-enhancing techniques, for example, social divisions could be further widened.”

British Medical Association, responding to the Working Party's consultation

The role of intellectual property in restricting access was also discussed, with the National Bioethics Committee of Jamaica writing:

“Control of the technology (Patents) could result in monopolies such as has overtaken that of the diagnostic tools for the BRCA1 and 2 genes for breast and ovarian cancer[...] Monopolies could significantly restrict availability especially in less developed societies”.

National Bioethics Committee of Jamaica, responding to the Working Party's consultation

The cost of neurotechnologies themselves and how this would affect access were mentioned by respondents. For example, the Dementia Services Development Centre, University of Stirling, wrote in its submission:

“...the expensive dementia epidemic is going to be in very old people and people in developing countries and we need to think about how affordable such technologies will be for them, as we decide to invest in their creation.”

Dementia Services Development Centre, University of Stirling, responding to the Working Party's consultation

ii) Suggestions for addressing issues

There were suggestions and comments about how to enable equitable access and/or prevent inequity. For example, the Mission and Public Affairs Council, Church of England recommended therapeutic applications being made publicly available, and the restriction of non-therapeutic applications for enhancement purposes:

“Once a particular neurotechnology is deemed to be therapeutically safe and effective (within acceptable limits), appropriate interventions ought to be made available within the NHS...”

Non-therapeutic (enhancement) use of neurotechnologies ought to be restricted so that individuals are prohibited from gaining an unfair advantage in education, employment, sport or in other ‘competitive’ activities.”

Mission and Public Affairs Council, Church of England, responding to the Working Party's consultation

h) Research

i) Issues for research involving animals

A few respondents described ethical issues relating to research involving animals. According to these respondents, there had been – and there was likely to be – the need for research involving animals in the development of neurotechnologies:

“All of the neurotechnologies mentioned in the consultation document have relied heavily upon the results of animal studies. The scientific literature includes many examples of studies describing invasive animal experiments...”

Royal Society for the Prevention of Cruelty to Animals, responding to the Working Party's consultation

“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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

“In our view the report arising from this consultation should recognise that, in order to progress some of these technologies for the purposes outlined in the consultation document, there will inevitably be some assessment and development in animal models, for either scientific or regulatory reasons”

Animal Procedures Committee, responding to the Working Party's consultation

The Royal Society for the Prevention of Cruelty to Animals also noted, however, that the development of some of the neurotechnologies could actually replace animal research with research involving humans: “...TMS on humans can be used to replace some studies that would previously have been conducted by creating brain lesions in non-human primates.” However, it reiterated that significant use of animals in research was likely.

There were particular concerns raised about the use of primates in neurotechnology research:

“The consideration of whether novel neurotechnologies should be developed must be framed within the ethical balance between potential harms to animals and the possible human benefit... The RSPCA believes that is totally unacceptable to cause animal suffering in the development of neurotechnologies that do not have clear therapeutic benefits”

Royal Society for the Prevention of Cruelty to Animals, responding to the Working Party's consultation

“Primate use is of considerable concern to the public for a number of reasons, in particular the potential for suffering due to the complex behavioural and social requirements and cognitive capacities of these animals...”

Animal Procedures Committee, responding to the Working Party's consultation

The Animal Procedures Committee also raised the issue of research involving animals, in the context of developing non-therapeutic applications. It wrote:

“The majority personal view among APC members is that it is unacceptable to cause animal suffering in the development of neurotechnologies that will be used to improve gaming, or to enhance abilities in humans who do not have any disability or impairment...”

Animal Procedures Committee, responding to the Working Party's consultation

The Royal Society for the Prevention of Cruelty to Animals further queried how ‘hype’ and misrepresentation of neurotechnologies could lead to unnecessary animal research.

“It is absolutely essential that the potential benefits of neurotechnologies are realistically predicted and critically scrutinised – otherwise animals could suffer needlessly and their lives could be wasted.”

Royal Society for the Prevention of Cruelty to Animals, responding to the Working Party’s consultation

ii) Suggestions for addressing issues

There were suggestions from the Animals Procedures Committee with regard to addressing such issues. These included: appropriate cost-benefit evaluation of use of animals; public awareness of animal usage; restrictions on use if suffering could not be justified; and scrutiny of purported benefits of neurotechnologies. Existing legislation, including the Animals (Scientific Procedures) Act 1986 and European Directive 2010/63/EU on the protection of animals used for scientific purposes, was also highlighted:

“There is already an ethical framework [for] this within the licensing process for animal procedures under the current ASPA, which requires that for each proposed project the likely adverse effects on animals shall be ‘weighed’ against the benefits likely to accrue as a result. The recently revised European Directive 2010/63/EU, which will be implemented in the UK from 1 January 2013, also requires that the purposes of a proposed project should justify the use of animals, and that the project authorisation process includes ‘a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment’.”

Animal Procedures Committee, responding to the Working Party’s consultation

Further, the Animal Procedures Committee suggested:

“The APC should review project licence applications that aim to develop neurotechnologies and involve procedures that may cause substantial (severe) suffering in any species. The NCPASP should take over this role when it comes into existence on 1 January 2013.”

Animal Procedures Committee, responding to the Working Party’s consultation

iii) Issues regarding research with humans

Respondents raised some concerns about research in humans, mostly in relation to BCIs. One respondent emphasised the importance of evidence-based research that targets specific populations:

“Evidence-based research should be promoted in BCI that is specific to the target populations. For example, patients with cognitive deficits might not be able to respond to this technology, or could respond to very simple types of BCI technology.”

Fofi Constantinidou, responding to the Working Party’s consultation

Also in relation to BCIs, Dr Paul McCullagh highlighted the importance of interdisciplinary research teams with broad expertise.

“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’.”

Dr Paul McCullagh, responding to the Working Party’s consultation

Dr Paul McCullagh also pointed to potentially upsetting outcomes of BCI research for research participants:

“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.”

Dr Paul McCullagh, responding to the Working Party’s consultation

iv) Suggestions for addressing issues

Respondents acknowledged the existence and applicability of existing regulation and governance for the oversight of research involving humans:

“Their development is sufficiently covered by existing regulatory processes, ie research ethics approval, professional codes of conduct, voluntary informed consent of participants, etc.”

Professor David Stanley, School of Health, Community & Education Studies, Northumbria University, responding to the Working Party’s consultation

“I would expect the same stringent standards to apply on human experimentation as is required elsewhere in medical testing.”

Anonymous respondent, responding to the Working Party’s consultation

Potentially new areas for oversight were identified, however. For example, an anonymous respondent highlighted a scenario where a researcher might be able to control the participants through a neurotechnology:

“If it becomes possible for research to be developed involving persons being able to subject others under some form of direct control, perhaps in these instances special safeguards ought to be put in place, as this potentially threatens the experimental subject’s ability to dissent in some contexts.”

Anonymous respondent, responding to the Working Party’s consultation

v) Other problematic research activities

The Mission and Public Affairs Council, Church of England, highlighted how research for the development of neurotechnologies could include ethically troubling techniques, such as “the use of stem-cells or genetic manipulation involving embryonic or foetal material or the use of trans-species material.”

The Christian Medical Fellowship raised a concern relating to the possible willingness of authorities to ignore or bypass regulation if the promise of a novel neurotechnology was attractive:

“It hardly matters what regulation is in place. The military, intelligence, security, anti-terrorist, law enforcement, counter-insurgency, mental health, social control, political control and applications of BCIs are likely to be so attractive to those industries, that the classified research and development of capabilities, and live applications thereof, are depressingly likely, even if ostensibly unlawful.”

The Christian Medical Fellowship, responding to the Working Party’s consultation

i) Regulation and governance

i) Issues

Several respondents described ethical issues relating to regulation and governance for therapeutic applications. Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr, of the Policy, Ethics and Life Sciences Research Centre, Newcastle University questioned the effectiveness of current regulators, in particular the Medicines and Healthcare products Regulatory Agency:

“...controversies over breast implants and metal hip replacements are raising difficult questions about the effectiveness of the MHRA... 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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party’s consultation

Dr Martyn Pickersgill, University of Edinburgh, highlighted not only an overwhelming amount of regulation which lead to disengagement and confusion of neuroscientists, but that regulation still failed to address the “emotional labour” of professionals dealing with research participants:

“As I have documented in a forthcoming article in *Science, Technology & Human Values*³, neuroscientists are sometimes overwhelmed by the amount of regulation they need to work with, leading to disengagement with this and confusion as to what governance frameworks apply where and when...

...this regulatory multiplicity sometimes fails to adequately account for the considerable emotional labour involved in working with research subjects: locating and dealing with (for instance) incidental findings or participants under the therapeutic misconception can be hard work and demands much from scientists.”

Dr Martyn Pickersgill, University of Edinburgh, responding to the Working Party's consultation

There were some comments about the underlying principles for current or future regulation/governance. For example, Dr Andrea L Malizia, psychiatrist and clinical psychopharmacologist, wrote:

“Making sure... that regulation does not unfairly restrict individual rights and most of all for medical applications that mechanisms AND resources for transparency and evaluation are in place.”

Dr Andrea L Malizia, psychiatrist and clinical psychopharmacologist, responding to the Working Party's consultation

The difficulty of regulating non-therapeutic applications was also raised; in particular in the private setting:

“[Regulation] 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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

The various healthcare arrangements in place across the UK were identified as an area for regulatory oversight to potentially prevent health tourism:

“Increasingly divergent health-systems between the different countries within the UK are likely to be an issue that will require careful monitoring and consideration, especially in case of intra-national medical tourism.”

Dr Martyn Pickersgill, University of Edinburgh, responding to the Working Party's consultation

³ Pickersgill M (2012) The co-production of science, ethics, and emotion *Science, Technology and Human Values* **37(6)**: 579-603.

j) Macro policy issues

i) Issues

Funding and opportunity costs were raised by a number of respondents. The Christian Medical Fellowship asserted that, owing to hype, neurotechnologies would divert research funding from more simple, yet still effective, solutions:

“Research funds can often be diverted to media-friendly and headline-grabbing research, rather than simple, low key but effective solutions that would primarily be useful for developing countries. We believe that this is a particular concern with neurotechnologies.”

Christian Medical Fellowship, responding to the Working Party’s consultation

The Dementia Services Development Centre, University of Stirling, expressed its concern that the clinical situation, for which novel neurotechnologies were being developed, was largely avoidable through provision of good care; however, this was currently lacking:

“Our chief concern is [that] often the horror from which they [those considering neurotechnologies] wish to escape is largely avoidable. It is generated by poorly educated staff, and badly designed systems. If offered a neural transplant in order to avoid the misery caused by that I might say “Yes, please!” even with all the risks and practical or ethical issues involved. But if I have to take that risk just because someone can’t organize a civilized care service, I might be aggrieved about the trouble and expense to which I am put, or for which my tax system would have to pay.”

Dementia Services Development Centre, University of Stirling, responding to the Working Party’s consultation

There were, however, comments encouraging the provision of funding for novel neurotechnologies, for either therapeutic or non-therapeutic applications:

“In principle, those neurotechnologies that address illness or disability ought to be promoted... funding strategies ought to be put in place to further their development.”

Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation

“Neuro-technological use should be promoted by providing research funding and resources to conduct relevant studies either with medical settings or for non-medical purposes.”

Chijioke G Ogbuka, Albert Gnaegi Center for Health Care Ethics, responding to the Working Party’s consultation

In instances where neurotechnologies were replacing carers, Scully and colleagues expressed concern over the impact of neurotechnology use on the care of the individual. They wrote:

“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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, at Newcastle University, responding to the Working Party’s consultation

Comments were also voiced with regard to whether the healthcare system would be ready and able to cope with the advent of widespread use of neurotechnologies. Dr Martyn Pickersgill, University of Edinburgh, highlighted the skills of healthcare professionals and health-services evaluation systems:

“Re-skilling of certain professional groups will be required, and potentially the creation of new forms of accreditation or even occupational categories in order to deal with, implement and monitor these. At the same time, the roles and responsibilities of existing groups may increase, decrease, or change in other ways... At the same time, health-services research and evaluation programmes will need to be in place to ensure technology implementation and patient care runs as planned.”

Dr Martyn Pickersgill, University of Edinburgh, responding to the Working Party’s consultation

K) Communication and representation

Several respondents described concerns that centred on communication or representation of neurotechnologies.

i) Misrepresentation and hype

There was an impression that neurotechnologies were being misrepresented in terms of their benefits. For example, the Royal Society for the Prevention of Cruelty to Animals wrote:

“...there are some concerns about the cogency of the claims that are made by neuroscience in this area...”

Royal Society for the Prevention of Cruelty to Animals, responding to the Working Party’s consultation

The British Medical Association highlighted media presentation as potentially impacting on public confidence:

“Media presentation of novel neurotechnologies, particularly where they have therapeutic uses, or have been developed from technologies designed for therapeutic applications can have a significant impact on the public’s understanding of medical science and on public confidence in medicine and medical science more widely...”

British Medical Association, responding to the Working Party’s consultation

Furthermore, the potential significance of intervening in the brain could act as a compounding factor:

“As the principal seat of human identity and personality the human brain could be argued to have particular status. Careless or sensationalist reporting of developments in neuroscience can lead either to demonization and distrust or to unfounded optimism.”

British Medical Association, responding to the Working Party's consultation

Cesagen identified a blurring of fact and fiction in the public's imagination, but also in that of scientists and researchers:

“The TECHNOLIFE public forum on mind & body enhancement, analysed at Cesagen, shows clearly that techno-scientific realities, science fiction and techno-scientific utopias are not well distinguished in the public imagination. Moreover, on the basis of our organised meetings with experts as part of the ICTethics project, we argue that research communities (leaders and visionaries) tend to blur these boundaries as well, in the ways in which knowledge is articulated and represented and the future depicted.”

Cesagen - the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party's consultation

Scully et al. argued that novel neurotechnologies were particularly susceptible to the hype that was prevalent in biomedicine and biotechnologies more generally:

“In the case of neurotechnologies this habit [of hype in biomedicine and biotechnologies] 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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, at Newcastle University, responding to the Working Party's consultation

Cesagen, the ESRC Centre for Economic and Social Aspects of Genomics, described ethnographic research, which showed that the risks of neural stem cell treatment were not always communicated in the clinic to the patients:

“French and US literature on previous human neural grafts of foetal stem cells, shows variable results with lesions re-occurring in some transplanted areas, and/or lesions occurring [in] non-grafted regions.⁴ Hughes' ethnography of a

⁴ Cicchetti, F., Saporta, S., Hauser, R. A., et al. (2009). Neural transplants in patients with Huntington's disease undergo disease-like neuronal degeneration. In *Proceedings of the National Academy of Sciences of the United States of America* 106, pp. 12483-8.; Keene, C. D., Sonnen, A., Swanson, P. D., et al. (2007). Neural transplantation in Huntington disease - Long-term grafts in two patients. *Neurology* 68(24), pp. 2093-8. ;Keene, C. D., Chang, R. C., Leverenz, J. B., et al. (2009). A patient with Huntington's disease and long-surviving fetal neural transplants that developed mass lesions. *Acta Neuropathol.* 117(3), pp. 329-38

research clinic found that this information was not always made readily available to patients.⁵

Cesagen – the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party’s consultation

The response continued, describing how representation of risks and benefits were replaced with a vague statement that tacitly implied some benefit of attendance at clinic:

“...risks and benefits tend to be subsumed under one or more of the following type of provisos:

a) “We are not doing any transplants at the moment, and in any case we don't know if you would be a suitable candidate. It’s likely that appropriate people would be in the early stages of disease.”

b) “It’s a very experimental procedure and [it’s] too early to say what the chances are;”

c) “You are in the right place for when developments start to come through.”

So there is a tacit implication that research clinic attendance may prove to be beneficial even if only in terms of information, not treatment.”

Cesagen – the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party’s consultation

With regard to neural stem cell therapy, the Association of British Neurologists observed the risk of: “Hype around what can be achieved in the first into man trials”.

ii) Consequences of misrepresentation and hype

Misrepresentation and hype were seen as problematic where they lead to false hope (especially in those who were vulnerable), the impact of this on autonomous decision making, financial exploitation of patients, difficulty in determining risk-benefit profile, and inappropriate diversion of resources, including animal usage:

“Any intervention on persons requires respect of the dignity of the person and of the autonomy of decisions. This is difficult to evaluate when hopes are stimulated irresponsibly by industry or markets.”

Prof Dr Fernando Lolas, University of Chile - Interdisciplinary Centre for Studies on Bioethics, responding to the Working Party’s consultation

“At all key stages – and indeed, in anticipation of major developments in neurotechnology – there needs to be open and public discussion about their applications... This is particularly important to avoid patients and their families out of desperation paying large sums of money to unregulated practitioners who may perform false and potentially dangerous treatments.”

British Neuroscience Association, responding to the Working Party’s consultation

⁵ Supra, n.11: Hughes, J. 2010. After genetics : Huntington's disease, local data, global neuroscience. (PhD) Cardiff University

“It is absolutely essential that the potential benefits of neurotechnologies are realistically predicted and critically scrutinised – otherwise animals could suffer needlessly and their lives could be wasted.”

Royal Society for the Prevention of Cruelty to Animals, responding to the Working Party’s consultation

Consequences of hype with regard to non-therapeutic applications were also specifically outlined. For example, the Mission and Public Affairs Council, Church of England, wrote:

“Of particular concern is the possibility that unrealistic expectations may be embraced or promoted, with individuals believing that enhancement will inevitably lead to better and happier lives.”

Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation

iii) Public understanding of neurotechnologies

An interesting backdrop to the communication of neurotechnologies was identified, in which current public understanding of neurotechnologies might act as a barrier to their acceptance. Dr Martyn Pickersgill, University of Edinburgh, wrote:

“There are...issues here around public understanding and acceptance of novel neurotechnologies. Many individuals may be deeply resistant to techniques that they will (rightly or wrongly) consider unsafe, inadequately researched, or overly invasive.”

Dr Martyn Pickersgill, University of Edinburgh, responding to the Working Party’s consultation

iv) Suggestions for addressing issues

Some suggestions for how to address issues of misrepresentation of hype are detailed below, included public engagement activities; effective communication by scientists; and the provision of information to the public rather than promotional material:

“There is a need to develop early-stage public engagement strategies around new technologies, which bring together scientists, the public and policy makers to discuss the science and any associated ethical and social issues. We do not believe that one particular type of public engagement activity is most appropriate for new technologies, but a range of approaches should be used, tailored to the needs of the issues or research in question.”

The Wellcome Trust, responding to the Working Party’s consultation

“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.”

European Brain Council, responding to the Working Party’s consultation

With regard to the potentially cooling effect of public understanding of neurotechnologies on their acceptance, Dr Martyn Pickersgill suggested inter-disciplinary engagement:

“Innovators and regulators will need to engage more closely with social scientists who have analysed trust in-depth.”

Dr Martyn Pickersgill, University of Edinburgh, responding to the Working Party's consultation

l) Dual use

i) Issues

Several respondents raised concerns over the potential dual use of neurotechnologies. For example, the National Bioethics Committee of Jamaica cited this as one of the most important ethical challenges raised by novel neurotechnologies:

“Wrongful or unethical use for possible “laudable” reasons from a Utilitarian perspective but trampling on individual rights for example in: i) Political / military purposes; ii) Consumerism; iii) Crime fighting...”

National Bioethics Committee of Jamaica, responding to the Working Party's consultation

The issue of dual use was raised specifically with regard to brain–computer interfaces. For example:

“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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

The Policy, Ethics and Life Sciences Research Centre, questioned whether the neuroscience community was aware of the initiatives to mitigate dual-use risk:

“...there is very little research on whether or not many neuroscientists are aware of these efforts or their implications for scientific responsibility... 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).”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

m) Non-therapeutic applications: enhancement

i) Issues regarding enhancement

Respondents described issues associated with use of neurotechnologies for enhancement. These included whether neurotechnologies ought to be used for enhancement purposes; as well as societal concerns such as the risk of creating a hierarchical society and – parallel to this – the risk of eroding societal values, thus placing already vulnerable individuals at increased risk:

“...whether we should use technology just to prevent disease and restore health, or whether its use can be permitted deliberately to enhance individuals? For example, if tremors could be eliminated, then why not for surgeons doing microsurgery?”

Christian Medical Fellowship, responding to the Working Party's consultation

“Once human value and rights depend on acquiring some particular level of enhanced biological, genetic or cognitive capacity we create a hierarchical ordering of society.”

Christian Medical Fellowship, responding to the Working Party's consultation

“...the potential for manufacturing an elite of ‘super-performers’; an associated possible erosion or re-definition of social beneficence and social justice for the benefit of the few...The cost of rejecting the equal status of all human persons would be high to existing and future vulnerable humans, especially those who possess less than the full complement of capabilities too often used to define humanness, (for example, embryos, the newborns, the terminally sick, those in PVS, the physically and mentally disabled etc)”

Professor David Stanley, School of Health, Community & Education Studies, Northumbria University, responding to the Working Party's consultation

As described in section g) Distributive justice and equity, concerns were raised regarding equity and access (i.e. who should have access to use for enhancement; how should this be determined) and, following on from this, concerns about solidarity and social cohesion:

“The use of neurotechnologies for non-therapeutic purposes such as cognitive enhancement can raise questions of social equity... the question of who gets access to enhancement will become important. Should the market be allowed to govern distribution, therefore potentially giving further advantages to the wealthy or should the equity costs mean that they are distributed equally through state subsidy?...”

...If the potential benefits of neurotechnologies are inequitably distributed, they could put pressure on solidarity. Where an already advantaged minority can

afford access to neuro-enhancing techniques, for example, social divisions could be further widened.”

British Medical Association, responding to the Working Party's consultation

Other issues raised included the risk of coercion, and any related challenges to autonomy; concerns over agency; and conflicts with religious beliefs:

“[There is also] the possibility that individuals may feel under pressure to make use of them. Stigma may also be attached to those who choose not to use enhancements, preferring to remain in a ‘natural’ or unenhanced condition... parents may also feel some pressure to enhance their children in order to give them a reasonable chance to compete on an even footing. Individual occupational groups – members of the military, airline pilots – may also come under pressure...”

British Medical Association, responding to the Working Party's consultation

The tension between the individual freedom to *choose to be enhanced* and societal values was highlighted by the Mission and Public Affairs Council, Church of England, as an important consideration encompassed in the enhancement debate:

“Communal responsibility-Individual Freedom: individual freedom to pursue, to apply or to receive the benefits of novel neurotechnologies must be balanced by the effects of such actions on others. The integrity and cohesion of society is undergirded by equitable access to treatment as well as by limits being placed on the advantages that individuals might gain through neurological enhancement...”

Mission and Public Affairs Council, Church of England, responding to the Working Party's consultation

Thomas R Kerkhoff, PhD, ABPP/RP, Clinical Professor, University of Florida, Department of Clinical & Health Psychology also underlined not being able to evaluate risk/benefits of use for enhancement given the lack of any parallel experience:

“A simplified dichotomy may be used to assign such devices to two categories: corrective technology and augmentative technology... In the first case, the operator (recipient of corrective technology) can hope to re-acquire experientially-based judgment regarding appropriate use of the technology, if the technology effectively bypasses structural or functional impairments. That experience is based upon living and learning about the world prior to technological introduction to the neural system. The second category places the operator in a realm of function that has little parallel in experience, hence real-world judgment may not be properly informed in making critical risk/benefit decisions regarding use.”

Thomas R Kerkhoff, PhD, ABPP/RP, Clinical Professor, University of Florida, Department of Clinical & Health Psychology, responding to the Working Party's consultation

There were also concerns raised about enhanced individuals who might act in a way that was detrimental to society. In addition, there were questions about how it would be decided that an individual be enhanced, and questions about responsibility and ownership.

n) Non-therapeutic applications: military use

i) Issues

Some respondents identified ethical issues relating to military applications (both state and non-state). As the following comment illustrates, there was concern about neurotechnologies affording the ability to act remotely, thereby making identification and attribution of responsibility more difficult:

“Terrorists could make remote, readily attack without sacrificing themselves; countries could make military attacks without taking responsibilities; hackers could invade computers or secret information base with less time and more security; thugs could kill people one thousand miles away without arrest... Easy to commit crimes, but hard to be traced”.

Deng Zhuo, responding to the Working Party’s consultation

Chijioke G Ogbuka, Albert Gnaegi Centre for Health Care Ethics, questioned whether the use of neurotechnologies would contravene current notions of just war:

“In warfare, is it fair and just to employ neuro-controlled arsenals against an opponent with human armies?”

Chijioke G Ogbuka, Albert Gnaegi Centre for Health Care Ethics, responding to the Working Party’s consultation

The Christian Medical Fellowship articulated concern over the effectiveness of regulation and oversight of research, given the interest from actors such as the military (and perhaps the capability of obscuring research by labelling it as classified):

“It hardly matters what regulation is in place. The military, intelligence, security, anti-terrorist, law enforcement, counter-insurgency, mental health, social control, political control and applications of BCIs are likely to be so attractive to those industries, that the classified research and development of capabilities, and live applications thereof, are depressingly likely, even if ostensibly unlawful.”

Christian Medical Fellowship, responding to the Working Party’s consultation

This view was echoed somewhat by the Mission and Public Affairs Council, Church of England, which wrote:

“Military use of novel neurotechnologies is inevitable with resultant improvements in defensive safety (for example, bomb disposal) and in the development of offensive capabilities (for example, remote-bombing).” *Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation*

o) Some overarching suggestions for an ethical framework

Respondents highlighted some overarching principles for addressing the ethical issues raised by neurotechnologies. The Wellcome Trust argued for the importance of clear and proportionate regulation that allowed the efficient and ethical translation of research. It submitted:

“Any therapy or technology used to intervene in the brain as a clinical treatment must have a robust evidence base demonstrating safety and efficacy. The research to produce this evidence should be supported by clear regulation that is proportionate to the risks and benefits and which allows the efficient and ethically sound translation of research into health benefit.”

The Wellcome Trust, responding to the Working Party's consultation

The Mission and Public Affairs Council, Church of England stressed the importance of appropriate caution (i.e. caution not impeding “appropriate medical and scientific progress”):

“Because of the intrinsic importance of the human brain and its relationship with the human mind (however such a relationship may be understood), there is a valid reason to err on the side of caution when contemplating novel neurotechnologies. Such caution, however, ought not to be permitted to prohibit appropriate medical and scientific progress.”

Mission and Public Affairs Council, Church of England, responding to the Working Party's consultation

Elsewhere, Prof James Giordano discussed the applicability of the precautionary approach.

“I argue that a simple precautionary principle is insufficient and counterintuitive in that potential burdens and risks of any new technique or technology will always tend to be greater than apparent benefits: simply, this is because benefits tend to be proximate – and the “driving force” of the majority of such technological developments - while burdens and risks occur with more protracted use in practice, occurrence and influences of other events, and/or acquisition of new information and knowledge (Giordano, Akhouri and McBride, 2009).”

Prof. James Giordano PhD, responding to the Working Party's consultation

Continuing, he instead advocated a ‘preparedness’ approach, to which there was societal buy-in:

“Preparedness is an active process that requires engagement of teams of personnel from multiple disciplines in an integrative convergent approach (see, for example, Giordano 2012), a pragmatic assessment of all available information, and use of scenario-gaming, modeling and evaluation. This [preparedness] approach is also important to informing and formulating guidelines and policy; policy enables funds to support research and translate research findings and products to clinically viable assets, and can direct economic resources toward provision of these technologies to accommodate the

needs and demographics of the patient population. But, the public must be conjoined to this process if it is to instantiate and empower neurotechnology as a viable social good (Benedikter, Giordano, 2011).”

Prof. James Giordano PhD, responding to the Working Party's consultation

Approaches for practice

The Mission and Public Affairs Council, Church of England, identified the possibility of case-by-case evaluation within a general framework:

“While each neurotechnology and the possible uses to which it may be put ought to be addressed in its own right, it is also possible to outline out a general approach.”

Mission and Public Affairs Council, Church of England, responding to the Working Party's consultation

p) Some overarching comments

i) The case for exceptionalism

Policy, Ethics and Life Sciences Research Centre considered whether intervening in the brain was ‘new’:

“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”.

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party's consultation

The British Medical Association expressed a similar sentiment:

“The fact that the focus of neurotechnological interventions is the human brain does not alter this fundamental ethical requirement [i.e. to provide maximum health benefit with minimum harm in accordance with the autonomously expressed preferences of individuals and in ways that are just, and where individuals lack autonomy, to base decisions on assessments of their interests broadly conceived.]... Given the burden associated with some psychological and neurological disorders and the radical restriction of ordinary human functioning that they can entail, there may be some justification for accepting larger than ordinary risks. The ethical assessment would not be different in kind...”

British Medical Association, responding to the Working Party's consultation

Scully et al question whether novel neurotechnologies do represented something different, or if they are a technologies just like any other.:

“...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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party’s consultation

Thus, Scully and colleagues identified that if one took account of the history of intervening in the brain, the understanding of the brain as the source of human identity and selfhood, and the directness of the intervention with novel neurotechnologies, exceptionalism could be identified:

“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...

A second reason is given by the socially and culturally embedded meaning given to the brain as a source of human identity and selfhood... 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.”

Jackie Leach Scully, Janice McLaughlin, Simon Woods and Michael Barr of the Policy, Ethics and Life Sciences Research Centre, Newcastle University, responding to the Working Party’s consultation

ii) Wider context to issues raised by novel neurotechnologies

Cesagen, the ESRC Centre for Economic and Social Aspects of Genomics, asserted:

“We take the view that growing concerns about the development of novel neurotechnologies are intimately tied in with prevailing diffuse but widespread concerns about developments in the biotechnologies more generally, and potential convergence with other technologies.”

Cesagen - the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party’s consultation

Cesagen further identified the ‘emerging’ nature of neurotechnologies and how they were influenced by stakeholders such as funders, users and R&D practitioners:

“Growing concerns over neurotechnologies relate to speculative and future-oriented visions of these technologies, albeit with reference to success in assisting some patients with Parkinson’s Disease and severe motor or mental

impairments. They are 'emerging'—more based in immature and provisional research-based scientific-technological knowledge, than matured and robust knowledge. They continue to be experimental while they are still passing into society where the learning and development needs to continue as part of the 'technology assessment' process. They are also more driven, shaped and promoted by a combination of funders, R&D practitioners, users, commercial beneficiaries and other stakeholders, than was previously the case.”

Cesagen - the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party's consultation

4. Regulation and governance of neurotechnologies

In their submissions, respondents debated appropriate regulation and governance for novel neurotechnologies; some examples are detailed below (specific recommendations are included in the previous section on ethical issues). Question 5 asked how, if at all, the development and use of novel neurotechnologies should be promoted, restricted and/or regulated; questions 10, 15 and 20 inquired as to what robust and effective regulation of, BCI, neurostimulation and neural stem cell research respectively, would look like, and whether more or less was needed.

Respondents held varying views on whether there was a need for additional regulation for therapeutic uses of neurotechnologies beyond what is currently in place.

i) Sufficient regulation

The Wellcome Trust highlighted the ethical issue of safe and effective technologies being inappropriately restricted or delayed:

“It would seem both unethical and significant waste of resources if techniques which are shown to be safe and effective, are prevented or unduly delayed in reaching patients.”

The Wellcome Trust, responding to the Working Party’s consultation

An anonymous respondent felt that there were analogous challenges associated with neurotechnologies and other new technologies:

“I am sure these [neurotechnology applications] would specifically include things I would be happy with, and things I wouldn’t be. But this is the same challenge we face with all new technologies”

Anonymous respondent, responding to the Working Party’s consultation

The British Medical Association approached this question by identifying which factors should be considered in assessing whether the regulation was necessary. These included any potential harms; on whom these harms were likely to fall; and whether there was a need to create public confidence. It concluded that:

“On the face of it, it is not clear that the specific therapeutic uses of the new technologies requires additional regulation.”

British Medical Association, responding to the Working Party’s consultation

The European Brain Council reported that there is already considerable and *appropriate* regulation in the UK and Europe:

“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

[neurotechnology] products as much as any other. Promotion to health care professionals should follow similar lines.”

European Brain Council, responding to the Working Party's consultation

ii) More regulation needed

Some respondents felt that additional regulation might be needed for neurotechnologies. For example, the Christian Medical Fellowship expressed concern that novel neurotechnologies could bring about scenarios that existing regulation might not respond to appropriately:

“...because new neurotechnology often allows us to perform activities in new ways, situations are arising in which we do not have adequate policies in place to guide us. We need to formulate and justify new policies (laws, rules, and customs) for acting in these new kinds of situations.”

Christian Medical Fellowship, responding to the Working Party's consultation

The British Medical Association, this time with regard to non-therapeutic applications, also asserted that additional regulation might be necessary in the context of enhancement:

“Should the potential for significant cognitive, and even moral enhancement become realistic, then the need for some forms of regulation would need to be seriously considered.”

British Medical Association, responding to the Working Party's consultation

Openness

A number of respondents expressed the need to foster openness in research and reporting, including more comprehensive collation and publication of clinical outcomes.

“Research should be encouraged within the public [domain] with each study undergoing thorough regulation and review and negative and positive results being openly published, so the communities can develop a thorough picture of outcomes.”

Anonymous, responding to the Working Party's consultation

In relation to data collation the Association of British Neurologist said:

“Creating a national database, with vigorous entry and exclusion criteria. Also comprehensive monitoring of agreed outcomes at regular intervals.”

Association of British Neurologists, responding to the Working Party's consultation

Should novel neurotechnologies be promoted or restricted?

There were mixed views about the promotion and restriction of novel neurotechnologies. For the most part, those advocating the promotion of novel neurotechnologies did so in the context of therapeutic applications and with a focus on appropriate funding and resource.

“In principle, those neurotechnologies that address illness or disability ought to be promoted... funding strategies ought to be put in place to further their development.”

Mission and Public Affairs Council, Church of England, responding to the Working Party’s consultation

“Neuro-technological use should be promoted by providing research funding and resources to conduct relevant studies either with medical settings or for non-medical purposes.”

Chijioke G Ogbuka, Albert Gnaegi Center for Health Care Ethics, responding to the Working Party’s consultation

One respondent felt there was a need to restrict novel neurotechnologies for certain uses such as non-therapeutic applications and that there was a need to provide clear guidance and criteria as to when novel neurotechnologies can be used with legal restrictions in place. Another respondent supported the idea that the use of neurotechnologies should be for medical use only:

“Neurotechnology can be a giant step forward in the treatment of brain and physical disorders, but the implementation of such treatments must have ultra strict rules and monitoring, by regulatory bodies, outside of government controls, and be confined to medical use only.”

Anonymous, responding to the Working Party’s consultation

Christians Against Mental Slavery also objected to the use of novel neurotechnologies that would contravene European Parliament Resolution A4-0005/99 Paragraph 27, which:

"calls for an international convention introducing a global ban on all developments and deployments of weapons which might enable any form of manipulation of human beings."

Christians Against Mental Slavery, responding to the Working Party’s consultation

Regulation of brain-computer interfaces

There was some doubt that the challenges raised by BCIs raised any novel issues. However, a number of respondents made recommendations about how regulation might be strengthened for BCIs. One respondent suggested that BCI-based interventions should be licensed by physicians or clinical psychologists and should be restricted initially to clinical care settings until more is known given the “available evidence of benefits, burdens, risks and harms”. Another respondent reported that “If BCI technology was deployed to home settings risk factors need to be assessed, as with all assistive technologies”. Other concerns expressed included “over-the-counter” use of BCIs:

“... we call for the provision of explicit language on any/all “over-the-counter” BCI-neurotechnologies that dictates medical clearance for use (as with many

other over-the-counter medical products), and 2) warns of possible adverse effects and consequences of use/misuse.”

Prof. James Giordano PhD, responding to the Working Party's consultation

Respondents answering question 10 identified general principles and an ethos that might be applied to the regulation of BCIs. Some respondents expressed the sentiment that regulation needed to be light on its feet, with appropriate flexibility so that “it can cope with rapid developments.” One respondent felt that regulation needed to be flexible enough to provide protection to vulnerable users and simultaneously access for those with hugely impaired quality of life. Developing this idea of regulation that serves the user, the Association of British Neurologists said that “Regulation...must be patient focused, for the wellbeing of the patient”.

There was some concern expressed that regulation should be expanded to provide more oversight:

“We have called for an expanded oversight and regulation of the industry, clinical and public use of these technologies and devices, and the level of education and specialized experience of providers.”

Prof. James Giordano PhD, responding to the Working Party's consultation

In relation to research, respondents reflected a desire to seem a more open process that could be scrutinised, although there was also awareness that sharing of research data can be problematic from a commercial perspective.

“Regulation of research into social use BCIs should be in force and results whether negative or positive should be published openly... we could learn more and legislate appropriately if the research were done in a public arena”

Anonymous, responding to the Working Party's consultation

“I would argue that all research needs to be made public but this then limits the chances firms have to be first movers to patent a technology and make a profit... perhaps all research needs to be made public to a special body whose members are forbidden from taking place in market activities. *Anonymous respondent, responding to the Working Party's consultation*

Regulation of neurostimulation

In answer to question 15, respondents focused significantly on the importance of patient understanding and awareness. This included issues about enhanced informed consent and selecting patients that are able to understand the risks involved. The Addiction Neuroethics Unit emphasised that in the context of psychiatric conditions, patients should be fully informed about any alternative treatment options available. Addiction Neuroethics also expressed some concern about the regulation of direct-to-consumer promotion and sales:

“...concerns [re premature promotion of TMS to treat serious psychiatric disorders] should be addressed by the regulatory bodies that approve the use of

clinical technologies and monitor the promotion and sale of products directly to consumers.”

Addiction Neuroethics, UQCCR, The University of Queensland, responding to the Working Party

In regard to policy guidelines Prof James Giordano PhD emphasised the importance of developing guidance based on current and accurate information and said that it “must avoid over-simplification, exaggeration, or miscommunication of potential capabilities, mechanisms, effects, as well as risks and/or harms of the technique and technologies in question.” There was also a desire to see less bureaucratic processes, especially for the use of established treatment in experienced centres. The Association of British Neurologists said:

“Centres that have experience in movement disorders and have a proven track record of safety and effective outcomes from functional neurosurgery should be freed from the repetitive funding bureaucracy that currently surrounds NHS commissioning, and decisions regarding the appropriateness of DBS for conventional indications should be made on clinical grounds focussing on each patient’s best interest. Audit figures should be requested to ensure a centre is performing to an expected standard.”

Association of British Neurologists, responding to the Working Party

The European Brain Council also reported that there was an ethical issue surrounding the time taken for new medicines and devices to reach patients and the need to speed up the innovation process. One respondent emphasised the need for flexibility to enable respect for people’s autonomous wish to engage in a procedure that is outside of the norm for their condition if they wish to and believe that it will offer them improved function.

Regulation of neural stem cell therapies

A number of respondents expressed the view that the regulatory landscape in the UK for neural stem cell therapies was adequate and that, for the most part, it allowed for stem cell research to take place with appropriate oversight from ethical bodies.

“The research community, in general, consider research with neural stem cells to be well regulated in the UK, allowing pioneering work to proceed in a carefully controlled manner.”

Wellcome Trust, responding to the Working Party

“I think that this work does need to be regulated and that in the UK we do this very well, as we take on board the views of all interested parties and move forward slowly with a consensus position.”

Association of British Neurologists, responding to the Working Party

Some respondents reiterated sentiments expressed in answering questions 10 and 15 such as the need for flexible regulation that is bureaucracy light and which stimulates and supports innovation.

It would be good to have a regulatory system in operation which freed scientists from the tyranny of paperwork, but which also gave security to everyone i.e the users/developers of the neural material, the owners of the material, the surgeons and the patients who receive the material. This may be in the form of access to neural materials being licensed, limited or regulated in some way. This may happen already in one way or another. It may also need a new regulatory body.”

Cesagen - the ESRC Centre for Economic and Social Aspects of Genomics, responding to the Working Party's consultation responding to the Working Party's consultation

Appendix 1: List of questions

1. Have you ever used a technology that intervenes in the brain, and with what consequences? Please describe your experience.
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?
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?
4. What are the most important ethical challenges raised by novel neurotechnologies that intervene in the brain?
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.
6. Have you used a BCI, and if so, with what consequences? Please describe your experience.
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?
9. Are there any particular ethical or social issues associated with BCIs?
10. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.
11. Have you used neurostimulation and if so, with what consequences? Please describe your experience.
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)?
14. Are there any particular ethical or social issues associated with neurostimulation?
15. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.
16. Under what circumstances would you use neural stem cell therapy?
17. What do you think of the risks and benefits of neural stem cell therapy?
18. Are there any particular ethical or social issues associated with neural stem cell therapy?
19. How do you feel about neural stem cell therapy being used for nonmedical purposes one day, for example for human enhancement?
20. What would robust and effective regulation of research in this area look like? Is more or less regulation needed? Please justify your response.