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

Dr Patricia Limousin

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

I work in the field of deep brain stimulation, and in particular its application to treat Parkinson's disease, dystonia and tremor. I am mostly involved in clinical research.

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

The main applications are the treatment of Parkinson's disease, dystonia and tremor.
Other applications are being investigated.

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

Other applications have started in the field of pain/headaches, epilepsy, Tourette, depression, OCD, cognitive impairment, anorexia (those have been done in some centers but not widely applied).

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

My research is mainly at the stage of clinical applications. Funding is the main limit.

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

This procedure is generally used when medications are not sufficient to help symptoms and patients are disabled by the their symptoms. More patients could benefit from those therapies.

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

The total cost of the procedure is approximately £30, 000. The battery needs to be changed every 5 years with recurrent cost of about £10,000. It is available on the NHS for some conditions, although dependent on PCT funding, therefore there are geographical discrepancies (some PCT would fund some conditions that other PCT would not fund).

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

No, need to be implanted by a neurosurgeon

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

Hopefully none. Some people might consider it to enhance some functions ex memory. That should be prevented in my view.

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

Yes, there are possible side effect from the implantation or the stimulation: hemorrhage, infection, seizure, speech problem, mood change as example.
Fortunately severe and irreversible side effects are rare in the hand of experienced surgeons and with careful selection of patients

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

Not with established indications like Parkinson, dystonia and tremor
Potentially more issues for other conditions when effect less established
Psychiatric conditions are also likely to raise more issues because of their complex nature and more complex issue of consent

Questions if you work with patients

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

Patient expect improvement of their symptoms and their quality of life

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

Most patients are willing to take the risks, described above because they have reached a stage when their symptoms are very debilitating and medications are not sufficient to help.

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

Detailed information is provided by the medical team. Some patients have done their own research in addition. If patient lack capacity to consent, rare occurrence, the usual procedure is followed.

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

To some level. Most patients improve, some more than others and they all have different expectations

Broader questions about the field of novel neurotechnologies

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

In 10 years I expect DBS will still be applied for many neurology conditions, probably with more sophisticated devices.
It is possible that for Parkinson’s disease in particular other approaches, possibly leading to regeneration will be available

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

The main issue is the cost to develop those project and process to get it approved

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

Not sure

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

I think there is a fine balance between making sure that the device are safe for human use and not making the process so complicated and expensive that it prevents developments that could benefit patients.

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

I think there is a hype often created by the media, that present every new therapy as a "cure" or other selling head-line.
It is important for Doctors to provide patients with a balanced and objective information

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

In think it depends which disease the technology is trying to treat. How severe is the disease. What are the alternative options. How well established are the effects and the risks of the procedure. There is also the issue of understanding and consent from the patient.

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

Clinicians, researcher, patients, patient associations, health care providers, manufacturers.
Recommendations would mostly apply to clinicians I expect
I would expect recommendations to apply those technology for diseases and not function enhancement, when disability is present and alternative not efficient, and a good reason to believe the therapy might be effective without excessive risk.
Precise information to the patient