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Issues in neurotechnology governance

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Foreword

This report provides a summary of the main discussion points emerging from the presentations, panel discussions, and oral statements made at the Expert Consultation on "Neurotechnology and Society", held on 14-15 September 2017, in Washington D.C., United States.

This Expert Consultation was conducted under the OECD's Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) project on "Open and Responsible Innovation: realising the potential of emerging technologies for health". The purpose of the meeting was to promote exchanges among experts, to identify and characterise opportunities and challenges, and to discuss next steps towards possible recommendations for the responsible development of neurotechnology. The agenda was informed by results from the BNCT project on "Emerging Technologies and the Brain", and the meeting highlighted areas where further analytical work may be needed. Results will guide ensuing BNCT work on Responsible Innovation in Neurotechnology.

This report aims to capture the opinions expressed by invited experts during the meeting. This report does not represent the views of the OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) or its delegates. The meeting was conducted on a not for attribution basis, under Chatham House rules.

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Key messages

The main findings and messages from the Expert Consultation are:

General

- Emerging neurotechnologies (e.g. functional magnetic resonance imaging, neuroprosthetics, invasive and non-invasive modulation, nerve- and brain-machine interfaces) offer a variety of potential applications in the therapeutic and non-therapeutic realms, many of which cannot be anticipated at this time. This powerful set of technologies might provide major societal benefits with responsible development and appropriate oversight.
- The unique power of neurotechnologies to engage questions of human identity, self-understanding and the natural boundaries of cognition have begun to fuel research and ethical inquiry across many jurisdictions.
- Neurotechnology innovation is developing fast and occurring in many different socio-cultural contexts. There is a need for continuous, inclusive, and international deliberation on neurotechnologies that balances both a sufficiently broad vision and a utility for specific community contexts.
- International recommendations for addressing pressing ethical, legal, social, economic and cultural challenges may be beneficial to ensure responsible advancement of emerging neurotechnologies. Consideration of these issues should span laboratory, clinical, and industry settings.
- Persisting knowledge gaps in brain science impact how certain neurotechnologies can and should be translated into clinical settings.
- Developing common definitions of concepts like “human enhancement” and “dual use” will be important to facilitate mutual understanding and cross-sectoral discussions.
- Do-it-yourself neurotechnologies, off-label use, and medical “tourism” all pose challenges for governance and counsel for international attention.

Informing governance

- Neurotechnological innovation should be balanced with appropriate institutional oversight. Trust and trust-worthiness, including the development of transparent governance with inclusive participation, are important factors in ensuring public support for new approaches in science and technology and will rightly impact professional and public acceptance.
- Careful consideration must be exercised by the public and policy makers in the uptake of neurotechnologies given the prevalence of untested claims, which is an area that continues to pose governance challenges.

- Neurotechnologies that make claims about a perceived benefit and/ or enhancement, rather than claiming to address disease per se, may not be overseen by regulatory authorities in some countries or regions, and may warrant the same level of scrutiny as products making therapeutic claims.
- While interventions into the human brain may raise specific challenges, experience with other emerging technologies may be useful in developing the necessary governance mechanisms for the responsible development and use of new neurotechnologies.
- Using neurotechnologies for the prediction of health and behaviour carries important implications for rights and entitlements in law, insurance, and employment.
- Given multiple calls for data sharing platforms in brain science, anticipating cross-cultural perspectives on appropriateness for use of neurotechnologies and resulting data that may cross national boundaries may be critical for considerations of governance and ethical evaluation.
- Additional principles on consumer protection, as much as on safety and efficacy, could help create the adequate context for innovation.
- It will be important to bring stakeholders together to provide relevant perspectives and broadly considered insights on dual use and misuse.

Involvement of stakeholders

- Increasingly powerful neurotechnologies have implications for advancing our understanding of what it means to be human. It is particularly important to ensure that policies are broadly informed, with genuine inclusion and representation of public values.
- Public and policy maker engagement needs to be more structured and focused on two-way, rather than one-way, communication. Good practices involving foresight and structured engagement with all stakeholders in research, development, commercialisation and use already exist in the field of neurotechnology and these activities could be built upon and further developed.
- It is crucial to build a recognition of the importance of social and ethical issues into the training of all those involved in developing and utilising novel neurotechnologies, thus principles of responsible innovation and public engagement should be incorporated into education curricula to foster a better understanding of benefits and risks. Strengthening of ‘neuro-literacy’ in the wider public, including, for example, patient groups, practitioners, and lawyers would help responsible use.
- Business, private investors, and foundations are critical communities of practice in neurotechnology innovation and use. They, too, should engage in the development and implementation of recommendations for responsible innovation in the field.

1. Introduction

This 1.5-day Expert Consultation (14-15 September 2017, National Academy of Sciences, Washington D.C., United States) brought together experts from across sectors to assess ethical, legal, societal, regulatory, and economic aspects of innovation in neurotechnology. Participants identified key opportunities and challenges in the field. The meeting was part of an ongoing OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) project to produce best practices and recommendations for the responsible development of neurotechnologies.

Addressing the wide-reaching effects of population ageing, including the increase in mental illnesses and neurological disorders, remains a top priority for many countries and is reflected at the highest levels of international dialogue, e.g. the 2015 G20 in Turkey (Turkey's G20 Presidency, 2015[1]), the 2016 G7 in Japan.

Mental and neurological disorders are projected to increase sharply in line with demographic ageing and the globalisation of unhealthy lifestyles. More than 25% of all years lived with disability and over 10% of the total burden of disease is attributable to mental, neurological and substance use disorders (World Health Organization, 2013[2]). Examples of brain disorders (mental illnesses and neurological disorders) include neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease, schizophrenia, epilepsy, depression, stroke, migraine, sleep disorders, traumatic brain injury, pain syndromes and addiction. For example, more than 1 in 3 Europeans experience mental health problems in any given year, and even more are affected indirectly. The global total economic costs of mental disorders were estimated at USD 2.5 trillion in 2010, of which indirect cost 68%, and indirect cost 32% (Hewlett and Moran, 2014[3]; Olesen et al., 2012[4]; Trautmann, Rehm and Wittchen, 2016[5]). Authors project a cumulative economic output loss associated with mental disorders of USD 16.3 trillion worldwide until 2030.

Governments, funders, and companies around the world are making unprecedented investments in brain research and the development of neurotechnologies. Cutting-edge science and novel technologies developed under large-scale and multidisciplinary research initiatives are already creating new pathways for understanding and influencing fundamental brain functions. The translation of breakthrough research into tangible products with positive impacts for society remains a critical goal.

Advances in brain science and neurotechnology present major opportunities for health innovation and societal benefits, but also raise difficult questions at the intersection of science, society and economy (Table 1). Dedicated research and development programmes in brain science are giving rise to a host of new approaches, techniques and capacities to visualise, understand, and intervene in the human brain. Due to the often perceived unique moral status and physical importance of the brain, developments in brain science and associated technologies carry unique ethical, legal and social issues (ELSI). On the other hand, neurotechnologies are in various stages of research and development there is a broad agreement among stakeholders that social aspects of brain

research and neurotechnology innovation must be examined alongside the scientific and technical ones.

Use of neurotechnological and other digital health devices is increasing inside and outside the clinical and research setting and the line between therapeutic and non-therapeutic applications is blurring (Khan et al., 2017[6]; Wexler, 2017[7]; White et al., 2015[8]). As innovation in neurotechnology redefines what is possible in terms of understanding the brain, disease prevention, therapy, and enhancement, the implications of neurotechnologies for ethics and the law remain largely unexplored (Ienca and Andorno, 2017[9]).

The OECD Working Party on Biotechnology, Nanotechnology, and Converging Technologies (BNCT) has helped produce a series of meetings and reports addressing Alzheimer's and other neurological disorders (OECD, 2015; OECD, 2016). A recent BNCT workshop, "Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science" (15-16 September 2016 Washington D.C., United States), fostered international dialogue and cooperation across national initiatives on issues of open and responsible innovation in the arena of the brain. A key message was that more might be done to share good practices and develop common understandings across brain research and neurotechnology initiatives.

Table 1. Examples of stakeholder groups, normative frameworks, issues (opportunities and concerns), and categories and potential uses of neurotechnologies

Stakeholder groups	Issues	Normative frameworks
• researchers and research institutions • health care professionals • business/ manufacturers • policy makers • patients/ consumers • regulators • civil society and publics • funders • payers	• enhancement versus therapy • consciousness • cognitive liberty, autonomy • privacy • human identity • dual-use • hype and false claims • education • distributive justice and access • democratic governance	• anticipatory governance • RRI (responsible research and innovation) • ELSI (ethical, legal, social issues) • open science/ open innovation • innovation foresight • neuroethics/neurolaw • human rights

Categories of neurotechnologies	Potential uses of neurotechnologies
• invasive and non-invasive modulation • monitoring/ imaging devices • neuroprosthetics • nerve- and brain-machine interfaces • artificial neural networks • brain modelling and mapping • artificial intelligence technologies	• diagnosis • therapy • enhancement • recreation • research and learning • governance • law enforcement/ control

Note: The Table was prepared as background information for the Expert Consultation. Neurotechnologies can be defined as "devices and procedures that are used to access, monitor, investigate, assess, manipulate, and/ or emulate the structure and function of neural systems" (Giordano, J. (2012), Neurotechnology: premises, potential, and problems, CRC Press).

Building on the strength of the BNCT to assemble diverse actors, the dialogue drew from the fields of neuroscience, neuroethics, Responsible Research and Innovation (RRI), open science and open innovation, science and technology studies, and approaches to innovation policy among others.

As a general matter, the key objectives of the BNCT project "Neurotechnology and Society" are to:

1. Pool ideas, norms, and approaches for achieving more responsible innovation in neurotechnology for health-related applications through a step-wise process of dialogue involving researchers, innovators, policy makers, health care professionals, and the publics.
2. Promote deeper international dialogue, engagement, and transparency on the ethical, legal, societal, regulatory, and economic aspects upstream of neurotechnology development.
3. Provide best practices and explore possible recommendations around the development of new and innovative neurotechnologies for health-related applications to facilitate rapid and responsible integration into practice.

The scope of the Neurotechnology and Society project includes the following:

- Surveying the range of ethical, legal, and social issues that could arise from scientific and technological agendas.
- Fostering international communication, collaboration, and coordination; strengthening alignment between stakeholders for neurotechnologies for health related applications and the public awareness and understanding of neurotechnologies.
- Addressing the need for brain science and emerging neurotechnologies for health-related applications.
- Considering the relevant stakeholders invested in the development of emerging neurotechnologies and the potential engagement and governance challenges.
- Integrating social sciences and humanities in research, development, commercialisation and product use.
- Exploring unique ethical, legal and social issues that arise with the perceived special status of the brain and artificial intelligence systems (e.g., privacy, morality, cognitive control, capacity for consent).

2. New frontiers in neurotechnology and society

The Expert Consultation aimed to identify and classify cutting-edge neurotechnologies (e.g. neuroprosthetics, cell implants in the brain, brain-computer interfaces, artificial intelligence technologies), and the ethical, legal, social, economic and cultural issues that arise with them. This included discussion of both the technological present and future. Examples of questions meeting participants discussed: how are novel neurotechnologies currently transforming research, health, and society; what are key trends and what does the future look like for different neurotechnologies; what human values and interests are most at stake?

2.1. Neurotechnology development and use

Meeting participants acknowledged the increasingly international enterprise of neurotechnological innovation. The specific and fast developing domains and dimensions of neurotechnologies pose particular importance to ELSI and, thus, require ongoing scrutiny.

Responsible innovation is important in that it can – and often does – provide methods and systems for relevant ELSI deliberation toward defining sound studies and uses of neurotechnologies. However, in some countries or regions such frameworks may not exert sufficient reinforcing and/ or oversight measures to govern the actual conduct of research and technology use. This level of direction and constraint can be provided in the form of best practices, but is traditionally enforced by policy (and law). Therefore, some in attendance posited that:

- A more reciprocal relationship between neurotechnology development and use, and regulatory policies and legal measures would be needed. In this way, science and technology should inform policy, and policy should guide science and technology and govern responsible innovation with respect to diverse cultural domains.
- ELSI analyses should begin with evidence (about science/ technology, its use, and its users as the focal object(s) of policy).
- ELSI deliberation and policy development should be culturally aware, humble, and responsive.

Participants noted that neurotechnologies are being used to both assess brain structure and function to establish patterns of states and conditions, and intervene to affect the brain and its functions. Participants also discussed other approaches to categorise neurotechnologies: for example, in accordance with its use (reading, writing, and restoring) or purpose (preventing, restoring, replacing, and augmenting).

Distinctions of what constitute treatment and enhancement are based on a moving target of what society considers, for example, typical brain functions, and neurologic and psychiatric conditions.

When approaching issues and questions of neuro-cognitive enhancement, some meeting participants noted that:

- The distinction between normality and abnormality is historically and culturally relative (e.g. what is the normal level of functioning for an 80-year-old man). Thus, the simple distinction of treatment/ enhancement needs to be evaluated on a case by case basis.
- The current known and anticipated capabilities and limitations of neurotechnologies to enhance performance should be defined and appreciated.
- Claims for neurotechnology-based human enhancement should be evaluated for safety and effectiveness with recognition that the boundaries of what is considered enhancement beyond facilitating health generates considerable debate.
- ELSI relevant to neurotechnology-based enhancement may be context- and culture-dependent.

Some participants noted that the scope and pace of neurotechnology innovation can foster misinformation and misconceptions about the actual capabilities, limitations, validity and value of current and newly emerging neurotechnologies. This situation can be exacerbated by the many premature and exaggerated claims made in this domain. Therefore, it will be increasingly important to develop and sustain proactive efforts to educate professional and public audiences about brain science and neurotechnology and about the ELSI generated by their developments and various current and future uses. There is opportunity to encourage researchers to be ethical stewards of their work.

2.2. Consideration of cross-cultural evaluations in technology development

Neurotechnologies are developed and employed in diverse socio-cultural contexts. These contexts define, and are influenced by the focus, scope, pace, and general understanding/ acceptance of research and innovation. Thus, in any attempt to address ELSI in neurotechnology, it is important to understand the broader, cross-cultural dimensions of technology as it is researched and developed. Toward such goals, some participants argued the need to describe shared and distinct needs, values, and desires of the stakeholders involved, and seek relative determination of distinctions, and fortification of commonality.

Some participants noted that the differing ELSI inherent to cultures of locations in which science is being conducted and technology being used must be acknowledged, respected, and dialectically engaged in ways that are knowledgeable, responsible, and responsive. This task is both a challenge and an opportunity for the development of principles and recommendations that can be employed to inform policies, and that support and govern the responsible use of neurotechnologies. In this light, several participants felt that it is vital to recognise that socio-cultural and economic needs may vary and can influence both direction and demand for neurotechnologies, and these must be considered in ethics; and, ELSI should be discussed in ways that are culturally accessible and responsive.

2.3. Neurotechnology innovation

There is concomitant pressure for rapid translation and for conservative pacing, which can affect neurotechnological innovation and implementation. Thus, the accelerated pace and scope of neurotechnological research and development would substantially benefit from an equal timescale of ethical engagement, and policy formulation.

Clinical translation of neurotechnology should balance rapid translation and restraint. The intersection of unknowns (i.e. - about the brain in health and disease, about aspects of certain technologies, and about the durable effects of technological intervention upon the brain and its functions of cognition, emotion and behaviour) may dictate considerations of whether and how certain technologies can and should be used in clinical and non-clinical (e.g. legal, workplace, lifestyle/ wellness) contexts. These are important for considerations relevant to the law, insurance, occupations, social bias, and stigma.

Given historically varied definitions of the term "dual use", some participants suggested to establish a common understanding of its meaning, role, and implications in both research and application(s):

- Several international groups (e.g. Nuffield Council; European Union Human Brain Project), have been and are engaged in conversations about dual use.
- A broad definition of dual use encompasses any/ all applications beyond clinical care, to include occupational and lifestyle optimisation, military/ warfare and/ or political/ security operations.
- Uses in these domains must be informed by share- and stake-holder groups. Therefore it will be important to bring together representatives from, e.g. various government and non-governmental groups, to any discourse on dual use to provide relevant perspectives and broadly considered insights.

2.4. Issues in neurotechnology innovation and use

The following topics were identified as important for ongoing discourse and deliberation in neurotechnology:

- Use of neurotechnologies to identify, for example, atypical brain function and neurologic and psychiatric conditions for clinical treatment.
- Identifying known sources of uncertainty in the use of technologies for evaluating subjective states, including consciousness and types of pain.
- Use and misuse of neurotechnologies outside of therapeutic settings (e.g., do-it-yourself and consumer-marketed) neurotechnologies for cognitive and behavioural optimisation and enhancement.
- Viability of neurotechnologies to compensate for problems with and/ or de-limit capabilities of pharmacological approaches to psychiatric conditions and diseases;
- The obligation to more carefully and accurately interpret and employ neurotechnology-derived data.
- Basis and conflicts of trust between scientists, commercial developers, policy makers, and the public.
- Address and define currently used terminology, e.g., autonomy, dignity, enhancement, dual use.

- The incorporation of information gained from neurotechnologies into decision-making arenas, for example: neurolaw, courts, insurance, and employment.
- Deliberate consideration and analyses of cultural and social issues.
- Studies and engagement of neurological processes of learning toward developing more scientific basis for education.

3. Responsible innovation and stakeholders

Calls for improved science education and increased public engagement have long been a staple of recommendation documents in biomedical research, including in brain science and neurotechnology (Anderson and Giordano, 2013[10]; Brownell, Price and Steinman, 2013[11]; Durant, 1999[12]; Hankins, 2013[13]). It is easy to come to a consensus on the need for better science education among the public and for talking with the public about science. Historically, "public engagement" has often meant science communication intended to inform the public about science to increase public support and reduce public fear or concern. What is also now recognised is that the "deficit model" of assuming the public is largely ignorant of science and its methodologies is counterproductive, dismissive, and inaccurate. Increasingly, calls for publicly engaged science are more substantive and more focused on two-way, rather than one-way, communication with the public, or at least an acknowledgment that there are deficits to be addressed on both sides (Stilgoe, Lock and Wilsdon, 2014[14]). The public, including policy makers, needs to better understand what is going on in laboratories and the researchers need to better understand the hopes, interests, and concerns of the public (and even reflect more on their own values as scientists) with respect to science and value (Marris, 2014[15]; Scheufele, 2014[16]).

While the day-to-day activities of researchers may not concern most members of the public, the challenging societal questions at morally fraught forks in the road often do, for example, questions related to the use of brain chip technology for human enhancement or the use of genetics to study and/ or explain human behaviour or intelligence (Funk, Kennedy and Podrebarac Sciupac, 2016[17]). With a few notable exceptions (e.g., science museums, biohacker spaces), inclusion of the public and social scientists in the scientific process is not a robustly supported endeavour within research institutions (Flipse, 2013[18]). For example, even in the explicit calls for engagement in various recommendations or advisory reports, resources are rarely assigned for these activities. Consequently, public values which warrant representation or at least consideration in the practice of science can be forgotten, risking a disconnect or conflict between public values and scientific research, and allowing science to evolve in ways that may run counter to the goal of improving human health and well-being.

Participants discussed current developments in neurotechnology with regard to public engagement; what can we learn from similar initiatives related to other emerging technologies or in existing global brain research initiatives; who are the relevant stakeholders in the development of neurotechnologies and how – and at what stage – they should be included in the innovation process; and who should support and evaluate efforts at inclusive engagement in the responsible development of neurotechnologies. As a corollary to engagement, participants also discussed what norms and frameworks exist for collaborative innovation to aid the responsible development of neurotechnologies.

3.1. Public engagement

During the workshop, the public engagement discussion started with a proposed definition of meaningful public engagement activities as activities that are designed to contribute to important decisions about science in a way that ensures that these decisions are meaningfully and broadly informed, with genuine inclusion and representation of public values. This definition or understanding of public engagement does not require unanimity or consensus, but does require a transparent and justifiable process of deliberation and the incorporation of the products of that deliberation into decision-making.

There is strong justification for education (of both the public re: science and scientists re: public views, values, and potential socio-political implications), public engagement, and openness, and transparency – in the field of neurotechnology particularly due to the implications of brain science for our understanding of what it means to be human, and the personal stake that each of us has in such understanding.

Key points from the discussion included:

- Public engagement and education (as a precursor to or component of engagement) are important to incorporate into innovation in neurotechnology.
- Further, it is critical to consider engagement activities internationally, and to have a broad definition of stakeholders (e.g. going beyond English-speaking countries), when developing technologies likely to have global impact.
- The Internet, social media and other creative electronic and in-person formats are powerful tools for engagement and knowledge transmission, but carry the risk for unvetted information and/ or unsubstantiated claims.
- A central challenge of public engagement is the translation of the outcomes of engagement activities into changes in policy and practice. There is a need both to have support from those empowered to make decisions to incorporate public views and values, and transparent, justifiable, and monitored pathways to incorporation of the same.
- How do we address situations in which engagement activities are used to bolster a decision already made or legitimate a predetermined outcome on the part of the decision makers?
- We must go further than to call for public engagement and identify actors who are responsible for funding, conduct, and assessment of these activities.

In summary, most participants felt that public engagement is important to the responsible development of neurotechnologies. Although some models exist, a central struggle is the meaningful integration of leanings from public engagement activities into decision-making in actual research and development contexts. New opportunities and capacities facilitated by the internet and social media may help.

3.2. Open science and open innovation

Building on the theme from Session 1 of responsible research and innovation (RRI), a critical component of RRI is openness and transparency. The open innovation discussion focused on norms and frameworks around collaborative innovation (e.g., open science,

open innovation, responsible research and innovation) that have emerged or are emerging to aid the responsible development of neurotechnologies. An important caveat to this discussion was that some neurotechnology research and development takes place in confidential settings (e.g. military, commercial R&D) and therefore cannot be open and transparent in the same way we might expect of other publicly funded research. Much can be learnt from experiences across neurosciences and genomics. Choudhury et al. (2014[19]) state that most significant challenges to data sharing in this field are sociological and ethical: data sharing can be constrained by concerns for the privacy of the human research participants who are the data sources, and the data-sharing permissions they have granted in consenting to participate.

Transparency and data-sharing are important and compelling in brain science, especially given the expense of some of the data collection and the value of often limited human data. Broad access to data can also democratise science, opening it up to public deliberation, and giving access to the next generation of innovators, who might not be at the institutions (or in the countries) where the data are being produced.

Open Science practices can enable non-traditional partners to have a greater ability to influence the direction and outcomes of the science, can accelerate research, and help establish a norm of sharing. These practices can also help to increase the quality of data itself, because more people can access, use and evaluate the data.

3.3. The private sector

Although publicly-supported research is often the focus of discussions on responsible innovation, private-sector, and philanthropic investments are playing a key role in the development of neurotechnologies that enable new understandings of the brain and provide innovative treatment approaches. Greater attention to the private sector is required both to enable and ensure responsible innovation in neurotechnology.

Product development and translation into markets are key moments in the gestation of technology. Private stakeholders should discuss the opportunities of better understanding societal needs, ethical, legal and regulatory implications; and the translation of innovative research into future markets. Policy makers could lead the development of methodologies for measuring resource needs and opportunities in responsible business practices. Funders play an important role in the development business cases for responsible translation of brain science into neurotechnology applications.

3.4. Summary of meeting discussions

The neurotechnology field often requires large public investments. The complexity of the human brain and resulting human behaviour (and the finite sample of humans willing to participate) has been driving the desire for promoting open science and data sharing. Therefore, research results should be shared as much as possible to maximise the utility of the data and the impact of the public investment. Data sharing and transparency are important in neurotechnological innovation, helping to crowdsource ideas, improve overall data quality, and expose bad actors earlier.

Open innovation is important both to public engagement and to the responsible development of neurotechnologies overall. Principles of responsible innovation, and public engagement could be incorporated into the education of trainees in the brain science, as a way to seed in the next generation of scientists the necessary norms.

International efforts at neurotechnology research, development, and regulation should incorporate both principles of open innovation and a norm of meaningful public engagement in scientific decision making. Examples of both are available, though efforts towards implementation and developing the norms necessary to maintain them in each field are substantial.

Public engagement forms an interesting and important start to conversations within the possible future OECD recommendations and best practices around neurotechnology development and use. Understanding the roles these different views and activities play in responsible innovation of neurotechnology is critical to its success. As brain science and neurotechnology have implications for our understanding of what it means to be human, it is particularly important for this area of science to ensure that critical decisions are meaningfully and broadly informed, with genuine inclusion and representation of public values.

4. Cross-cutting issues

Any effort to coordinate national responses to a neurotechnology development and application should consider which arguments for or against international coordination apply to that neurotechnology, which could help determine the need for and the form of any international coordination in that context.

The two criteria used to identify potentially relevant applications of neurotechnologies were: 1) those applications that were likely to present significant policy, social and/ or ethical issues within the next decade; that 2) could and should be addressed at the international level. Participants identified three neurotechnology applications with policy significance:

- brain modulation and behaviour control
- predictive brain health/ behaviour
- novel neurotechnologies for diagnosis and therapy.

Cross-cutting issues that might apply to all specific applications of neurotechnologies and that possibly address any international coordination effort include:

- age/ race/ class/ social/ ethnic diversity in science
- cross-cultural similarities and differences
- respect for persons, informed consent, substitute decision-maker
- special protection for the brain (site of personhood, identity, consciousness, rationality) – for social reasons, not in and of itself
- social outcomes of new neurotechnologies (employment, relationships, cohesion, equality, social equity)
- incorporation of public values into innovation – public engagement;
- well-being – social, economic
- fairness – who participates in research? Who benefits from research?
- intellectual freedom and responsibility
- data access and interoperability
- transparency
- limiting hyperbole/ hype/ fear
- “Neuroliteracy” (i.e. - understanding of brain science)
- responsible stewardship – prudence; duty of due care
- need for interdisciplinary training and collaboration of scientists
- continuity of care with novel experimental interventions.

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ANNEX A: Expert Meeting Agenda

Agenda

Expert Consultation: "Neurotechnology and Society"

14-15 September 2017

National Academy of Sciences
2101 Constitution Ave NW
Washington D.C.
United States

Introduction and aims

This 1.5-day Expert Consultation will bring together leaders from across sectors to assess ethical, legal, societal, regulatory, and economic aspects of innovation in neurotechnology. The meeting is part of a larger OECD project to produce points to consider and best practices in the field, and to explore possible recommendations for the open and responsible development of neurotechnology. This Expert Consultation will serve as an important starting point for a larger Workshop in spring 2018. The meeting should culminate in a short report that outlines points to consider, best practices, and/ or approaches for stakeholder consideration, and discusses possible next steps in this larger international initiative.

Rationale and scope

Addressing the increase in diseases associated with an aging population and mental illness remains a top priority for many countries and is reflected at the highest levels of international dialogue, e.g. the 2016 G7 in Japan and the 2017 G7 in Italy. Neurotechnology can be defined as devices and procedures that are used to access, monitor, investigate, assess, manipulate, and emulate the structure and function of the central nervous system. Advances in neuroscience and neurotechnology present major opportunities for health innovation and societal benefit, but also raise difficult questions at the intersection of science, society and economy (Table A.1).

The OECD Working Party on Biotechnology, Nanotechnology, and Converging Technologies (BNCT) has helped produce a series of meetings and reports addressing Alzheimer's and other neurological disorders (OECD, 2015; OECD, 2016). A recent BNCT workshop, "Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science" (15-16 September 2016 Washington D.C., United States), fostered international dialogue and cooperation across national initiatives on issues of open and responsible innovation in the arena of the brain. The meeting also identified key challenges and barriers to integrating ethical, legal and social concerns upstream in technological development and within neuroscience research. A key message was that more might be done to share good practices and develop common understandings across national research initiatives and jurisdictions.

Table A.1. Examples of stakeholder groups, normative frameworks, issues (opportunities and concerns), and categories and potential uses of neurotechnology

Stakeholder groups	Issues	Normative frameworks
• researchers and research institutions • health care professionals • business/ manufacturers • policy makers • patients/ consumers • regulators • civil society and publics • funders • payers	• enhancement versus therapy • consciousness • cognitive liberty, autonomy • privacy • human identity • dual-use • hype and false claims • education • distributive justice and access • democratic governance	• anticipatory governance • RRI (responsible research and innovation) • ELSI (ethical, legal, social issues) • open science/ open innovation • innovation foresight • neuroethics/neurolaw • human rights

Categories of neurotechnologies	Potential uses of neurotechnologies
• invasive and non-invasive modulation • monitoring/ imaging devices • neuroprosthetics • nerve- and brain-machine interfaces • artificial neural networks • brain modelling and mapping • artificial intelligence technologies	• diagnosis • therapy • enhancement • recreation • research and learning • governance • law enforcement/ control

Note: the examples listed in this table are not exhaustive and apply to the OECD project "Open and Responsible Innovation in Neurotechnology".

Day One (Thursday, 14 September 2017)

08.30-09.00 ► Registration & breakfast

09.00-09.15 ► Welcome messages

09.15-12.30 ► Session 1: Mapping the new frontiers in neurotechnology and society

Moderator: Prof. Dr. James Giordano; Chief, Neuroethics Studies Program- Pellegrino Center for Clinical Bioethics, and Professor, Departments of Neurology and Biochemistry, Georgetown University Medical Center, Washington, D.C., USA

Identify and classify cutting-edge neurotechnologies (e.g. neuroprosthetics, cell implants in the brain, brain-computer interfaces, artificial intelligence technologies) and the ethical, legal and social issues that arise with them. This will include discussion of both the technological present and future.

Key questions to be discussed:

- How is novel neurotechnology currently transforming research, health, and society?
- What are key trends and what does the future look like for different neurotechnologies?
- What key human values and interests are most at stake?

12.30-14.00 ► Lunch

14.00-15.30 ► Session 2: Responsible innovation, stakeholders, and publics

Moderator: Dr. Debra J.H. Mathews (Assistant Director for Science Programs, Johns Hopkins Berman Institute of Bioethics; Associate Professor, Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, MD, USA)

Identify key frameworks and best practices in the responsible development of neurotechnology, i.e. practices that align the emergence of technology with the values, needs, and concerns of stakeholders and publics. Discuss the question of which actors must be involved and when, in any responsible development of neurotechnology. Discuss goals and mechanisms for stakeholder involvement, and identify new forms of collaborative innovation.

Key questions to be discussed:

- What actions are stakeholders taking to consider ELSI? In what fora are they meeting?
- Who are relevant stakeholders/ publics in the development of neurotechnology and how -- and at what stage -- should they be included in the innovation process?
- Are there practices in other fields that have proven effective at aligning innovation with public values, interests, and goals?
- What norms and frameworks around collaborative innovation (e.g., open science, open innovation, responsible research and innovation) have emerged or are emerging to aid the responsible development of neurotechnology?
- Who does/ will support and evaluate efforts at inclusive engagement in responsible development of neurotechnology?

15.30-16.00 ► Coffee break

16.00-18.00 ► Session 3: Defining the components of possible recommendations

Moderator: Prof. Dr. Gary E. Marchant (Prof. Gary Marchant, Faculty Director and Regents Professor, Center for Law Science & Innovation, Arizona State University, USA)

Neurotechnology raises a plethora of ethical, social, policy and legal issues. In this session, we want to identify and prioritise those applications and issues that meet both of the following two criteria: 1) they are issues of substantial societal importance that are likely to be feasible and have some potentially problematic implications (even if also some beneficial implications and applications) over the next decade or so; and 2) they are issues that lend themselves to cross-national coordination because for example they may create transboundary issues, may result in the creation of “risk havens” or medical tourism, may violate fundamental norms of human rights, or some other reason that warrants international coordination. Building on the previous sections, and considering the existing landscape of governance instruments, this session identifies major areas that might compose a set of recommendations coming from the OECD member states.

Key questions to be discussed:

- Do existing sources of governance at the local, national, and international level adequately address the goals of open and responsible development of neurotechnology?
- What is taxonomy of issues of greatest importance that should be included in (international) guidance?

18.00-19.30 ► Reception

Day Two (Friday, 15 September 2017)

08.30-09.00 ► Breakfast

09.00-12.00 ► Session 4: Distilling advice on best practices for possible recommendations

Group work towards possible recommendations on "Open and Responsible Innovation in Neurotechnology". Presentation of key learnings from Day 1. What expert advice might inform a possible effort to develop recommendations? Discuss key governance issues and possible scope of 2018 meeting.

12.00-12.30 ► Meeting summary

12.30 ► End of meeting