# Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science

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**Technological advances have the potential to dramatically increase our understanding of the human brain, treat and cure injury and disease, and enhance our general well-being. While advances in neuroscience hold great promise, they also raise profound ethical, legal, and social questions. In this vein, the Organization for Economic Co-operation and Development (OECD) convened an international workshop in September 2016 to explore responsible research and innovation in brain science.**

## Introduction: Neurotechnology and Society

There are still major gaps in our understanding of how the brain functions in health and in disease. Significant advances in neuroscience, technology, and fundamental tools are needed to treat conditions such as depression, schizophrenia, and Alzheimer's disease and to address the growing global burden that brain-related injuries and illnesses represent (OECD, 2015). Cutting-edge research and tools developed under large-scale and multidisciplinary research initiatives are already creating new pathways for influencing fundamental brain functions. But such intercession is not without risks; research on the human brain raises profound ethical, legal, and social questions that, if not adequately addressed, could undermine the uptake of safe and effective interventions.

There is broad agreement that ethical, legal, and social issues should inform the trajectory of this work and feed into the scientific research agenda. There are some notable efforts to do so across the world. But there have been few opportunities to examine whether and how that is being done. To address this, the Organization for Economic Co-operation and Development (OECD), in collaboration with the Arizona State University, United States of America (U.S.), and the National Academies of Sciences, Engineering, and Medicine, U.S., convened a one and a half day workshop titled *Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science* (15–16 September 2016, National Academy of Sciences, Washington, D.C.).

The workshop brought together key international stakeholders for the purposes of moving the discourse and debate beyond the narrowly construed notion of neuroethics as ethical philosophy and/or safety and efficacy assessment. Discussions focused on how society and policy makers might better anticipate, before products hit the regulatory system or market, the governance challenges raised by, e.g., cognitive enhancement, non-therapeutic use of neuromodulation, and convergence of the human brain with artificial intelligence (AI) systems. A primary objective of the workshop was to identify the key challenges and barriers to integrating ethical, legal, and social concerns upstream in technological development and within neuroscience research. There was no singular or definitive answer. However, workshop participants identified core approaches and principles that, if operationalized, could better enable the development of better technological outcomes.

## Frameworks for Integrating Brain Science and Society

Today, many national programs of research and innovation explicitly aim to increase the interplay, and overlap, between scientific and societal issues. The international Human Genome Project (1990–2003) was one of the earlier large-scale initiatives in which social scientists worked in parallel with the natural sciences in order to consider the ethical, legal, and social dimensions of their work (Murray and Livny, 1995; Walker and Morrissey, 2014). The deliberation of ethical, legal, and social implications (ELSI) and "responsibility" in nanotechnologies is another example of how societies, in some jurisdictions, have approached research and development (R&D) activities and the role of the public in shaping (or at least informing) their trajectory. The nano-policy discourse and public engagement started in the mid-1990s and offers important lessons from various economic, social, scientific, environmental, and legal perspectives (Simakova and Coenen, 2013). The case of geoengineering ("the deliberate large-scale manipulation of the planetary environment to counteract anthropogenic climate change," https://royalsociety.org/topics-policy/publications/2009/geoengineering-climate/) raises "dual-use" dilemmas that are recognized in synthetic biology and other areas. Actions and activities promoted by these frameworks may include, for example, embedding social scientists in research labs, commissioning parallel work in law and ethics, and engaging the public in a range of different dialog activities.

ELSI activities are also shaping research agendas and practices within various

 

major national brain activities. An explicit goal of the U.S. BRAIN Initiative is to advance brain science toward positive social outcomes and to engage with patients, advocacy groups, and the public. One stated aim is to generate a discourse around the challenges of brain health and the societal benefits, risks, and unrealized promises. Focusing on mainly ethical implications of brain science, the Neuroethics Workgroup of the U.S. BRAIN Initiative Multi-Council Working Group (MCWG) plays an advisory role to identify ethical issues of importance to funded BRAIN research. The MCWG is tasked to identify, and draw out, long-term concerns that require further discussion and public engagement. The U.S. Defense Advanced Research Projects Agency (DARPA) is working on cutting-edge neurotechnologies that may have broad societal impacts. In order to engage with these issues, DARPA established an independent expert panel focused on ELSI. This body uses an operational neurotechnology risk assessment and mitigation paradigm, which is designed specifically for the purpose of proactively addressing issues raised by new and emerging technologies as part of their research programs.

The European Union (EU) has adopted a more institutional approach to "responsibility," "responsible development," and "responsible innovation" for science and technology. Such terms have been increasingly operationalized within funding programs and have gained relevance in research and innovation policy at the supranational level (Owen et al., 2012). These earlier terms have since been superseded in the policy, funding, and research discourse by a more formal framing of "Responsible Research and Innovation" (RRI) (Tancoigne et al., 2016). The EU's approach to RRI seeks to mainstream the consideration of science and society and underpins major European Commission (EC) research initiatives, including the Horizon 2020 Framework Program for research and innovation. Here RRI aims to widen the scope of formal processes of ethics review for research and innovation into a more open approach that addresses wider societal implications of science, services, and products. Nanotechnologies provided the first case-study for RRI practitioners; tools and methods were developed and tested with the now ubiquitous technology including, for example, the EC's *Code of conduct for responsible nanosciences and nanotechnologies research* (http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf).

Looking specifically at national brain projects, we can see numerous attempts by stakeholders to systematically integrate brain science and society (Shen and Gromet, 2015). For example, the Work Programme 2016 of the French National Research Agency (ANR) promotes collaborative research in humanities and neurosciences to better understand the social dimension of human brains, e.g., memory, behaviors, conscience, thought, language, and relationships with others (http://www.agence-nationale-recherche.fr/en/funding-opportunities/work-programme-2016/). The two key ELSI and RRI mechanisms of the EU's Human Brain Project (HBP) are the integrated Ethics and Society Subproject and the external Ethics Advisory Board. The Ethics and Society Subproject is fully embedded into the HBP and has a dual role: first, it aims to create an open and transparent discussion with all stakeholders, including the public; second, it raises awareness among scientists and other project stakeholders about the social implications of future outcomes.

## Responsible Research and Innovation

But what exactly is RRI? Given the differences of opinion that exist in relation to definition, let alone framing, it is not surprising that challenges still exist in applying the RRI framework to emerging technologies such as neurotechnologies. This is despite the availability, today, of excellent "toolkits" and practical guidance material to assist with their implementation (http://www.rri-tools.eu). During the workshop, Dr. Christine Aicardi (Senior Research Fellow, Human Brain Project Foresight Lab, Department of Global Health & Social Medicine, King's College London, UK) noted, for example, that "it is a difficult task to integrate a strong ethics mindset into research and technology development while advancing the kind of innovation our project pursues in brain science and neurotechnology."

While there is no one formally agreed upon definition, von Schomberg—a central figure in the development and implementation of RRI—has offered the following definition:

> A transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society) (von Schomberg, 2013).

Others define RRI as:

> An approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation. It implies that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society (https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation).

Yet others define RRI as:

> A science policy framework that attempts to import broad social values into technological innovation processes whilst supporting institutional decision-making under conditions of uncertainty and ambiguity. In this respect, RRI re-focuses technological governance from standard debates on risks to discussions about the ethical stewardship of innovation (Schroeder and Ladikas, 2015).

It is clear that RRI is designed to encourage stakeholders to collectively discuss avenues for advancing societal goals through technology, including

moral, ethical, legal, and social implications of research and innovation (Owen et al., 2013). RRI tools and approaches have been applied to other emerging technologies, including synthetic biology and information and communication technologies. Despite this, the challenge still remains for scholars, researchers, policy makers, and users to entertain on-going multi-stakeholder conversations and to translate elements of RRI into practice (de Jong et al., 2016).

## Anticipatory Governance

If it is a touchstone of RRI that social values should not be addressed only as products make their way into the market, but also during their development and refinement, then the concept of "anticipatory governance" might offer some practical guidance on its implementation. Arizona State University Professor David Guston, who was present at the workshop, has defined anticipatory governance as "a broad-based capacity extended through society that can act on a variety of inputs to manage emerging knowledge-based technologies while such management is still possible" (Guston, 2014). Such an approach combines techniques for anticipation, the development of realistic scenarios, and public engagement to help inform policy and the development of an appropriate governance framework. These techniques have been used in relation to emerging technologies over the last 10 years, with public engagement and scholarship focusing on nanotechnologies, synthetic biology, and geoengineering in particular (Foley et al., 2015).

Novel brain devices, such as thought-controlled computing and Deep Brain Stimulation (DBS), would benefit from anticipatory governance early in the research and development process. Questions over safety and efficacy should be considered alongside questions on the potential impacts of such applications on human dignity, privacy, and equitable access. But anticipatory governance is not necessarily easy. Indeed, meaningful dialogic public engagement is both costly and politically risky (Stilgoe et al., 2014). But upstream public engagement and stronger integration of current neuroscience into academic curricula would help build the capacity for rational discussion with the public about what is "hype," what constitutes "science fiction," and what is *actually* within the short to medium term.

The underlying argument here is that outcomes can be achieved through innovation when the research and development processes incorporate future-orientated, collective action, in tandem with mechanisms that promote transparency and accountability. Questions that can help guide the ELSI/RRI process include, for example:

- Who benefits, how, and what are the (potential) costs?
- What are the uncertainties and what are the potential implications if we are wrong?
- Who controls access to the science and the technology, and under what conditions?

## The Case of Non-invasive Neuromodulation

Some neurotechnological applications appear to be uncontroversial (including, for example, brain interfaces as diagnostic tools to interpret and treat brain disorders) but may have a significant impact on human performance, equity, and health. Non-invasive neuromodulation devices are increasingly investigated as a treatment for a variety of other neurologic disorders, including epilepsy, migraine, movement disorders, amyotrophic lateral sclerosis (ALS), tinnitus, and chronic pain (National Academies of Sciences, Engineering, and Medicine, 2015). While not a wide-spread practice at this time, it has the potential to become so as the technology matures. In addition, neuromodulation devices are also being increasingly employed outside of clinical settings for non-therapeutic purposes, including cognitive enhancement, via both consumer products and "do it yourself" devices built at home with readily available components.

In March 2015, the Forum on Neuroscience and Nervous System Disorders at the National Academies of Sciences, Engineering, and Medicine (the Neuroscience Forum) hosted a workshop on non-invasive neuromodulation (National Academies of Sciences, Engineering, and Medicine, 2015). Workshop discussions highlighted that despite the potentially significant therapeutic benefits offered by current, and future generations, of non-invasive neuromodulation devices, fundamental scientific and technical questions remain about the mechanism(s) through which the devices impact and interact with the brain, long-term consequences, and the effects of varying the multiple parameters associated with non-invasive neuromodulation (e.g., coil geometry and placement, pulse timing, number and spacing of sessions). Non-invasive neuromodulation devices also raise important ethical, legal, and social questions related to authenticity and the self, enhancement, use in vulnerable populations (e.g., in children or individuals with mental illness), involuntary use (e.g., court-ordered or psychiatrist-ordered), and unsupervised use. These questions are particularly poignant in relation to non-therapeutic applications.

These issues were explored in more depth, and in an international context, during the OECD Workshop. At this time there is an absence of guidance material that can assist stakeholders to engage with, and actively build in, the ethical, legal, and social implications of this technology. The development of "soft law" instruments, including guidance material and best practice documents, may be a critical and necessary step forward to help relevant stakeholders deal with the ELSI dimensions posed by non-invasive modulation in the short and medium terms. Such soft law instruments can be designed to encourage actors to actively consider questions around identity and autonomy. Professor Henry Greely of Stanford Law School has argued that while it will be important to deal with unproven claims around the health and well-being benefits, the real ELSI issues will occur when we can reliably interfere with an individual's mind. Such a statement stresses the need for ELSI-framed discussions now, rather than waiting until the technology has been proven to be safe and effective for therapeutic applications.

## Avoiding Neuro-hype

In order to ensure that the science and its advances are not oversold, evidentiary standards must be developed and upheld by policymakers, scientists and industry. During the workshop, Dr. Christine Aicardi raised the following questions: Why neurotechnology deserves so much attention? And how do users like clinicians and patients know if the new tools for health or

**Box 1. Key Policy Implications Emanating from the OECD Workshop**

- Public research funders, private investors, and foundations are particularly well positioned to shape the downstream trajectories of neurotechnology R&D and to ensure that mechanisms to promote responsible innovation are in place.
- Regulators and policy makers can, and should, work with all stakeholder groups, including the public and private sector, to better define the line between therapeutic and non-therapeutic applications, especially in the realm of enhancement technologies. Ideally, this would be done before products enter the market.
- The employment of anticipatory governance processes, and development of subsequent instruments, would assist in directing the strong "technological push" of brain science towards addressing pressing societal needs. For this to be effective, and credible, there is a need for experimentation and examples of governance and public deliberation approaches across sectors (for example, funders, academia, industry, and ethics advisory groups).
- Better integration of current neuroscience into academic curricula, the clinical environment, and the wider public discourse would aid in promoting rational, and balanced, discussions about the future trajectory of neuroscience and neurotechnology.
- Future work on responsible innovation could include: (1) deepening the discussion on selected ethical and legal aspects of brain science; (2) actively engaging with patients and patient organizations in order to better understand their position(s) with regard to the use of neurotechnology in clinical research, diagnosis and therapy; (3) developing a matrix of frameworks of further integrating RRI into emerging technologies by different stakeholders; and (4) collecting evidence about the use and impact of RRI in science, technology, and innovation processes both within, and external to, the EU borders.

well-being actually work as described? Where regulation does not yet exist, what can policymakers do to provide the required evidence about product safety and efficacy? Much can be learned from other scientific domains and advances, but unique aspects of the human brain still remain that make it "different" and therefore subject to excitement as well as "neuro-hype." There is also a role to be played here by patient advocate groups, health insurance companies, and other relevant parties. Societies would benefit from more accountability for how possible future neurotechnologies are being developed and implemented, including projected timelines.

## Regulatory Challenges

Responsible innovation will mean addressing significant regulatory challenges presenting this emerging field. As one participant in the OECD Workshop, Dr. Hannah Maslen (Postdoctoral Research Fellow, University of Oxford), put it, "regulators are key to ensure standards are respected." Yet, even in the short term, regulatory agencies are challenged by shifts in technology paradigms that include, for example, a rise in product complexity and a melding of natural, medical, and social sciences. For instance, the rise in direct-to-consumer electrical and magnetic brain stimulation devices raises important questions of governance, including, for example, what level of risk presented by these devices should be accepted and approved for the direct-to-consumer market? And on the condition of what level of benefit? Because the manufacturers of most devices for cognitive enhancement do not make therapeutic claims about the product, only basic safety standards apply. However, given the uncertainty about potential risks that such products may pose, regulatory action is required.

Furthermore, non-therapeutic use of neurotechnologies is difficult to regulate. As an alternative to the minimal risk and self-regulation approach to cognitive enhancement devices, Maslen et al. (2014) support the concept of applying medical device regulations with an evidence-based assessment of potential benefits and risks. However, she suggested that there is greater difficulty present in ascertaining the weight that should be ascribed to so-called "lifestyle" or "enhancement" benefits, compared to clinical benefits. This gives regulators reason to leave more room for consumer assessment, while still requiring manufacturers to demonstrate the veracity of their claims about measurable improvements to an individual's capacities. This would, arguably, better serve consumer needs. However, it would also place a sizeable burden on innovators and manufacturers, who would be required to show evidence of the benefits that they claim their devices confer and of successful minimization of potential risks.

## Open Innovation

The idea of responsible innovation conveys the notion that if configured correctly, new forms of governance arrangements may accelerate, rather than hinder, innovation. This is because potential problems are clarified ahead of time, leaving pathways open for research and development. And parties and publics external to the science and its development may play a cooperative role in developing innovations that will deeply benefit their lives, or that of their community. New modes of open science and open innovation can assist in fostering collaborative forms of collaboration that incorporate the goals, and needs, of multiple stakeholders.

The term "open innovation" does not have a widely agreed meaning but tends to describe a move from the individual innovator to a global collective, through which researchers and business share information and use external knowledge to advance science and product development (OECD, 2008). Through various forms of open innovation, firms can, and should, use internal and external ideas, all potential pathways available to them in order to get their product to market and advance the technology (World Intellectual Property Organization, 2010). Open innovation also encourages companies to find external partners for commercializing innovations (i.e., divestment, spin-out, spin-off) (https://www.innovationpolicyplatform.org/content/open-innovation).

Finding the right dose of openness and an environment of appropriate regulation (however defined) may, however, be challenging, especially in regards to an

emerging technology that is evolving and maturing quickly. Some stakeholders argue that a wider use of disruptive innovation would promote socially acceptable outcomes and better manage unwanted effects (http://www.economist.com/news/special-report/21700762-techies-do-not-believe-artificial-intelligence-will-run-out-control-there-are). Others point to the trade-offs of openness. Bostrom (2016) has, for example, argued that openness is positive when talking about safety measures and goals of the technology. However, openness about source code, science, and possibly capabilities might lead to a tightening of the competitive situation, "increasing the probability that winning the AI race is incompatible with using any safety method that incurs a delay or limits performance." Openness can also promote transparency and alternative research pathways. But this needs to be done in a way that addresses privacy risks and respects the individuals whose data are being shared (e.g., patient's data or tissue samples may be used in a very different way than expected) (Institute of Medicine, 2015).

The Montreal Neurological Institute and Hospital (the Neuro, McGill University, Canada) has initiated a bold experiment for the purposes of embracing and promoting open science. The experiment aims to go beyond open data and sharing of biosamples; rather, the aim is to make all results, data, and publications from its research freely available to anyone who wishes to access it. Collaborators will be required to do the same. Arguably, the most surprising component of their approach is that the research team will not pursue patents on any of its inventions for at least the first 5 years (to then be reviewed). According to Richard Gold, Professor of Law at McGill University, a key reason why neuroscience lags behind other research areas in terms of therapeutic output is the complexity of datasets in brain research.

## Policy Implications

One of the main lessons arising out of the OECD Workshop was the need for greater transparency and collaboration, especially in relation to data sharing, and the implementation of mechanisms that would allow for more open and responsible innovation. Participants also emphasized the need for greater coordination between actors at the global level, with a specific focus on the development of standards and governance frameworks that address broader social needs and values (see Box 1). This can, and should, be done in ways that are accessible to the public and inform in such a way as to present a clear and balanced perspective. Stakeholders should seek to demystify the science and the technologies, seeking to differentiate between what is real and what exists (at least at that time) in the realm of science fiction. There is a very real risk that the neuro-hype and false promises can give rise to mistrust and unintended social effects. Should this happen, society's response could hamper the translation of products into the market, or result in their outright rejection altogether.

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