Neurotechnology at the OECD: The role of the private sector in governance

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Emerging neurotechnologies offer significant potential for the promotion of health, well-being, and economy. At the same time, neurotechnology raises issues of (brain) data privacy, the prospects of human enhancement, the regulation and marketing of direct-to-consumer devices, the vulnerability of cognitive patterns for commercial or political manipulation, and further inequalities in use and access. Engaging this challenging terrain, the member countries of the Organisation for Economic Cooperation and Development (OECD) have recently enacted Council Recommendation on Responsible Innovation in Neurotechnology. The Recommendation is the first international instrument in its field. This article discusses the context and content of the Recommendation, highlighting its unique "responsible innovation" approach which spotlights the role of the private sector in technology governance.

Introduction

Emerging neurotechnologies have the potential to radically change how to understand human cognition and behaviour. Defined as "devices and procedures that are used to access, monitor, investigate, assess, manipulate, and emulate the structure and function of neural systems" (Giordano, 2012), they also offer tremendous potential for the promotion of health, well-being, and economy. Mental and neurological disorders (e.g. Alzheimer's disease and other dementias) cause great human suffering and are increasingly recognised as major causes of death and disability worldwide. They often remain untreated and impose significant economic and social welfare costs, elevating their importance to the highest national and international policy levels (Garden and Winickoff, 2017).

Neurotechnology is redefining what is possible in terms of monitoring and intervention in clinical and non-clinical settings, with great promise for improving mental health. Spearheaded by large national and international flagship initiatives in brain science and fuelled by a clear medical need, research both in the public and private sector has made considerable advances. In particular, the convergence between neuroscience, engineering, digitalisation, and artificial intelligence (AI) is becoming a key driver of innovation and will disrupt existing practices as well as traditional boundaries between medical therapies and consumer markets.

At the same time, neurotechnology raises a range of unique ethical, legal, and societal questions (Yuste, 2017). These questions include issues of (brain) data privacy, the prospects of human enhancement, the regulation and marketing of direct-to-consumer devices, the vulnerability of cognitive patterns for commercial or political manipulation, and further inequalities in use and access (Nuffield Council, 2013). Governance issues surrounding neurotechnology affect the entire innovation pipeline, from fundamental brain research, cognitive neuroscience, and other brain-inspired sciences to questions of commercialisation and marketing.

Engaging this challenging terrain, the 36 member countries of the Organisation for Economic Cooperation and Development (OECD) have recently enacted Council Recommendation on Responsible Innovation in Neurotechnology (the "Recommendation"), adopted on 11 December 2019 (OECD, 2019).

The Recommendation is the first international instrument in its field. Over a period of over five years, the OECD led a series of multi-stakeholder workshops that explored strategies for the responsible development and use of innovative neurotechnologies (Marchant and Tournas, 2019). It is soft law, non-binding from a legal matter but enforced through moral suasion and regular monitoring across countries.
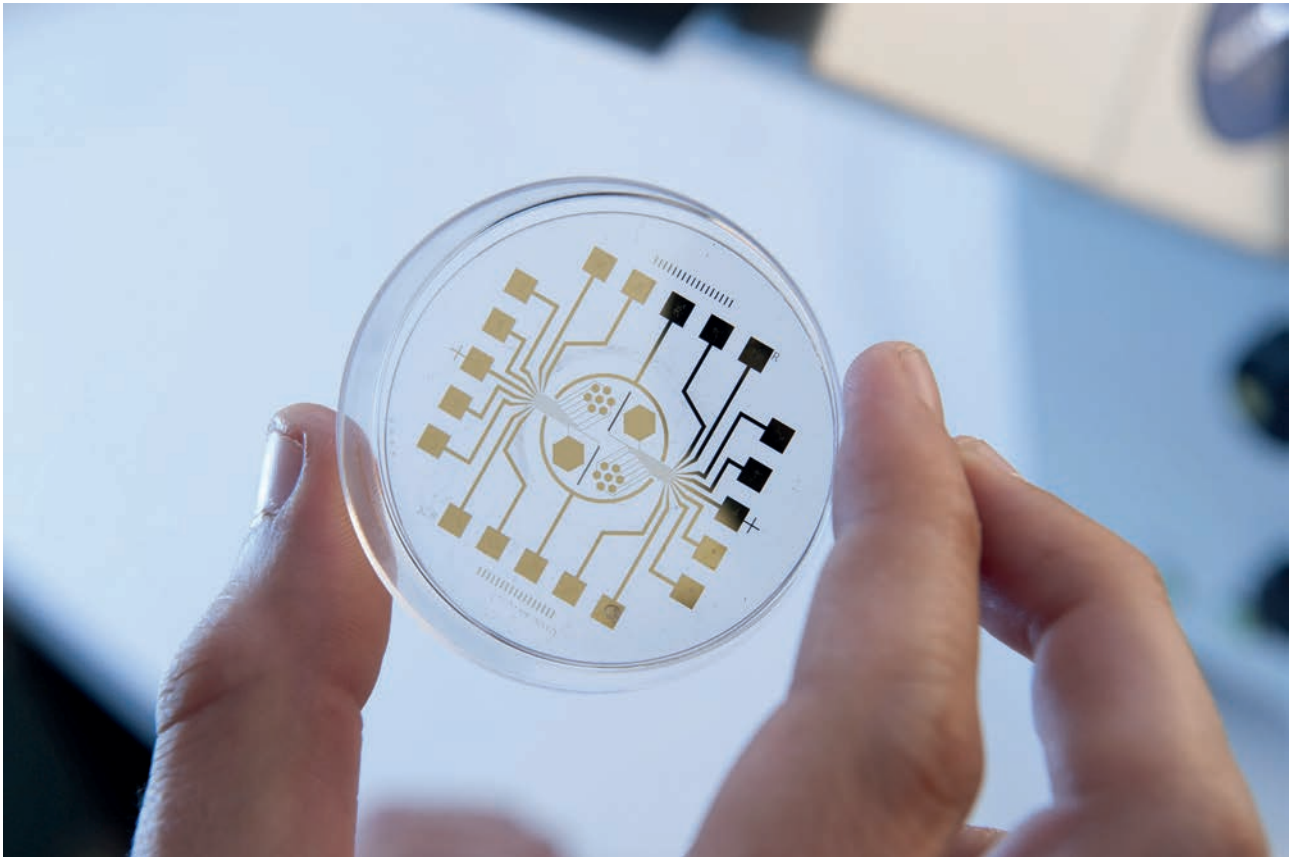
Une micro-électrode.

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"Governance issues surrounding neurotechnology affect the entire innovation pipeline, from fundamental brain research, cognitive neuroscience, and other brain-inspired sciences to questions of commercialisation and marketing."

This article discusses the context and content of the Recommendation, highlighting its "responsible innovation" approach. Next it explores in more depth one of the unique aspects of the Recommendation, that is the role of the private sector in responsible innovation.

The OECD Recommendation

With origins as the administration agency of Marshall Plan, the OECD is a body of 37 countries with advanced economies and that share a commitment to "Bretton Woods"-style liberal democratic principles. The OECD carries out multiple functions which, when combined, distinguish it on the international landscape. First, it operates as a diplomatic space, where countries come together to negotiate sets of common actions such as an agreement on international profit shifting [1]. Second, it is a research institution or "think tank" meant to create a common knowledge base through research and data collection for public policy across countries to help facilitate cooperation and exchange.

Finally, the OECD is a forum for making "soft law". Its nearly 169 OECD Recommendations, adopted by the consensus of OECD members, function as normative frameworks for a large array of policies. Soft law refers to policy instruments with moral or political force but without legal enforceability. OECD Recommendations would qualify as soft law. According to the OECD [2] : "OECD Recommendations are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation".

Examples of soft law include private standards, general policies, guidelines, principles, codes of conduct, and forums for transnational dialogue.

Developing international soft law at the intersection of science, technology and innovation is one of the OECD's activities. Over the last few years, in addition to the neurotechnology recommendation, the OECD has developed the OECD Recommendation of the Council on Artificial Intelligence [3]. It helped shape the G7 agenda on AI, and has formed the basis of the new international Global Partnership on AI [4] and the creation of an AI Policy Observatory [5].

(1) https://www.oecd.org/tax/beps/

(2) https://www.oecd.org/legal/legal-instruments.htm
(3) https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449
(4) https://gpai.ai/
(5) https://oecd.ai/

The Recommendation of the Council on Responsible Innovation in Neurotechnology aims to help public and private actors address the ethical, legal and social challenges of neurotechnology while encouraging innovation. The Neurotechnology Recommendation is made up of nine principles (see Box 1), each principle being specified with more detailed recommendations that are not included here.

Box 1. OECD Recommendation of the Council on Responsible Innovation in Neurotechnology

1. Promote responsible innovation
2. Prioritise safety assessment
3. Promote inclusivity
4. Foster scientific collaboration
5. Enable societal deliberation
6. Enable capacity of oversight and advisory bodies
7. Safeguard personal brain data and other information
8. Promote cultures of stewardship and trust across the public and private sector
9. Anticipate and monitor potential unintended use and/or misuse

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Responsible Innovation approach

Ultimately, technology will be useless unless it can be diffused and built into society in ways that are trusted and socially robust – trustworthy, debated, accessible, and socially acceptable.

Recognising this axiom, the Recommendation embodies a "responsible innovation" approach, finding inspiration in the field of Science and Technology Studies (Stilgoe *et al.*, 2013) and work funded by the European Union under the Horizon 2020 work programme. The responsible innovation approach seeks to cope with the so-called Collingridge Dilemma at the heart of technology governance: regulating too early can stifle innovation but regulating further downstream may be too late to influence how technology operates in society (Collingridge, 1980). It seeks to anticipate problems in the course of innovation and steer technology to best outcomes, and include many stakeholders in the innovation process (Guston, 2014; Winickoff and Pfortenhauer, 2018).

Good governance actually can actually enable, not constrain, technology. This insight – focused on governance from the perspective of innovation – sets the Recommendation apart from many other, if not all, international instruments dealing with technology in society. In realizing a responsible innovation system, at least five overarching elements stand out and make this instrument unique among related statements: 1) alignment with goal-oriented innovation policy; 2) inclusivity; 3) anticipation;

and 4) deliberation. Each is finding increasing potency in innovation policy.

Alignment
Recommendation responds to calls to better align research, commercialisation and societal needs, i.e. promotes "mission-oriented" and "purposive" technological transformation to better connect innovation to mental health.

Inclusivity
When talking about inclusive innovation, attention usually focuses on technological divides and access inequality. The Recommendation brings attention to further forms of inclusivity, i.e. how the inclusion of stakeholders, citizens, publics, and systematically excluded actors within the innovation process can help drive innovation through "co-creation" (Winickoff and Pfortenhauer, 2018).

Anticipation
From an innovation perspective, end-of-pipe-approaches can be inflexible, inadequate and even stifling. In the realm of technology governance, governments and policy makers are currently experimenting in the form of test-beds, sand boxes, new technology assessment methods and foresight strategies.

Deliberation
Deliberation is more demanding than public participation as it implies an iterative exchange of views in hopes of finding reasoned discourse and even common ground. The approach demands the enhancement societal capacities to understand, communicate on, and shape technology through the course of development so that technology might advance under conditions of trust, enabling their development to market.

Role of the Private Sector in Responsible Innovation

Whereas many ethics of technology codes place duties on scientists and clinicians, this Recommendation also advances an institutional approach, targeting guidance to funding agencies, oversight bodies, and companies. In particular, the Recommendation reflects that fact that companies have a critical role to play in governance as they are on the front lines of product development, regulation, diffusion and marketing and should commit themselves to a responsible innovation framework (see Box 2).

Tools and approaches for responsible governance of neurotechnology are emerging [6] There has been considerable experimentation among companies about how to address the unique social, ethical, and legal

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(6) Many of these were aired at the 2018 OECD Shanghai Workshop, "Minding neurotechnology: delivering responsible innovation for health and well-being" brought together more than 120 leaders from 12 countries from government, companies, academia, venture capital, and insurance companies to shed light on the benefits, challenges, and options of strengthening responsible innovation in the private sector.

aspects raised by novel neurotechnology, especially those related to the collection and use of "personal brain data" [7]. Emergent "good practices" in the private sector include for example the appointment of advisory boards on ethical, legal and social questions; the development of guidelines and principles; greater emphasis on responsible technology transfer; and interest in socially responsible investment (Pfortenhauer *et al.*, 2021).

Importantly, many approaches known from the public sector do not easily translate to companies. Especially start-up companies lack the organizational and financial resources, and face considerable pressures of speed and scale that tend to discourage costly and slow deliberative exercises. Moreover, approaches from other sectors do not easily translate to neurotechnology. A mix of soft and hard governance tools (e.g. industry standards, regulatory processes) is needed for different sectors and different applications. These should provide clear pathways for developers that give certainty in routes to market as well as gaining societal approval. Experience with other emerging technologies suggests opportunities in including roles for researchers, clinicians, industry, governments, and civil society in governance models. Frameworks such as Corporate Social Responsibility or Responsible Business Practices could be enriched with approaches of Responsible Research and Innovation, and vice versa (Pfortenhauer *et al.*, 2021).

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(7) "Personal brain data" is information relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health, or mental states.

Analytical work from the OECD on neurotechnology governance yields further insights on the modalities of private sector governance for neurotechnology.

An explicit commitment to principles of responsible development upstream can promote the trust and trustworthiness that are crucial for success

Responsible design considerations early in the pipeline as part of the innovation process itself can support the social robustness and acceptability of new products and services, increase end-user trust, and ensure that innovation delivers for and with society (Winickoff and Pfortenhauer, 2018). Transparency is critical to build trust in the ways data will be collected, managed and used.

Sound regulation is key to enable robust innovation trajectories

Soft-law measures and self-regulation are important building blocks of responsible innovation. However, clear and better aligned regulatory frameworks are equally needed to create certainty and ensure a high-level of user protection. Overall a functional, bottom-up approach, starting with the assessment of the technical peculiarities of different classes of applications, is to be preferred to the adoption of broad and all-encompassing principles.

There are large potential gains to be derived from data sharing

International collaboration in neurotechnology innovation should include a focus on sharing of personal brain data. Significant cultural differences exist, and a diversity of governance systems can complicate data sharing. The standardisation of personal brain data collection, curation, and sharing will not only drive new discovery, but will also be essential to obtain broader value from the data. Privacy concerns will always have to be taken into account.

Public deliberation can contribute directly to value creation

Public engagement is critical in the development of robust neurotechnology futures and for a comprehensive governance approach. Innovation in neurotechnology must be a collaboration between science and society: currently, the public is too frequently viewed through the lenses of knowledge deficits and trust deficits (OECD, 2018).

Investors play a key role in enabling responsible innovation

Investment is the lifeblood of the start-up driven neurotechnology industry, without which innovations cannot reach the marketplace. Questions of funding, public-private partnerships, grants, and public markets play a key role for addressing challenges of responsible innovation effectively. Guidance on "responsible investment" could help support such efforts.

Conclusion

As a general matter, there is an urgent need to develop shared frameworks for how novel technology develops in a responsible way. New governance mechanisms will likely be

required to address how these technologies challenge our understanding of risk and uncertainty, economic and cultural change, human agency and other broad impacts on society. The Council Recommendation on Responsible Innovation in Neurotechnology is one such framework in the context of one technology, but there will likely be the need for others.

Responsible technology development and effective governance must involve the private sector as a central actor early on, especially in global contexts. At the same time, the private sector has a key interest in demonstrating responsibility and integrity. Experience with innovation trajectories in other emerging technologies (e.g. nanotechnology) reveal that upstream engagement can be crucial for identifying and mitigating public concerns early in the development process. Companies are keenly aware that the entire neurotechnology business sector can be harmed and public trust can be undermined by single bad corporate actors in the field.

A lesson from the governance from other emerging technologies, whether e.g. neurotechnology, gene editing or nanotechnology, is that there is critical need for a broader discussion to help define goals and elaborate scientific questions. Such a discussion is critical for developing trust and trustworthiness with end users, and can help tailor emerging technologies better to the needs of those they are designed to help. Only then will technology truly operate in and for societies.

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