


Commentary

Principles and Priorities for Responsible Innovation in Neurotechnology for Canada

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Introduction

On December 11, 2019, the Organisation for Economic Co-operation and Development (OECD) adopted the recommendation on responsible innovation in neurotechnology.¹ The recommendation was the product of interdisciplinary and intersectoral conferences held in prior years, culminating in Shanghai, China, in 2018 (Figure 1). The endeavor was motivated by ethical, legal and social challenges arising on the neurotechnology landscape, both as they pertain to the health and well-being of humans in society and to their contributions to economic growth.

All member countries are asked to develop right-fit implementation strategies for the principles. As a signatory country, the present work begins a dialogue on the adaptation of the principles to Canada's needs. Other countries, such as the USA, France, and the United Kingdom have delivered guidance for their jurisdictions. This is the first for Canada.

The Working Group for this guidance was convened by Health Canada as part of the OECD implementation team. We met over 15 months to discuss the OECD principles at face value and the process for developing an implementation strategy for Canada, all against the backdrop of Canadian values and evolving neurotechnology on a global scale.

The OECD and Canada

The OECD is an intergovernmental organization comprising 38 member countries. Founded in 1961, the organization is dedicated to shaping policies that foster prosperity and opportunity. The OECD provides a platform for governments, policymakers, and citizens to support the development of evidence-based standards that address global social, economic

and environmental issues, and the expansion of world trade on a multilateral, nondiscriminatory basis in accordance with international obligations.

Canada's OECD team advances the country's views and values at the levels of committees and working parties, disseminates the results of OECD work to Canadians, and increases public knowledge of Canada's role in the organization. To date, the work of the OECD has had substantial influence on Canadian law and policy. For instance, the Federal Court of Appeal noted that OECD guidelines played a role in shaping Canadian standards for the protection of personal information (*Englander v. TELUS Communications Inc.* [F.C.A.], 2004 FCA 387), and the Supreme Court of Canada considered OECD data regarding Canada's prescription drug spending rates when considering regulatory efforts to combat high drug prices (*Katz Group Canada Inc. v. Ontario [Health and Long-Term Care]*, 2013 SCC 64).

Principles for Responsible Innovation in Neurotechnology for Canada

To advance the OECD goals for Canada, we narrowed down the original nine principles into five guiding principles for the full life cycle of neurotechnology that are both responsive to the Canadian context and anticipatory of future initiatives in the country (Figure 2). We accept the definition of neurotechnology as any device that is used to record, monitor or change brain structure or function for either medical or nonmedical purposes, and either invasively using interventions deep in the brain or noninvasively. Neural stimulation or recordings, ablation, and open and closed loop modulatory interventions are examples. The reorganization of the principles links the OECD principles to a range of existing Canadian initiatives and entities that we feel are well-placed to take forward the project of responding to neurotechnological

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- Principle 1. Promoting responsible innovation
- Principle 2. Prioritising safety assessment
- Principle 3. Promoting inclusivity
- Principle 4. Fostering scientific collaboration
- Principle 5. Enabling societal deliberation
- Principle 6. Enabling capacity of oversight and advisory bodies
- Principle 7. Safeguarding personal brain data and other information
- Principle 8. Promoting cultures of stewardship and trust
- Principle 9: Anticipating and monitoring potential unintended use and/or misuse.

Figure 1. OECD principles for responsible innovation in neurotechnology (OECD, 2019).

- Principle 1. Physical and personal safety, trust, and privacy
- Principle 2. Societal deliberation and stewardship
- Principle 3. Inclusiveness and Indigeneity
- Principle 4. Public, private, and international collaboration
- Principle 5. Strengthened oversight

Figure 2. Guiding principles for responsible innovation in neurotechnology (Canada, 2024).

innovation. We also propose additional aspects of certain OECD principles in consideration of the Canadian social, political, and commercial context.

The set of five principles uses the original OECD Principle 1 as an overall framing rather than as a principle per se. In keeping with the Government of Canada's whole-of-government blueprint, we situate public trust and transparency at the heart of the endeavor as it underpins a "healthy and functioning democracy." Our approach seeks to maximize social benefits while remaining grounded in justice, with an emphasis on fairness, protection of rights and the importance of creativity and entrepreneurship for the Canadian economy. Attention to and anticipation of future applications are core organizing themes as they encompass both new uses of existing methods and methods that are imaginable but yet to be realized. We consolidate OECD Principles 2 and 7 into a single principle that includes physical and mental safety, Principles 5 and 8 pertaining to societal deliberation and stewardship and Principles 6 and 9 into strengthened oversight. We expand Principle 3 to include specific attention to the rights of marginalized populations, children, people under-represented in neurotechnology trials and clinical applications and Indigenous people.

Principle 1. Physical and personal safety, trust and privacy

Advances in neurotechnology offer a tremendous potential for improving the lives of Canadians. At the cornerstone of responsible innovation lies the embodiment of privacy and safety by design. By considering privacy at the forefront of innovation, demonstrating a commitment to transparency and accountability, and dedicating resources to safeguard personal and physical safety, trust can be established between Canadians, organizations and their products. In parallel, government and regulatory commitment to physical and personal safety, privacy and security can promote responsible neurotechnological innovation in line with Canadian values. Organizations such as Health Canada work to reduce health risks to humans and ensure physical safety.

However, the concept of safety reaches far outside the structure of the brain and body today and encompasses the notion of national security. Federal programs such as the Canadian Safety and Security Program foster partnerships among government organizations (federal, provincial, territorial, municipal and Indigenous) and collaboration with industry and academia, to ensure the development of innovative science and technological advances that promote the overall safety and security of Canadians. In our opinion, the original OECD Principle 7 focused on safeguarding personal brain data, and other personal information should be expanded to consider these notions of safety that include privacy of mind,² physical safety and national security for the Canadian context.

Principle 2. Societal deliberation and stewardship

Canada is a leader in patient-oriented research and public engagement about science. Through the implementation of initiatives such as the Strategy for Patient-Oriented Research (SPOR), Canada has transformed the role of the patient into an active partner who helps guide health research and in turn health outcomes. SPOR has provided a forum dedicated to fostering collaboration between patients, health researchers, health professionals and policymakers to improve health outcomes and enhance patient care through translational research. Through this commitment, Canadian researchers have advanced powerful new methods and refined older ones for engaging patients and the public in the full continuum of health research from conceptualization and study design to the dissemination of results and clinical translation. We aim to leverage these methods to support the building of public trust fostering transparency, stewardship, and ongoing collaboration. By adhering to the Five Safes Framework and through effective transparency and accountability, Canada can protect sensitive information from being accessed inappropriately, ensure adherence to best practices, and promote trust in science while fostering the development of patient-centric innovations.

Principle 3. Inclusiveness and indigeneity

This principle is closely related to the original OECD Principle 3 but has social and cultural justice as its focus. In this regard, the principle emphasizes the importance of closing health disparities among culturally marginalized populations, in particular those living in rural and remote regions of the country and largely populated by Indigenous peoples. It applies to engagement in research that is respectful of local practices and values, adherence to agreements, data sovereignty (<https://fnigc.ca/ocap-training>), and access to beneficial results through clinical and commercialized care. An understanding of different values and perspectives about brain wellness across Indigenous and other historically neglected populations is vital to the successful advancement of this principle in Canada.⁵

Principle 4. Public, private and international collaboration

Canada has emerged as a global leader in its successful implementation of public–private partnerships within the infrastructure sector. The nation's successes inform future international and national collaborative partnerships in science, technology and innovation. In line with this thinking, the Natural Sciences and Engineering Research Council of Canada (NSERC) established the Alliance Fund. The alliance aims to strengthen research and development collaborations between Canadian university researchers, private sector and public sectors, as well as international research organizations to support the generation of new knowledge and novel technologies that create economic, environment and societal benefits to Canadians. Aligned with these strategic goals, many Canadian neuroscientists have moved away from a siloed approach to research and innovation toward a collaboration ecosystem that is interdisciplinary, intersectoral, and international. This collaboration is essential for the efficient development of technologies that respond to key needs, anticipate potential risks, develop social acceptance and regulatory structures to support translation from research to clinical use, and strive to put in place a culture of open science to capitalize on the substantial public investments in research. In addition, these collaborations can be extended to include private interests to not only identify the imperative for new interventions that may reduce the burden of neurologic or psychiatric disease, but to ensure that implementation meets the standards of fairness and public good on a worldwide scale.

Principle 5. Strengthened oversight

The importance of effective oversight has been heightened in many jurisdictions due to the rise in consumer neurotechnologies. Professional regulatory and institutional oversight bodies of academic organizations or hospitals cannot keep up with the evolution of brain experimentation in the private sector, either in terms of the scope of their responsibility for academic–industry partnerships or in the speed with which the domain is expanding. Large enterprises such as Meta, Neuralink and Google are engaged in ongoing applied neuroscience research to directly record and derive insights from nervous system activity. However, while large US-based organizations frequently rely on both internal and external (independent) research review and ethics boards, we have little information about the standardization of external ethics review among Canadian neurotechnology companies, most of which are much smaller and less well-resourced. To help Canadian

private and public sector neurotechnology groups adhere to best practices and to the OECD principles, organizations such as Health Canada can supply companies with appropriate support materials outlining nationally accepted criteria for responsible neurotechnology development. In addition, oversight bodies such as the Office of the Privacy Commissioner of Canada, along with provincial information and privacy commissioners, should consider and stay abreast of new developments in neurotechnology to better encourage and enforce compliance with Canadian privacy laws including provincial statutes like Ontario's *Personal Health Information Protection Act, 2004*, and the federal *Personal Information Protection and Electronic Documents Act*.

Conclusion

Canada has a long history of groundbreaking research in basic and clinical neuroscience and in neuroethical deliberation,^{3,4} and recent attention to the integration of Indigenous and cross-cultural priorities for brain health and well-being has brought new values and methods to the foreground of many new endeavors.⁵ These efforts have been supported by cross-sectoral Canadian investments in large- and small-scale research and training programs involving neurotechnology. Canadians have responded to these investments with innovations in commercialized neurotechnology for medical use,³ for research and for nonmedical consumer uses, with the creation of world-class neuroentrepreneurship incubators and the development of global leaders in the neurotechnology space. This Commentary serves both as a focal point for active within-country vetting about responsible innovation as advanced by the OECD, among all participants holding federal, provincial and private support – and those who aspire to it – alongside continued conversations with others on the national and international landscape.

In April 2024, the OECD released a toolkit based on its own refined principles – from nine to five – to offer further specifics and examples across thematic implementation goals for neurotechnology innovation. The online resource, intended to guide policy-makers for planning and delivering new infrastructure, will be most useful in Canada if it is contextualized with Canadian values and principles. Overall, the principles for Canada's responsible innovation in neurotechnology must speak to everyone: developers and recipients alike. All Canadians, in their own ways, are vested in the safety, engagement, inclusivity, collaboration, and oversight of advances for brain health and wellness.

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