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Humanistic neurotechnology: a new opportunity for Spain

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Executive summary

The world is mobilising resources to alleviate the human suffering and economic burdens associated with the Global Burden of Disease for brain conditions like Alzheimer's disease, Parkinson's disease, stroke, and mental disorders. Major advances in addressing these diseases have benefited from a convergence of research and development including neuroscience, engineering, digitalisation and AI. In the past two decades, governments, academic and industry researchers, and private sector actors, have made unprecedented investments into neuroscience research and neurotechnology innovation. This trend has continued even in light of the COVID-19 pandemic with post-pandemic programmes for economic recovery, including Spain's Recovery, Transformation, and Resilience plan prioritising neurotechnology development.

Advances in neurotechnology are rapidly evolving and complicated to understand. Companies routinely featured in the media such as Neuralink, simultaneously promise hope for enabling patients with paralysis to communicate alongside claims promising future brain-AI symbiosis that would not be out of place in the realms of science-fiction. Academics, social scientists, health experts, patient organisations and policymakers are making more calls to explore the ethical issues that exist or could arise from neurotechnology's current and future applications. While communities around the world express a clear need for expanded and novel treatment for growing burdens from brain diseases, they are mixed on their opinions on the use of neurotechnology that extends beyond medical applications, for example in military contexts or for cognitive enhancement. Accordingly, there is a clear and urgent need to proactively address these issues in a way that can promote future neurotechnology innovation that aligns with the needs and interests of society.

Within this global context, Spain is developing a model for growing a neurotechnology ecosystem within a guiding framework of *humanismo tecnológico* (technological humanism). The term has been increasingly appearing in Spanish public and policy conversations and seeks to put humans at the centre of technological development. Furthermore, technological humanism frames the recently adopted Spanish Digital Rights Charter, which among other things, highlights the need to establish protections against threats that neurotechnology could pose for individual and collective human rights. The Charter describes rights for preserving individual identity, data protection, and the need to regulate neurotechnologies aimed at cognitive enhancement. Therefore, the launch of Spain Neurotech, Spain's new neurotechnology centre that, among other focus areas, seeks to address related ethical and legal issues, is a response not only to the growing public need to find solutions for treating disease and promoting innovation, but also notably to the recently adopted Digital Rights Charter.

However, implementation of the soft law Digital Rights Charter, which offers recommendations and reflections rather than legislating hard law positions in this area, faces several challenges. As yet, a consensus has still not been reached or articulated globally on how to define the term neurotechnology. Neurotechnologies can generally be considered devices that enable a direct connection to the brain, spinal cord or both. Commonly, these technologies work by sensing or stimulating brain activity, potentially as a means of then modulating it. Medically applied neurotechnologies or those in development for clinical purposes such as for diagnosis, replacement or restoration of lost abilities through injury or disease represent the most advanced forms of neurotechnology.

Investments have contributed to remarkable clinical feats including allowing individuals who were once paralysed to move or even communicate again with loved ones. However, neurotechnology also poses a range of thorny issues from the familiar ethical challenges of equity, justice, and privacy to expanded concerns related to threats to agency, autonomy, and identity. In the future, these technologies may increasingly extend beyond the clinic. Yet even today, the consumer market is already exploring neurotechnology applications in education, the workplace, the military and for marketing purposes. In this expanding context, regulators face increasingly complex challenges to ensure these applications remain in the best interests of the humans who use them.

Currently, a patchwork of regulatory entities, at the local and global levels, struggles to keep pace with the speed of development in emerging technologies. Emerging technology governance scholars suggest a multi-prong approach, both exploring existing hard law mechanisms and attempting to create more near-term solutions with soft law mechanisms. Proposals for novel ‘neurorights’ prompt deeper exploration of how existing human rights law can be adapted to address the expanded concerns posed by neurotechnology. Legal scholars also continue to explore how existing regulation might need to be adapted to cover governance gaps, particularly around neurodata privacy protections in the consumer domain.

Spain, therefore, currently has an opportunity to further develop its leadership in digital rights through Spain Neurotech, building on the current momentum gained through existing neurotechnology governance conversations and the application of technological humanism to advance both policy and technical solutions for the global neurotechnology innovation ecosystem.

Glossary

B

Brain machine interface (BMI): a device that allows transmission of brain activity to external devices like a robotic arm or computer cursor. Also called brain computer interface (BCI).

C

Cosmetic neurology: a term coined by Anjan Chatterjee in 2004 that refers to elective cosmetic surgery, where brain interventions are not necessarily oriented around healing, but instead self-improvement.

D

Deep brain stimulation (DBS): a surgical procedure whereby electrodes are surgically implanted in specific structures of the brain. Sometimes called a "pacemaker for the brain", the electrodes are connected to a battery pack which allows electrical current to be delivered to the brain.

E

Electroencephalography (EEG): a device comprised of small electrodes that can detect electrical activity in the brain from outside the skull. EEGs can be placed in a headcap or headband and worn by individuals during brain recordings.

Electro-convulsive therapy (ECT): a process used to treat major depression. Patients are anesthetised and then have electrical currents passed through their skull via externally placed electrodes to change activity in circuits throughout the brain.

F

Functional magnetic resonance imaging (fMRI): a device that can estimate activity in the brain by measuring blood flow while a person performs a task. A person sits in a large, enclosed tube while magnets rotate around the person's head to measure movement of blood to active brain cells.

H

Humanistic neurotechnology: defined by Digital Future Society as neurotechnology that is shaped by considering human welfare holistically and the promotion of human rights.

***Humanismo tecnológico* (technological humanism):** a model of technological development, centred on the human being, that aims to reduce social inequalities and protect human rights by ensuring technology is at the service of people and the general interests.

N

Nervous system: includes the central nervous system (the human brain and spinal cord) and the peripheral nervous system (the nerves that connect the central nervous system to the rest of the body).

Neuroenhancement: the process of increasing human abilities beyond what is typical or average through brain interventions.

N

Neurofeedback: a process that involves recording brain activity through EEG or fMRI, offering real-time representations of that activity such as an image, and training patients to control their brain activity by concentrating or relaxing in order to modify those cues.

Neuroimaging: methods that sense brain activity, formatting visual outputs via representations of either electrical wave forms (such as with EEG) or even colorised images of brain structures (such as with fMRI).

Neurolaw: a field dedicated to considering how neuroscience and neurotechnology might be used in legal contexts.

Neuromarketing: the use of a series of neurotechnologies like EEG to measure unspoken responses to products such as arousal or attention to products.

Neuromodulation: a method to target the cranial or spinal cord nerves with the purpose of altering the activity of neurons.

Neuron: the most basic unit and building block of the nervous system. Neurons are also called brain cells.

Neuroprostheses: devices that can replace and even extend functions of the nervous system.

Neurorights: a movement that calls for the creation of novel human rights to protect against the unique threats posed by unchecked neurotechnology.

Neuroscience: the study of the nervous system.

P

Positron emission tomography (PET): a brain imaging method which relies on injecting radioactive substances into the bloodstream that can be used to tag markers of specific diseases when they enter the brain.

R

Re-identification: the ability or process that enables identification of individuals from data even when personal information has been removed.

T

Technosolutionism: a framing of solutions that propose naïve technical solutions as a bandage to problems that bear more complex social dimensions, such as poor healthcare infrastructure or poor working conditions.

Transcranial electrical stimulation (TES): the process of exchanging electrical current between a positive and negative electrode placed on the head, which can alter the electrical activity of the brain.

Transcranial direct current stimulation (tDCS): a particular kind of TES that uses constant unidirectional current, similar to a battery that powers electric vehicles, as opposed to alternating current which is often found in common household outlets. Transcranial alternating current stimulation also exists known as tACS.

Transcranial magnetic stimulation (TMS): a form of stimulation which uses a figure-eight shaped magnet coil to disrupt brain activity.

Introduction: why are we discussing neurotechnology?

The brain as a global priority

The world is mobilising resources to alleviate the human suffering and the economic strains associated with the Global Burden of Disease[1] for brain conditions like Alzheimer's disease, Parkinson's disease, stroke, and mental disorders. Accordingly, spurred on in part by major advances from a convergence of research and development including neuroscience, engineering, digitalisation and AI, the past two decades have seen unprecedented resources dedicated to neuroscience research and neurotechnology development (Garden et al. 2016; Global Neuroethics Summit Delegates 2018; SharpBrains 2020; Quaglio et al. 2021; Research and Markets 2022).

This convergence of different scientific and technological fields, unprecedented levels of investment, and a plethora of exciting advances and developments in neurotechnology innovation have built and continue to build global momentum around neuroscience and neurotechnology. The human brain is now seen as an international priority area.

In 2013, the European Union launched the Human Brain Project, a long-term and large-scale research initiative that drives digital brain research with over 500 researchers spread across 16 countries and 123 institutions (Human Brain Project and EBRAINS n.d.). In the same year, the U.S. Obama administration launched the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, which aims to discover "exactly how the brain enables the human body to record, process, utilise, store and retrieve vast quantities of information, all at the speed of thought." (NIH n.d.).

Global momentum then helped to establish the International Brain Initiative in 2017, which brought together emerging and existing brain projects from the EU, US, Canada, China, Japan, South Korea and Australia (Global Neuroethics Summit Delegates 2018; Quaglio et al. 2021). This year (2023) has seen the launch of Spain Neurotech, which aims to become a national neurotechnology centre that can promote international neurotechnology innovation (La Moncloa 2022).

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[1] The Global Burden of Disease is a metric that quantifies loss associated with prevalence of disease, injury, or other health risk factors (Institute for Health Metrics and Evaluation n.d.)

In many cases, neurotechnology innovations make their way to patients and the general public through efforts led by companies like INBRAIN, Neuralink, Blackrock Neurotech, BrainGate, Synchron and others (Velasquez-Manoff 2020). Available technologies are largely developed as medical devices focused on enabling interfaces with the brain and spinal cord to restore loss of functions from disease or injury. For example, brain implants have enabled patients with spinal cord injuries and paralysis to operate a screen cursor or move a prosthetic arm by focused concentration and intention alone. Brain stimulating electrodes, implanted inside the brain, are already clinically approved for treating movement disorders like Parkinson's disease and are also being explored for intractable depression, obesity, and obsessive-compulsive disorder (OCD) (Vedam-Mai et al. 2021).

Some wearable experimental neurotechnologies such as those developed by companies like Neuroelectrics, use head caps or headbands to try and treat epilepsy in adults and children. Bitbrain, for example, designs technologies to support rehabilitation from paralysis, while also developing wearable technology that can be used for gaining measured emotional responses to be used for marketing research purposes. There are also wearable technologies designed for recreational purposes like gaming or relaxation (Coates McCall et al. 2019) often blurring the lines between medical and non-medical applications (Paek et al. 2021).

However, in spite of the promise of significant benefits, the development of these new technologies is not free of controversy and presents ethical, legal, and social challenges. Some academic scholars have proposed that brain research may lead us to understand core mechanisms of human identity, personality, memories, emotions, and intentions (Global Neuroethics Summit Delegates 2018), going as far as to suggest that technology will be able to "decode people's mental processes and directly manipulate the brain mechanism underlying their intentions, emotions and decisions" (Yuste et al. 2017). Accordingly, even with a focus on transformative therapeutic outcomes, unprecedented circumstances may give rise to the need to consider ethical implications that may be at odds with clinical benefits. Questions also arise as to what might happen if these technologies, designed for medical use, were eventually used in individuals who were not sick, perhaps to enhance cognitive abilities.

Companies like Neuralink routinely feature in the media (Saez 2023), simultaneously promising hope for enabling patients with paralysis to communicate alongside claims promising future brain-AI symbiosis that would not be out of place in the realms of science-fiction. This is often branded as "neuroscience theatre" (Regalado 2020). For example, Neuralink and OpenAI co-founder Elon Musk hopes that, in the not-too-distant future, anyone could have devices implanted in their brain to "figure out how we coexist with advanced AI, achieving some AI symbiosis" (Ibid.). Neuroscience theatre withstanding, neurotechnology's convergence with AI does raise a legitimate point which some policymakers have already begun to address. Managing the ethical, legal, and social challenges of neurotechnology will mean recognising how neurotechnology innovation fits in a broader ecosystem of converging emerging technological breakthroughs in engineering, digitalisation, AI and others.

About this report

The report offers a first step in an exploration of the needs and timely opportunities to positively impact the global trajectory of responsible neurotechnology development. The first section provides an overview of the global state of the art of neurotechnology and how these technologies are currently being explored in clinical contexts and beyond. The second section then offers a landscape of the current global debate on ethical, legal, and social challenges associated with neurotechnology development. The report concludes with initial recommendations for policymakers to facilitate "humanistic neurotechnology", defined by Digital Future Society in this report as neurotechnology that is shaped by considering human welfare holistically and the promotion of human rights.

Therefore, the purpose of this work is to help policymakers understand:

- What neurotechnology is, how it is currently applied, and what the current research objectives are for the future.
- Key social, ethical, legal, and regulatory challenges presented by these new technologies, especially the concerns that arise from the abuse or unintended consequence of their use.

This report should also be useful to civil society organisations working on advocacy activities related to the risks of neurotechnology implementation. All readers are welcome to share this report with their respective organisations and networks as a resource.

Why now

The former Ministry of Economic Affairs and Digital Transformation led Spain's efforts to develop a Digital Rights Charter, adopted as soft law in 2021. The Charter offered a reflective framework of interpretation for existing hard laws. Building on this, the Ministry together with the regional government of Madrid and the Autonomous University of Madrid has launched Spain Neurotech, which was described as "a response to the principles and priorities of Spain's Digital Rights Charter" (La Moncloa 2022). This report marks a recognition of the convergence of these efforts in neurotechnology growth with increasing momentum for human-centred technology development in Spain.

Through the recently adopted Digital Rights Charter, Spain has already included provisions for digital rights in the use of neurotechnologies. The Charter describes rights for preserving individual identity, data protection, and the need to regulate neurotechnologies aimed at cognitive enhancement (Ministry for Economy and Digitalization in Spain n.d.). Nadia Calviño, former First Vice-President of the Government of Spain and Minister for the Economy and Digital Transformation, noted that the charter aims to "ensure a humanistic digitisation that puts people at the centre" (La Moncloa 2021). This statement is consistent with a recurring framing for emerging technology governance in Spain called *humanismo tecnológico* (technological humanism) (Digital Future Society 2021).

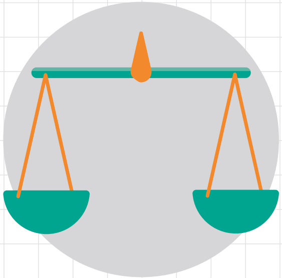
The creation of Spain Neurotech is also meant to promote a forum for implementing the principles of the Digital Rights Charter. Furthermore, while Spain's neurotechnology ecosystem is growing, this proactive—rather than reactive—approach could serve as a useful model for global efforts in neurotechnology innovation.

Humanistic neurotechnology

Drawing from the term "technological humanism", Digital Future Society defines "humanistic neurotechnology" as neurotechnology that is shaped by considering human welfare holistically and the promotion of human rights.

Humanismo tecnológico (technological humanism)

The term humanismo tecnológico has been increasingly appearing in Spanish public and policy conversations around the social implications of technological developments (Digital Future Society 2021). Technological humanism can be defined as "A model of technological development centred on the human being, that aims to reduce social inequalities and protect human rights by ensuring technology is at the service of people and the general interests" (Ajuntament de Barcelona 2021).



What is neurotechnology and how is it applied?

Interest in neurotechnology is consistently increasing and societies will need to understand what they are and what the impacts of interacting with them could be. The public will also need guidance on how to distinguish the headline-grabbing hype from the scientific reality. To that end, before moving to the ethical, legal, and social implications of neurotechnology, the following section will define and look at definitions of neurotechnology, illustrate different kinds of neurotechnologies and explore the contexts of their application.

Defining neurotechnology

Simply put, neurotechnologies are devices that enable a direct connection to the brain, the spinal cord, or both (Müller and Rotter 2017). Generally, these technologies work by sensing or stimulating brain activity or both, potentially as a means of then modulating it.

However, neurotechnologies are a very broad and complicated category of devices, often defined differently by different entities. Generally, different entities emphasise certain features of neurotechnology and its capabilities. For example, the OECD (author of the first international standard in ethical neurotechnology innovation) definition of neurotechnology encompasses "devices and procedures" (Garden et al. 2016; UNESCO International Bioethics Committee 2021). The Institute of Electrical and Electronics Engineers (IEEE), the largest engineering professional society in the world, highlights research aspects by defining neurotechnology as providing "greater insight into the brain" (IEEE brain n.d.). Neurotech Network, a technology advocacy group for patients and families, emphasises the medical applications defining neurotechnology as "medical electronics" specifically for humans excluding the large ongoing body of neurotechnology research in nonhuman animals (Neurotech Network n.d.).

Figure 1.
Example of neurotechnology definitions

Type of entity	Definition
Policy and intergovernmental organisations	“**devices and procedures** that are used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of neural systems” (OECD 2019)
International professional societies	“any technology that provides **greater insight into brain** or nervous system, or affects brain or nervous system function” (IEEE brain n.d.)
Lived experience advocates	“**medical electronics** that interact with the **human** nervous system” (Neurotech Network n.d.)

Each of the entities in the table are critical stakeholders highlighting important dimensions and context for neurotechnology research and translation for public use. However, the ambiguity and lack of broader consensus in defining neurotechnology can also present challenges when attempting to create and implement ethical guidance and regulation[2]. This will be discussed further in the section on ethical, legal, and social implications (ELSI). Regardless, it is possible to recognise a consistent feature of neurotechnology, which is that neurotechnologies are designed to connect in some way to the brain and spinal cord to either sense or modify activity in the brain.

Neurodata

The data collected from neurotechnologies is often referred to as ‘neurodata’. However, ‘neurodata’ is another term that lacks consensus and has implications for regulation, which will be discussed further in the ELSI section. There are also variations on what terms people use to describe data collected from neurotechnology.[3]

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[2] Others have used terms interchangeably with neurotechnology like ‘neural interface’ (Royal Society 2019) or Brain Computer Interfaces (Brunner et al. 2015; Borman 2021; Future of Privacy Forum 2021) or Brain Machine Interface (BMI), which engineers might describe as a type of neurotechnology (IEEE Standards Association 2020).

[3] Because this report primarily targets policymakers, the term neurodata is used throughout this report.

Figure 2.
Terminology to describe data collected from neurotechnology

Term	**Definition**
Neurodata	“**first order**” data from brain cells or neurons including “their electrical, hemodynamic, and chemical activity, their anatomical components, their connections, etc.” (Future of Privacy Forum 2021)
Neural data	“data that are recorded **directly or indirectly** from an individual’s brain, such as with brain imaging, intracranial recordings, or brain computer interfaces” (UNESCO International Bioethics Committee 2021)
Mental data	“any conglomeration of **mental representations and propositional attitudes** that corresponds to **the experience** of thinking, remembering, planning, perceiving, and feeling” (Ienca and Malgieri 2022)
Neuroscience data	“transcends raw measurements to comprise derived data as well as metadata that describe the full **set of processing steps** and **analysis** used to produce data” (Eke et al. 2022)

These definitions vary on how the data is acquired, what kinds of information can be interpreted from them, and accompanying protocols to analyse the data. For think tanks, such as the Future of Privacy Forum, neurodata is considered “first order” data from brain cells, meaning the direct collection of information from the brain (Future of Privacy Forum 2021). A report by the UNESCO International Bioethics Committee (2021) defines neural data more expansively as data collected directly through electrodes that touch brain cells to those that are indirectly collected through devices that do not require surgery or are wearable.

For academic groups, neurodata or brain data has been discussed as a category that may be more wide reaching and better referred to as “mental data” (Ienca and Malgieri 2022). The use of mental data is an even broader category of data that is collected directly or indirectly from the brain. Mental data could be argued to come from devices that might not be considered neurotechnologies. For example, mobile phones that collect data from texts might reveal information about mood, perhaps in more revealing ways than current neurotechnology can detect. A consortium of brain research projects purports to modernise the definition of neurodata, which they refer to as “neuroscience data”. In their view, neurodata should be considered not just the data collected from the brain but also the algorithms used to process those data (Eke et al. 2022).

Implantable vs non-implantable neurotechnologies

Some neurotechnologies, like deep brain stimulation (DBS), require the surgical implantation of a long electrode to deliver electrical current to deep structures of the brain as a means of relieving symptoms from movement disorders like Parkinson's disease. Like a pacemaker for the heart, DBS delivers electrical pulses to the brain. These technologies are often called invasive or implantable neurotechnologies.

Figure 3.
Deep brain stimulation (implantable)

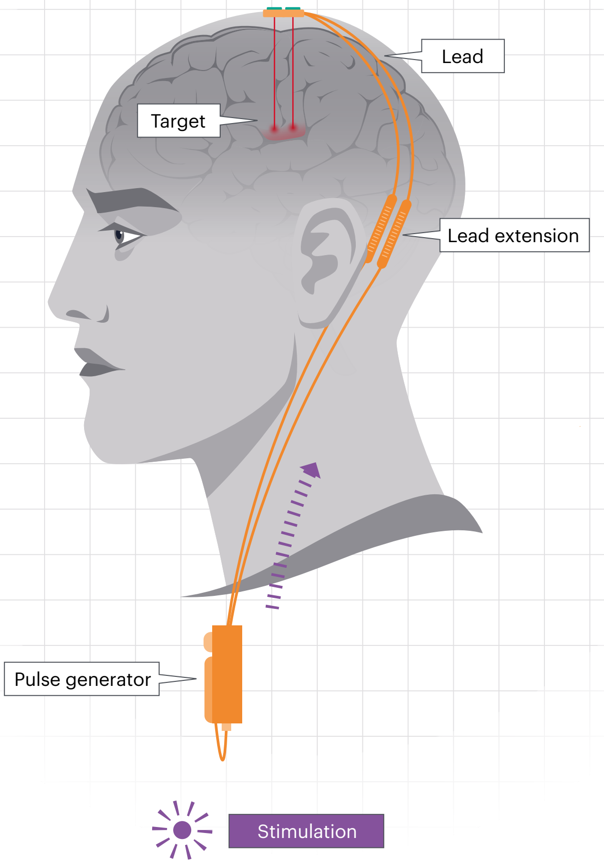

Image source: Digital Future Society's own image based on Cavagnoli 2023

Other neurotechnologies do not require surgery and are often referred to as non-invasive or non-implantable[4]. Instead of surgery, individuals can sit inside a machine, as is the case with a magnetic resonance imager (MRI). MRIs are routinely used in hospital settings to take pictures of the body, but these devices are specialised in measuring 'functional' brain activity also called fMRI. An fMRI machine is an important tool for researchers to understand how the brain functions while someone is performing a task. fMRI is often used to aid surgical planning in the brain to target better sites for electrode implantation or even for planning removal of brain tumours.

Some non-implantable neurotechnologies take on a wearable form. Electroencephalography (EEG) is often embedded in wearable forms of neurotechnology. EEG headcaps such as the wearable fabric headcaps developed by companies like Neuroelectrics are dotted with multiple EEG sensors to measure brain activity. The headcap is also equipped with a battery pack to deliver electrical current without requiring surgery like DBS. The Neuroelectrics headcap is being explored as a means to treat a wide range of conditions from Parkinson's disease in aging individuals to epilepsy in children.

Figure 4.
An EEG headcap (non-implantable)

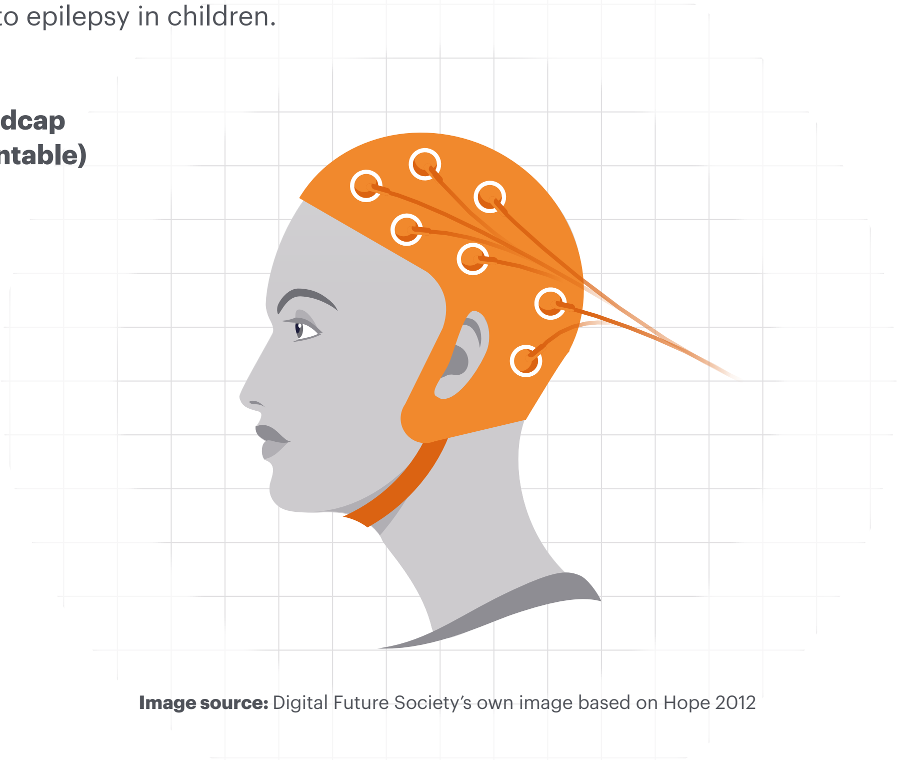

Image source: Digital Future Society's own image based on Hope 2012

With the understanding that neurotechnologies can sense and stimulate the nervous system either through surgical implantation or not, the next section describes the different kinds or categories of neurotechnologies that mediate these activities.

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[4] The distinction between invasive and non-invasive originates from physical considerations of risk. Invasive interventions are those that pierce the skin. However, for neurotechnology, a risk assessment based on invasive and non-invasive could lead to erroneous assumptions about risk. For this reason, the division between invasive and non-invasive has been heavily contested. Even without surgical implantation, a wearable cap that delivers brain stimulation through the skull can also come with significant risks and have effects that are also impacting the structure and function of the brain in similar ways to implanted devices.

Invasive vs implantable

Importantly, neurotechnology may also complicate risk assessments for safety. Safety considerations for biomedical technologies offer as a first consideration, how invasive of a procedure a technology may involve, such as piercing the skin with an injection or a full surgery that requires anaesthesia. Implanted devices require specialised expertise, often with surgeons having to open the skull to install the electrode. The risk is often assumed to be greater for implantable rather than non-implantable devices. Non-implantable devices do not require surgery, yet the impacts can still be quite invasive. For this reason, this report uses the terms non-implantable rather than "non-invasive" for greater accuracy.

Furthermore, as neurotechnology evolves, additional methodologies could blur these lines further. There is an emerging area that is considered an intermediate space between implanted and non-implanted, called minimally or minutely invasive (Gaudry et al. 2021). Researchers project a continuing trend for miniaturising technologies, that might otherwise require a significant procedure, to become injectable or inhalable electronics. These could then be externally modulated using transcranial magnetic stimulation (TMS), transcranial electrical stimulation (TES), or focused ultrasound (Patch 2021).

Figure 5.
Ultra-small implantable technology

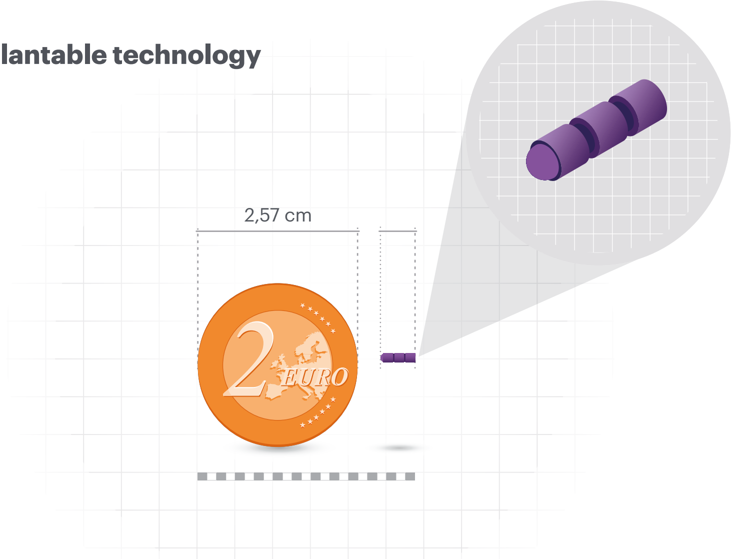

Image source: Digital Future Society's own image based on Iota Biosciences n.d.

Kinds of neurotechnology

Neurotechnologies are often grouped based on their capabilities: how they **sense** brain activity, **modify** brain activity, or **enable better transmission** of brain activity often to other external devices.

IEEE brain[5] describes three primary kinds of neurotechnology:

- Neuroimaging technologies that sense brain activity.
- Neuromodulation technologies that can modify brain activity.
- Neuroprostheses and brain machine interfaces (BMI) that can enable brain activity or transmit it to other external devices.

Despite these groupings, it is important to note that these technologies are often used together when applied in research settings or medical contexts. These groupings are meant to help give insights into the flavour of neurotechnologies currently being developed and deployed.

Neuroimaging technologies

Neuroimaging technologies can sense brain activity with the output often formatted as visual representations of either electrical wave forms (such as with EEG) or even colourised images of brain structures (such as with fMRI).

Neuroimaging technologies are widely utilised in routine medical practice. Methods include electroencephalography (EEG), which involves attaching a number of small round electrodes to a series of locations on the surface of the scalp. EEG caps worn in clinics can, for example, assess dysfunctional brain activity during sleep or diagnose seizures. EEGs are also widely used in research and clinical settings[6].

Neuroimaging technologies, like functional magnetic resonance imaging (fMRI) can estimate activity in the brain by measuring blood flow while a person is performing a task. As noted above, these technologies have been used in hospitals to determine appropriate sites for brain surgery. However, fMRI is also a useful research tool for better understanding brain function such as decoding what a brain has seen or even heard without requiring a person to verbally report it. For example, over a decade ago, neuroscientist Jack Gallant used fMRI to reconstruct images that research participants had previously seen in the lab (Nishimoto et al. 2011).

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[5] IEEE Standards Association is a leading consensus-building entity that has developed global standards for a variety of technologies from consumer technology to artificial intelligence systems. Their categorisation of neurotechnologies might be a useful framing to consider in light of future standards developed for emerging neurotechnology.

[6] Notably, despite broad use this 100-year-old technology is not optimised for people with coarse curly hair typical of those with African descent (Taylor and Rommelfanger 2022).

Viewed image reconstruction

In 2011, the neuroscientist Jack Gallant's lab asked research participants to study a series of specific movie clips while having their brains scanned with fMRI. The brain activity measured from the first movie viewing was fed to a computer. The computer was able to learn how to associate the shape and motion represented in the movie clips with brain activity. The computer was also trained on random YouTube videos, so it could learn to predict what brain activity might correspond to those videos. Next, fMRI was used again to measure brain activity while the participants were watching a second movie clip. Based on the brain activity measured from this second movie clip, the computer programme selected portions of a variety of images from its video training set to reconstruct blurry images similar to what the participant had seen (Nishimoto et al. 2011).

Potential future applications could include communicating with those who cannot communicate verbally such as individuals who have experienced stroke or are in a coma. Gallant's work also became widely discussed among the public, policymakers and academics for its potential implications in the courtroom, which will be discussed further in the ELSI section.

Neuromodulation technologies

Neuromodulation technologies are devices that target the nerves of the brain or spinal cord with the purpose of altering or modulating the activity of those nerves[7]. Neurotechnology interfaces with the brain or spinal cord to deliver electrical stimulation. This is also called neurostimulation.

One of the oldest neuromodulation techniques is electro-convulsive therapy (ECT) to treat major depression. With ECT, patients are anesthetised and then have electrical currents passed through their skull via externally placed electrodes. While ECT can be useful, newer neuromodulation techniques, like deep brain stimulation (DBS), are being explored experimentally to treat intractable depression. Unlike ECT, DBS entails first surgically implanting a long electrode into deep structures of the brain with patients often awake for parts of the procedure. Being awake and able to communicate with surgeons ensures greater precision for the electrode placement, accounting for individual variability in brain structures. DBS is already widely offered for reducing tremors in patients with Parkinson's disease.

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[7] A useful resource from the International Neuromodulation Society can be found on their website (https://www.neuromodulation.com/about-neuromodulation)

More recently DBS has been approved for psychiatric disorders like severe obsessive-compulsive disorder (OCD)[8]. While technologies like DBS have offered enormous therapeutic benefit, a small number of cases where patients experienced dramatic, unwanted personality changes have raised concerns about the risks to personal identity that may come with brain interventions (Wilt et al. 2021).

DBS

One striking 2004 case reported a 62-year-old patient who received DBS treatment to alleviate symptoms of Parkinson's disease. The patient experienced mania following the treatment and after 3 years became financially ruined due to the mania he was experiencing (Leentjens et al. 2004). The mania coincided with periods when the stimulator had been activated and could be "turned off" by deactivating the stimulation. When the stimulator was turned off the patient's symptoms left him bedridden because they were so severe, yet when the stimulator was turned on, the patient was manic and so could not be permitted to live independently.

Ultimately, the patient chose to leave the stimulator on even though it meant he would be required to live in a psychiatric institution. Although infrequent, cases like these have raised questions among medical ethics scholars, researchers, and policymakers as to whether current regulations and protocols are sufficient to empower patient decision-making in light of potential changes in fundamental features of their personality brought on by brain interventions.

Another type of neuromodulation technology is transcranial electrical stimulation, commonly known as TES. TES, through the exchange of current between a positive and negative electrode placed on the head, can alter the brain's electrical activity. Clinical companies, like Neuroelectrics have integrated TES into wearable EEG head caps to attempt to read or sense errant electrical activity and then deliver a current to reduce seizures in children.

Some types of TES like transcranial direct current (tDCS) are simpler. Direct to consumer versions of TES, like tDCS stimulators, have attracted an experimental community of users given its relatively simple composition: setup of the device involves soaking sponges in saline and connecting wires to a battery. This technology will be discussed more in the non-medical applications of neurotechnology section.

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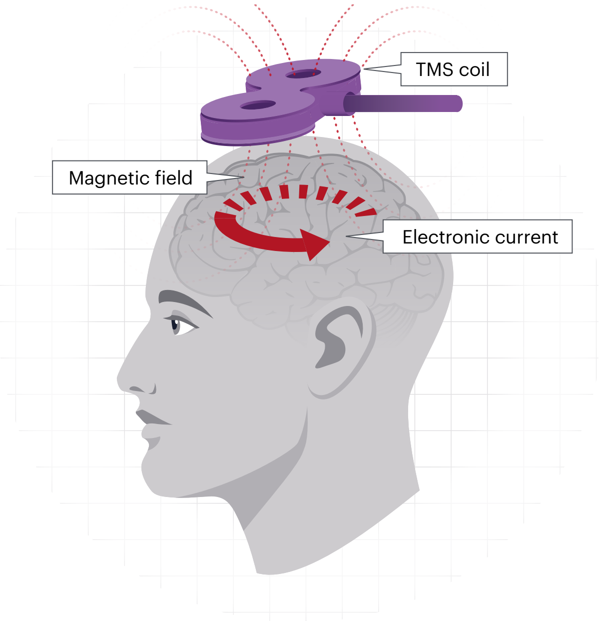
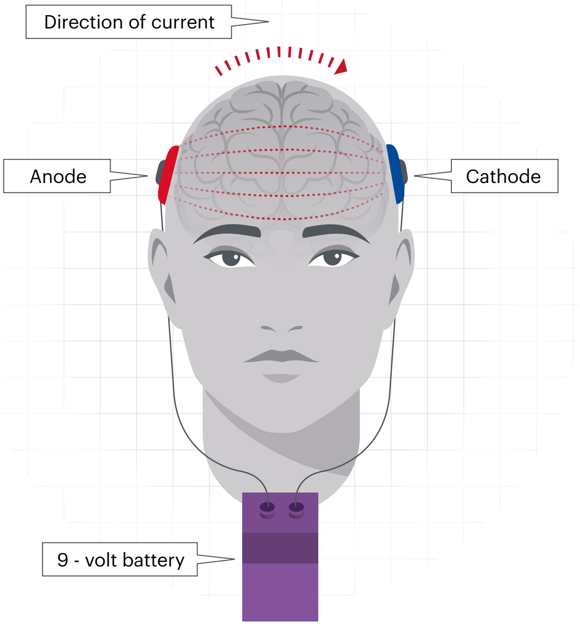
[8] DBS has been approved by the US FDA under a Humanitarian Device Exemption and received an EU CE-mark to use for intractable, severe obsessive-compulsive disorder. With this kind of regulatory approval, the device can be used in these patients. However, the technology is too immature to have developed consensus-level guidelines from professional medical societies.

Figure 6.
TMS (A) and tDCS (B)

6. A
Transcranial magnetic stimulation (TMS)

A form of stimulation which uses a figure-eight shaped magnet coil to disrupt brain activity





6. B
Transcranial direct current stimulation (tDCS)

A particular kind of transcranial electrical stimulation (TES) that uses constant unidirectional current, similar to a battery that powers electric vehicles, as opposed to alternating current which is often found in common household outlets. Transcranial alternating current stimulation also exists known as tACS.

Image source: Digital Future Society's own image based on Kim et al. 2020

Neuroprostheses

Neuroprostheses are devices that can replace and even extend functions of the nervous system (Bavishi et al. 2018). For example, neuroprostheses can replace or restore a patient's sensory abilities such as vision or enable movement in individuals with spinal cord injuries (Kasten et al. 2015).

An example of one of the most common and oldest neuroprostheses is the cochlear implant, which comprises of electrodes implanted on the auditory nerve. The implant acts as a prosthetic for transmitting sound and can restore hearing. Newer neuroprostheses include retinal prostheses, first approved in the EU in 2003 and then in the US in 2013. Retinal prostheses send electrical signals to parts of the brain that mediate vision and enable sensitivity to light and movement that can help patients regain some independence.

Figure 7.
Cochlear implant

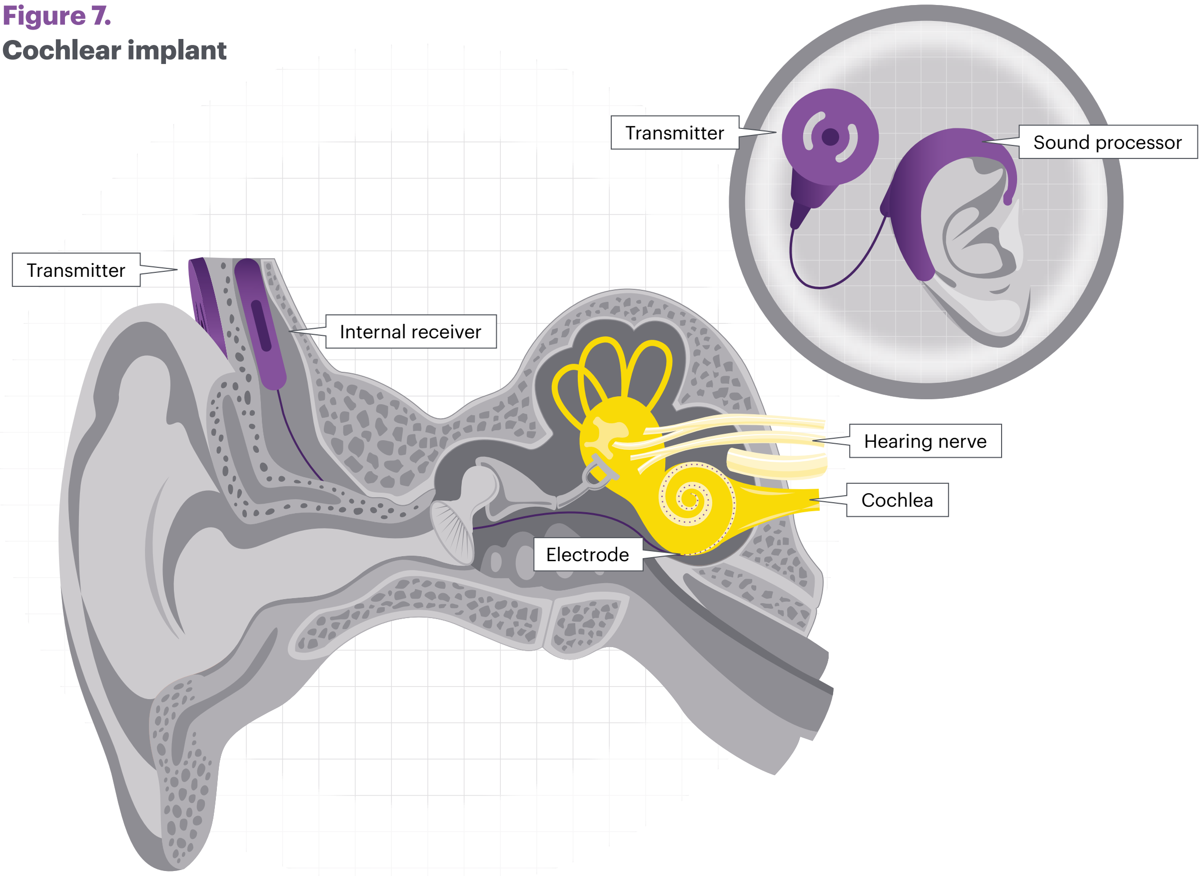


Image source: Digital Future Society's own image based on Medical gallery of Blausen Medical 2014

Some neural prostheses, called **brain machine interfaces** (BMI) (also called brain computer interfaces; BCI) allow communication with external devices like a robotic arm or a computer cursor. BMI are largely communication technologies that connect the brain to an external device (Trimper et al. 2014; Müller and Rotter 2017). They can be mediated via surgically implanted electrodes or via wearable sensors like EEG.

One example of an implanted BMI is the electrode array, a small grid of many electrodes, which is implanted on the surface of the brain. These electrodes can stimulate and record activity from the brain, typically a part of the brain associated with movement. Experimentally these electrodes have been implanted on the area of the brain associated with moving vocal cords to enable patients with paralysis to communicate a list of trained words by imagining speaking those words (Moses et al. 2021).

In some cases, the brain can interface not just with a device, but also with another brain. Researchers have used brain-to-brain interfaces, also called BrainNet, to explore new ways of expanding human connection and communication abilities. In the example illustrated in figure 8, researchers used non-implanted devices to mediate communication among several people playing a Tetris-like game (Jiang et al. 2019).

Figure 8.
The BrainNet architecture

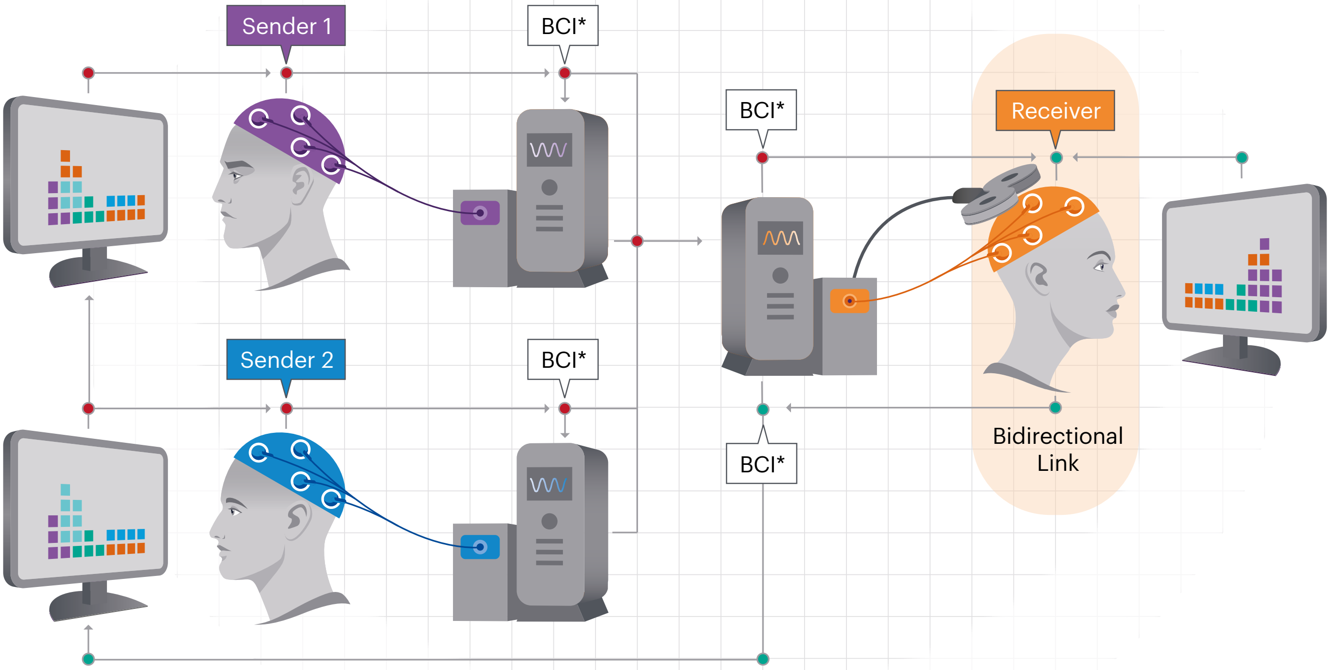


Image source: Digital Future Society's own image based on Jiang et al. 2019

BrainNet: a direct brain-to-brain interface

Jiang et al. recorded brain signals from “senders” wearing an EEG cap and sent them to “receivers” sitting beneath a transcranial magnetic stimulation (TMS) magnetic coil delivering focused stimulation to the receiver’s brain. Groups of senders and receivers—referred to as a BrainNet—were able to collaboratively decide how to rotate shapes so they would fit together in a puzzle game (e.g., Tetris®). The experiment was not designed with clinical intent, but more to understand how the technologies might be able to interface.

The individuals in the BrainNet were in separate rooms and unable to see, hear or speak to one another. The senders wearing an EEG cap could see a screen with a moving block at the top of the screen and the shape it needed to fit in the bottom of the screen, while the receiver could only see the block at the top of the screen. The senders needed to convey to the receiver what direction to rotate the block. The senders focused on a blinking light under the word yes or a light blinking at a different frequency for no. By focusing on the corresponding blinking light, the EEG was able to detect the brain activity corresponding with light frequency. A computer then deciphered this activity as corresponding to yes or no. If the message was yes, the coil the receivers were sitting beneath would deliver stimulation to the receiver’s brain, over their visual cortex, causing them to see a flash of light.

As an added component, the researchers wanted to see if the receiver would learn how to identify and trust the more accurate sender. To do so, the software randomly sent an incorrect answer from one of the senders to the receivers. Over time, the participants learned to identify the more reliable sender. Researchers suggested this study could serve as a model of human social networks, wherein individuals need to be able to sort reliable and unreliable sources of information.

The communication in this experiment was extremely slow and directed information through a server designed solely and limited to this experimental task. However, if it becomes possible to speed up the process or even connect to a general-purpose server and easily access and operate through the Internet, there are numerous potential speculative applications from gaming to remote control in work or even theatre of war settings (Trimper et al. 2014; Jiang et al. 2019). Largely, researchers are not considering the implications of broader use beyond the laboratory, but if the technology improves there will be ethical challenges to proactively address (see part 2 of the report).

Medical use cases

By far, the greatest investment, developments, and applications of neurotechnology have been directed at addressing medical concerns (Brunner et al. 2015; SharpBrains 2020). Neurotechnologies have been approved for use in medical contexts for decades. Some of these are described above: cochlear implants to restore hearing, deep brain stimulation (DBS) for alleviating symptoms of Parkinson's disease (Harmsen et al. 2020) and TMS for depression (Hutton 2014; Cohen et al. 2022). As has been seen with other emerging technologies, technological development often begins with medical applications in mind and then, as the safety and efficacy profile improves, the technology becomes applied and accessible to a larger public (Robinson et al. 2022).

Even now some neurotechnologies are being explored to augment human experience through applications in gaming and wellness, as well as in more controversial settings such as workplaces and for national defence. Some companies straddle the medical and non-medical divide. For example, neurotechnology companies like Bitbrain have developed EEG devices that can be used to help patients who have experienced stroke operate a wheelchair, while also developing simpler models of their technology for marketing firms to measure brain activity associated with emotional reactions to consumer products.

This section offers example applications of neurotechnology in the medical field. Medical neurotechnologies are being used for the purposes of basic research to better understand disease, but also toward replacing, restoring, or augmenting human functioning. While not an exhaustive list, a few examples are described below.

Diagnosis

Imaging neurotechnologies are being used for assessing and diagnosing diseases. For example, EEG has long been part of routine diagnosis for sleep disorders, epilepsy, and even for distinguishing between disorders of consciousness (like a coma) from brain death.

Brain diseases of aging: More recent uses of neurotechnology include other types of brain imaging like positron emission tomography (PET), which relies on injecting radioactive substances into the bloodstream, which will then be used to tag markers of specific diseases when they ultimately reach the brain. PET has been used to confirm characteristic patterns of brain degeneration specific to Parkinson's disease.

More recently, researchers have been exploring the use of PET imaging to identify stages of brain pathology in patients with Alzheimer's disease. The hope is that with early-stage identification of Alzheimer's, researchers will be able to better develop early interventions to slow the disease and the onset of symptoms (Cassinelli Petersen et al. 2022).

Replacement

Impaired vision or auditory sensing: As noted above, while cochlear implants are well established in the medical community, new implants are being explored to replace damaged tissue, such as retinal implants or retinal prosthetics (Finn et al. 2018; Strickland and Harris 2022) and are described as offering restored "artificial vision".

Recently, patients with commercial retinal implants (Strickland and Harris 2022) as well as patients with an experimental brain implant for epilepsy (Hamzelou 2023) lost access to their devices when the companies who made them either went bankrupt or were acquired in a merger. In both cases patients reported the implants as being critical to their daily functioning or even a key part of who they are, representing what some have described as new forms of human rights violations. The call for novel rights will be discussed in part 2 of the report.

Impaired spinal cord function and paralysis: Non-implanted devices have been used to help people with spinal cord injuries walk again. Electrodes can be attached to the skin near the spinal cord to help damaged tissue better respond to signals from the brain. In turn, muscles can then be activated to move. A similar device embedded in a wearable robotic suit can bypass the injured spinal cord. For example, when the person wearing the suit chooses to move, the suit can detect the brain signals sent to their leg muscle via the skin around the muscle. These signals can then be used to operate prosthetic limbs that are attached to the person's legs (Sczesny-Kaiser et al. 2015). Companies like Bitbrain have developed a non-implantable, wearable EEG solution for helping patients with spinal cord injuries. Bitbrain's EEG device can be integrated with a device that stimulates arm muscles. The signals from the brain are able to bypass the injured spinal cord and connect with the muscle-stimulating device and promote the arm and hand movements to grasp objects.

Also, while DBS may be considered a 'pacemaker for the brain', similarly, spinal cord pacemakers are being developed to help patients with spinal cord injuries. Patients have been able to regain an ability to walk via spinal implants, which help mediate signals from the brain to the spinal cord up to four years after the spinal cord injury took place (Wagner et al. 2018).

Restoration and augmentation

Paralysis and loss of function of communication or movement: Devices implanted on the surface of the brain (e.g., motor cortex) can also help people who have lost the ability to move or speak due to stroke or acquired injury to move a cursor. For example, one small coin-sized implanted device called BrainGate can help enable patients to type on an electronic keyboard or use a robotic hand to grab items (Vilela and Hochberg 2020).

Neurotechnology in this space has been a particularly competitive area for the private sector. Leading start-up companies such as Spain's INBRAIN Neuroelectronics and US-based companies like Neuralink and Synchron are actively hosting clinical trials aimed at decoding the human brain to restore patients' abilities to communicate and move after significant disease or injury. Elon Musk, Neuralink's Founder and CEO, aspires for the technology to ultimately become a device available for healthy audiences to use for augmentation.

Figure 9.
A setup similar to BrainGate

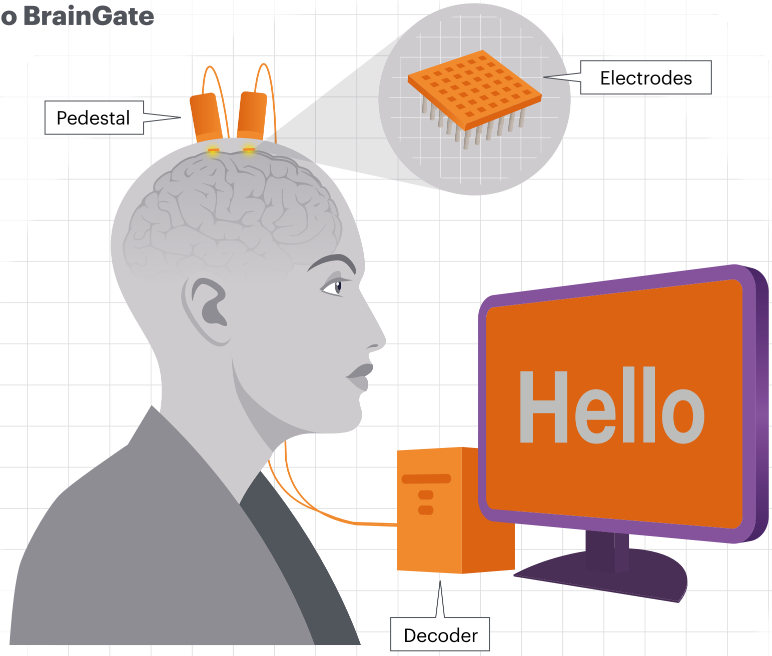


Image source: Digital Future Society's own image based on Balougador 2007

Psychiatric disorders: As DBS has become more established and viewed clinically and scientifically as having a favourable safety profile, exploration of its use across a variety of conditions, including intractable depression, Tourette syndrome, addiction, anorexia nervosa, and schizophrenia has begun (Harmsen et al. 2020). DBS has also been used in children to treat dystonia[9] and is being explored to treat other paediatric neurological disorders like paediatric OCD (Muñoz et al. 2021).

Various disorders: An intervention dating back to the 1960s called neurofeedback is now being enhanced by advancements in neurotechnologies. Neurofeedback is a process that involves recording brain activity through EEG or fMRI, offering real-time representations of that activity such as an image, and training patients to control their brain activity by concentrating or relaxing in order to modify those visual cues (Hampson et al. 2020; Tursic et al. 2020). Patients are asked to modulate their brain activity to a set level, often through a game-like interface that represents their real-time brain activity. Neurofeedback continues to face scrutiny with researchers questioning unstandardised studies and attributing effects to the placebo response. Still, neurofeedback has maintained public appeal and has also found its way to the consumer market (Wexler et al. 2020), which will be discussed further in the non-medical applications section.

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[9] Dystonia is involuntary and often painful co-contraction of muscles that can result in involuntary twisting or repetitive movements.

Non-medical use cases

Most neurotechnologies that have found their way to the consumer have roots in being designed for medical applications. Higher risks with new technologies are generally accepted when the benefit is to address a severe illness or disease. Over time, however, as touched on earlier, increased success with efficacy and positive safety profiles makes these technologies more palatable to a non-medical context as well. In addition, continued application in the medical context generally goes hand-in-hand with improving these technologies to become smaller and more efficient, cost efficient, and accessible (Gaudry et al. 2021).

For now, neurotechnologies, especially those that do not require surgical implantation, are finding their way into the non-medical arena. Non-implantable neurotechnologies such as simplified forms of EEG or transcranial electrical stimulation (TES) that can take a wearable form function are being sold for a variety of applications such as gaming, future of work, self-improvement and wellness, education, national defence, and marketing.

Gaming

The gaming industry has consistently enjoyed a market of technology early adopters including the use of EEG headsets and, accordingly, has introduced EEG headsets that can record and interpret user brain activity as well as linking it with other gaming devices such as drones or VR headsets. With these interfaces, when the computer recognises electrical activity measured in the brain that corresponds with focus or attention, an action can happen in the game such as moving an object in a virtual environment or moving a real physical drone.

Brain-controlled virtual reality

In 2017, US start-up Neurable collaborated with Spanish-based VR graphics company estudiofuture to create the first “brain-controlled VR game” called Awakening (Strickland 2017). The device comprised of a VR headset attached to a head strap containing seven embedded EEG sensors. In the hands-free game, the player focuses on grabbing an object in the game creating the experience of telekinetically moving the object in the virtual environment. The game ultimately did not appeal to a large enough market. Investors and customers alike wanted a product that could measure and do more, such as provide analytics for attention and arousal and new ways to use the brain to control and interact with devices. Through this process, the company reports drawing interest from companies wanting to use the technology to train employees in safe virtual environments, such as those working in dangerous environments like, for example, repairing electrical powerlines (Molnar 2020). The technology also drew interest from those who wanted to enhance training and performance of military personnel. These types of applications will be discussed further below.

Work

While EEG devices can be used to train employees by assisting with active participation and focus in virtual reality scenarios as described above, neurotechnologies also appeal to employers because of their ability to passively record brain activity, without the user having to actively engage. For example, without requiring the user to press buttons or interact with the technology. Wearable devices can monitor brain activity passively while individuals are engaging in routine tasks and then, when certain activity is detected, such as patterns that suggest the employee is tired or stressed, alert the user via visual or auditory cues. The user can then choose to modify their behaviour if needed. In these ways, the technology is purported to help individuals improve or enhance their behavioural responses at work.

EEGs as a means to help improve workplace safety through the monitoring and alerting of employees who may be fatigued or showing brain signatures associated with lack of focus are already prevalent. The construction, trucking, and aviation industries are already deploying neurotechnologies worldwide, but now neurotechnology applications for office workers, including those working remotely, are also being explored. The development of some neurotechnologies beyond simply detecting arousal or distraction is also taking place with, for example, InnerEye's system using EEG signals recorded from experts to train or 'mentor' AI models as a kind of prosthetic decision-making device (Ackerman and Strickland 2022).

InnerEye security assistance

Figure 10.
How the InnerEye system works

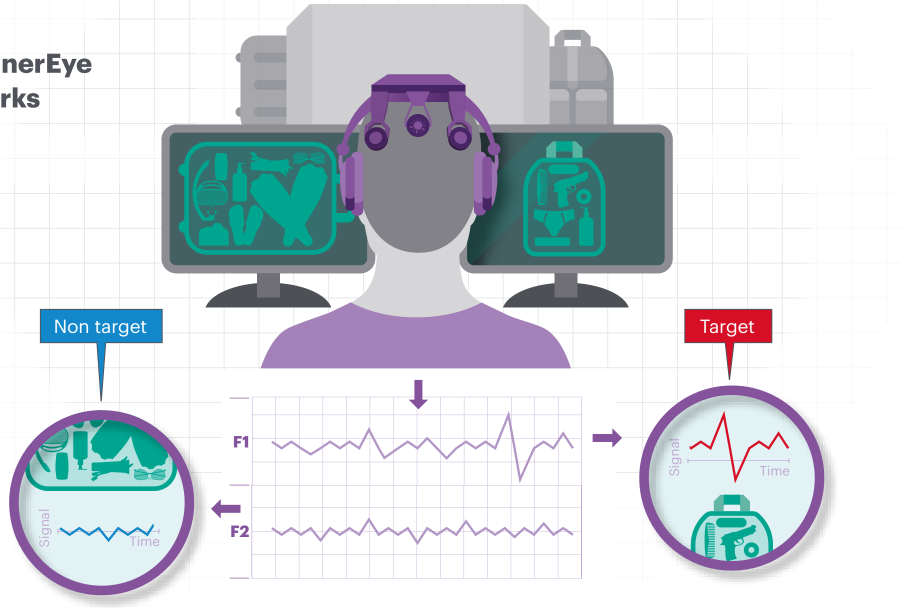

Image source: Digital Future Society's own image based on Ackerman and Strickland 2022

InnerEye security assistance

Israeli start-up, InnerEye is partnering with a handful of international airports to help security agents more quickly and accurately identify objects in bags passing through x-ray scanners. InnerEye claims that individuals trained with their EEG-based device will be able to better detect unusual or suspicious items in suitcases. In a typical process the work of a security agent involves staring at fleeting x-ray images of innumerable bags and their contents. Typically, in this process, the brain has to process the visual imagery from the x-ray first by detecting the image, followed by the brain noting whether the viewed object is unusual. The next steps involve the brain processing a decision to act or not, and then which action to take, such as pushing a button or deciding what to say. Over time, this process or “cognitive load” can become tiring for the brain and InnerEye attempts to reduce the overall cognitive load by bypassing it.

By wearing the InnerEye headset, security workers can passively look at images without having to concentrate on looking for something unusual. InnerEye’s AI system classifies the worker’s brain response to various x-ray images and can alert the individual when a brain signature that suggests they have seen something unusual that requires further attention. Reducing cognitive load enables the same worker to maintain focus longer while looking at more images. InnerEye calls this “hybrid decision making” combining human expertise with AI.

Self-improvement (enhancement and wellness)

For self-improvement the market has seen both brain sensing technologies and brain stimulating technologies. Companies like Swiss-based IDUN and US-based Emotiv have responded to a growing market with EEGs that can measure brain activity from the inner ear. IDUN refers to these as “brain-sensing earbuds” that could one day be integrated into hearing-aids and other consumer audio equipment. IDUN’s white paper suggests that the popularisation of earbuds has presented an opportunity to integrate many kinds of health tracking sensors, similar to what we now see in smartwatches (IDUN n.d.).

Transcranial direct stimulation (tDCS), a kind of TES, has been explored as a means to enhance efficacy of training and boost the effects of exercise, such as increasing muscle strength (Wang et al. 2022) or improving reaction time and accuracy on tasks (Davis and Smith 2019; Feltman et al. 2020). There are warnings to heed, however, such as those relating to placebo effects (Schambra 2014) or the negative costs to other cognitive functions when some abilities are improved (Sarkar et al. 2014).

The consumer market for self-improvement is ever-growing despite scepticism of scientifically proven enhancement, with a strong appetite for affordable and novel interventions evident. Direct to consumer neurotechnology like tDCS has appeal given its previously mentioned appearance of simplicity. Direct to consumer companies include US-based company BrainDriver, which offers a tDCS device, a user manual along with instructions for electrode placement sites for specific effects such as "reducing risk taking" to "increased organisation" and "improving mood" (BrainDriver n.d.).

Neurofeedback and working memory

Spain-based Bitbrain has a suite of both medical and non-medically oriented technologies. Bitbrain has created an EEG-based technology that can be used in a neurofeedback system to enhance working memory (i.e., the kind of memory used to recall a list when shopping in a supermarket), attention and multi-tasking. They suggest that they have developed accompanying software programmes that can help maintain cognitive function during aging as well as "enhance performance in athletes, army, or special corps" (Bitbrain n.d.).

Education

EEGs have also been used to monitor brain activity in school children and continue to be explored for new applications in "personalised learning" (Kosmyna and Maes 2019). However, when these technologies were used in education, parental backlash resulted in the discontinuation of the programme (Standaert 2019).

Applications in the classroom

In 2019, BrainCo, a US and Chinese partnered company, deployed their headsets to monitor the attention of primary school children in China. The children wore the donated devices for 30 minutes at a time throughout the day with the goal of improving concentration and learning. Local media highlighted parents' concerns that the devices would be used to control their children and violate their privacy. Also, while company representatives stated that the data was stored on the school's database, teachers reported that the data was transferred to the BrainCo company server. The experiment was halted after one year.

National defence

As described in the cases above, neurotechnologies like InnerEye, which offer the promise of reducing reaction time and decreasing cognitive load have made neurotechnologies an attractive target for militaries who are eager to partner with neurotechnology startups. Similarly, technologies that have the potential to be used as part of neurofeedback strategies to enhance memory or multi-tasking, like those being explored by Bitbrain, also have potential applications for everyday citizens, but could be particularly useful in high-risk, high-stress environments like those present in contexts of national defence.

Another likely candidate for the use of neurotechnology in the context of the military is for remote operation of drones in the theatre of war. The interest in using EEG headsets to operate drones has led to an annual Brain-Drone Race which has been ongoing since 2017 (Brain-Drone Race n.d.). While not in current deployment, there is also potential for military personnel who have sustained significant injuries that might otherwise prevent them from actively participating in battlefield scenarios being able to maintain combat abilities.

Brain machine interfaces in action

Recently, OpenBCI collaborated with German technologist and disabled rights activist Christian Bayerlein and worked with a global set of collaborators including Chinese personal computer company Lenovo, a Finnish VR company and American 3D-printing companies to enable Bayerlein to fly a drone using BMI technology. OpenBCI, an organisation that creates open-source tools for BMI with the aim of promoting broader access to these technologies, offers the product called Neurofly. OpenBCI’s products have long been adapted and utilised by an international community of enthusiasts such as Bayerlein. Bayerlein has a degenerative disease that prevents his brain from being able to transmit signals to his voluntary muscle. The video demonstration shows Bayerlein connecting sensors to his muscles that transmit signals to a software program, which detect his concentrated efforts to move digital buttons that in turn fly a drone (OpenBCI 2023). OpenBCI also recently launched a product called Galea, a combined VR and brain sensing headset which can also be used in similar ways.

Marketing

A combination of neurotechnologies, such as brain imaging devices (e.g., fMRI, EEG) have been used in an area of research called neuromarketing or consumer neuroscience (Balconi and Sansone 2021). The field is over 20 years old and continues to be explored as a marketing tool in the hopes of better understanding consumers unspoken preferences. Neuromarketing techniques can include measuring individuals’ brain activity while they watch video campaigns or examine product labels. The idea is that a direct measure of the brain might provide less biased or filtered information than opinions shared by participants in spoken or written form.

The validity of insights gained remain controversial and in question—and even banned in countries like France (Oullier 2012), but this uncertainty has not diminished the appetite of consumer product developers for neuromarketing. Spain, for example, has at least six neuromarketing consultancies that have existed for a decade who laregely rely on EEG readings (Núñez-Cansado et al. 2020). Globally, companies like Coca Cola have been openly using neuromarketing techniques since at least 2013.

Neuromarketing: the Coke-Pepsi challenge

One well-known neuromarketing experiment from 2004 is the Coke-Pepsi challenge (McClure et al. 2004). The study revealed the importance of labelling in influencing consumer preferences. While in a fMRI brain scanner, participants drank either Coke or Pepsi, but were not told what they were drinking. When participants drank their favourite drink, parts of the reward systems of the brain showed increased activity. The results showed about half preferring Coke with the other half preferring Pepsi.

However, when participants were told what they were drinking, the ratio of preference for Coke over Pepsi shifted to 3:1. In addition, the researchers noted the activation of parts of the brain associated with attention, memory and habit formation. The researchers concluded that the shift in reported preference and brain activity was likely due to recalling references to Coke commercials and branding.

Marketing teams attempting to tap into the subconscious preferences of consumers is not new. However, studies like this one have inspired a neuromarketing industry where product developers see neuroscience as a competitive edge. While not scientifically proven, ethicists have raised concerns that tapping into these brain insights might be used to create products that consumers simply cannot resist or are perhaps even addictive.

Much of the most controversial uses of neurotechnology are associated with these kinds of non-medical applications. Even with medical applications as a priority, it is likely that eventually these technologies will become cheaper, safer, and take on simpler human interfaces that will allow for broader commercial access and deployment. For these reasons, there is growing global concern for the ethical, legal, and social implications of the increasing applications of neurotechnologies in society.

Key ethical, legal, and social implications to consider

By its very nature, neurotechnology captures the imagination, inciting both excitement and fear when considering the varied applications discussed in the previous section. When digging deeper below these emotional responses, however, a plethora of issues arise concerning ideas of safety, equity and justice, and suitable regulation. The following section will explore these issues in greater detail covering growing concerns about neurotechnology, some of the ethical conundrums it raises, and how guidance and regulation is being shaped to help steer the development of neurotechnology in line with the challenges it presents.

Growing public and policy concerns about neurotechnology

It is important to reiterate that the most sophisticated neurotechnologies relate to clinical applications. However, in the future, more applications of these technologies may extend beyond medical contexts. One of the key concerns is that the unregulated development and application of commercial devices could have profound and perhaps unanticipated effects on society and the individual experience. Neurotechnology, like many emerging technologies, could also amplify social inequalities and offer corporations, hackers, governments, and other actors new ways to exploit and manipulate people intentionally and create new risks for unintentional manipulation.

Academics, social scientists, health experts, patient organisations and policymakers are making more calls for consideration of the ethical issues that arise from neurotechnology's current and future applications, especially related to devices used for non-medical purposes. In online surveys with over 2,000 Germans, respondents demonstrated "moderate willingness" to use neurotechnologies as well as moral reservations about using neurotechnology for enhancing function (i.e., in a non-medical application) (Sattler and Pietralla 2022).

Younger respondents were generally more willing to use neurotechnologies even for enhancement purposes. In a Human Brain Project sponsored citizen consultation, 2,048 Europeans from 20 European countries revealed public concerns of neuroscience being used for dual use purposes (e.g., political, security, intelligence, or military applications) (Bådum and Jørgensen 2018). Similar trends were seen in a survey of over 10,000 Americans: 56 percent reported that widespread use of "brain chips" to improve cognitive function would be bad for society and 60 percent expressed concerns that they would be pressured to receive a brain chip regardless (Pew Research Center 2022).

In a survey with 100 BCI researchers from Europe, Asia, Australia, and South America, 61 percent of researchers claimed that assistive BCIs do not change the participant's identity. However, numerous ethical guidelines for neurotechnology mention ethical concerns related to personality and identity changes through neurotechnology use (Yuste et al. 2017; Pham et al. 2018; OECD 2019; Royal Society 2019; UNESCO International Bioethics Committee 2021; O'Shaughnessy et al. 2022).

At the moment, as highlighted at various international working groups, there is a need for more international instruments, effective guidance and the creation of mechanisms for implementation of existing ethics guidelines (OECD n.d. b; Global Neuroethics Summit Delegates 2018; Pham et al. 2018; Johnson 2020; O'Shaughnessy et al. 2022; Tournas and Johnson 2023). A number of countries are exploring new regulation including proposals for novel human rights: "neurorights" (O'Sullivan et al. 2022).

Some countries are looking at creating new licencing requirements and export control regulation for neurotechnology (Borman 2021) and other policy think tanks have suggested regulatory gaps for neurotechnologies and the data acquired from them (neurodata) (Future of Privacy Forum 2021; UNESCO International Bioethics Committee 2021; Regulatory Horizons Council UK 2022). Chile has become the first country to amend and create new constitutional protections for data acquired from brain technology as well as for protecting against potential human rights violations posed by neurotechnology. Spain in its Digital Rights Charter has also included specific provisions for neurotechnology which will be discussed further in the following section.

Overview of ethical issues presented by neurotechnology

Technological development is not free from the social contexts in which it is derived. The research and development of neurotechnology serves as a social mirror revealing our individual and collective curiosities and aspirations to have greater ability to harness the human brain. For example, the EU Human Brain Project lists under its strategy and vision, a goal to better understand the nature of consciousness (Human Brain Project n.d.). The US BRAIN Initiative factsheet states that the mission of BRAIN is to understand "the human mind". Notions of consciousness and the mind are deeply culturally rooted and philosophically engrained (Rommelfanger et al. 2023). Striving to glean insights from brain sciences and then attempting to translate those findings into society will undoubtedly be complicated on an ethical, legal and social level.

Ethical considerations

Over the past fifteen years, more than twenty consensus written guidance documents related to neurotechnologies have been developed (O'Shaughnessy et al. 2022) with a more recent proliferation in the past five years. A recent analysis by O'Shaughnessy et al. identified a number of consistent themes and ethical issues featured.

Safety: Preventing harm and ensuring safety should be a priority in the development and deployment of any technology, but it is especially needed with emerging technologies where the risk profile is evolving. A priority for mitigating risks for physical safety is consistent with existing regulation for medical device development and application. However, guidance for neurotechnology includes calls for deeper consideration of physical safety, including particular sensitivity when deploying neurotechnology in children wherein a brain intervention could irreversibly change the course of a child's brain development into adulthood.

There is also the backdrop of the troubled past malpractices of brain surgery for mental disorders that came to larger global controversy in the 1970s. In these cases, adults underwent treatment wherein parts of their brain were surgically destroyed with imprecise science and techniques often, with grave effects and death. While today's medically-oriented brain interventions are vastly improved, the full risk profiles of emerging neurotechnology mediated treatments are still being discovered.

Those neurotechnologies directed to a general consumer population may also present unchecked safety concerns. Consumer technologies often do not require the same level of safety demonstrations, scientific rigor, or post-market monitoring of medical technologies, which may necessitate new regulation or enhanced monitoring. Additionally, as increasing knowledge of the brain has revealed its intimate role in generating critical features of emotions, decision-making, and personality, there is growing awareness of the high stakes of harms that can arise from intervening with the brain. Even neurotechnologies developed with physical safety in mind can harm individuals in non-physical ways, as described in the descriptions of ethical considerations for equity, justice, privacy, and other 'atypical' concerns, like agency, autonomy, and identity described below.

Equity and justice: Another group of concerns focuses on equity and justice. As with the issue of safety, considerations of equity and justice are also concerns for any technology. However, the threat and stakes may be more severe with neurotechnology. As neurotechnologies have the potential to fundamentally alter an individual's brain capacity to perform tasks, some international groups have asked whether neurotechnology has the potential to create more unique or extreme inequities for those who may not have access (Global Neuroethics Summit Delegates 2018). For example, if cognitive enhancing technologies do become available, how would we protect against lack of access—as happens with many new technologies—that could further disenfranchise peoples and countries and further deepen inequalities?

In addition, neurotechnologies used in these ways may set new standards of normal or better than well. Citizens may feel compelled to use enhancers as part of the 'new normal' to keep up or stay competitive. Along with changing norms could come discrimination and penalisation for those who may choose not to take advantage of enhancing technologies. Discrimination is also a topic discussed under the next issue of privacy.

Privacy: In today's era of big data, the need for careful data management and protection is a priority for many governments. With brain data, there are also numerous concerns around privacy infringements where some groups have claimed that given the personal and detailed nature of brain data, it may become increasingly difficult to protect against re-identification. The need for additional regulation in this space will be discussed further below. Issues with privacy protection are complicated by the many dimensions of privacy as well as the myriad downstream impacts to an individual's personal freedoms in light of privacy violations. Privacy concerns include a variety of interests such as physical, informational, decisional and proprietary (Laurie et al. 2010). Particularly relevant to data collected from neurotechnology are threats to:

- Informational privacy: brain data could be misused or misinterpreted leading to discrimination.
- Decisional privacy: individuals might lose influence or control over how their brain data are stored, processed, or shared.
- Proprietary privacy: brain data might be considered so intimate and sensitive, that it could be considered personal property with some proposals suggesting it should be treated the same as organ donation (i.e., cannot be purchased or sold) (Wajnerman Paz 2022).

Privacy and brain data

Activity of the brain that is read as raw data and can be added to training data sets for machine learning algorithms. Brain data can also be processed and interpreted to understand:

- Degenerative states of the brain such as atypical brain activity seen in a diseased brain like Alzheimer's disease.
- Disorders such as depression.
- Future changes in behavioural states such as in seizure onsets.

The immense data acquired from all neurotechnologies often requires significant infrastructure for storing, processing, interpreting, and even sharing, which can also introduce multiple points for privacy threats and data misuse.

As noted above, in the context of brain data, some scholars have advocated for the notion of "mental data", that is privacy protections for the interpreted information directly derived from brain data or even those non-directly derived such as thoughts archived in text messages. This will be discussed further below in the section on special regulation for brain data.

Atypical considerations (agency, autonomy, identity): While the ethical considerations above may be very familiar, some less familiar or "atypical" harms associated with neurotechnologies include threats to agency, autonomy, and even identity. Intervening with the brain, being able to read (sense) and write to (stimulate) the brain, may actually alter, or be perceived as altering, an individual's identity or interfering with their freedom.

For example, when a person is implanted with a device that relieves their depression, the lens through which they have experienced the world for so long, has their identity changed? And if it has changed, has the intervention violated their identity? Some argue this would be equally true of the long-term effects of orally administered anti-depressants while others suggest that the speed and sometimes immediate changes associated with brain stimulation, make neurotechnologies a particular threat. If a BCI connected to a prosthetic arm harms a researcher, is the patient to blame or the malfunctioning prosthetic? How would you really know who or what the agent of harm was?

Free will and the law

As early as the 1980s, neuroscientist Benjamin Libet suggested that he could use EEG recordings to detect a change in brain electrical activity, a "readiness potential", before a person was aware of it and report their intention to move their finger (Libet et al. 1982). Neuroimaging technologies, like fMRI can estimate activity in the brain by measuring blood flow while a person performs a task. The Libet results were also confirmed by researchers who, using fMRI, could identify the decision a person had made on a particular task, up to ten seconds before the research participant was aware of their decision (Soon et al. 2008). Over 10 years ago, fMRI was used to recreate digital video clips from a bank of videos that research participants had seen before (Nishimoto et al. 2011).

These kinds of studies continue to draw public attention to debates on whether "free will" exists and how, if at all, brain imaging should be used in the courtroom (Parens and Johnston 2014). Some legal scholars caution against overly reductionistic conclusions (i.e., "my brain made me do it") or "brain overclaim" when attempting to deploy brain imaging in the courtroom decisions (Morse 2006). Regardless, these lines of research have contributed to a field of "neurolaw" dedicated to considering how neuroscience and neurotechnology might be used in legal contexts (Chandler 2018).

Important contexts for implementing ethical guidance

Existing guidance also refers to three primary target areas for governance including medical practice, neurotechnology research and public policy.

Medical practice: In medical practice concerns have emerged around techno-solutionism: some problems may propose naïve technical solutions as bandages to problems that bear more complex social dimensions, such as weak healthcare infrastructure or poor working conditions. There are also concerns in the cases when clinical research studies involve offering treatments to patients. At the end of some clinical research studies, a device offering a great reduction in suffering and offering restored functions could be removed or no longer be financially supported (Hendriks et al. 2019). This could be the case for instance of patients who have lost voluntary movement due to suffering amyotrophic lateral sclerosis (ALS), who are then able to speak through prostheses received via a clinical trial. It raises questions around the responsibilities towards participants (patients) when the trials are complete.

Uncertainty over the continued use of devices can be true even when they are already commercially available. As noted above, in 2022, upon acquisition of the US-based retinal implant company Second Sight, patients lost access to the maintenance of their implants. Should the technology malfunction, their devices cannot be repaired or replaced by the company, and they will become entirely blind again (Strickland and Harris 2022). This could potentially leave them feeling like a part of themselves and their identity has been lost.

Another grey area relates to off-label use of neurotechnologies. The neuroscientist Anjan Chatterjee coined the term "cosmetic neurology" wherein the neurologist may be asked to reconsider the scope of their clinical duty (Chatterjee 2004). Cosmetic neurology refers to elective cosmetic surgery, where interventions are not necessarily oriented around healing, but instead self-improvement. For example, neurologists are being asked to prescribe drugs like Ritalin to individuals who lack a diagnosis, simply to augment or enhance their cognitive performance. If improving quality of life is within the duties of physicians, should they prescribe enhancing interventions? Might the same requests occur with other emerging neurotechnologies?

Research: For researchers, numerous guidelines call for additional ethics training for scientists to help them better understand the ethical implications of their work and to include ethical considerations in their scientific explorations. One recent research group who developed a methodology for analysing brain imaging (i.e., fMRI) to decode participants imagined speech or storytelling, also scientifically explored the implications for privacy. For example, even though the research was still very preliminary, researchers did additional experiments to assess whether an individual could resist decoding their information: decoding participants imagined speech, was not possible without cooperation and will likely continue to be technically infeasible to do without active voluntary participation in the future (Tang et al. 2022).

The sharing of open data is being promoted to accelerate advances in science and to facilitate improved sharing of social goods, while researchers also explore optimal ways to not only share, but also protect data and data donors from re-identification and other potential privacy violations (Eke et al. 2022). Open data sharing practices, usually attempt to remove identifying information such as name and birthday, from data placed in shared repositories. However, given the uniqueness of brain data there may be ways to—intentionally or unintentionally—figure out who brain data belongs to, or re-identify them.

For example, some researchers have shown that it is possible to identify who data came from using only anatomical data from the brain (Valizadeh et al. 2018). Others have shown that machine learning techniques could be used to re-identify people based on their EEG data (Jayarathne et al. 2020). Even without identifying information like names and birthdays, combinations of other available data such as location and time-tags from when data was collected, or even public social media data can potentially be used to re-identify individuals. However, whether or not it is even possible to re-identify particular kinds of brain data remains an open area of research.

Public policy: Existing guidance also calls for public policy solutions to promote cross-sectoral dialogues and international cooperation on issues related to ethically aligned innovation as a means to offer ethical oversight and foresight as well as providing more opportunities for public education and engagement on emerging neurotechnology. Of particular concern are gaps in regulation between medical and non-medical consumer products and more recent conversations in the US have focused on BCI export control (Bureau of Industry and Security n.d.), which might require additional licencing to prevent potential misuse, particularly in ways that could jeopardise national security (Borman 2021).

Highlights of the global neurotechnology guidance landscape

The vast abilities and broad applications of neurotechnologies create challenges in designing meaningful and actionable guidance. So far calls for high-level (often norm-setting) guidance fall short in this regard. Still, these documents can lead to important calls for action. Key document and milestones in global neurotechnology governance conversations are highlighted below.

The first international standard for neurotechnology

After a multi-year process of multistakeholder engagement led by the OECD Working Party on Bio-Nano- and Converging Technologies (BNCT), the first international standard on responsible innovation in neurotechnology was adopted as a legal instrument by the OECD (OECD 2019) and its 38 member countries (OECD n.d. a). Spain has been a member of the OECD since 3 August 1961.

The OECD Recommendation on Responsible Innovation in Neurotechnology includes 9 principles:

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

The Recommendation also highlights the importance of the following throughout the innovation process:

- Embodying values of stewardship trust, safety, and privacy.
- Building capacity for foresight, oversight and advising.
- Facilitating inclusive processes of societal deliberation, innovation, and collaboration.

While not legally binding, by 2024 all member countries are expected to report how they respectively implemented the guidance. The OECD BNCT is currently drafting an implementation toolkit, which will highlight more detailed actions a variety of stakeholders might choose to pursue.

Novel human rights

Another ongoing and active conversation calls for a revisiting of existing human rights and even proposals for novel human rights called “neurorights” (Ienca 2021; Ligthart et al. 2021; O’Sullivan et al. 2022; Rommelfanger et al. 2022).

Of note is that moral values are often described in terms of ‘rights’. This usage of rights is not necessarily intended to mean rights as laws (Ligthart et al. 2021). For example, rights may not necessarily intend to create new laws, but instead may call for stronger affirmation of public values around certain issues. Legal rights are technical instruments situated in varying structures of law, such as regulation, constitutional law or international law. Even so, enforcing legal rights in the context of the law or court system requires clear definitions that facilitate practical applications. So far, calls for novel neurorights have resulted in three types of goals:

1. To generate new and distinct legal instruments, as seen in the Chilean Constitution.
2. To offer a framework that can promote awareness and spur moral debates on neurotechnology in society, as seen in Spain’s Digital Rights Charter.
3. To call for emphasis and affirmation of values to protect existing legal rights as they pertain to neurotechnology, as seen in Spain’s Digital Rights charter and UNESCO’s recommendations on neurotechnology.

More recently the global conversation has focused on points 2 and 3.

Chilean Constitutional Amendment and Bill: Neurorights proponents suggest that existing human rights laws and treatises will not suffice in light of unique threats posed by neurotechnologies. One prominent US-based group, called the Neurorights Foundation, has lobbied for the adoption of five proposed neurorights:

1. Mental privacy
2. Personal identity
3. Free will
4. Fair access to mental augmentation
5. Protection from bias

Inspired by the Neurorights Foundation, in 2021, Chile became the first country to pass neurorights legislation, amending its constitution to include a neuroprotection bill protecting brain data as well as mental privacy, personal integrity, self-determination, and equal access to neurotechnologies that can enhance human abilities. As a pioneer, Chile has been first to receive celebration as well as first to face challenges in implementation.

Chilean digital rights activists as well Chilean physicians have raised concerns that the new neuroprotection bill and its lack of conceptual clarity could compromise their ability to treat patients and hinder additional neurotechnology access (Rommelfanger et al. 2022). Legal scholars from Latin America not only critique the practicality of creating novel rights, but also call for greater integration of voices from other Latin American countries (Borbón and Borbón 2021). The Chilean bill has evolved and initially contested notions such as "psychic continuity" have been removed. Still, concepts like "mental integrity" remain a challenge for legal scholars to interpret as there is no consensus on meaning.

A group of scholars has recently suggested that the varying philosophical and ethical definitions of the terms detailed in the proposal of novel neurorights requires further work on transparency and explanation to ensure alignment on these concepts (Ligthart et al. 2021). They state, "it is debatable to what extent it is desirable and necessary to translate and condense them [neurorights concepts] into the existing human rights system." Without this clarity, these proposals may not offer additional enhancements over the UN's Universal Declaration of Human Rights, the European Court of Human Rights (ECHR) or instruments like the Convention on the Right of Persons with Disabilities, all of which call for protections for "mental integrity."

Spain's Digital Rights Charter: Several proposals for integrating concepts related to neurorights have already been developed such as with Spain's Digital Rights Charter. It is important to note that while charters such as this one are not meant to be legally binding texts, they do offer frameworks and tools for interpreting existing laws. In order to allow greater time for consensus-building, creating new laws is typically a slow process by design. Some argue this makes it difficult for laws to keep pace with the rapid speed of technological development. A non-legally binding charter, therefore, could potentially support a more rapidly developing neurotechnology ecosystem. In this way, Spain's Digital Rights Charter has resulted in a valuable case study into how such a framework could promote humanistically-driven neurotechnology development.

In July 2020, President Pedro Sánchez shared Digital Spain 2025, a bold agenda of reform, investments and specific activities to guide Spain's technological growth (Ministry for Economy and Digitalization in Spain n.d.). At the heart of this agenda are measures to ensure alignment with constitutional values and protection of both individual and collective rights. Digital Spain 2025[10] outlines ten areas for action. Point 10, states a goal for a National Charter for Digital Rights by 2025.

In Spain, the recent boost to the neurotechnology ecosystem has been facilitated not only by economics, but also humanistic factors that are demonstrated in the charter. Nadia Calviño, the minister for Economy and Digital Transformation and first vice-president of Spain noted that the charter aims to "ensure a humanistic digitisation that puts people at the centre." When debuting the charter, President Sanchez noted that the charter aimed to be "pioneering" in nature helping Spain lead the fight for rights around the globe. The Charter outlines rights for preserving individual identity, data protection, and the need to regulate neurotechnologies aimed at cognitive enhancement (Ministry for Economy and Digitalization in Spain n.d.).

The Ministry of Economy and Digital Transformation has also been a critical player in the launch of Spain Neurotech, together with the regional government of Madrid and the Autonomous University of Madrid, which has explicitly been created to provide a forum for implementing the principles of the Digital Rights Charter. Among the core focus areas of Spain Neurotech, a key pillar will be "Developing the ethical and legal rules necessary for the application of new people-centred technologies, involving society in scientific activities" (La Moncloa 2022). In this way, Spain Neurotech promises a proactive model for humanistic neurotechnology innovation and regulation.

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[10] There is an updated Digital Agenda 2026 document. It has two additional action areas: PERTE: Strategic Projects for Economic Recovery and Transformation and RETECH: Territorial Networks for Technological Specialization. The document can be found here: https://espanadigital.gob.es/en

UNESCO

UNESCO's Report on Ethical Issues in Neurotechnology: The UNESCO international Bioethics Committee (IBC) also explored the proposal for neurorights and more broadly the ethical issues associated with neurotechnology. They concluded that "neurorights embrace certain human rights already recognised in national laws, international laws, international human rights instruments, and other consensus instruments" (UNESCO International Bioethics Committee 2021). The report specifies areas of concern related to neurotechnology that could be explored within existing human rights law:

1. Cerebral/mental integrity and human dignity
2. Personal identity
3. Freedom of thought, cognitive liberty, and free will
4. Mental privacy and brain data confidentiality
5. Distributive justice
6. Discrimination/bias
7. Misuse
8. Augmentation/enhancement
9. Interests of the child
10. Informed consent

The report also suggests enhanced global dialogue and for Member States to "adopt laws to regulate the use of neurotechnology, such as recording brain activities, especially when its purpose is not for scientific research, medical needs, or the administration of justice". It also recommends special consideration for children: "Member States should consider law or other mechanisms to regulate the use of paediatric neuro-enhancement tools in children". Finally, the report recommends specific actions and actors including Member States, the research community, industry, the media, and the public.

The ongoing debate

More recently, a collaboration between the Council of Europe, which is an international organisation dedicated to upholding human rights law, and the OECD has been exploring the question of whether there is a need for new human rights. Similar to UNESCO, the collaboration's final report concluded that novel neurorights laws might be premature, offering that a next step could include the development of an interpretative guide to existing human rights that considers the contexts of neurotechnological applications (O'Sullivan et al. 2022).

However, the question remains open. The United Nations Human Rights Council has an advisory committee that aims to complete a similar assessment and report on the human rights impact of neurotechnologies by 2024 (UN Human Rights Council n.d.). Until recently, the Congress of Deputies had planned an investigation of applications and ethical implications of neurotechnology that would also address open questions about needs for neurorights (Oficina C n.d.). This has been postponed, however, in light of the advancement of the general elections from their original scheduled date in September to July 2023.

Points to consider for regulation

Different neurotechnology context considerations

As noted above in the overview, neurotechnologies have made their way into a variety of sectors and contexts. Some devices enable communication or operation of a drone without movement, others purport to improve concentration and focus. Ethical evaluations for the use of the same technology may change across different circumstances, culture and contexts (Global Neuroethics Summit Delegates et al. 2018). For example, an individual may be willing to use a wearable brain stimulator for wellness and gaming for self-improvement. However, individuals may not want to use the same stimulator if they feel pressure to use neurotechnology to enhance their productivity at work.

For this reason, regulation that suggests blanket prohibitions of neurotechnologies have been argued to be less useful than regulation to mitigate specific harms and specific contexts for potential misuse (Jwa and Poldrack 2022). The same context specific considerations are being explored not only for neurotechnology hardware, but also specifically the data acquired and processed by them.

Special regulations for neurodata may be necessary

Several groups have consistently highlighted gaps in protection for brain derived data and, in particular, the inferences related to processed brain data, and there have been numerous recommendations for neurodata governance frameworks (Wachter and Mittelstadt 2019; Rainey et al. 2020; Future of Privacy Forum 2021; Hallinan 2021; Eke et al. 2022; Ienca et al. 2022; Jwa and Poldrack 2022).

As noted above, regulating neurodata can also become complicated given the lack of consensus around what it comprises. In addition, with algorithms for interpreting data along with increasingly large data sets improving, it may become increasingly possible to garner greater insights about individuals or groups of people. These kinds of data may not only be able to re-identify individuals as noted above but may also feel more intimate or personal than other kinds of biometric data.

The cultural uniqueness of neurodata: Some researchers and scholars have argued that neurodata are technically no different than other kinds of biometric data. Others have argued that neurodata are both personal and sensitive because they reveal processes that enable the "human mind" (Ienca and Malgieri 2022). There are further researchers and scholars who argue that while not necessarily technically unique, some claim brain data are culturally unique. Even though not technically different, legal scholars have suggested the cultural uniqueness is enough to prompt special regulation for neurodata (Jwa and Poldrack 2022). With this framing, brain data as proxies of mental activity may be unique, personally identifiable and sensitive by their very connection to the brain.

Neurodata and highlights from the GDPR[11]

Personal data: According to Article 4 of the GDPR, neurodata may be considered "personal data." Article 4 of the GDPR defines biometric data as "personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person". While scientifically difficult, re-identification of individuals through their brain data has been shown to be possible. In laboratory settings, 30 seconds of non-implanted brain recordings could be used to identify to whom they belonged (da Silva Castanheira et al. 2021).

Special category data: Also, according to the GDPR it is unclear whether neurodata might be considered a special category of personal data, or data that is also considered sensitive. Processing of neurodata has been experimentally used to identify and predict behavioural traits and preferences. In the consumer neurotechnology market, wearable devices are often sold as being able to offer insights into arousal, stress, and mood. Consumer neuroscience or "neuromarketing" as described above, has used a combination of external brain recording and imaging to not only determine the best marketing strategies for products, but also to assess political views (Halpern 2020). Article 9 of the GDPR prohibits the processing personal data to reveal political opinion in order to identify a person.

Neurodata as part of a digital data ecosystem: Further complicating privacy considerations for neurodata protection is the extent to which these data are combined with a variety of other types of data in an increasing Internet of Things (IoT) digital ecosystem. For example, brain derived data can be connected to voice recordings, data acquired from smartphone usage and applications, or even publicly available social media feeds. All of these data could be combined to detail a fairly intimate depiction of a person's mental state and processes, and their life. Furthermore, predictions could be made about future mental states and health, not only from brain-derived data but also other digital data too (Faurholt-Jepsen et al. 2016; Insel 2018; Knott et al. 2021) .

Integrating advances in artificial intelligence (AI), especially machine learning (ML), will be critical to future capabilities and insights gained from neurotechnologies. A recent example comes from a combination of brain imaging (fMRI) with large language learning tools (i.e., GPT) to decode brain activity correlated to imagined or heard narratives (Tang et al. 2022).

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[11] The UK's Information Commissioner's Office recently also offered a preliminary analysis of brain data regulation which explores the context of the UK GDPR (Information Commissioner's Office 2023).

There have also been recent calls from academic and industry researchers to consider issues of ethical AI development more deeply in the context of neurotechnology (Farisco et al. 2022; Berger and Rossi 2023). Accordingly, protecting neurodata will likely require a combination of innovative technical (Kapitonova et al. 2022) and policy solutions (Eke et al. 2022).

Opportunities for new models of governance

As described in the above sections, neurotechnology has been met with recommendations and guidelines and well as the creation of new, or revised laws. Governance strategies can broadly be grouped into two categories. Hard laws refer to obligations that can be legally enforced in a court. Soft laws are generally recommendations and guidelines that are voluntary to follow and typically lack sanctions if broken although they can become enshrined as enforceable hard laws over time.

Soft law strategies for neurotechnology

Addressing the pacing problem: Traditional regulation can be powerful, particularly because of its enforceability. However, as governance scholar Gary Marchant notes “sweeping traditional regulation may be inadvisable given how fast the technologies are progressing, which would likely make any regulatory enactments obsolete before their ink dried.” The “pacing problem” is a term that describes the challenge of fast developing technologies that impact societies faster than regulation can be created (Marchant et al. 2020). For these reasons, soft law and self-governance tools have been promoted for emerging technologies like AI and neurotechnology in particular. The speed of development and the myriad new ways in which emerging technologies like neurotechnology will be applied make coordinating a government-response that can comprehensively protect across all contexts practically extremely difficult (Johnson 2020; Marchant et al. 2020). This is why the OECDs Recommendation for Responsible Innovation in Neurotechnology, as an international approach, and Spain’s Digital Rights Charter, as a national approach, offer promising frameworks that could be applied in the near-term for addressing the ethical, legal, and societal issues arising from neurotechnologies.

Patching gaps in jurisdiction: Some neurotechnologies can complicate traditional regulatory jurisdictions. For example, medical-grade consumer neurotechnology used for wellness purposes may fall outside of traditional regulatory jurisdictions. Traditional consumer product regulators may not have the expertise to evaluate neurotechnologies when they hit the market (Kuersten and Hamilton 2016). Also, medical regulators may believe consumer neurotechnolgies are not in their jurisdiction of regulation. Furthermore, the evolving context of neurotechnology and neurodata is even more complicated by their combined use with other technologies like AI. These kinds of “technological convergence” may also present complications in regulatory jurisdictions (Johnson 2020). The benefit of tools like the Spanish Digital Rights Charter is not only that it accounts for such technological convergence, but that it also adaptable for use by a variety of organisations, removing the need for them to be limited to specific regulatory or even geographic jurisdictions.

Engaging the private sector

Neurotechnology development continues to be driven by small and medium sized companies, rather than large corporate conglomerates. In recognition of private sector influence on societal directions for neurotechnology, policy scholars and entities like the OECD have increasingly recognised the importance of engaging the private sector in order to create and implement neurotechnology governance (Brunner et al. 2015; Garden et al. 2016; Moss and Rommelfanger 2021; Pfotenhauer et al. 2021).

In addition to co-developing guidance and professional codes of conduct, other strategies for cross-sectoral collaboration have included creating regulatory sandboxes. Regulatory sandboxes allow partnerships between regulatory entities and private sector companies to test protocols for responsible technology regulation and compliance that also avoid unnecessary burdens on companies to implement. In 2022, in line with Spain's Digital Spain 2025 agenda, the government of Spain and the European Commission organised an event to launch a pilot for a Regulatory Sandbox on Artificial Intelligence (AI) (European Commission 2022). Led by Spain, the pilot project has the aim of creating an AI system of sandboxes for all of the EU. A similar pilot for neurotechnology regulation could also provide value models and processes for countries aiming to integrate societal considerations into the neurotechnology innovation ecosystem.

The path forward for neurotechnology governance is likely a combination of both hard and soft law instruments. Soft law instruments can be developed in the near term to set best practices and norms, while traditional hard laws can also be developed through more transparent and long-term processes with enforcement capability within set jurisdictions. Gaps and redundancies could be addressed by inter-agency coordination, joint policy-making, and shared technological assessment teams who have subject matter expertise in neurotechnology (Johnson 2020).

Human-centred frameworks

The active and vibrant global conversation on how to responsibly develop neurotechnology for society has presented an opportunity to proactively integrate more human-centred approaches. For AI, several reports have discussed ethics by design (European Commission 2021) or hearken back to calls from the 1960s for integrating humanistic values (Mesthene 1969) into technology development. As noted earlier in this text, an important movement characterised by the term *humanismo tecnológico* (technological humanism) has been increasingly appearing in Spanish public and policy conversations around the social implications of technological developments (Digital Future Society 2021). The concept of technological humanism frames the Spanish Digital Rights Charter. This framework offers an opportunity to reflect on considerations relevant to neurotechnology development as well as upgraded considerations for past proposals for human-centred approaches.

Conclusion and recommendations

Neurotechnology developments and their convergence with other emerging technologies like AI promise great transformations for human lives across the globe. Governments, academic and industry researchers, and private sector actors have made and continue to make unprecedented investments in neuroscience research and neurotechnology innovation. To ensure these investments lead to positive transformations, policymakers must have continued awareness and foresight to ensure adequate guidance is currently available or developed to facilitate proactive engagement with neurotechnology developments.

Neurotechnology is a complex and evolving field. Even the term, neurotechnology is not universally defined. The data derived and processed from neurotechnology has also been inconsistently circumscribed. Lack of consistent terminology around these technologies will be a fundamental hurdle in establishing any guidance for them moving forward. While neurotechnologies can take a variety of forms, they seem to consistently share a variety of single or combined capabilities. These include reading (sensing), writing (stimulating), and read-write feedback systems. Through these systems, neurotechnologies have offered replacement of damaged parts of the nervous system, restoration of function for those who have lost the ability to move and speak, and augmentation of function through the connection of external devices like robotic arms.

Investments have contributed to remarkable clinical feats including allowing individuals who were once paralysed to move again or even communicate with loved ones. However, neurotechnology also poses thorny issues related to familiar ethical challenges of equity, justice, and privacy as well as expanded concerns related to threats to agency, autonomy, and identity. In the future, these technologies may increasingly extend beyond the clinic.

At local and global levels, a patchwork of regulatory entities struggles to keep pace with the speed of development in emerging technologies. Emerging technology governance scholars have suggested a multi-prong approach including an exploration of existing hard law mechanisms and attempts to create more near-term solutions with soft law mechanisms. Proposals for novel ‘neurorights’ prompt deeper exploration of how existing human rights law can be adapted to address expanded concerns posed by neurotechnology. Legal scholars also continue to explore how existing regulation might need to be adapted to cover governance gaps, particularly around neurodata privacy protections in the consumer domain.

Spain, through its Digital Rights Charter has already included provisions for digital rights in the use of neurotechnologies. The charter describes rights for preserving individual identity, data protection, and the need to regulate neurotechnologies aimed at cognitive enhancement (Ministry for Economy and Digitalization in Spain n.d.). Now, Spain has an opportunity to promote and lead, through the creation of the Spain Neurotech center, the development of neurotechnology within the framework of technological humanism and digital rights.

Recommendations

Currently, there are over 20 sets of neurotechnology and ethics guidelines (O'Shaughnessy et al. 2022) including a transnational legal standard, the Recommendation for Responsible Innovation in Neurotechnology, and explicit guidance from UNESCO for a variety of stakeholders to act as discussed above. In addition, there are also a number of reports emerging from think tanks such as the Regulatory Horizons Council (UK), Information Commissioner Office (UK), Future of Privacy Forum (US) and international consultancies such as Accenture and Deloitte in partnership with the World Economic Forum. Spain has a variety of opportunities to work locally and multi-laterally to join, build upon, adapt or develop new neurotechnology governance efforts. There is a consistent call in the reports mentioned to better engage private sector ecosystem partners.

Importantly, neurotechnology will impact many groups of stakeholders, all of which should be involved in supporting the development of technical and policy solutions (IEEE brain n.d.; OECD 2019). These stakeholders include individuals for the healthcare ecosystem, neuroscientists and engineers, ethicists, device and software industry representatives, government entities, medical device companies, patients and lived experience advocates, and potential consumers and end users of commercially available neurotechnology. The UNESCO International Bioethics Committee Report on Neurotechnology calls for additional engagement of the public and industry, and advocates for facilitating public-private partnerships to develop more robust neurotechnology governance strategies (UNESCO International Bioethics Committee 2021). Furthermore, while Spain's neurotechnology ecosystem is growing, this proactive—rather than reactive—approach could serve as a useful model for global efforts in neurotechnology innovation.

Specific near-term activities could include:

1. Examining existing legal frameworks for promoting empowered use of neurotechnologies.
2. Seeking to develop enhanced protections for neurodata, particularly those data that may be used beyond the medical context.
3. Considering the regulation of neurotechnologies by context (e.g., protecting against forced use in schools or the workplace, and other specific misuses).
4. Promoting education and inclusive engagement on neurotechnologies with the public using the framework of technological humanism.
5. Strengthening local public-private, cross-sectoral dialogue to promote robust soft-law and hard-law solutions.
6. Joining national, transnational and global efforts to promote human-centred neurotechnology development (e.g., OECD Recommendation implementation, Spain Digital Rights Charter).

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About the Institute of Neuroethics

The Institute of Neuroethics is the first think tank wholly dedicated to neuroethics. The Neuroethics and Neurotech Innovation Collaboratory explores how evolving neuroscience challenges societal definitions of disease and wellness, cross-cultural neuroethics, and cross-sectoral neuroethics policy. The boutique consultancy Ningen Neuroethics Co-Lab implements applied neuroethics and strategy.

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