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RESEARCH BRIEF
BETWEEN SCIENCE-FACT AND SCIENCE-FICTION: INNOVATION AND ETHICS IN NEUROTECHNOLOGY

INTRODUCTION

In recent years, the public has borne witness to the rapid emergence of neurotechnology (NT), with clinical trials capturing widespread attention from both media outlets and within expert circles. While claims of 'mind reading' and 'mind control' technology often lean towards hype, notable progress is taking place in connecting the mind to machines through the brain. Largely due to its CEO's media strategy, the ongoing clinical trial of Neuralink's human brain chip is perceived by the global public as pioneering in its field.[1] Yet, numerous other players, including public entities,[2] academic research teams[3] and private companies,[4] have been engaged in clinical trials for many years, making significant strides in developing cutting-edge NTs. This has led to a swiftly growing body of scientific knowledge and neurotechnological applications, as well as commercialized products.

Alongside this technological advancement, voices raising fundamental ethical concerns have become more pronounced. Neuroscientists, ethicists and legal scholars have become engaged in vibrant debate around the need to anticipate possible disruptive effects before NTs become pervasive across various sectors of society. Recognizing the importance of these ethical concerns as well as human rights impacts, several international organizations are taking proactive steps. In 2019, the Organisation for Economic Co-operation and Development (OECD) adopted a recommendation to promote responsible innovation in the development of NT.[5] The UN Educational, Scientific and Cultural Organization (UNESCO) through its International Bioethics Committee is working towards the establishment of an ethical framework.[6] Finally, the UN Human Rights Council's Advisory Committee is developing a study to assess the human rights challenges and impacts as well as the potential opportunities provided by NTs.[7]

This report seeks to contribute to these standard-setting processes. First, it provides an overview of the current state-of-the-art in NT. It explores the various societal domains where NT is being used or is anticipated, and identifies key trends that should be monitored from a norm-setting perspective. Second, the report will elucidate the principal moral concerns and dilemmas inherent to the application and diffusion of NT, and which should guide the establishment of robust regulatory frameworks. This analysis highlights that understanding the functioning, applications and realistic prospects of NTs, while distinguishing between scientific advancements and speculative narratives, is crucial for effective regulation. Moreover, it recognises that identifying ethical concerns is a sine qua non, before addressing the potential human rights impacts and developing regulations at the national and international levels.

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EVOLVING NEUROTECHNOLOGIES: APPLICATIONS, TRENDS AND TRAJECTORIES

THE MAIN TYPES OF NEUROTECHNOLOGY

Neurotechnology (NT) is an umbrella term which broadly refers to any device or method that can be used to record or modify human neural activity.[8] NTs result from the convergence of scientific innovations in various fields, including neuroscience, computer science, bioengineering, chemistry, medical science, and material science. They include a diverse array of devices and methods which seek "to access, monitor, investigate, assess, manipulate, and/or stimulate the structure and function of the neural systems of natural persons."[9] Through their direct connection to the brain, these technologies can interfere with an individual's mental states and processes.

NTs can be categorised according to their main purpose:

I. **Neuroimaging:** The monitoring and recording of brain structure and functioning;
II. **Neuromodulation:** Influencing or altering the functioning of the brain;
III. **Brain-computer interfaces:** Facilitating operational connectivity between the brain and machines.

As discussed below, advanced NTs tend to interlink these functions. Neuroimaging, for example, is an essential element of brain-computer interfaces, and indispensable to the development of neuromodulation methods and so-called 'closed-loop systems'.

I. Neuroimaging

Neuroimaging technologies are used to monitor and record both the structure and functioning of the brain. Structural neuroimaging methods include magnetic resonance imaging (MRI) and computer tomography (CT). These are used in medical settings, for example to diagnose brain lesions, or to explore brain areas where NTs should be implanted. Functional neuroimaging is used to measure brain activity, and includes non-invasive techniques such as electroencephalogram (EEG), functional magnetic resonance imaging (fMRI) and positron emission tomography (PET).[10] The most accurate information on brain activity patterns, however, requires invasive techniques such as electrocorticography (ECoG), which involves placing electrodes directly on the brain's surface. The current progress in neurotechnology, particularly in frontier applications like brain decoding and brain-computer interfaces (infra), is primarily driven by advancements in functional neuroimaging.

Data on the structure and functioning of the brain generated by neuroimaging technologies (also known as 'neurodata') facilitates a detailed analysis of brain activity patterns. When processed by sophisticated artificial intelligence (AI) algorithms, researchers can use this neurodata to correlate patterns of brain activity with imagined language, emotions, visual images or movements. The translation of neurodata into information on mental states – including cognitive, perceptive, and affective states – is referred to as 'brain decoding'.

BRAIN DECODING

Decoding mental states from brain activity patterns recorded by neuroimaging methods is a field of particular interest in cognitive neuroscience. Using sophisticated decoding algorithms, studies have shown that it is possible to extract information on individuals' mental processes and states, including visual perception, [11] memories,[12] semantic knowledge,[13] emotions,[14] dreams,[15] inner speech[16] and intentions.[17] The process, however, is technically complex. Decoding visual perception, for example, requires that study participants' have their brain activity measured via fMRI while watching videos. This data, linked to time-stamped visual stimuli shown, is then used to create and train a decoding algorithm. This algorithm is applied to new fMRI data recorded while the same participants watch videos they have not seen before, allowing scientists to reconstruct the visual experience in the form of images from the new video that participants were seeing.[18]

These results demonstrate that NT is able to establish statistically significant correlations between neural patterns and specific mental states.[19] Moreover, the pace of progress in AI capacity to extract patterns from large datasets suggests that the spectrum and accuracy of 'extractable' mental information will grow quickly and exponentially. Today's techniques, however, furnish relatively crude information on mental states, require controlled laboratory settings and remain error-prone. Assertions that current NT is capable of 'mindreading' is thus an overstatement, and the risk of commercially-available devices capable of decoding complex mental states such as thoughts or emotions in real time is presently low.[20]

II. Neuromodulation

Neuromodulation (also called neurostimulation) technologies aim to influence brain activity by modifying, bypassing or substituting existing neural structures or processes.[21] Typically, the alteration of neural activity is induced by exposing the brain to electrical currents or magnetic fields. A prime example is Deep Brain Stimulation (DBS), a procedure that delivers precise electrical pulses to targeted areas via electrode arrays surgically implanted in the brain. This stimulation can remedy abnormal neural activity, for example in neurological disorders such as Parkinson's disease, dystonia, or epilepsy, and psychiatric disorders such as major depression or obsessive compulsory disorder. Another example is Spinal Cord Stimulation (SCS), whereby electrodes implanted in the spinal cord alleviate pain, or enable movement in persons suffering from certain kinds of paralysis.

Non-invasive neuromodulation methods use magnetic fields or electrical currents to stimulate specific areas of the brain via, for example, a coil (Transcranial Magnetic stimulation, TMS) or electrodes (Transcranial Direct Current Stimulating, tDCS) placed directly above targeted brain regions on the scalp. Focused ultrasound similarly allows for the manipulation of brain activity by stimulating or inhibiting specific neural circuits in a highly selective manner.[22] These techniques are explored for their use in the treatment of a wide range of neurological disorders, and as a tool for (non-medical) cognitive enhancement.[23] Vis-à-vis invasive measures, however, their efficacy is limited due to the physical barriers presented by hair, skin and skull.

OPTOGENETICS

Optogenetics is a technique that genetically modifies brain cells in a manner to make their functioning susceptible to modulation by light pulses.[24] It ranks among the most advanced neuromodulation techniques, due to both its potential for delivering precision modification in brain processes and the associated risk of manipulating mental states. Indeed, one study reported positive early results in behavioural manipulation, showing that optogenetics applied to mice in combination with behavioural training could steer their actions in a targeted way.[25] Other studies have shown a potential for modifying memories.[26]

III. Brain-computer-interfaces

A third category of NT facilitates operational connectivity between a brain and an external machine, and is commonly referred to as a brain-computer interface (BCI). BCIs employ neuroimaging to record brain activity signals, which are further translated into technical commands that can operate external devices such as robotic limbs, wheelchairs or computers. Importantly, the linkage established by BCIs allows external devices to be controlled solely by brain activity, thus bypassing neuromuscular pathways.[27]

To date, the main application of BCIs has been therapeutic. Using BCI technology, individuals affected by Amyotrophic Lateral Sclerosis (ALS), cerebral palsy, stroke or spinal cord injury have been empowered to move a cursor, type or use a prosthetic/wheelchair using their minds. Commercial applications are being developed, however, including for recreational 'neuro-gaming' and neural-interfaces such as mind-operated computer systems and remote controls.[28]

BRAIN-TO-BRAIN INTERFACE

A ground-breaking, yet highly experimental category of developing NTs targets the connection between two or more brains, allowing for direct communication between individuals. While highly speculative, a proof-of-concept was demonstrated by a group of researchers in 2019 in a study that enabled three participants to collaboratively play the computer game 'Tetris'. In the experiment, EEG was used to decode the brain activity of two players while they were taking decisions related to turning blocks. These decisions were translated into stimulation commands and transferred to the third player who could not see the computer screen. The stimulation signals were integrated in their brain and, through an EEG interface, transferred back into the Tetris game. In short, the game was conducted on the basis of two players' decisions being transferred via the brain of the third player.[29]

INVASIVE VERSUS NON-INVASIVE NT

In medical and neuroscientific terms, ‘invasiveness’ is primarily used to distinguish between applications requiring the surgical implantation of an external object into the brain, such as electrodes or implants, and those that function without penetrating skin, skull or brain tissue.[30] Invasiveness is closely linked to efficacy; because it eliminates physical barriers such as hair, skin and skull, invasive neuroimaging provides more detailed and reliable information and invasive neuromodulation more precise and effective stimulation. Such intrusiveness also explains why the development and application of invasive NTs is limited to devices with a medical purpose. Indeed, no invasive BCI, DBS or invasive imaging is currently applied outside biomedical research or medical treatment settings.[31] This said, interest in the development of non-invasive tools — such as EEG-driven BCIs[32] and more reliable transcranial neurostimulation[33] — is growing steadily, likely due to their commercial potential.

Importantly, the users of NT devices tend to perceive ‘invasiveness’ quite differently from the medical community of practice, instead attaching importance to how devices impact mental processes and daily routines as opposed to their physical intrusion. This suggests that there is value in understanding invasiveness in terms that encompass the physical, mental and lifestyle impacts of NTs.[34] It would follow that the use of non-invasive wearable brain-monitors with the ability to access someone’s mental sphere or the deployment of tDCS to alter individuals’ emotional states, could and should be considered invasive.[35] From a normative perspective, more invasive technologies – either because they require surgery or effect individuals’ psychological state – justify stricter regulation. This would particularly apply to closed-loop systems, where individuals (or their physicians) are no longer in control of the functioning of the device.

CURRENT AND ANTICIPATED MEDICAL APPLICATIONS

While the vast majority of NT is developed for medical application, most of the advanced treatments are still in trial phases, and thus not recognised by relevant regulatory bodies for systematic use in healthcare practice. This should not distract from the established uses of NTs and the important progress being made, however. Neuroimaging, for example, has long been pivotal in diagnosing and monitoring neurological abnormalities and disorders.

CLOSED-LOOP SYSTEMS

Neurotechnological closed-loop systems enable therapeutic interventions that take place on the basis of real-time neuroimaging information. An example would be a device that delivers drugs alleviating the symptoms of depression cued to the moment that neuroimaging identifies a neural event indicating symptoms onset.[36] Although largely in the development stage, another therapeutic response is closed-loop neurostimulation.[37] This could, for instance, detect brain states indicative of an upcoming epileptic seizure, upon which a brain stimulation to prohibit a seizure would be initiated, without the need for active interference by the patient or a physician.

It is essential for locating and describing brain lesions and tumours, and in the future may be a crucial tool to identify biomarkers for disorders including epilepsy, Alzheimer’s disease[38] and major depressive disorders.[39] Forms of neurostimulation have also been approved by various national and international bodies for the treatment of specific neurological disorders.[40] The most prominent technique is DBS — a treatment tool to alleviate motor symptoms (such as tremor) in patients with Parkinson’s disease, dystonia and epilepsy.[41] DBS may also be effective in treating other neurological, psychiatric and cognitive conditions. For example, it has shown potential in mitigating the symptoms of Alzheimer’s disease (by slowing down memory loss and enhancing memory performance),[42] and in addressing treatment-resistant depression, dementia, obesity and addiction. [43]

While DBS will likely remain confined to the medical sphere (due to the need for invasive surgery), research is underway to develop non-invasive neurostimulation approaches that might be applied to conditions including Parkinson’s disease, epilepsy, depression, anxiety disorders and eating disorders. While such a (non-invasive) approach is likely to be less robust than (invasive) DBS,[44] the scope for application is far wider, with important implications for equality of access.

Finally, BCI technology is primarily being developed for medical applications, showing particular promise in neuro-prostheses that restore motor and communication functions in patients suffering from neurological conditions and brain injuries.

NEURO-PROSTHESES

One of today's most promising BCI applications is neuro-prostheses.[45] Starting around a decade ago, research showed that invasive BCIs can allow tetraplegic individuals to control a robotic arm solely by imagining the movements desired (for example picking up and drinking from a cup).[46] More recently, a non-invasive EEG-based BCI was created which enabled participants in the trial to accurately control both a robotic arm and a computer cursor.[47] In another study, a bidirectional BCI[48] (which incorporates brain stimulation) enabled a paralysed patient to regain a sense of touch through neurosensory feedback delivered via a robotic arm.[49]

In addition to robotic limbs, BCI technologies have been developed to assist persons with locked-in syndrome — a condition where the patient has lost all muscle-based communication capacities such as speech, blinking or finger movement. Utilising non-invasive neuroimaging, researchers have successfully decoded brain activity to translate a patient's yes-or-no responses to questions put to them orally.[50] BCI technology has likewise enabled paralysed patients to create text on a computer by imagining the act of writing the desired letter,[51] and to engage in hands-free texting, e-mailing, online banking and shopping, again by imagining those actions.[52] A final breakthrough is the development of a decoder able to extract semantic content directly from the brain.[53] This constitutes a paradigm shift, demonstrating the future potential for an operational 'thought to text' device that could restore the power of communication to victims of stroke, anarthria and other forms of paralysis.[54] However, it has to be noted that, despite significant progress, none of these applications are currently at a stage where they are systematically deployed in healthcare practice.

COMMERCIAL, MILITARY AND OTHER NON-MEDICAL APPLICATIONS

The capacity for NTs to interfere with brain processes — and by doing so, to monitor and alter mental processes — is increasingly being considered as marketable outside of medical contexts. This potential (or risk) of dual use will lead to increasing interplay between the medical and other domains.

I. Lifestyle and wellness

The market for neuroimaging-based lifestyle devices is rapidly expanding, with a proliferation of consumer-ready headsets, headbands and helmets that monitor a user's brain activity. These devices provide feedback on and insights into mental states like focus and mood, and are marketed as 'personalized mental wellness' tools to boost productivity, alleviate stress or aid meditation.[55] Another development (although consumer access is currently very limited) is software integrating non-invasive neuroimaging into BCI devices, suggesting a future where fully BCI-controlled smartphones or computers may become commonplace.[56]

In addition, there is a growing direct-to-consumer availability of non-invasive neurostimulators that promise cognitive enhancement and heightened feelings of well-being.[57] Such devices include tDCS headsets that optimise focus, attention and alertness,[58] treat insomnia, or alleviate the symptoms of anxiety, stress or depression,[59] and neurostimulation patches designed to enhance energy, mood and productivity.[60]

BRAIN IMPLANTS FOR HEALTHY PEOPLE?

One aim behind the development of effective, non-invasive NT devices is to avoid the risks inherent in brain surgeries and brain implants, such as infection or cerebral bleeds. Indeed, such risks are a principle bottleneck hampering the crossover of the most advanced NTs into non-medical domains. This begs an important question around whether healthy persons, in a distant future, might accept the risks associated with brain surgery in order to have their brain capacities enhanced, or enable a BCI connection to an external device such as a computer or smartphone.

The market potential of such an innovation has not escaped the attention of NT companies. In May 2023, a US-based company was authorized by the Food and Drug Administration (FDA) to conduct a clinical trial involving a "cosmetically invisible" neuronal implant in a human subject that allowed the user to control a mobile device from any location. The procedure involved implanting micron-scale threads into specific regions of the brain responsible for movement control, each of which comprised electrodes that connected to an implant. The stated aim of the experiment was to evaluate the safety of the implant and surgical robot, while also assessing the functionality of the BCI for use in paralysis-affected patients. The company's CEO, however, had already hinted at its ultimate goal, which was to develop brain implants enabling BCI interaction with external electrical devices available to the public for non-medical purposes.[61]

II. Gaming

The integration of BCI with entertainment applications represents a frontier in the rapidly evolving landscape of NT. Companies are developing devices that not only allow players to perform actions using their minds, but also allow the brain activity of a player to modify the gaming experience by changing its course according to players' mental states. While most of these devices are still in the development stage, some are commercially available. For example EEG headsets are being integrated with virtual reality (VR) headsets, enabling the real-time adaptation of VR games based on the neural activity of the player.[62]

Another advancement is EEG-based BCI headsets that allow users to control digital characters and objects on a screen (changing their shape or altering the image scale), using only their minds.[63] Some functionality barriers still remain; principally, in order to work properly, the device must be calibrated to a user's specific brain activity which takes time and adds expense to the product.

III. Neuromarketing

At the level of marketing, the brain has been touted as "the newest business frontier".[64] Indeed, over the last few decades, neuroscience has been explored as a tool through which retailers could gain a better understanding of the consumer mind. Principally, neuromarketing entails the use of data obtained thought neuroimaging to analyse consumers' mental reactions to marketing stimuli.[65] By exposing how conscious or unconscious decisions are made, these techniques allow retailers to optimise product and service sales, but also adapt marketing strategies to influence the decision-making processes of targeted groups of consumers.[66] Predictive profiling is an important factor in these strategies. Based on the data collected on consumer mental states and dispositions, individuals are classified and categorized into specific groups. Persuasion methods are then developed and tailored to the way such groups process information, or exhibit preferences.[67] While their use in commercial practice is currently limited, neuromarketing techniques are already quite successful in eliciting specific responses and changing consumer's behaviour,[68] making growth in the future highly likely.

IV. Employment

In the employment context, NTs are viewed as new managerial tools.[69] Existing products include surveillance headbands that track employee fatigue levels[70] and/or productivity.[71] More advanced applications seek to asses employees' cognitive load, focus and fatigue while simultaneously providing feedback (for instance in the form of auditory stimuli) to keep employees in (or guide them back into) a focused state.[72] Such devices may reduce workplace accidents and/or improve public safety, especially in sectors such as transportation, aviation or factory work.

As non-invasive neuromodulation devices that promise of boosting attention levels are already available on the market, is not unreasonable to think that, in non-too-distant future, workers may come under increasing pressure to use such devices, for example by employers seeking to optimise productivity or innovation.

USING THE PREDICTIVE NATURE OF NEUROTECHNOLOGIES IN WORKFORCE MANAGEMENT

Insofar as predictive NTs may in the future provide insight into an individual's mental traits and behavioural dispositions, they could be used to inform decision-making on hiring, disciplinary actions and the termination of workers.[73] Indeed, until recently, one company promoted a neuroimaging based service to "reveal in the most objective way all essential elements you need your employees to possess".[74] A future could therefore be imagined where job applicants are required to undergo a neuroimaging screening to profile their mental characteristics, cognitive capacities, and perhaps even their beliefs, emotions and intentions. This creates a risk of discriminatory decision-making against a worker based not only on their cognitive capacities, but also on their beliefs, opinions, personality traits, sexual orientation etc.

V. Education

Neurotechnologies that monitor and enhance focus and productivity may also have utility in education contexts. Most studies in this domain concern non-invasive EEG devices,[75] and some results support the idea that such monitoring may contribute to the effectiveness of learning processes.[76] This objective was tested in a controversial pilot project carried out in 2019 by an US company in a Chinese primary school, where students were asked to wear a "focus headband" with the aim of assessing their attentional states. The experiment was terminated following complaints by parents.[77]

VI. Military domain

Like many other technologies, NTs crafted for civilian use may develop 'dual use' functionality and thus 'spill over' into the military domain. NT may also be specifically developed in weaponised forms.[78] The main areas of research relate to 'augmented soldiers', the primary goal of which is to enhance perception and decision-making processes,[79] and to detecting deficiencies in the neurological processing of soldiers and applying neurostimulation to remedy them.[80] Another area of research concerns BCI-controlled 'neuroweapons',[81] and BCI-enabled feedback loops, whereby a soldier's neural information can be used to modify their equipment and/or control external devices such as drones.[82]

Other uses being explored in the military context, although not explicitly linked to the conduct of hostilities, include the use of NT to detect deception in interrogatory processes,[83] neuromodulation to treat post-traumatic stress disorder (PTSD) in veterans, and optogenetics to modify selected memories.[84]

> **THE AUGMENTED SOLDIER**
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> Advances in NTs may give rise to an augmented soldier in the future. Examples of research underway include BCI-driven exoskeletons that would function as a 'warrior suit' by enhancing the performance of soldiers.[85] DARPA, through its Next-Generation Nonsurgical Neurotechnology (N3) program, is working on a BCI helmet or headset that would enable two-way communication between soldiers' brains and machines. This could facilitate complex collaborations, such as risk assessment, and task execution such as controlling drones or robots.[86] Such innovations introduce the prospect of thought-controlled weapons;[87] indeed DARPA has reported on the successful steering of an aircraft stimulator by paralysed persons through an implanted BCI.[88]

VII. Criminal and forensic contexts

The use of NTs in the criminal justice context is an expanding area of research.[89] Principally, information on the structure and functioning of the brain can reveal aspects of an individual's physical or mental health status that may affect their responsibility under criminal law. Moreover, exploratory brain decoding is being studied as a means of interrogating the memories of suspects or witnesses, to verify/fact check witness statements, and as a lie detection method.[90] Specifically, through the analysis of brain activity, NTs could reveal whether the suspect or a witness has knowledge of certain information crucial to the forensic investigation or judicial proceedings.[91]
It is important to emphasise that while brain decoding has been considered by courts,[92] its lack of solid scientific foundation has (up until now) prevented its use as investigative methods in a criminal justice context.[93] Likewise, while there is speculation that neuroimaging could be used as a predictive tool, estimating for instance the chances of recidivism,[94] and neurostimulation as a means for rehabilitation limiting the risk of future criminal or antisocial behaviour,[95] these are the subject of complex ethical debate.

TRENDS IN THE NT INDUSTRY AND DEVELOPMENT

Interest in the NT sector — both on the part of private and public entities — is rapidly increasing.[96] Research programmes have been established by various governments, including the US, the EU, Japan, Korea, China, Australia and Canada. Recent projections indicate that the neurotech device sector will experience a compound annual growth rate of 14.4 percent, propelling its value from US$11.3 billion in 2021 to US$24.2 billion by 2027.[97] Annual investments by private actors in neurotech companies have also increased significantly over the past decade, from US$331 million in 2010, to US$7.4 billion in 2020.[98] Such public sector and commercial interest has undoubtedly enabled important scientific and technological advances, evidenced by the number of new devices reaching the market. Against this backdrop, four general trends can be identified.

I. Development and early commercialization of wearable devices for non-medical purposes

Although the vast majority of NTs are still developed for medical purposes, rapid technological advancements are shifting the production, commercialization and retailing of NT towards markets with considerably less regulation.[99] In particular, an increasing pressure to commercialise NT devices for the wider public — including for leisure and employment — has shifted research and innovation towards non-invasive and wearable NT devices.

This trend has resulted in escalating ethical concerns. Specifically, the production of NT in a less regulated context heightens the risk of misuse, jeopardizing human dignity and human rights. Even for the NT devices commercially available today, the full scope of privacy, safety and security risks is not entirely understood. The long-term mental health implications of using of non-invasive brain monitors and neuromodulators, for example, has not been the subject of longitudinal, large scale study.[100]

II. Blurring the distinction between medical and non-medical devices

It is now possible to purchase non-invasive brain stimulators that offer to monitor and enhance cognitive capacities such as memory and focus, and augment feelings of well-being.[101] Some of these products are advertised as

medical devices, and others as wellness and enhancement tools.[102] For instance, the same wearable neurostimulator for the treatment of insomnia and anxiety is considered a wellness application in some countries (the UK and the EU) but in others (the US) requires approval under the medical device regulation.[103] This blurring of the lines between medical and non-medical devices raises a number of concerns. For example, manufacturers of non-medical NTs may claim that their devices offer medical benefits, or consumers with reduced access to medical care may turn to commercial devices to address health issues.[104]
Generally speaking, NT manufacturers self-determine if their products are classified as medical devices, and thus whether to apply regulations pertaining to their marketing. When registered as a medical device, advanced regulatory frameworks — such as those applying in the EU and the US — classify devices according to their risk level. Based on this classification, the competent authority will apply a more or less strict review to assess the device's safety and efficacy before it can be marketed. While a laudable approach to public safety and privacy protection, such approaches may incentivise manufacturers to sidestep stringent medical device requirements by tailoring their product in a way that allows it to labelled as a wellness device.

In the US, for instance, manufacturers of neurostimulation devices could largely avoid the authorisation procedures for medical devices by marketing such products as wellness devices (requiring compliance only with consumer law). In a recent move however, Food and Drug Administration (FDA) explicitly excluded non-invasive neurostimulators from the (non-binding) list of low risk devices.[105] In 2021, they were classified as medium risk (class II),[106] and DBS as high risk devices (class III). This suggests that the FDA is looking to enforce the higher safety and privacy standards applicable to medical devices.[107]

Similarly, in the EU, a 2017 regulation categorises medical devices on the basis of the risk posed to users, leaving it within the discretion of the neurotech manufacturer to determine whether a device should be classified as medical or non-medical.[108] Here, however, the incentive to label devices as non-medical in order to evade stricter safety and privacy requirements has been limited. Under a new 2022 regulation, virtually all neurostimulation devices are considered medical devices, as neurostimulation devices for non-medical use are explicitly included under the class III category (highest risk), on par with invasive medical NTs. The requirements imposed on these devices include a quality assurance system audit, and an assessment of the design and functioning of the device. Surprisingly, this qualification only applies to non-medical NTs; non-invasive medical neurostimulators are labelled class II devices.[109]

Despite these steps, many groups remain concerned. Specifically, they cite the absence of regulatory oversight over (non-medical) neuroimaging devices, and the unpredictable privacy and safety risks, as sufficient justification that all NTs be considered medical devices for regulatory purposes.[110]

III. Entanglement between neurotechnology and AI

The development of AI and NT are intimately intertwined. AI and Machine Learning (ML) algorithms have been pivotal to the steady increase in knowledge on the structure and functioning of the brain. Chiefly, these technologies facilitate the processing of large data sets and the identification of discreet patterns within extensive sets of complex neurodata.[111] AI algorithms are also indispensable for the real-time connecting of neurodata patterns/activity to desired operational commands — the key to operationalizing the use of BCIs.[112]

On a normative level, this interconnectedness between AI and NT implies that the ethical and legal concerns related to AI processing should also be taken into account in the context of NT. Data protection concerns and the risk of algorithmic bias in NTs, are among the risks commonly highlighted.

ALGORITHMIC BIAS

Algorithmic biases – systematic discrimination in the outcomes produced by algorithmic processing – are a key concern in AI ethics.[113] Such outcomes are mainly driven by unrepresentative datasets used to train the algorithms, or implicit assumptions perpetuated in an AI design.

In the context of NT, algorithmic bias risks considerably affect the performance of NT for certain groups who may be underrepresented in neurodata sets, such as racial minorities, women, youth and older persons. Collecting extensive, accurate and representative data on brain functioning to underpin the development of new NT applications and their ongoing optimisation, is essential. Only when all groups are fairly represented in clinical trials, enjoy equal access to commercial NTs, and are included in all relevant monitoring and assessment stages, can bias be eliminated and universal efficacy achieved.

NEURODATA

Neurodata is data pertaining to the structure and functioning of the brain generated by neuroimaging devices.[114] This data is collected by monitoring the brain through sensorial equipment, followed by algorithmic and statistical processing of the raw data generated. This data can then be processed to reveal physiological information, such as age, sex and health status, or mental information, for instance on emotions or perceptions. Neurodata thus provides a unique window into an individual that can unveil sensitive characteristics such as future health, sexual orientation, intentions and decision making.[115] It is considered by many to be the "ultimate resort of informational privacy",[116] because it both "includes unexecuted behaviour, inner speech or other non-externalized action" and can be collected without the meaningful control of the data subject.[117]

IV. Increasing processing and sharing of neurodata

As the use of NTs becomes increasing widespread, so does the availability of data generated by them. Such neurodata is an invaluable resource for non-profit actors seeking to advance the scientific understanding of the human brain and develop medical treatments for patients suffering from neurological disorders. Partly because of this, the neuroscience has transitioned from a predominantly closed science model (marked by limited data sharing) to a predominantly open science model, resulting in a dramatic increase in publicly available neurodata. While this significantly broadens the opportunities for scientific innovation, a balance needs to be set to ensure that privacy concerns relating to neurodata are managed. This is especially important given the vested interests in acquiring neurodata on the part of commercial actors, insurance companies, social media platforms, political actors etc. Indeed, such information can be integrated into big data strategies aiming at profiling individuals according to e.g. health status, or to influence their opinions and behaviour.

MAIN ETHICAL CONCERNS

Despite questions around current levels of efficacy, all indications point toward a future where NT will be widely used in different areas of society and for non-medical purposes. This will likely include devices that inadvertently or intentionally alter behaviour and personality constituting features. While perhaps inevitable, such diffusion may have disruptive effects on fundamental human values. These technologies directly interact with the brain, the organ responsible for life-sustaining functions, as well as all human experiences, including perception, intelligence, emotion and behaviour. Insofar as NT builds a bridge that connects people's mental inner sphere to the outside, via the brain, it has the capacity to affect the elements of what it means to be human. Some of these ethical dilemmas relate to medical applications and have been under debate for several decades. Others — particularly the integration of NTs into the less regulated commercial sectors where profit-maximization is the key metric of success — pose new challenges. Established safeguards such as informed consent, for example, may not be deemed relevant, highlighting the urgent need for ethical guidelines aligned with human rights principles. Such guidelines should address four main ethical concerns.

I. Privacy

The development and operation of NTs require the collection, processing, storage and sharing of large amounts of neurodata. From this data, inferences on both the physiological and mental characteristics of individuals can be discerned, introducing novel concerns around the concept of 'mental privacy' i.e. individuals' privacy interests in their mental states. Indeed, the informational richness of neurodata renders NT a valuable tool across a variety of contexts for acquiring personal information for a range of ends, extending from those in the public interest (well-being, safety and security) through to the malign (profit-making, exploitation, discrimination, interference in democratic processes). This raises important questions around, for example, the permissibility of utilizing NTs as surveillance tools in the civilian domain, in employment contexts, or in processes within the justice system.

'MINDREADING' AND 'MINDSTEERING' THROUGH NEUROTECHNOLOGIES? NOT A REALITY, YET

Despite widely held presumptions, even today's most advanced NTs do not enable 'mind reading' or 'mind steering'.[118] Rather, they facilitate reverse inferences on mental states through the interpretation of brain activity patterns, or generate alterations in mental processes by influencing such patterns. Even then, the intricacies of how the brain encodes mental information in neural circuits, and the precise impact of neuromodulation on mental states remains far from fully understood. Until such knowledge barriers are overcome, targeted steering of mental processes and behaviour, as well as accurate real-time 'mindreading' will remain distant goals.[119] This is not an invitation for complacency, however. The direction and the pace of neurotechnological advancement all speak to the need for a precautionary approach whereby ethical and legal guidance is developed alongside and in anticipation of the increasing abilities of technology to encroach on mental processes.

II. Autonomy

As with most new (bio)technologies, questions around whether individuals can provide free and informed consent over the use of NTs, and the processing of data they generate, is a delicate concern that is not yet fully understood or explored. A particular issue is the ethics of mental autonomy i.e. the extent to which individuals can and should retain control over their mental capacities and processes. Indeed, the capacity to intervene in mental states and processes may have far-reaching implications for this foundational form of autonomy and interconnected/dependent human capacities such as personal identity, agency, authenticity and sense of self.[120]

III. Integrity

All dimensions of the NT lifecycle — from its development through to its end use — carries a risk of harm to impacted individuals' health (physical and mental) and wellbeing.

IV. Equality

The development and use of NTs risk creating negative externalities in terms of equality, non-discrimination and social justice. Chiefly, if NTs are only accessible to certain segments of society, existing disparities may be exacerbated (e.g. around health), while new forms of inequality may emerge (e.g. around access to mental enhancement technologies). At the same time, the widespread use of NT as a means to gather (mental) information create risks for discrimination based on brain characteristics, mental traits or mental states, including 'neuroprofiling'. The scope for discrimination on the basis of mental information that individuals have not externally disclosed is a significant concern.

Against the backdrop of these fundamental axes, more concrete ethical and societal tensions and dilemmas come into focus. These dilemmas embody the tension between the potential of NTs to be used for positive purposes and the disruptive effects of their misuse when introduced into societal domains without careful reflection. A robust regulatory and standard-setting approach towards NT should acknowledge these dilemmas and strive to strike a balance between conflicting interests in a manner that optimally contributes to the human dignity.

PRECAUTION AND INNOVATION

Any normative framework for managing the emergence (bio)technologies must balance the importance of avoiding unjustified alarmism that might stifle innovation, while also guarding against potentially harmful and irreversible side effects. In line with the precautionary principle, although NTs are still in an early stage of development and their most disruptive impacts potentially decades away, it is imperative that regulators take a proactive approach underpinned by continuous monitoring and updating of risk analyses. The aim should be to ensure responsible innovation without unduly impeding scientific and technological progress.

EMERGING TECHNOLOGIES AND INFORMED CONSENT

Ensuring the free and informed consent of any individual exposed to NTs is essential for safeguarding their privacy, autonomy and integrity. Meeting the requirements of 'free' and 'informed' consent, however, presents challenges. Principally, the innovative nature of NTs makes fulfilling the information requirement around consent difficult. Currently, it is challenging to articulate the full (mental and physical) effects and potential risks of NTs. For example, the precise impact of neuromodulation on mental processes and the information that can be decoded from neurodata, both now and in the future, remains unclear. Arguably, without such information, individuals are unable to provide informed consent for using NTs in medical treatment, for enhancement, or when agreeing to the collection and processing of neurodata by a third party. Additionally, internal or external pressures may lead to a situation where consent is not truly free. As availability increases, the use of NTs – such as for cognitive enhancement purposes – may create a 'new normal' where individuals feel compelled to use NT to remain competitive in society, in sports, education or employment. An effort to ensure wide and equal availability of NTs may inadvertently increase pressure on those who are not inclined to use brain monitors, neurostimulators or BCIs to adopt these in certain aspects of their lives. In this regard it should be highlighted that power dynamics, such as those between employers and employees, may limit individuals' freedom to choose whether or not to use NTs. Indeed, there are several examples of workplaces requiring employees to use new technologies for the purpose of boosting their productivity, as well as employees opting for enhancement to heighten their competitiveness and accomplishments.[121] Finally, pressure to consent to the use of NTs may stem from a dependency that individuals develop towards neurodevices.[122] Indeed, individuals who become fully dependent on a technology can lose the ability to decide not to use it, potentially compromising their autonomy. For example, if someone relies on neurostimulation to enhance their mood, will they then be free to choose to stop the stimulation, considering that this decision may be influenced by the stimulation of their brain processes?

MENTAL AUTONOMY AND MANIPULATION

A critical step in developing clear normative guidance on NTs is distinguishing between acceptable ways to affect and influence people's mental states, and illegitimate interferences with mental autonomy. Moreover, guidance on acceptable interferences with an individual's body must be complemented by clear ethical and moral guidelines on which forms and instances of interfering with mental states are acceptable, and those that would amount to illegitimate mental manipulation and modification. Current unacceptable methods include coercive re-education, indoctrination, or the forced administration of psychoactive drugs. It is crucial to establish which uses of NT should complement this list. The looming prospect of 'neuro power' over individuals, whereby neuroscientific insights and neurotechnological applications are designed and used to modulate thoughts and behaviour, with the aim of economic and political optimisation, suggests a need to further develop legal theory on mental manipulation.[123]

DATA-DRIVEN ADVANCEMENT, SURVEILLANCE AND 'BIG DATA'

The increasing availability of NTs that monitor brain activity raise significant privacy concerns. As noted above, Neurodata is essential for the operation of many NT devices and contributes to the advancement of scientific understanding of the (disordered) brain. However, the data represents a high-value commodity insofar as it can be integrated into Big Data processing by commercial and political entities to optimize economic or political gains. Such risks are discussed by some scholars under the notion of 'neuroliberalism,' which leverages emerging tools to influence human behavior for economic and political purposes, drawing insights from neuroscience, psychology and behavioral sciences.[124] A related phenomenon is 'surveillance capitalism,' where widespread collection and analysis of personal data shape market strategies, particularly in the digital realm, to predict and manipulate individual behaviour.[125] Neuromarketing, for example, raises fundamental questions about the extent to which third parties should be allowed to collect and process data on mental processes in order to influence decision-making and exploit preferences. The question for regulators is whether, to fully protect individual privacy, the collection and processing of data on mental states and cognitive abilities should be subject to the same regulations as other personal data, or prohibited altogether?

ENHANCING MENTAL CAPACITIES AND PERSONAL DEVELOPMENT

A significant proportion of (commercial) NT research and development concerns tools designed to optimize the mental capacities of healthy individuals. While some devices aim to enhance people's health and well-being, others seek to optimize productivity in competitive contexts such as employment and education. Certainly, in environments where rapid innovation, efficiency, up-scaling and profit maximization are lead mantras, neuroenhancement tools are regarded positively. It is questionable, however, whether it is ethical to expose workers in an employment setting to technologies that monitor or enhance their productivity, especially when these technologies may encroach upon their privacy, autonomy, integrity, and consequently, their personal development and dignity. In short, productivity might be enhanced, but at what cost?

CONVERGENCE AND DIVIDE BETWEEN TECHNOLOGY AND HUMAN BEINGS

Progress in NT signals an increasing convergence between humans and machines — not only between machines and the human body, but also machines and the human mind. In the future, this might manifest in 'hybrid minds',[126] and/or a permanent connection between the human brain and computers or the Internet.[127] Some see such an evolution as challenging views on personhood and the essence of what it means to be human. Others, however — such as advocates of transhumanism — view the use of enhancing NTs as a valid means to transcend the limitations of human beings and their naturally-occurring variable capabilities. The merging of humans and technology also blurs the biological boundaries between humans and non-humans. Individuals with NT implants may fully integrate the technological device as part of their identity, erasing the distinction between their physical body and the implant. This raises intriguing ontological and phenomenological questions, as well as moral inquiries. What do fundamental values such as human dignity, autonomy, integrity, privacy and equality mean under a transhumanist worldview where individuals are 'updated by technology?[128] The central question is whether society should adhere to the technological imperative that prescibes that if a certain technology can be created, it should and will be used?[129] Alternatively, should regulation place a ban on any technology that alters human nature, or restrict its use to protect individuals and society from the negative externalities that will inevitably extend from NT-enabled enhancement?

CONCLUDING REMARKS

Neuroimaging, neuromodulation, and BCIs represent the forefront of rapid advancement in NT, with these different categories operating in a mutually reinforcing manner. However, NT remains in its early stages as a scientific discipline. Despite some remarkable achievements, a majority of neurotechnological developments are still in nascent phases and not yet ready for widespread application beyond laboratory settings. Significant challenges, including cost and long-term effectiveness and safety validation, must be addressed before reliable and efficient NT can be integrated into societal domains such as wellness, gaming, education and employment. This must be viewed against the exponential investments by both public and private entities into neuroscientific research and neurotechnological development. Projections strongly suggest that the NT market will continue to grow rapidly in the coming decades. While the primary focus of this development remains on medical innovation and the creation of advanced tools to enhance the treatment of individuals with neurological or psychiatric disorders, there is a growing commercial appetite to market consumer-oriented NT devices.

The seemingly inevitable integration of NT into various aspects of daily existence will undoubtedly enhance the quality of life of many individuals. However, its broad adoption also necessitates a careful consideration of its potential disruptive effects on both individual and collective human dignity. Ethical concerns surrounding the uses and potential misuses of NT by various societal actors must be identified and addressed. This paper provides a foundation for answering some of these questions, particularly with respect to standard-setting. It has outlined four general axes of ethical concern and highlighted some of the dilemmas arising from current trends in NT development when viewed in light of these ethical considerations. Building on these findings, the human rights impacts of NTs can be more thoughtfully anticipated, thereby bolstering the efficiency and effectiveness of standard-setting processes in this domain.

END NOTES

[1] Considerable criticism surrounds the formal evolution of Neuralink's trial for not registering the trial in the public data base and not publishing the results in scientific, peer-reviewed journals but rather through social media updates. Hart, R. Experts Criticize Elon Musk's Neuralink Over Transparency After Billionaire Says First Brain Implant Works, Forbes 26 February 2024. Accessed on 29 March 2024 via https://www.forbes.com/sites/roberthart/2024/02/26/experts-criticize-elon-musks-neuralink-over-transparency-after-billionaire-says-first-brain-implant-works/.

[2] An example of this is the US White House's BRAIN initiative, a private-public partnership that aims at revolutionising the understanding of the brain and accelerating the development of innovative neurotechnologies.

[3] For instance, the research team creating Braingate started clinical trials in humans for brain-computer interfacing technology already in 2004.

[4] For example, Australian based neurotech company Synchron started a first clinical trial with an NT implant in 2019.

[5] OECD. Recommendation on Responsible Innovation in Neurotechnology, 2019. This recommendation, addressed to governments and innovators, is the first international standard in this domain. The document contains nine principles aimed at guiding them in the development of neurotech health applications.

[6] The UN Agency has stated its willingness to lead global dialogue on the ethics of neurotechnology and has recently initiated a standard-setting process with a view of developing an ethical framework on NT. This process will certainly build on the ground-breaking report elaborated in 2021 by its International Bioethics Committee (IBC) Ethical Issues of Neurotechnology, 2021, SHS/BIO/IBC28/2021/3Rev.

[7] By resolution 51/03 on "Neurotechnology and Human Rights" (6 October 2022) the Human Rights Council requested the Advisory Committee to develop an study on "the opportunities, challenges and gaps posed by neurotechnology to the protection and promotion of human rights" including recommendations on how they can be addressed "in a coherent, holistic, inclusive and action-oriented manner". This is the first initiative specifically focusing on policy-oriented human rights guidance in this area.

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[62] An example is the DSI-VR300 form Neurospec https://www.neurospec.com/Products/Details/1077/dsi-vr300 (Accessed on April 11 2024).

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