unesco

DOWNSTATE
HEALTH SCIENCES UNIVERSITY

UNIVERSITÀ DEGLI STUDI DI MILANO BICOCCA

THE RISKS AND CHALLENGES OF NEUROTECHNOLOGIES FOR HUMAN RIGHTS

Published in 2023 by the United Nations Educational, Scientific and Cultural Organization (UNESCO), 7, place de Fontenoy, 75352 Paris 07 SP, France, University of Milan-Bicocca – Department of Business and Law, Via Bicocca degli Arcimboldi, 8, 20126, Milano MI, Italy and State University of New York (SUNY) Downstate, 450 Clarkson Avenue, Brooklyn, NY 11203, United States of America

ISBN: 978-92-3-100567-1

Graphic design: Katharine Mugridge
Copyeditor: Natalie Lowe
Cover Image: © Pixels Hunter/Shutterstock.com

https://doi.org/10.54678/POGS7778

SHORT SUMMARY

Do we need neurotechnology governance?

The field of neurotechnology broadly encompasses any electronic device or method that can be used to read or modify the activity of neurons in the nervous system. Its potential to help cure mental illnesses and neurological disorders may amount to one of the most important medical achievements throughout history, opening a highway of hope for people suffering from diseases that go from Parkinson, Alzheimer's, stroke and addiction to hearing loss and blindness.

Recently, this technology has broken into the market leading to an increased availability of direct-to-consumer products that may be used for recreational and mental augmentation purposes. However, the effects of these technologies are still unclear and their unregulated use entail unprecedented risks for human rights related to freedom of thought, mental integrity and to some of its underlying pre-conditions such as dignity, identity or human agency.

This publication compiles the viewpoints of several of the experts that participated in an international workshop in November 2021 to explore the risks of these brain technologies, and whether existing international legal frameworks are sufficient to protect human rights. Part I focuses on the science and technology advances and tries to convey both the fascinating opportunities and broad challenges that they pose, while Part II highlights the ethical aspects and human rights risks resulting from non-medical applications of neurotechnologies, while looking at the potential and limits of a multi-layered response to grant the needed protection.

Total amount invested in neurotech firms reached

$33.2 billion

in 2021.

unesco

"Since wars begin in the minds of men and women it is in the minds of men and women that the defences of peace must be constructed"

THE RISKS AND CHALLENGES OF NEUROTECHNOLOGIES FOR HUMAN RIGHTS

Acknowledgements

Developed under the direction of: Gabriela Ramos, Assistant Director-General for Social and Human Sciences, UNESCO

Co-edited by: Marta Sosa Navarro, Salvador Dura-Bernal, Carla Maria Gulotta and Clare Stark

Internal Review Committee: Mariagrazia Squicciarini, Lihui Xu, Marta Sosa Navarro, Salvador Dura-Bernal, Carla Maria Gulotta and Clare Stark

Special thanks goes to all of the authors that contributed to this publication: Gabriela Ramos, Jonathan R. Wolpaw, Eduardo Fernández Jover, Francesca Gasparini, Aurora Saibene, Stefania Bandini, Roberto Andorno, Silvia Salardi, Arleen Salles, Philipp Kellmeyer, Pia Acconci and Hervé Chneiweiss.

Special thanks also goes to: the University of Milan-Bicocca, Department of Business and Law for their financial contribution to make this publication possible and to Martin Wickenden and Katharine Mugridge for layout and design.

Table of Contents

1. Foreword

by Gabriela Ramos, Assistant Director-General for Social and Human Sciences, UNESCO

Neurotechnology, and the ethics surrounding it, are among the most important and pressing issues of the day.

Substance use and mental and neurological disorders account for more than 10% of the disease burden worldwide, incurring huge economic costs. The two most common mental disorders alone (anxiety and depression) account for $1 trillion in global losses each year.[1] This burden is only expected to grow in the coming decades as the world's population ages. According to the latest projections from the United Nations Department of Economic and Social Affairs (DESA), the number of people aged 65 and over will double to 1.5 billion by 2050.[2] In light of this, advancements in neurotechnology offer us renewed hope in its potential to provide new treatments and to improve preventive and therapeutic options for the millions of individuals who suffer from neurological and mental illnesses. This is particularly pertinent in view of the COVID-19 pandemic and widespread digital transformation, which have had significant effects on mental health worldwide. According to a study by the World Health Organization (WHO), in the first year of the COVID-19 pandemic alone, the global prevalence of anxiety and depression rose by 25%.[3]

The application of neurotechnology goes far beyond the medical sphere. As you will see several authors discuss in this publication, it possesses the immense potential to improve student learning and cognition. Neurotechnology also facilitates features such as thought-to-text creation, as well as virtual and augmented reality systems that are supported by brain control and can be used for entertainment. These exciting possibilities have naturally driven rapidly growing investment into neurotechnology. The latest research shows that the total amount invested in neurotech firms reached $33.2 billion in 2021, a 60% increase on the previous year.[4]

1. World Health Organization (WHO). N.d. *WHO Special Initiative for Mental Health.* Accessed at: https://www.who.int/initiatives/who-special-initiative-for-mental-health (30 September 2022)
2. United Nations Department of Economic and Social Affairs (DESA) (2019). *Our world is growing older: UN DESA releases new report on ageing*. Accessed at: https://www.un.org/development/desa/en/news/population/our-world-is-growing-older.html. (30 September 2022)
3. WHO (2022). *COVID-19 pandemic triggers 25% increase in prevalence of anxiety and depression worldwide*. Accessed at: https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide. (30 September 2022)
4. NeuroTech Analytics (2022). *Global Neurotech Industry Investment Digest 2021*. Accessed at analytics.neurotech.com/neurotech-investment-digest.pdf. (30 September 2022)

However, while we celebrate the vast opportunities offered by the advancement of neurotechnology, if we are to reap collective benefits for all of humanity we must also tackle the novel ethical and human rights challenges that arise with the development and deployment of neurotechnology.

As rightly highlighted in the report of UNESCO's International Bioethics Committee (IBC) on ethical issues of neurotechnology (2021),[5] we need to assess how far current human rights frameworks are equipped to protect neural rights, or whether there is a need for a new set of neuro-specific human rights, such as the right to cognitive liberty, mental privacy, mental integrity and psychological continuity.

The IBC has recommended that UNESCO convene a multidisciplinary group of experts to develop a policy-oriented governance model that monitors progress in the field and examines whether the issues raised are being effectively covered by the current legal frameworks. This governance model would build on the existing human rights architecture and incorporate the relevant principles identified in this report. It would also need to take a stock of various initiatives that countries have begun to take, in isolation, aimed at protecting human rights against the abuse of (neuro) technologies, in an explicit way such as the case of Chile, Spain and France[6], or inexplicitly, such as the case of Brazil, Italy, or Germany[7], to name a few. It is therefore essential that we build a shared global understanding of the interactions between neurotechnology, ethics and human rights – just as we have done regarding the human genome and artificial intelligence at UNESCO in the past. It is in this context that this publication – jointly undertaken by UNESCO, the University of Milano-Bicocca and the State University of New York Downstate – is being launched.

Salvador Dura-Bernal begins by doing an excellent job of laying the groundwork, covering the state of the art and the challenges of neurotechnology. Various experts then contribute to discussions on an array of scientific, ethical and legal issues concerning neurotechnology. For instance, the current capacity of neurotechnology to record and transmit neural data means that sensitive information stored by the brain may become dangerously accessible in the near future in ways that infringe upon mental privacy. This is particularly concerning given that neural data is increasingly sought-after not only within the medical sector, but also in the consumer market as a resource used to drive users to choices and behaviour that ensure higher profitability. Such manipulation may even go beyond the business context to enforce certain groups or their ideas, such as antivax movements, xenophobic ideologies or misogynistic beliefs, undermining social cohesion and democracy. This warrants discussions on how human rights are factored in when addressing the ethical issues of neurotechnology, as elucidated by Carla Gulotta and Roberto Andorno, among others. Separately, Silvia Salardi also raises key questions on the acceptability of human enhancement in the face of neurotechnology developments.

5. International Bioethics Committee of UNESCO (IBC) (2021). *Report of the International Bioethics Committee (IBC) on the ethical issues of neurotechnology*. Available at https://unesdoc.unesco.org/ark:/48223/pf0000378724.
6. The constitutional reform undertaken by Chile, the Digital Rights Charter of the Government of Spain, and the Charter for the responsible development of neurotechnologies of the Government of France present several different ways to achieve the same end: regulating and protecting human rights against the advances of neurotechnology.
7. The Civil Internet Framework approved in the Brazilian Congress, the Declaration of internet at the Italian Chamber of Deputies, or the work of the Data Ethics Commission established by the German government addressed inexplicitly and partially the risks associated with the development of neurotechnology.

The ethical and human rights implications of neurotechnology are amplified further by the rapid convergence between neurotechnology and other emerging technologies such as artificial intelligence (AI). As the most recent and global framing on AI and a forward-looking blueprint, UNESCO's Recommendation on the Ethics of AI includes a provision which states that *"Ethical questions related to AI-powered systems for neurotechnologies and brain-computer interfaces should be considered in order to preserve human dignity and autonomy"*. In addition, it calls on Member States to develop guidelines for human-robot interactions and to pay special attention to *"the possibility of using AI to manipulate and abuse human cognitive biases"*. The Recommendation also acknowledges the importance of raising awareness about AI technologies that recognize and mimic human emotions especially when children are involved. Amid the ongoing implementation of the Recommendation around the world, special attention should indeed be paid to the development and convergence of neurotechnology with AI, a discussion that Stefania Bandini engages with in her contribution.

UNESCO has led global initiatives in the ethics of science and technology for decades. From genetic engineering to robotics and artificial intelligence, open science and now neurotechnology, we are committed to continuing to work to develop universal ethical standard-setting instruments, advancing global ethical reflection and working with Member States to strengthen their capacities to ensure that new technologies are developed and applied in a way that benefits humanity and the planet as a whole.
In light of our commitment, I wish to thank the various contributors for their work and invite you to consider the points that they put forth, trusting that this publication will serve as a preliminary but crucial steppingstone in informing the discussion on the regulation and governance of neurotechnology for the good of all.

2. Introduction to part I: State of the art and challenges of neurotechnology.

Salvador Dura-Bernal, Assistant Professor of Neuroscience, State University of New York (SUNY) Downstate, and Research Scientist, Nathan Kline Institute for Psychiatric Research

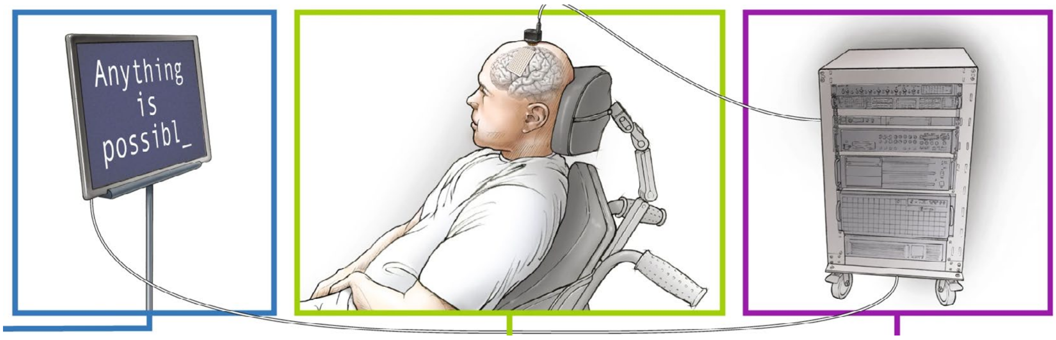
Brain-machine interfaces can now help people with paralysis to move and feel, deaf people to hear and blind people to partially recover sight. What for many still sounds like science fiction, is now a reality resulting from monumental advances in brain science and technology over the last 30 years.[8] The field of neurotechnology broadly encompasses any electronic device or method that can be used to read or modify the activity of neurons in the nervous system. These powerful neurotechnologies have demonstrated their potential to treat many brain diseases and disorders. Recently, they are also being made available to healthy individuals for recreational and mental augmentation purposes. However, the effects of these technologies are still unclear and may pose risks to basic human rights related to mental privacy, identity, agency, equitable access and others. In November 2021, we organized an international workshop to explore the risks of these brain technologies and whether existing international legal frameworks were sufficient to protect our human rights. This publication compiles the viewpoints of several of the experts that participated in the workshop.[9] First, we focus on the science and technology advances and try to convey both the fascinating opportunities and broad challenges that they pose.

Altering sensory perception and controlling robotic arms

Dr Mesgarani kicked off the workshop with an eye-opening overview of the far-reaching application of neurotechnologies in today's world. Since 1997, a technique called deep brain stimulation has been used to eliminate Parkinson's tremors by monitoring and delivering electric impulses to a deep region of the brain known as the basal ganglia (Okun 2012). Another widely adopted neurotechnology are cochlear implants, small electronic devices that stimulate the cochlear (hearing) nerve, enabling patients with hearing loss to perceive the sounds around them (Zeng et al. 2008). In recent years, neurotechnologies have started to conquer an age-old challenge: restoring vision to the blind. In his fascinating workshop talk, Dr Fernández Jover explained how they managed to restore the ability to discern shapes and letters in a person who had been completely blind for 16 years (Fernández et al. 2021). This was done by implanting electrodes in the rear part of the brain known as the visual cortex, a region composed of millions of neurons

8. World Science Festival. Decoding the brain. 14 Apr 2022. Available at https://www.youtube.com/watch?v=K7QBnuF6dHg
9. Sosa Navarro M., Gulotta C.M., Dura-Bernal S. International Workshop on the risks and challenges of neurotechnologies for human rights. Nov 2021. Available at https://www.youtube.com/watch?v=ALhkaKPuAZA

and responsible for processing electrical signals sent by our eyes (in healthy individuals) – neuroscientists generally agree that "we see with our brain, not our eyes". However, the way visual information is encoded in the cortex is highly complex and not fully understood, so restoring high-quality vision will likely require very precise stimulation of many thousands of neurons. Dr Macknik and Dr Martinez-Conde have been working towards this goal by developing a novel type of visual prosthesis that can stimulate visual cortex neurons with such precision that it will be able to evoke sight of a single star in the sky (Macknik 2019).



Schematic depiction of Dr. Chang's brain-computer interface to decode speech from the brain of an individual with severe limb and vocal paralysis.
Adapted from Metzger et al. 2022 https://doi.org/10.1038/s41467-022-33611-3
(under a Creative Commons License).

Paralysed patients are also benefiting from extraordinary advances in brain-machine interfaces. To enable them to communicate with the external world, Dr Mesgarani and Dr Chang, among others, have developed devices that decode speech directly from the electrical signals recorded from their cortex (Akbari et al. 2019; Moses et al. 2021). Mr Copeland, a pioneer research participant who has been instrumental in shaping the future of brain-machine interfaces, provided the workshop with a vivid first-hand description of his experiences. Mr Copeland was left paraplegic after a car accident and became the first person to control a robotic arm and recover touch sensation through a brain implant in the cortex (Flesher et al. 2021). He described the neuroprosthetic as

"very intuitive to control, [...] I don't have to strain, it really is just as easy as thinking move and grasp; so in that way, it is kind of an extension of myself, but I also see it as a tool that I'm controlling that is separate from myself".

Mr Copeland's achievements include playing the Sonic, the Hedgehog video game, fighting a lightsaber duel and even shaking hands with President Obama, all through mind-controlled neuroprosthetics.[10]

10. Ibid.

Modifying emotions and eliciting memories

Restoring sensory and motor function is undoubtedly an astounding achievement, but perhaps the most perplexing neurotechnologies are those that modify our emotions, memory and cognition. Patients with treatment-resistant depression – the most severely depressed patients who have not responded to any other treatments – can now be treated using the same deep brain stimulation technique used for Parkinson's disease. After electrical stimulation of the brain regions associated with processing emotions and regulating behaviour, the severely depressed patients exhibited a significant improvement in depression symptoms (Cromwell et al. 2019). Importantly, the antidepressant effects were sustained over a long period of time. A 36-year-old woman who had suffered severe depression since childhood was implanted with a closed-loop neuromodulation system that could detect changes in her brain activity associated with the onset of depressive thoughts or feelings. After detecting these biomarkers, the device delivered a tiny dose of electricity for six seconds that immediately alleviated her symptoms. One year later, she described how the cycles of negative obsessive thoughts had stopped, and her "overwhelming emotions and darkness" had disappeared (Scangos et al. 2021).

A recent astonishing study demonstrated that electrically stimulating memory-related brain regions elicited vivid memory flashbacks in people with Alzheimer's disease. These memories included very specific past experiences or objects, such as a childhood summer house or eating a sardine sandwich 23 years ago (Deeb et al. 2019). Remarkably, some memories acquired more detail with increased stimulation. Advances in our understanding of how memories are stored in the brain has also led to neurotechnologies that can improve memory performance by up to 20% (Ezzyat et al. 2018). This is a promising treatment for patients with memory loss, a widespread condition that can result from, among others, Alzheimer's disease, stroke and head injury.

Present and future challenges

Despite these impressive advances, neuroscience is generally considered to be in its infancy, and understanding the brain remains an extremely complex and unsolved problem. Part of this complexity stems from the large number of highly interconnected regions (each neuron is estimated to receive 10,000 synaptic connections from other neurons), and the many different interacting scales involved – genetic, molecular, cellular, circuit, system or behaviour. Brain plasticity further complicates the problem by continuously modifying the brain's structure and function over time (see Dr Wolpaw's article). These factors make it very challenging to accurately decode brain signals and predict the effects of neural stimulation.

Most of the results described above used invasive neurotechnologies, generally requiring surgery to record or stimulate inside the person's skull. This contrasts with non-invasive technologies, such as electroencephalography (EEG) or transcranial magnetic stimulation (TMS), which work from outside the skull, eliminating the risks of surgery and implants. However, while invasive technologies can be very precise – even targeting individual neurons – non-invasive technologies typically record or modify the combined activity of millions of neurons, making it harder to decode information and to control the effects of neurostimulation. Nonetheless, there have been major advances in non-invasive technologies, for example, in wearable EEG-based brain-computer interfaces (see Dr Gasparini's article), and their applications are thriving, ranging from neuroprosthetic control and treatment of brain disorders to education, entertainment and marketing (Portillo-Lara et al. 2021). Given the accessibility and ease of use of non-invasive technologies, these have rapidly proliferated as commercial devices available to the general public. Since this will be used outside of highly controlled academic or clinical environments, there is an increased risk of technology misuse or abuse. This is particularly true for the growing number of neurostimulation commercial devices using TMS or transcranial direct current stimulation (tDCS). Their effects are not yet fully understood and so may cause undesired results or even damage our brains (Boes et al. 2018).

There is now overwhelming evidence, some of which was described here, that neurotechnologies have the potential to decode and alter our perception, behaviour, emotion, cognition and memory – arguably, the very core of what it means to be human. This has major ethical implications as these devices could be used to invade people's mental privacy and modify their identity and sense of agency, for example by manipulating people's beliefs, motivations and desires. Neural enhancement poses an additional risk as this could lead to further inequalities. Although some have argued these risks are currently inexistant and it is too early to regulate neurotechnologies, recent evidence and the rapid pace of innovation present a compelling case that we might actually be late. Regulation will be especially important given private tech companies' already massive and growing investment in neurotechnology.

As with other revolutionary technologies, such as artificial intelligence (see article by Dr Bandini), we must aim to harness their potential for good. A crucial step towards this, and the aim of this publication, is to disseminate and increase public awareness of the topic, so people can make informed decisions and help steer international organizations and governments in the right direction.

References

Akbari H., Khalighinejad B., Herrero J-L., Mehta A. D., Mesgarani N. (2019). Towards reconstructing intelligible speech from the human auditory cortex. *Sci Rep.* 9, p. 874.

Crowell A. L., Riva-Posse P., Holtzheimer P. E., Garlow S.J., Kelley M. E., Gross R. E., et al. Long-Term Outcomes of Subcallosal Cingulate Deep Brain Stimulation for Treatment-Resistant Depression. Am J Psychiatry. 2019; 176, pp. 949-956

Deeb W. Salvato B., Almeida L., Foote K. D., Amaral R., Germann J., et al. (2019). Fornix-Region Deep Brain Stimulation–Induced Memory Flashbacks in Alzheimer's Disease. *New England Journal of Medicine* pp. 783-785. doi:10.1056/nejmc1905240

Ezzyat Y. Wanda P. A., Levy D.F., Kadel A., Aka A., Pedisich I. et al. (2018). Closed-loop stimulation of temporal cortex rescues functional networks and improves memory. *Nat Commun*. 9, p. 365.

Fernández E., Alfaro A., Soto-Sánchez C., Gonzalez-Lopez P., Lozano A.M., Peña S, et al. (2021). Visual percepts evoked with an intracortical 96-channel microelectrode array inserted in human occipital cortex. *J Clin Invest.* 131. doi:10.1172/JCI151331

Flesher S. N. Downey J. E., Weiss J. M., Hughes C. L., Herrera A. J., Tyler-Kabara E. C. et al. (2021). A brain-computer interface that evokes tactile sensations improves robotic arm control. *Science*. 372, pp. 831-836.

Macknik S. L. (2019). A new type of visual prosthesis. In: Scientific American Blog Network [Internet]. Aug 2019 [cited 12 May 2022]. Available at https://blogs.scientificamerican.com/illusion-chasers/a-new-type-of-visual-prosthesis/

Moses D. A., Metzger S. L., Liu J.R., Anumanchipalli G. K., Makin J. G., Sun P. F. et al (2021). Neuroprosthesis for Decoding Speech in a Paralyzed Person with Anarthria. *New England Journal of Medicine*. pp. 217–227. doi:10.1056/nejmoa2027540

Okun M. S. (2012). Deep-brain stimulation for Parkinson's disease. *N Engl J Med.* 367, pp. 1529-1538.

Portillo-Lara R., Tahirbegi B., Chapman C. A. R., Goding J. A., Green R. A. (2021). Mind the gap: State-of-the-art technologies and applications for EEG-based brain–computer interfaces. *APL Bioengineering*. P. 031507. Doi:10.1063/5.0047237

Scangos K. W., Khambhati A. N., Daly P. M., Makhoul G. S., Sugrue L. P., Zamanian Het al. (2021). Closed-loop neuromodulation in an individual with treatment-resistant depression. *Nature Medicine*. pp. 1696–1700. doi:10.1038/s41591-021-01480-w

Zeng Fan-Gang et al. (2008). Cochlear implants: system design, integration, and evaluation. *IEEE Rev Biomed Eng.* 1, pp. 115-142.

3. Neurotechnologies may change the brain in unpredictable ways.

Jonathan R. Wolpaw, M.D. Director, National Center for Adaptive Neurotechnologies, Albany Stratton Veterans Administration Medical Center, Professor of Biomedical Sciences, State University of New York

Neurotechnologies offer many potential benefits. Initially, the benefits are likely to be mainly for people with severe neuromuscular disorders. As advances continue, these technologies may also benefit others. As this publication demonstrates, neurotechnologies also present risks and challenges. Many of these are well recognized and are receiving appropriate attention. However, one potentially momentous consequence of neurotechnologies has received very little attention to date.

Recent advances in brain research show that the brain continues to change throughout life. These changes result from the interactions between the brain and the outside world that occur continually in all of us as we go about our daily lives. It is through these changes that we acquire new skills and learn new information. Up to now, interactions between the brain and the outside world have occurred primarily through the sensory nerves that convey input (vision, audition, touch, smell, taste) from the outside world to the brain and the motor nerves that convey output from the brain to the muscles that produce movements, speech and so forth. The brain has evolved over millions of years to interact with the outside world through these natural pathways. Thus, these interactions are well-controlled and carefully monitored, and the changes they produce in the brain are beneficial; they enable us to gain new abilities and new information.

Neurotechnologies do not fit into this natural format. They create interactions between the brain and the outside world that bypass these well-established natural sensory input and motor output pathways. They bypass the natural sensory input pathways by stimulating brain cells through implanted devices or through electromagnetic fields produced by external devices. They also bypass the natural motor output pathways by recording signals directly from brain cells with implanted sensors or external sensors such as scalp EEG recording electrodes. Neurotechnologies create unnatural interactions with the outside world, highly artificial interactions that the brain did not evolve to produce. These unprecedented interactions are unlikely to be as well-controlled and carefully monitored as natural interactions. Consequently, they may change the brain in unprecedented ways, producing changes in the brain that are unusual and possibly non-beneficial. They could conceivably impair important functions or even create abnormal or harmful behaviour.

These considerations have a still more fundamental implication.

As neurotechnologies that circumvent the brain's natural sensory input and motor output pathways become increasingly integrated into brain function and as they produce changes in brain cells and their connections, they will require a reappraisal of what exactly it means to be human. This reappraisal will be needed on multiple levels – philosophical, theological, biological, ethical, legal and societal. It is likely to be comparable in complexity and difficulty to the appraisal necessitated by the recent development of methods for modifying the human genome.

At the same time, two reassuring factors mitigate this admittedly forbidding prospect. First, despite considerable effort over several decades, existing neurotechnologies are still primitive and have correspondingly limited capabilities. Their future progress is likely to be similarly slow. Thus, there should be time and the opportunity to recognize and address the unexpected and undesirable effects of the changes in the brain produced by neurotechnology-based interactions with the outside world. Second, the brain is a remarkably robust and resilient organ, and may well prove far less susceptible than is feared to the development of deleterious changes resulting from the increasing use of neurotechnologies. Nevertheless, those engaged in neurotechnology research and development, those concerned with their ethical and legal aspects, and ultimately all those who use these technologies should always keep in mind the possibility and implications of unpredictable changes in the brain.

4. Intervening in the brain: challenges and future prospects.

Eduardo Fernández Jover, Institute of Bioengineering, Faculty of Medicine, University Miguel Hernandez and CIBER BBN.

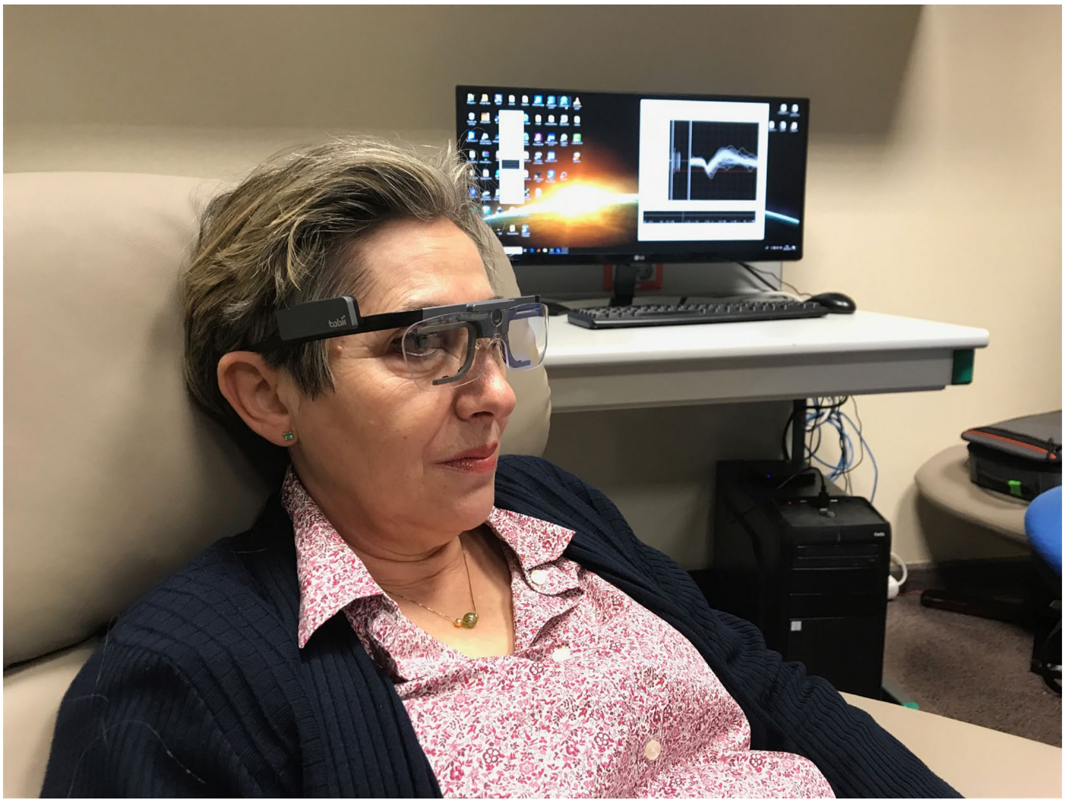
The possibility of interfacing the nervous system with electronic devices has long fascinated scientists, engineers and physicians. Recent technologies developed over the last few decades allow for interactions between an increasing number of neurons, enabling the simultaneous recording and stimulation of brain functions. This opens the door to new possibilities for intervening in the brain, from electronic implants restoring lost sensory functions such as auditory or visual prostheses to deep brain stimulators controlling motor disorders and brain-machine interfaces, which now provide hope of increasing mobility and independence for paralysed patients. There is now even speculation that these technologies may play a role in enhancing the capabilities of healthy human beings.

As more and more patients benefit from these approaches, interest in neurotechnology has grown significantly. However, the scientific and engineering problems associated with these technologies are much more complex than originally believed and there are still many unresolved issues. For example, there are important gaps in our understanding of the neural code and the way the brain handles artificial stimulation, which limits our ability to interact with the brain. Furthermore, in some instances, it may also be hard to limit the effects of electrical stimulation to a specific target pathway. Despite the above-mentioned issues, things we thought were impossible or unthinkable in scientific terms are now a reality. For instance, until the 1960s, many researchers thought that, regardless of the number of electrodes used, a helpful frequency representation of auditory information would never be reached. However, thousands of profoundly deaf people now use cochlear implants in daily life and most of them can easily understand speech and communicate via telephone.

While the benefits of reaching viable therapies for a broad range of patients with injuries or diseases of the nervous system are beyond any doubt, we should also consider the potential risks and limitations of connecting such devices to the brain. There is little question that the neural prostheses in clinical use today, such as cochlear implants or deep brain stimulators, are helpful and clearly benefit the users by far outweighing the risks involved. Nonetheless, we should also keep in mind that central neural implants require invasive surgical procedures to connect the artificial devices to the human brain and all surgeries, whether elective or necessary, involve some risks. Furthermore, electrodes are prone to degradation. Therefore, a major problem with all the available neural electrodes to date is their long-term viability and biocompatibility. Another limitation is that present devices connect the neural tissue with a relatively small number of electrodes, as compared with the host of neurons involved in any sensory or motor pathway. Moreover, even the most advanced devices are still far from mimicking the anatomical and physiological connections of any real neural network (we have to consider that a single neuron has thousands of biochemical contacts, called synapses, and thus receives inputs from many other neurons). On the other hand, extensive efforts are still needed to address the engineering challenges of communicating with hundreds or thousands of electrodes, and these devices should be wireless to reduce post-surgical complications such as the risk of infection. In this context, power and communication constraints, as well as heat dissipation in the brain, pose significant challenges. Consequently, there is still a clear need to develop new implantable technologies optimized for high channel count.

Fortunately, there are many technical improvements on the way. In addition, the risks are becoming increasingly manageable, so connecting electronic devices with the central nervous system is already routine in medical practice. These technologies, which are primarily intended to provide medical help when all other treatment options fail, therefore hold promise for many other future medical applications and also spark the imagination, making it possible to provide the human body with new functions or capabilities. Until now, we have only had the capacity to make relatively modest enhancements to people. However, the convergence of innovations in neurotechnology, nanotechnology, neurology, neuroscience, neurosurgery and other fields raises the possibility that we could enable much more dramatic improvements. Therefore, it is time to assess the potential benefits, risks and limitations of connecting new devices to the central nervous system as well as the ethical issues involved in two-way communication with the brain.

Brain implants for therapeutic purposes are apparently uncontroversial, but we now have sufficient knowledge to go beyond clinical trials. In this framework, some questions arise. For example, What criteria should be used to select appropriate candidates for these technologies? Does a human being cease to be a “human” if some parts of her or his brain are supplemented by electronic implants? If so, up to what point? To what extent might such implants have a significant impact on the human body or psyche? How far can brain implants give an individual a specific capability that could become a threat to society? Will there be a need for new legislation on these emerging technologies? If a particular intervention results in side effects that require treatment, should the cost of this treatment be covered by insurance? The list is almost endless. Moreover, the direct connections with the brain open up the possibility for individuals to communicate with each other, control robots and machines with their thoughts, or to be constantly connected to the internet.



Brain implant developed by Dr. Fernandez-Jover stimulates the visual cortex of a blind person, allowing her to see simple shapes and letters.

At this point, a stringent risk assessment must be conducted before implanting any device into the brain, and surgery should not be performed without full awareness of all the consequences. Furthermore, implantation should be excluded if there are less invasive and less risky ways to achieve the same goals, although there may be circumstances where an implant could conceivably be more acceptable than an external device.

An early and thoughtful discussion of the potential benefits and risks of brain implants will lay the groundwork for a responsible application of this very promising technology. Our mission is to anticipate well in advance what might be a problem and provide clear ideas and guidelines. However, we must proceed cautiously and not set unrealistic expectations or underestimate the risks and obstacles that still remain to be resolved.

5. Brain-computer interfaces (BCIs) and wearables: reliability, ethics and security as assessed by a computer scientist from a multidisciplinary point of view.

Francesca Gasparini, Associate Professor of Computer Sciences, head of the Multimedia Signal Processing Laboratory and PhD Aurora Saibene, University of Milano-Bicocca.

Electroencephalography allows brain activities and functions to be recorded and interpreted in a non-invasive way. The resulting electroencephalographic (EEG) signals have largely been exploited to provide brain-computer interfaces (BCIs) (Kubler et al. 2006) that allow direct communication between humans and machines for a variety of applications, from medical ones (e.g. wheelchair control) to more playful ones (e.g. playing video games).

In recent years, there has also been a rise in the use of **wearable** devices for BCI control, devices that can easily be accessed by the general public. In fact, users seem to find wearable EEG-based BCIs more comfortable (Di Flumeri et al. 2019) and easy to accept. However, numerous questions and concerns arise when facing this kind of technology, especially with regard to the device's **reliability**, **neuroethics** and **neurosecurity**.

Starting with **reliability** issues, there are numerous devices on the market providing popular playful and well-being applications which rely on the use of mass devices such as smartphones (Ienca and Haselager 2016). Moreover, these technologies have been exploited for marketing campaigns to assess consumers' needs and preferences by using their neural responses.

However, it seems that the performance of these devices does not match those of their medical counterparts (Duvinage et al. 2013), and that there is a serious absence of comparisons between wired and wireless devices (Roesler et al. 2014), which could provide a better assessment of the reliability of wearable technologies.

This clearly highlights the issues related to the ethical and security aspects of BCIs. **Neuroethics** therefore assume a particular importance as a discipline that must consider brain-related knowledge and, in the BCI domain, its practical application with respect to human value systems (Illes 2007; Haselager et al. 2009).

There are three main players in this domain: (i) BCI experts, who usually come from an interdisciplinary team, including engineers, computer scientists and neuroscientists; (ii) BCI users, who are the target for these technologies; (iii) the media, which has the power to influence the masses and their perception of BCIs. Grübler et al. (2014) interestingly proposed a survey to provide an accurate representation of the main concerns, suggestions and observations of these three groups.

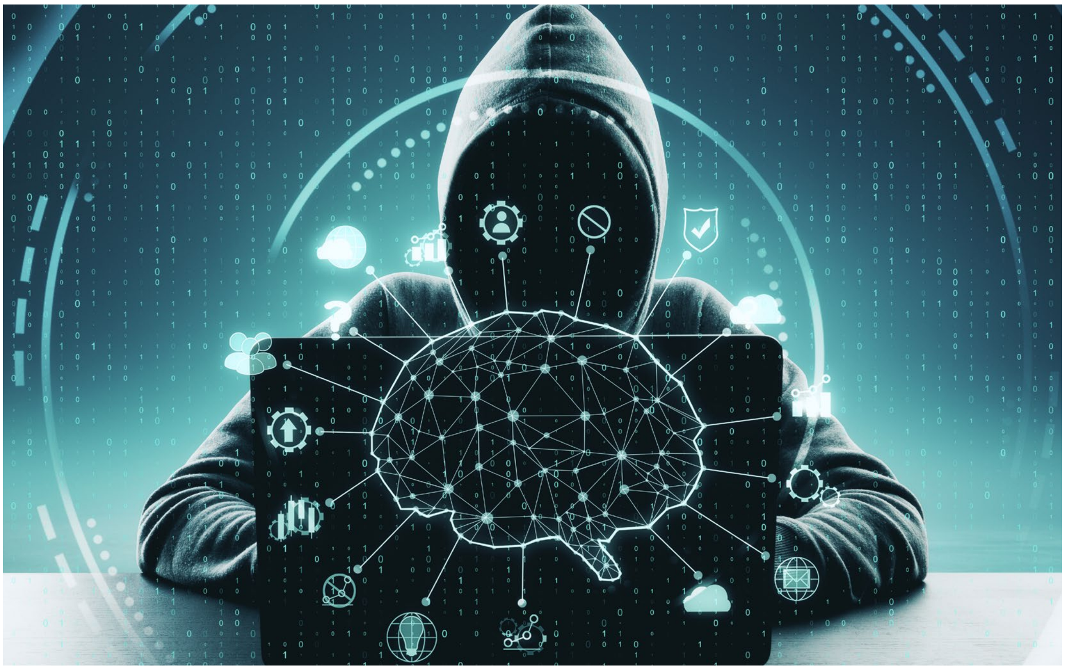
The authors discovered that BCI experts call for the need to avoid unrealistic expectations, especially when BCI-related themes are covered by the mass media. Moreover, they found that there may be some limitations to the real efficacy of the proposed systems due to BCI illiteracy and demanding procedures for experimental completion. Finally, they pose some questions about morality, responsibility and security. In particular, they highlight the importance of defining the responsibilities of both the users and the experts who are involved in different phases of the BCI deployment.

BCI users are, of course, very interested in the possibility of improving their condition (e.g. post-stroke rehabilitation) and are very curious about these technologies. However, they can end up feeling frustrated given the difficulties they may face in using the BCIs and the discomfort caused by using EEG devices, which they find are mostly impractical to use in everyday life.

All these observations have seen an evolution and better formalization in the work by Coin et al (2020), who defined three main groups of ethical issues: physical, psychological and social ones.

The physical group involves user safety, which can be undermined by the user her/himself or by a malicious individual. Physiological factors may involve considering the possibility of acquiring more autonomy, which could maybe come at the cost of dehumanizing the user or changing the concept of personhood. The social factors are numerous and should include a redefinition of normality, more detailed informed consent and work on responsibility and regulation, and should also cover concerns about privacy and security.

Neurosecurity can be considered a substructure of neuroethics and has been defined by Denning et al. (2009) as *"the protection of the confidentiality, integrity and availability of neural devices from malicious parties with the goal of preserving the safety of a person's neural mechanisms, neural computation and free will".*



Brain computer interfaces: is accessibility bidirectional?

© Golden Dayz/Shutterstock.com

The risk of brain hacking (Ienca and Haselager 2016) is therefore real with the presence of a malicious player in the BCI system who could manipulate: (i) the BCI input, thus modifying the signal that is passed to the system for BCI control; (ii) the measurements that usually affect the BCI output, cracking the data and disrupting some functions; (iii) decoding and classification, for example by adding noise to the signal or changing machine learning components; (iv) and the feedback, which could cause physical and psychological harm by changing the response given to the user.

The hacking described clearly has numerous implications (Ienca and Haselager 2016; Agarwal et al. 2019) with respect to dual use, the development of safeguards, clarification of informed consent, privacy and security issues in terms of user rights, physical and psychological safety, and user autonomy.

Therefore, talk about ethical and security issues and work on addressing them requires a multidisciplinary effort. It requires the involvement of ethicists and security experts as well as neuroscientists, engineers, computer scientists and other figures related to the design and development of a BCI system (Kubler et al. 2006; Ienca and Haselager 2016; Haselager et al. 2009; Bonaci et al. 2014; Burwell et al. 2017).

References

Agarwal, A., Dowsley, R., McKinney, N. D., Wu, D., Lin, C. T., De Cock, M. and Nascimento, A. C. A. (2019). Protecting privacy of users in brain-computer interface applications. *IEEE Transactions on Neural Systems and Rehabilitation Engineering* 27(8), pp. 1546–1555.

Bonaci, T., Calo, R. and Chizeck, H.J. (2014). App stores for the brain: Privacy and security in Brain-Computer Interfaces. In 2014 IEEE International Symposium on Ethics in Science, Technology and Engineering. IEEE pp. 1–7.

Burwell, S., Sample, M. and Racine, E. (2017). Ethical aspects of brain computer interfaces: a scoping review. *BMC medical ethics* 18(1), pp. 1–11.

Coin, A., Mulder, M. and Dubljević, V. (2020). Ethical aspects of BCI technology: what is the state of the art? *Philosophies* 5(4), p. 31.

Denning, T., Matsuoka, Y. and Kohno, T. (2009). Neurosecurity: security and privacy for neural devices. *Neurosurgical Focus* 27(1): E7.

Di Flumeri, G., , Aricò , P., Borghini, G., Sciaraffa, N., Di Florio, A. and Babiloni, F. (2019). The dry revolution: Evaluation of three different EEG dry electrode types in terms of signal spectral features, mental states classification and usability. *Sensors* 19(6):1365.

Duvinage, M., Castermans, T. Petieau, M., Hoellinger, T., Cheron, G. and Dutoit, T. (2013). Performance of the Emotiv Epoc headset for P300-based applications. *Biomedical engineering online* 12(1), pp. 1–15.

Grübler, G., Al-Khodairy, A., Leeb, R., Pisotta, I., Riccio, A., Rohm M. and Hildt, E. (2014). Psychosocial and ethical aspects in non-invasive EEG-based BCI research—a survey among BCI users and BCI professionals. *Neuroethics* 7(1), pp. 29–41.

Haselager, P., Vlek, R. Hill, J. and Nijboer, F. (2009). A note on ethical aspects of BCI. *Neural Networks* 22(9), pp. 1352-1357.

Ienca, M. and Haselager, P. (2016). Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity. *Ethics and Information Technology* 18(2), pp. 117-129.

Illes, J. (2007). Empirical neuroethics: Can brain imaging visualize human thought? Why is neuroethics interested in such a possibility? *EMBO reports* 8(S1): S57-S60.

Kubler, A., Mushahwar, V. K., Hochberg, L. R. and Donoghue, J. P. (2006). BCI meeting 2005-workshop on clinical issues and applications. *IEEE Transactions on neural systems and rehabilitation engineering* 14(2), pp. 131-134.

Roesler, O., Bader, L., Forster, J., Hayashi, Y., Heßler, S. and Suendermann-Oeft, D. 2014). Comparison of EEG devices for eye state classification. *Proc. of the AIHLS*.

6. Regulating AI? The EU's first steps and future BCI-based scenarios.

Stefania Bandini, Full Professor of Computer Science, Systems and Communication, University of Milano-Bicocca and RCAST – Research Centre for Advanced Science and Technology, University of Tokyo.

Artificial intelligence (AI) has the potential to transform many fields of human activities, both in the industrial environment and in societies. It requires considering a range of implications from ethics to well-being. The European Commission (EC) set up a High-Level Expert Group (HLEG) which recently produced ethics guidelines for trustworthy AI,[11] addressing AI producers and users to consider the three principal components of trustworthy AI, which should be:

- **lawful** – complying with applicable laws and regulations;
- **ethical** – ensuring adherence to ethical principles and values;
- **robust** – from a technical and social perspective since, even with good intentions, AI systems can cause unintentional harm.

One of the main aspects of this approach considers the development of a *"human-centric approach to AI [that] strives to ensure that human values are central to the way in which AI systems are developed, deployed, used and monitored, by ensuring respect for fundamental rights, including those set out in the Treaties of the European Union and Charter of Fundamental Rights of the European Union, all of which are united by reference to a common foundation rooted in respect for human dignity, in which the human being enjoy[s] a unique and inalienable moral status. This also entails consideration of the natural environment and of other living beings that are part of the human ecosystem, as well as a sustainable approach enabling the flourishing of future generations to come".*

The human-centric AI component comprises the development, deployment and use of AI systems that adhere to ethical principles of respect for human autonomy, prevention of harm, fairness and explainability. Moreover, it addresses situations involving vulnerable groups (children, people with disabilities and others at risk of exclusion), and situations characterized by asymmetric power (e.g. employers and workers, businesses and consumers). Finally, it recommends considering that AI systems pose new forms of risks, which could have negative impacts and are difficult to anticipate, identify or measure.

The core of the guideline for trustworthy AI is summarized in a list of seven requirements that AI systems should meet, in which both technical and non-technical methods should be used for their development:[12]

11. European Commission, Directorate-General for Communications Networks, Content and Technology, *Ethics guidelines for trustworthy AI*, Publications Office, 2019, https://op.europa.eu/en/publication-detail/-/publication/d3988569-0434-11ea-8c1f-01aa75ed71a1/language-en
12. Ibid.

- human agency and oversight, including fundamental rights;
- technical robustness and safety, including resilience to attack and security, a fall back plan and general safety, accuracy, reliability and reproducibility;
- privacy and data governance, including respect for privacy, quality and integrity of data, and access to data;
- transparency, including traceability, explainability and communication;
- diversity, non-discrimination and fairness, including the avoidance of unfair bias, accessibility and universal design, and stakeholder participation;
- environmental and societal well-being, including sustainability and environmental friendliness, social impact, society and democracy;
- accountability, including auditability, the minimization and reporting of negative impact, trade-offs and redress.

The need to regulate AI has pushed forward research in this subject. In the near future, more findings will likely be translated into potential applications that will have an impact on our daily lives. The field of brain-computer interfaces (BCIs), which directly involves the human body, is one of the challenging research areas that will demand special attention.

The recent consolidation of AI techniques in our daily life and in the design of novel products and services allows for many "off-the-shelf" AI-based technologies to be used. The availability of a huge amount of data (Big Data) from sophisticated computational activities and/or the fast-growing, low-cost sensors, which are often networked and connected, has also contributed to a rise in the potential of a new generation of AI-human body interactions.

Moreover, research on BCIs provides a set of methodologies for integrating computers and external mechatronic devices, operating on the basis of brain signals that are detected and interpreted, and allowing solutions to be developed that support disabilities or are dedicated to the industrial sector. The research and development of BCI-based technologies, along with the increasing development of AI, will surely have an impact on a strong AI-focused industry (Industry 4.0) and health care (Surgery 4.0), and lead to progress towards the development of AI-based eco-systems. In a circular process, advanced AI algorithms (e.g. machine and deep learning) support improvements in the systems performance of BCIs, as well as achieving better outcomes and, in turn, deal with the real-life challenges of BCIs more effectively.

Despite the time gap characterizing the separation between the technological progress and the definition of principles/rules for the design of appropriate regulation policies (as developed in the EU recommendations for human-centric and trustworthy AI), research on BCIs in the field of AI offers the opportunity to develop new collaborative cross-disciplinary teams, in which different knowledge sources converge in the design of possible future scenarios and where early involvement of the field of law is becoming mandatory.

PART II

7. Introduction to part II: The limitations and opportunities of current legal and ethical approaches to the risks for human rights posed by neurotechnologies.

Carla Gulotta, Associate Professor of International Law, University of Milano-Bicocca and Marta Sosa Navarro, Researcher in International Law, University of Milano-Bicocca.

"For the first time in history, we are facing the real possibility of human thoughts being decoded or manipulated using technology".

– Yuste, R., Genser J. and Hermann, S.,
"It's time for neurorights", *Horizon,* 2021

The ultimate goal of the international workshop on the risks and challenges of neurotechnologies for human rights, co-organized by the University of Milano-Bicocca and the State University of New York (SUNY) Downstate Health Sciences University was to contribute to the scientific discussions and to policymaking in an area of knowledge that brings together scientific progress, in the light of the emergence of new neurotechnologies with non-medical applications.

Neuroscientists, engineers and computer scientists presented a comprehensive update of existing neurotechnologies, both in terms of medical and non-medical applications, which was thoroughly examined from a human rights perspective by philosophers, jurists and experts in neuro-ethics.

Two days of stimulating interdisciplinary discussions led researchers in brain-computer interfaces, bioethics, neurology, computer science, artificial intelligence and international law to identify a common language, the necessary first step towards a proper contribution in this area. The questions and debates that were triggered also evidenced how ambitious this single objective is and how important it is to keep this channel of communication open if effective regulation is to be drafted, both to guarantee equal access to scientific progress and to protect human rights from the impact of these technologies.

The experts that took part in the scientific panel from day one described the new technologies applicable to the human brain, allowing us to understand their unprecedented potential in tackling conditions and diseases, both physical (related to motor skills or the recovery of the senses) and mental (as in the treatment of depression).

This tremendous scientific progress must be fostered and supported and cannot be stopped. This is true even if the thought-provoking speakers who participated in the more ethical and legal panel from day two described the “dark side” of these technologies when applied to the human brain. Some of the reported risks, which are all the more serious when affecting children and adolescent brains still under development, are more conceptual and philosophical and relate to the capacity of neurotechnology to interfere with our humanness. The scientific community is called upon to make a continued effort to monitor and assess new advancements to prevent dehumanization from taking place in the name of efficiency/productivity.

The role of the law is paramount. The complexity of the challenge calls for a multi-layered response:

First, from the perspective of international law, the international human rights framework provides consolidated protection against possible abuses of neurotechnology from public administrations and governments which should not be overlooked: whether existing human rights conventions and charters must be supplemented with innovative norms is questionable, but it can certainly be asserted that they will have to be skilfully managed through the interpretation and analogical application of their norms.

From an international governance approach, UNESCO has proved that intergovernmental organizations are already playing a valuable role in addressing this need for clarification and in urging their Member States to grant protection in their legislations to emerging new forms of violations of fundamental rights.[13]

In addition to qualifying individuals’ neural data in terms of new or reshaped human rights, the protection of this data, and physical and mental health, must be enshrined at the national level. We have had discussions with Senator Girardi on the architecture of the first normative intervention on this topic and we believe that, following constitutional reform, the Chilean bill, which aims to turn these new technologies into a public good, deserves to be studied attentively and serve as a model.

It is unquestionable that the regulatory steps taken by the different players may vary according to the protection already afforded under existing rules: privacy is better protected in the European Union (EU) thanks to the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016) than it is in the United States of America; the proposal for an Artificial Intelligence Act (COM(2021) 206 final of 21 April 2021) may, among other things, tackle some of the risks that result from the application of AI to brain data retrieved through neurotechnology. This binding initiative adds to the soft law that offers practical guidance in this area, such as the Ethics Guidelines for Trustworthy AI. Since May 2021, in the European Union, equipment intended for brain stimulation that applies electrical currents, or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain have been regulated like medical devices using similar technology (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, amended by Reg. 2020/561 of 20 April 2020). We must now examine the effectiveness of these regulations.

13. This can be inferred from the International Bioethics Committee (IBC) recommendations to States included in the Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology, 15 December 2021.

These two days also proved that a renewed law-making process is necessary. Not only do legislators need to be supported by technical committees of experts (scientists, philosophers, ethicists) when dealing with the regulation of neurotechnology, but efforts need to be deployed to inform the general public on neurotechnology advancements. The potential and risks of neurotechnologies are a big unknown and represent unintended damage to the democratic legitimacy of any enacted or future legislation. In this regard, it is also our responsibility to disseminate knowledge and the result of our research on the emergence of possible new risks and to ask for timely and effective protection.

As part of the scientific committee behind this initiative, this is the commitment we make: we intend to conduct an appropriate follow-up to this workshop, starting with this publication, that will hopefully result in establishing a community of practice among the willing to continue studying neurotechnology advancements from a multidisciplinary approach.

This workshop evidenced that the complexity of this topic requires narrowing the object of analysis and examining the issues raised. It is in this spirit that on 10 June, a follow-up seminar was organized on neurotechnologies and consumer rights to shed some light on the legal challenges of regulating the non-medical applications of neurotechnologies already available on the market from a comparative perspective.

In the coming years, we will see an increasing application of neurotechnologies in the commercial and military spheres. The migration of these methods to record, interpret or alter brain activity from the medical arena, which is ruled by highly protective bioethical standards, to the consumer market is already highlighting the need to examine neurotechnology from multiple perspectives. We are facing a game-changer that will modify our way of understanding not only the concept of (mental) privacy but more transcendental concepts such as human agency, identity or dignity.

In Antonio Gramsci's words: *"The old world is dying, and the new world struggles to be born: now is the time of monsters".*

Let us anticipate the upcoming challenges to ensure we prove Gramsci wrong.

8. Why human rights are crucial in responding to the challenges posed by neurotechnologies.

Roberto Andorno, Associate Professor (Privatdozent) of Bioethics and Biomedical Law at the Faculty of Law and Senior Research Fellow and Coordinator of the PhD Program in Biomedical Ethics and Law, Faculty of Medicine, University of Zurich, Switzerland.

Neuroscience is giving us new insights into the brain's functioning and offers unprecedented possibilities for accessing, collecting, decoding and altering information from the human brain, and even for predicting and influencing individuals' behaviour. Brain imaging techniques, various forms of brain-computer interfaces, transcranial and intracranial electrical stimulation, and other related technologies have great potential to improve the well-being of neurological patients by providing new diagnostic, preventive and therapeutic tools. Besides the medical applications, advances in this area offer new opportunities for individuals to self-monitor their mental health and cognitive performance, for brain-controlled computer use, for communication purposes and even for entertainment.

However, these same technologies open the door to unprecedented threats to human rights and human dignity. The privacy of our minds is clearly one of the key values at stake in this area: neurotechnological tools are able to record and store a great volume and variety of mental data, which can potentially be accessed by third parties without the individual's consent, or with consent that is obtained by fraud or coercion. These third parties could be very varied: companies for marketing purposes, employers interested in looking into their employees' minds to monitor their concentration at work, schools wanting to scan children's brains to see if they are paying sufficient attention to lessons, and even authoritarian States interested in identifying opponents to the regime.

In addition to concerns about mental privacy, neurotechnologies also generate disquiet about the possible emergence of new and more sophisticated forms of mind control, and the urgency to ensure freedom of thought and self-determination. It is noteworthy that freedom of thought is not to be understood here merely in the traditional sense that people should be free to express their opinions or beliefs (*forum externum*), but in the literal sense of the freedom to think by themselves without being monitored by others (*forum internum*).

Concerns about the misuse of neurotechnologies have led in recent years to a growing debate about the role that human rights can or should play in this area. One of the central questions is whether we need new human rights in this area (so-called neurorights), or whether it would suffice to expand existing human rights or at least to reinterpret them in a way that ensures their applicability to new challenges. Several proposals have been made in this regard (see, for instance, Ienca and Andorno 2017; Yuste et al. 2017; Lavazza 2018; Bublitz 2022).

This paper's goal is not to enter into this particular debate but briefly to address a preliminary and more fundamental question: why are human rights expected to play a key role in dealing with the emerging issues in this field? To answer this question, it is helpful to consider that human rights are the most basic entitlements to have or obtain something, or for people to act in a certain way simply by virtue of their human condition. Human rights are not just one category of rights among others; they are far more important than, for instance, contractual rights (i.e. the rights that we have because of the contracts we have signed and which typically relate to the exchange of goods and services). Human rights aim to preserve the conditions that are required to live a life with dignity and to flourish as human beings. These basic human interests include, among others, life, physical and psychological integrity, freedom from torture and inhumane or degrading treatment, privacy, non-discrimination, freedom of thought and expression, access to education and health care, etc. In other words, human rights are the highest and most precious rights that individuals may claim because they directly relate to people's status as individuals. Indeed, human rights are ultimately no more than the concrete norms that are needed to flesh out in society the principle of human dignity from which they derive.[14]

It is true that, when considering the opportunity of recognizing new rights or of expanding existing rights to cover new challenges, we must be very careful in examining whether this move is really justified or not. Otherwise, the new rights may contribute to the unfortunate phenomenon of rights inflation, which risks diluting the core idea of human rights. However, even taking this caveat into account, this paper argues that the human interests that are potentially jeopardized by neurotechnological developments are sufficiently important to deserve being protected by human rights norms. After all, the brain is the organ most closely linked to our thoughts and memories, in short, to the core of our personality (our "self"). For this reason, the data from our brain activity are much more sensitive and valuable than any other category of personal data. Furthermore, it is not only the access to people's brain data that is a matter of concern. Neurotechnologies can also potentially be used to alter brain data, and thereby to influence people's identity and behaviour. There is no doubt that we are facing here a broad spectrum of unprecedented threats to human personality that demand a robust response from the legal system and, in particular, but not only, from human rights norms.

Eleanor Roosevelt, chairperson of the Drafting Committee of the Universal Declaration of Human Rights (1948)

14. "Recognizing that these rights derive from the inherent dignity of the human person" (Preambles of both the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights, 1966).

Besides the regulations that may be adopted at the domestic level, it is clear that some minimal international standards relating to neurotechnology are also necessary. As science becomes increasingly globalized, a coherent and effective response to the new challenges raised by science should also be global. It is interesting to remember that around the end of the 1990s, the international community made significant efforts, especially within the framework of UNESCO, to address the then new challenges posed by genetic technology and to adopt specific international declarations. It is perfectly conceivable – and desirable – that, similar to what happened with the "genetic revolution", specific international human rights standards will be developed for dealing with the ongoing neurorevolution. The report on the ethical issues of neurotechnology adopted by the UNESCO International Bioethics Committee (IBC) in December 2021 is a good first step in that direction (UNESCO, IBC 2021). Interestingly, the report refers explicitly to the possibility of developing an International Declaration on Human Rights and Neurotechnology with the aim of protecting values such as, among others, human dignity, mental integrity, mental privacy, personal identity and freedom of thought. At the same time, it encourages Member States to ensure that domestic laws are adapted to protect these values. The way forward towards this ambitious goal will require significant efforts and close cooperation among States and other relevant stakeholders.

References

Bublitz, J. C. (2022). Novel Neurorights: From Nonsense to Substance. *Neuroethics,* 15, p. 7.

Ienca, M. and Andorno, R. (2017). Towards New Human Rights in the Age of Neuroscience and Neurotechnology. *Life Sciences, Society and Policy* 13(1), p. 5.

Lavazza, A. (2018). Freedom of Thought and Mental Integrity: The Moral Requirements for Any Neural Prosthesis, *Frontiers in Neuroscience*, 12 (82), pp. 1-10.

Yuste, R. Goering, S., Arcas, B. *et al.* (2017). Four Ethical Priorities for Neurotechnologies and AI. *Nature* 551, pp. 159-163.

UNESCO, International Bioethics Committee (2021), Report of the International Bioethics Committee of UNESCO (IBC) on the Ethical Issues of Neurotechnology, Paris, UNESCO, 15 December 2021.

9. Human enhancement technologies: ethical and legal issues.

Silvia Salardi, Associate Professor of Philosophy of Law and Bioethics, School of Law, University of Milano-Bicocca.

1. Human enhancement debate: origin and state of the art

The 2009 Human Enhancement Study released by the Panel for the Future of Science and Technology (STOA) was the first institutional, all-embracing European document dealing with the ethical-legal issues arising from the use of science-based and technology-based interventions in the human body and the brain with the aim of improving individual performance. The discussion about human enhancement goes back to the 1960s and was carried out by American sociologists (Pitts 1968; Zola 1972). At that time, the analysis was focused on the use of drugs for strictly non-therapeutic purposes and was framed by the debate on the medicalization of society. Today, the same debate considers a wider range of developments in genomics, prosthetics, neurotechnology, biomedical engineering, human-machine interaction, artificial intelligence and nanomedicine. The Council of Europe and the European Union, with the contribution of STOA, are trying to define the European way of maintaining human enhancement on an ethical and human rights footing. Indeed, the most recent technological advances in enhancement that integrate neurotechnology with artificial intelligence systems pose new and unprecedented ethical-legal questions. To legally frame the use of this technological progress and to protect human beings from the potential risks connected with its use, expert voices have been raised in favour of expanding the current list of human rights to include neurorights. In their view, these neurorights should specifically be dedicated to contrasting possible violations of human dignity as they will be focused on protecting our brain and mind.

Human enhancement through neurotechnology raises specific ethical questions

2. Ethical and legal issues of neurotechnological enhancement

The appropriateness of the normative solutions that will be adopted depends on how the numerous ethical problems will be faced. The human enhancement perspective offers an interesting angle to investigate some specific issues that may not emerge from other perspectives. The following is a non-exhaustive list of issues that need to be analysed when discussing neurotechnological enhancement: (1) the degree of invasiveness of the technology used; (2) the purpose for which the technology is used (therapeutic enhancement or non-therapeutic enhancement) and the different target groups; (3) technological enhancers that require medical interventions and technological enhancers that are directly marketed to consumers.

The degree of invasiveness of the neurotechnology lies between two extremes: (a) surgical interventions that may or may not be reversible (i.e. chip implants or gene therapy); (b) neurotechnology marketed directly to consumers (i.e. computer-brain interfaces).

a. Neurotechnology based on medical interventions requires an in-depth discussion about the acceptability of human enhancement as part of medicine. Indeed, the main problem concerns non-therapeutic enhancement by means of medical procedures. The ethical debate presents multifaceted positions. For some authors, human non-therapeutic enhancement is a risk for medicine as it negatively impacts on the role of the physician and on the normativity and value of medical ethics. In their view, human enhancement will modify the traditional object and target group of medicine moving from illness to recovery and from patient to client. It will also deprive the category of care of its assumed intrinsic and natural meaning. For others, medicine has already incorporated this new phenomenon as testified by the contents included in some codes of medical ethics. For instance, Article 76 of the Italian Code of Medical Ethics was revised in 2017 and is dedicated to enhancement medicine. This article states that *"medical doctors being asked to provide or prescribe non-therapeutic treatments aimed at achieving cognitive/physical enhancement should always be guided by the highest standards of respect and protection for human dignity, identity and integrity, and operate in accordance with the principles of proportionality and precaution. Medical doctors are required to obtain written informed consent, after explaining all possible risks arising from the proposed treatment and should turn down any request for treatment or prescription that they consider disproportionate or unacceptably risky due to their invasive or irreversible nature"*. Indeed, when neurotechnological enhancers are used under medical supervision, any procedure carried out on the patient is framed by the strict rules that govern the physician-patient relationship (respect for autonomy, high standard of information, etc.) (Salardi 2017; Salardi 2018; Salardi 2020). These rules allow and ensure a high-level protection of individuals and respect for high safety standards.

b. Contrary to the above-mentioned situations, neurotechnology directly marketed to consumers targets healthy individuals. Based on this premise, ethical and legal questions are of a different, albeit interconnected, nature: (1) how healthy subjects achieve a relevant understanding of the possible scopes and side effects of enhancers if there is no mandatory medical or any other competent supervision; (2) where healthy individuals can get relevant expert information to make autonomous choices; (3) how healthy individuals may be protected against players who clearly have economic interests in selling products on a massive scale and simultaneously have the power to influence the market as well as decision-makers at the institutional level.

3. Institutional controls of human neurotechnological enhancers directly marketed to consumers: some recommendations to protect consumers

The protection of consumers from violations of human rights requires a proactive attitude by institutional actors. This can be achieved through the following steps:

- **a fair communication/information process** concerning the risks and benefits of neurotechnological enhancers through institutional channels where experts are directly in contact with the public;
- **availability of competent and/or medical supervision** in case of possible side effects, questions regarding the use of neurotechnologies, etc. through institutional public and private channels (private channels should meet the requirements of transparency and fairness);
- **truthful information and transparency regarding commercial interests** in the large-scale diffusion of direct-to-consumer neurotechnologies;
- **a clear explanation of the state of scientific/technological progress** in bio-enhancing techniques to avoid misunderstandings by and the manipulation of lay people;
- neurotechnologies accessing brain data should be **ethically designed by default.**

References

Pitts, J. R. (1968). Social Control: The Concept, International Encyclopaedia of Social Sciences, vol. 14, Macmillan, New York.

Salardi, S. (2017). Destined to be superhuman. Moral bioenhancement and its legal viability, *Biolaw Journal*, 3.

Salardi, S. (2018). The "Project of Moral Bioenhancement" in the European legal system. Ethically controversial and legally highly questionable, *Journal of Philosophy of Law*, VII: 2.

Salardi, S. (2020). When the "age of rights" meets the "age of technology", in *Neuroscience and Law. Complicated Crossings and New Perspectives*, Springer.

Zola, I. K. (1972). Medicine as an Institution of Social Control, in P. Conrad (eds.), *The Sociology of Health and Illness: Critical Perspectives*, Worth, New York, 1972.

10. Some reflections on the neurorights debate.

Arleen Salles, Senior Researcher at the Centre for Research Ethics and Bioethics (CRB), Uppsala University.

The development and use of a large variety of invasive and non-invasive technologies that interface with the brain show promise in a number of contexts. At the same time, insofar as they record brain activity and/or modulate its function, they prompt questions and concerns about their potential impact on our belief system and our humanness itself. A few articles and documents describing salient ethical challenges, articulating approaches to understanding them and providing recommendations on how to manage them have been published in recent years (O'Shaughnessy et al. 2022).

Lately, some scientists and neuro-ethicists have proposed special rights, known as "neurorights" (Ienca 2021, Ienca and Andorno 2017, Lavazza 2018, Yuste et al. 2017) as a regulatory solution to the challenges raised by neurotechnologies. Seemingly sceptical of the capacity of existing laws and regulations to provide the necessary protections, proponents of neurorights call for

"a new international legal and human rights framework […] that can be understood as a new set of human rights for the brain"

– (Yuste et al. 2021).

Such a proposal has generated a lively debate. Concerns range from whether the articulation of a new set of rights might undermine existing human rights and the possibility of rights inflation, to how to address the relevant conceptual ambiguities and practical challenges in the proposal (Bublitz 2022; Rommelfanger et al. 2022). I would like to point to two related issues that would benefit from more reflection.

More societal engagement is needed for neurotechnology governance

One has to do with how concerns about neurotechnologies and the solutions offered are conceptualized and understood. In fact, the claim that neurorights constitute the regulatory solution to the potential issues raised by neurotechnologies depends on how both the problem and the solution are framed. As is well known, how issues are identified, defined and presented has a significant impact on public opinion and on people's thinking about the kinds of solutions they are willing to accept. Indeed, framing plays a significant role in how people understand and assess neurotechnologies and their potential consequences, and which options they consider appropriate and inappropriate.

Of course, the topic of the impacts (good and bad) of neurotechnology warrants careful consideration. However, there is a tendency within proponents of neurorights to frame neurotechnologies as fundamentally dangerous despite acknowledging that they might have some good effects for humans. The choice of a frame, however, is an ethical move, in this case designed to support the idea that there are no other appropriate legal tools to regulate neurotechnologies and that international consensus on the articulation of neurorights is needed. However, this issue warrants attention for two reasons. First, the proposed frame is not necessarily always justified and can be the product of neurohype or speculation (Bublitz 2022). Second, this frame can be blind to the fact that how people interpret neurotechnologies and the challenges they raise is, importantly, shaped by their specific cultural, economic and political contexts, as are the frameworks they use to regulate them (Herrera-Ferrá et al. 2022). In short, in order to find the right solution (whether such a solution is a set of new rights or not), it is important first to identify the problem not just in general terms, but also as reflective and constitutive of specific social and historical contexts. Thus, a more granular understanding of how different aspects shape how neurotechnologies and their challenges are understood would significantly improve the discussion as to how to regulate them and the appropriateness of the neurorights framework.

How are we to achieve such an understanding? Engagement may play a crucial role. To date, the discussion on neurotechnology's impact and its regulation has largely taken place without significant engagement with those who will be directly affected both by the technology and the corresponding regulatory efforts: communities of patients and citizens. My second point is, then, that to understand the main issues better, and to contend with the ethical and regulatory challenges surrounding emerging neurotechnologies, we need to engage meaningfully with diverse publics and stakeholders representing a variety of views.

The call for engagement when thinking of neurotechnologies is not new. In the last years, the academic literature, policy documents and project proposals have highlighted the importance of the role played by engagement with diverse publics. To illustrate, in its efforts to align research and innovation with broader societal values, the European Commission has adopted an approach (Responsible Research and Innovation) that calls for participatory practices and the active engagement of different stakeholders and citizens across the entire research process (Owen 2013; Von Schomberg 2013). The underlying assumption is that citizens' interests and needs should steer the research agenda from the very beginning and that this can only be done via participative processes that take societal needs as a starting point (Bitsch 2021).

Along the same lines, in its Recommendation on Responsible Innovation in Neurotechnology, the Organisation for Economic Co-operation and Development (OECD) calls for robust public engagement, noting that responsible innovation must "enable societal deliberation on neurotechnology". The Council of Europe's Strategic Action Plan on Human Rights and Technologies in Biomedicine states that *"[i]n order to guarantee that the directions of innovation and the ethical challenges raised by technological developments are robustly deliberated, governance should go hand in hand with broad and informed public dialogue"*. The recently published Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology points to the importance of engagement, noting that it *"must be made inclusive by embracing public values in the innovation and development process".*

In all of the above cases, engagement entails more than promoting communication: it requires engaging in multistakeholder dialogues and deliberation to ensure diverse inputs into decision-making processes. Ultimately, this activity is expected to further the rights of citizens to be informed and participate in decision-making processes, to raise awareness about the issues and to improve science and its outcomes by aligning it with the needs, priorities and values of the different societies (Das et al. 2022).

Developing a more participative discussion on neurotechnologies, their meaning and implications in different societies, and on the tools that could be used to regulate them, is key insofar as the topic is particularly vulnerable to misinformation and hype. A participative discussion entails going beyond a one-way transmission of information about the threats of emerging neurotechnology or the desirability of specific solutions from expert communities to a largely passive and diverse public. To contribute to the discussion, efforts should focus on opening spaces for diverse publics and research communities to engage in joint reflection on neurotechnologies, their potential implications and on the relevant mechanisms for managing them.

The neurorights discussion forces us to think very carefully about how to understand emerging neurotechnologies, the challenges they pose and their potential remedies. Calls for neurorights help to raise key issues, even if they pose concerns. In the end, they suggest that there is still work to be done in understanding and addressing the relevant challenges and in making sure that the tools we use to do so are grounded in strong considerations.

Funding: This research was supported by the European Union's Horizon 2020 Framework Programme for Research and Innovation under the Specific Grant Agreement no. (945539) (Human Brain Project SGA3).

Acknowledgements: I thank M. Farisco and A. Wajnerman Paz for their comments on a previous version of this paper.

References

Bitsch, L., Rekve, K., Neuhaus , S. V. (2021). The Landscape of Science, Ethics and Public Engagement and its Potential for the Future. (Kavli Foundation).

Bublitz, J. C. (2022). Novel Neurorights: From Nonsense to Substance. *Neuroethics* 15, p. 7.

Das, J., Forlini, C., Porcello, D., Rommelfanger, K., Salles, A., and Delegates, G. N. S. (2022). Neuroscience is Ready for Neuroethics Engagement. In SSRN.

Herrera-Ferrá, K., Munoz, J. M., Nicolini, H., Saruwatari Zavala, G. and Martinez Bulle Goyri, V. M. (2022). Contextual and Cultural Perspectives on Neurorights: Reflections Toward an International Consensus. *AJOB Neurosci*, pp. 1-9.

Ienca, M. (2021). On Neurorights. *Front Hum Neurosci* 15, 701258.

Ienca, M., and Andorno, R. (2017). Towards new human rights in the age of neuroscience and neurotechnology. *Life Sci Soc Policy* 13, p. 5.

Lavazza, A. (2018). Freedom of Thought and Mental Integrity: The Moral Requirements for Any Neural Prosthesis. *Frontiers in Neuroscience* 12, p. 82.

O'Shaughnessy, M., Johnson, W. G., Tournas, L., Rozell, C., and Rommelfanger, K. (2022). Neuroethics guidance documents: Principles, analysis, and implementation strategies

Owen, R., Heintz, M., Bessant, J. (2013). Responsible Innovation (Chichester: UK: Wiley & Son).

Rommelfanger, K., Pustilnik, A., and Salles, A. (2022). Mind the Gap: Lessons Learned from Neurorights. In Science and Diplomacy (AAA Center for Science Diplomacy).

Von Schomberg, R. (2013). A vision of responsible research and innovation. In Responsible Innovation, R. Owen, M. Heintz, and J. Bessant, eds. (Chichester, UK: Wiley & Son).

Yuste, R., Goering, S., Arcas, B.A.Y., Bi, G., Carmena, J.M., Carter, A., Fins, J.J., Friesen, P., Gallant, J., Huggins, J.E. et al. (2017). Four ethical priorities for neurotechnologies and AI. *Nature* 551, pp. 159–163.

Yuste, R., Genser, J., and Herrmann, S. (2021). It's Time for Neuro-Rights: New Human Rights for the Age of Neurotechnology. *Horizons,* pp. 154–164.

11. Neurotechnology and fundamental rights: conceptual and ethical foundations.

Philipp Kellmeyer, Research Group Leader, Neuroethics and AI Ethics Lab, Medical Center – University of Freiburg, Faculty of Medicine, University of Freiburg; Research Fellow, Freiburg Institute for Advanced Studies, Albert-Ludwigs-University of Freiburg; Researcher, Institute for Biomedical Ethics and History of Medicine (IBME), University of Zurich.

Introduction

In recent years, devices that can measure bodily functions, such as fitness trackers or smart watches, have entered the consumer market but have also shown their potential for biomedical research and clinical medicine. In combination with other types of data, such as movement data from a smartphone's geolocation sensor or a person's user entries in mobile apps, these biodata have become important and sought-after types of personal data. Increasingly digitized health care systems, such as direct-to-consumer devices and apps, especially in combination with analytic approaches from artificial intelligence (AI), could play an important role in developing more personalized approaches to diagnosing, predicting and treating diseases, and improving health and well-being (Topol 2019). Yet, at the same time, the rapid introduction of such consumer health technology often occurs without sufficient scientific research to back up the positive claims of the devices and apps, and regulatory responses are slow and difficult to harmonize across globalized markets.

This unregulated wave of digital consumer health technology poses substantial ethical, legal and societal challenges and risks. For example, if consumer health technologies are not sufficiently vetted and validated, the unsubstantiated claims to improve health and well-being could harm unsuspecting people, particularly individuals who are vulnerable, for example due to impaired health or for other reasons (Herzog et al. 2021). From the perspective of global public health, digital (consumer) health technologies also provide unique opportunities, for example by bringing advanced diagnostics and teletherapy to underserved or remote places as well as in the context of public health responses to pandemics (Budd et al. 2020). Yet there is also the risk that an overreliance on digital technologies, without the concomitant building of human capacities to deliver health care in digitized environments, may exacerbate the existing "digital divide" and impede access to medical services, especially in socio-economically disadvantaged communities.

In the context of this rapid digitization and the rise of consumer health technologies, neurotechnological devices carry yet another set of hopes but also grave ethical and legal concerns.

What are neurotechnologies and how do they work?

Neurotechnology, in a narrow sense, can be understood to be devices that measure brain activity or brain structure and/or that interfere with brain activity (for example via electrical stimulation). Common methods of measuring brain activity are electroencephalography (EEG) or functional magnetic resonance imaging (fMRI).[15] Measuring brain activity with fMRI is a popular method in biomedical research and increasingly also for clinical applications, but the large and complicated machines that are needed make them impractical for mobile application. EEG consists of a set of sensors that are placed on the skull and is a common diagnostic device in neurology. If these measured brain signals are not only analysed but are also used to operate another device, this is called a brain-computer interface (BCI). Apart from their medical utility, they enable, for example, patients with paralysed limbs to operate service robots or communication software. Importantly, each method for measuring brain signals and the information that can be gleaned from these signals has limitations in resolving spatial, temporal and frequency-related properties.[16] These methodological limitations, however, are often not addressed in the marketing and promises around consumer neurotechnologies. Consumer neurotechnologies are devices that are marketed and targeted directly at consumers, for example BCIs for entertainment, neurofeedback or relaxation. The market for such consumer neurotechnologies, driven by big technology companies as well as specific neurotech start-ups, is steadily growing (Ienca, Haselager et al. 2018) creating important ethical concerns and questions concerning the potential impact on fundamental rights.

What are important ethical concerns and how might fundamental rights be affected by neurotechnologies?

There are a number of important ethical concerns that are raised by consumer neurotechnologies, particularly in connection with AI-related methods for analysing brain data or operating BCIs. These ethical concerns are directed at different levels of consideration: (1) the level of individual users of neurotechnology; (2) the level of grouping users into various categories based on their brain measurements; and (3) the impact of neurotechnologies at a societal scale.

At the level of individual users and their interaction with neurotechnologies, we have to ask whether consumer neurotechnologies might put individuals at risk, for example by overpromising on the potential for improving health and well-being, or by exploiting the brain data that are collected by these devices for commercial purposes (by companies) or for “neurosurveillance” practices (e.g. by employers or States). At the level of populations of users, for example if consumer neurotechnologies were to become available on a larger scale, there is a risk that the combination of brain data from these devices with other types of highly personal data (from smartphones, social media and other contexts) might allow certain brain-related characteristics to be identified – for example, attention, vigilance and other functions – a so-called “neurotype” that could be used to profile new users (who are not even using the neurotechnology)

15. There are also other methods, such as measuring blood-flow in brain regions (which correlates with bioelectric brain activity) using optical sensors, e.g. near-infrared spectroscopy (NIRS), but the most common approaches are EEG and fMRI.
16. EEG, for example, has a very good temporal resolution but limited spatial resolution, which means that brain signals can be tracked in time with high precision, but the source of the signals, that is, where in the brain the activity comes from, is very difficult to estimate. fMRI, in contrast has a very high spatial precision but compared to EEG the measurement is much slower.

and categorize them for the purpose of "neuromarketing" or other kinds of potentially exploitative personalized digital targeting. Concerning the impact that consumer neurotechnology might have on society, there are concerns that – much like in other kinds of digital tracking technologies – the possibility to monitor brain activity might fuel societal trends for self-tracking and self-optimization and thereby increase the demand for non-medical enhancement of brain functions, for example via self-administered drugs or neurostimulation devices (Yuste et al. 2017). Another important societal concern is the emergence of military neurotechnology research and development related to possible military uses. Military funding agencies, such as the United States Defense Advanced Research Projects Agency (DARPA), are among the biggest sponsors of neurotechnology research and development.[17]

In relation to fundamental rights, such as freedom of thought, a debate has emerged in recent years that asks whether this rise of neurotechnology and its convergence with AI requires new kinds of fundamental rights ("neurorights") or the re-interpretation of existing human rights in light of these technological developments.

The debate around "neurorights": do we need new fundamental rights?

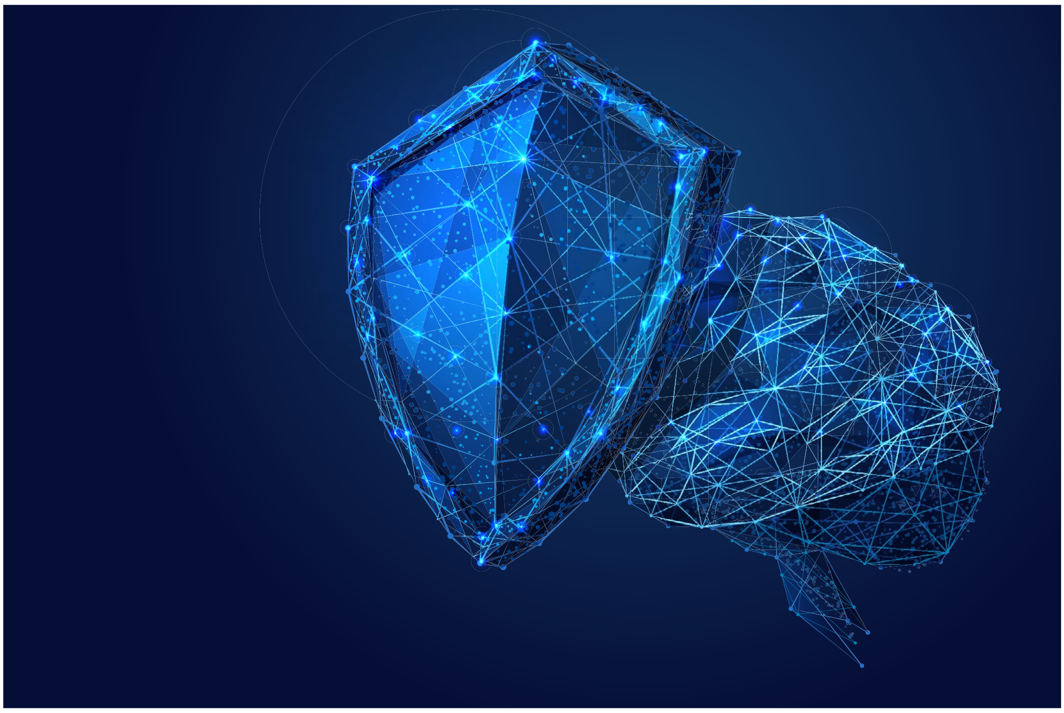
Unlike for clinical devices, consumer neurotechnologies currently lack an effective and comprehensive approach to regulation. The reasons are, for example, that they are deliberately marketed and framed around terms such as "well-being", "relaxation" and other paramedical notions, presumably in an effort to avoid the tighter regulatory regimes in medical device regulation. However, this means that the consumer market is becoming inundated with unproven, if not fraudulent, neurotechnologies that may create harm to unwitting individuals who use them for recreational or health-related purposes. This "regulatory gap" between the misregulated clinical neurotechnology area and the underregulated consumer neurotechnology market needs to be addressed with effective consumer protection regulations and laws, not only with non-binding instruments such as guidelines or recommendations for ethical self-regulation as is currently the case.

While this regulatory gap can be addressed by existing legal concepts and pathways of regulation and consumer protection, a broader concern that has arisen in the context of neurotechnology is the question of whether these devices will eventually create the possibility to decode thoughts, feelings and other forms of mental content from brain data (Ienca and Andorno 2017; Kellmeyer 2018). At the moment, most neuroscientists would agree that current neurotechnologies lack the capacity for a fine-grained decoding of mental content (such as thoughts). However, future neurotechnologies, especially with refined methods for measuring brain activity and analysing the data with AI-related methods, might well create the possibility to infer mental content from brain data, e.g. by adding brain data into multimodal data analytics frameworks that also contain many other types of personal data.

17. DARPA projects on neurotechnology include the targeted elimination of memories as well as BCI approaches for "silent talk", i.e. enabling soldiers to communicate using their brain activity (Regalado 2015). These are just some of the many ethical concerns around neurotechnologies and AI. For further reading see e.g. (Goering et al. 2021; Kellmeyer 2019; Kellmeyer 2018; Ienca, Jotterand and Elger 2018; Yuste et al. 2017)

Therefore, as an exercise in normative precaution, it seems legitimate to ask whether we need to formulate new laws that explicitly protect our mental content from being accessed and "read" or from being actively intervened upon, for example by neurostimulation methods. The former concern, protecting mental content that might be revealed by brain data analytics, is most often called "mental privacy", the latter concern, protecting undue interference with mental experience, is called "mental integrity" (Kellmeyer 2022; Ligthart et al. 2021; Ienca and Andorno 2017). Another important concern that is invoked in the debates around "neurorights" is the notion of "cognitive liberty", invariably referring either to our positive freedom to be able to interfere with our own brain function or a concept akin to mental privacy as described above (Farahany 2012; Bublitz 2013).

In the current debate, ethics and law scholars are divided on the question of whether new fundamental rights are necessary or whether the interpretation of existing human rights (and constitutional rights in a national context) suffices to protect mental privacy and mental integrity. At the same time, however, some countries, most notably Chile but also Argentina and Spain, are already deliberating and discussing proposed neuroprotection laws to that effect. Notably, however, there is still a lack of a unified conceptual understanding of the underlying notions, such as mental privacy and mental integrity, which might result in these legal initiatives to potentially under-, mis- or overregulate on these issues.



Protecting the brain from unwarranted and unwanted interference has become an important focus of 'neurorights

The way forward: a multi-level governance approach to neurotechnologies

From my perspective as a neurologist and neuroscientist, the key opportunities of emerging neurotechnologies, particularly in combination with other technologies such as AI, but also virtual reality (VR), lie in providing innovative and novel approaches to: (a) diagnosing and treating diseases and disorders in medicine, particularly in neurology and psychiatry; (b) developing assistive technologies for people with functional impairments or other disabilities; (c) developing novel approaches for basic neuroscientific research to better understand how the nervous system works in humans and non-human animals. At the same time, as sketched out above, the emergence and rise of consumer neurotechnology poses substantial ethical and legal challenges that require a complex, integrated, international and multi-level governance approach to regulating neurotechnologies and the use of brain data (Goering et al. 2021; Ienca et al. 2021).

One possibility would be to introduce a certification system for consumer neurotechnology devices that includes, inter alia, scientific evidence-based standards, a transparent explanation of the data and algorithms used in the device, mechanisms for continually monitoring the use of these devices in the population in terms of emerging risks and unknown hazards (e.g. a mandatory reporting system of adverse events), regular audits of the companies producing and disseminating these devices and other measures. Concerning the governance of brain data as an emerging class of highly sensitive personal biometric data, we have recently proposed a multi-level governance approach that provides guidance on how to apply which governance instrument (e.g. ethics codes, laws, regulatory rules) in which contexts (e.g. consumer, clinical or mixed) (Ienca et al. 2021).

To ensure that neurotechnologies are aligned with human rights and are conducive to promoting human capabilities and flourishing, the international community needs to develop a human rights-based multi-level governance approach. This includes not only the level of ethical guidelines but also, importantly, a process of context-sensitive national legislations and regulations together with concerted efforts for supranational harmonization.

The integration of neurotechnology into military technology is an area of growing concern and, in my opinion, not yet sufficiently addressed by the international community. While governments and military research organizations are among the main drivers of neurotechnology innovation, the use of neurotechnology for military and security purposes is currently not sufficiently governed nor monitored to ensure compliance with international humanitarian laws and ethical norms. The international community, under the auspices of the relevant United Nations mechanisms, such as international disarmament and non-proliferation treaties (e.g. the Biological Weapons Convention or the Chemical Weapons Convention) may consider developing clear criteria and processes for the use of neurotechnology in military and security contexts that ensure compliance with international human rights and humanitarian laws.

References

Bublitz, J.-C. (2013). My Mind Is Mine!? Cognitive Liberty as a Legal Concept. *Cognitive Enhancement,* 233–264. Springer, Dordrecht. https://doi.org/10.1007/978-94-007-6253-4_19

Budd, J., Miller, B. S., Manning, E. M., Lampos, V., Zhuang, M., Edelstein, M., Rees, G., Emery, V. C., Stevens, M. M., Keegan, N., Short, M. J., Pillay, D., Manley, E., Cox, I. J., Heymann, D., Johnson, A. M. and McKendry, R. A. (2020). Digital technologies in the public-health response to COVID-19. *Nature Medicine*, 26(8), 1183–1192. https://doi.org/10.1038/s41591-020-1011-4

Farahany, N. A. (2012). Incriminating thoughts. *Stanford Law Review*, 64(2), pp. 351–409.

Goering, S., Klein, E., Specker Sullivan, L., Wexler, A., Agüera y Arcas, B., Bi, G., Carmena, J. M., Fins, J. J., Friesen, P., Gallant, J., Huggins, J. E., Kellmeyer, P., Marblestone, A., Mitchell, C., Parens, E., Pham, M., Rubel, A., Sadato, N., Teicher, M. and Yuste, R. (2021). Recommendations for Responsible Development and Application of Neurotechnologies. *Neuroethics*. https://doi.org/10.1007/s12152-021-09468-6

Herzog, L., Kellmeyer, P. and Wild, V. (2021). Digital behavioural technology, vulnerability and justice: Towards an integrated approach. *Review of Social Economy*, 0(0), pp. 1–22. https://doi.org/10.1080/00346764.2021.1943755

Ienca, M. and Andorno, R. (2017). Towards new human rights in the age of neuroscience and neurotechnology. *Life Sciences, Society and Policy*, 13, p. 5. https://doi.org/10.1186/s40504-017-0050-1

Ienca, M., Haselager, P. and Emanuel, E. J. (2018). Brain leaks and consumer neurotechnology. *Nature Biotechnology*, 36, pp. 805–810. https://doi.org/10.1038/nbt.4240

Ienca, M., Jotterand, F. and Elger, B. S. (2018). From Healthcare to Warfare and Reverse: How Should We Regulate Dual-Use Neurotechnology? *Neuron*, 97(2), pp. 269–274. https://doi.org/10.1016/j.neuron.2017.12.017

Ienca, M., Fins, J. J., Jox, R. J., Jotterand, F., Voeneky, S., Andorno, R., Ball, T., Castelluccia, C., Chavarriaga, R., Chneiweiss, H., Ferretti, A., Friedrich, O., Hurst, S., Merkel, G., Molnar-Gabor, F., Rickli, J.-M., Scheibner, J., Vayena, E. and Kellmeyer, R. Y. P. (2021). Towards a Governance Framework for Brain Data. *ArXiv:2109.11960 [Cs, q-Bio]*. http://arxiv.org/abs/2109.11960

Kellmeyer, P. (2018). Big Brain Data: On the Responsible Use of Brain Data from Clinical and Consumer-Directed Neurotechnological Devices. *Neuroethics*. https://doi.org/10.1007/s12152-018-9371-x

Kellmeyer, P. (2019). Artificial Intelligence in Basic and Clinical Neuroscience: Opportunities and Ethical Challenges. *Neuroforum*, 25(4), pp. 241–250. https://doi.org/10.1515/nf-2019-0018

Kellmeyer, P. (2022). Neurorights: A Human-Rights Based Approach for Governing Neurotechnologies. *The Cambridge Handbook of Responsible Artificial Intelligence—Interdisciplinary Perspectives*. Cambridge University Press.

Ligthart, S., Douglas, T., Bublitz, C., Kooijmans, T., and Meynen, G. (2021). Forensic Brain-Reading and Mental Privacy in European Human Rights Law: Foundations and Challenges. *Neuroethics*, 14(2), pp. 191–203. https://doi.org/10.1007/s12152-020-09438-4

Regalado, A. (2015, November 26). *DARPA Program Seeks to Use Brain Implants to Control Mental Illness*. MIT Technology Review. http://www.technologyreview.com/news/527561/military-funds-brain-computer-interfaces-to-control-feelings/

Topol, E. J. (2019). High-performance medicine: The convergence of human and artificial intelligence. *Nature Medicine*, 25(1), pp. 44–56. https://doi.org/10.1038/s41591-018-0300-7

Yuste, R., Goering, S., Arcas, B. A. y, Bi, G., Carmena, J. M., Carter, A., Fins, J. J., Friesen, P., Gallant, J., Huggins, J. E., Illes, J., Kellmeyer, P., Klein, E., Marblestone, A., Mitchell, C., Parens, E., Pham, M., Rubel, A., Sadato, N., Wolpaw, J. et al. (2017). Four ethical priorities for neurotechnologies and AI. *Nature*, 551(7679), 159. https://doi.org/10.1038/

12. International organizations and their approaches to neuroscience and neurotechnology.

Pia Acconci, Full Professor of International Law, University of Teramo.

This is the first outcome of my research project on the relevance of neuroscience in the actions of international organizations operating within and outside the United Nations system, with the aim of identifying what main conclusions can be drawn and what research lines can be proposed from an international law perspective, given that the literature is scarce (Spain Bradley 2021; Narváez Mora 2019). So far, I have found that UNESCO, the World Bank, the Organisation for Economic Co-operation and Development (OECD), the Council of Europe and the European Union (EU) have been the most engaged international organizations in this field. Relevant non-State players have been scientists, education experts and non-governmental organizations specialized in development assistance.

As to conjectures, neuroscience has been investigated both as a risk to human rights, democracy and society at large and an enhancement for research, education, human development and a new approach to the economy at large. By acting as facilitators, international organizations have promoted neuroscience as an enhancement and dealt with neuroscience as a risk.

As to neuroscience as a risk, the OECD achieved a significant result by publishing the Recommendation on Responsible Innovation in Neurotechnology in 2019. It is the first international standard for governments and innovators and stresses the importance of safeguarding personal brain data and other information, safety assessments, inclusivity, scientific collaboration, stewardship and trust across the public and private sector, as well as anticipating and monitoring unintended use and/or misuse. The Recommendation suggests establishing advisory bodies for societal screening and oversight.[18] UNESCO has been another active international organization and has published expert reports. These outline the risks arising from "the commodification of brain data", ethical issues of neurotechnology, particularly of the brain-computer interface (BCI), the need to safeguard human brain integrity, personal identity, free will, mental privacy and decision-making capacity, monitoring the impact of neurotechnologies on the brain of young people and informed consent.[19] On 23 November 2021, UNESCO adopted its Recommendation on the Ethics of Artificial Intelligence to show how an ethical approach through international cooperation could, among others, tackle such risks and render artificial intelligence a tool for development.[20]

18. For further information see https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm
19. See in particular the Report of the International Bioethics Committee of UNESCO, SHS/BIO/IBC-28/2021/3 Rev., 15 December 2021 https://unesdoc.unesco.org/ark:/48223/pf0000378724
20. The UNESCO Recommendation is available at https://unesdoc.unesco.org/ark:/48223/pf0000381137

At the regional level, the Council of Europe has contributed by recommending common actions, in accordance with the rule of law, democracy and human rights. As with the OECD and UNESCO, its bodies have pointed out the need to prevent malign use and the need for safety and precaution, privacy and confidentiality, capacity and autonomy, equity, integrity and inclusiveness, public trust through transparency, consultation, education and awareness.[21]

As to neuroscience as an enhancement to research, education, human development and a new approach to the economy at large, UNESCO has underlined the connections between neurotechnology, artificial intelligence and education, in order to: enhance the positive connection between scientific "knowledge on learning", education policies and practice; encourage the application of brain research and neurobiology to education; use neuroscience to improve the learning process by providing useful confirmations for artificial intelligence; support equality in child learning processes, that is, inclusive education; and promote the achievement of the Sustainable Development Goals (SDGs), particularly SDG 4 as far as equity and quality of education are concerned.[22] The World Bank has also shown an interest in investments in early childhood to achieve the brain's full developmental potential and resilience, prevent the risks of an ageing brain and for socioeconomic success in terms of "better-paying jobs, healthier lifestyle choices, greater social participation, and more productive societies".[23] The World Bank has supported specific pilot programmes on brain development, as a "central element in early childhood programmes in developing countries", for example in Bangladesh, Colombia and Kenya, as a tool for human development through "the retention of brain functions across a lifespan", together with adequate nutrition and environment, and resilience, which is the capacity to recover from adversity. These programmes aim to investigate how to "develop full brain potential", how to "expand education access in the developing world" and what connection can be established between early life experiences and brain structure and function (Abadzi 2006; Chapko 2015 and others). The OECD has investigated a new approach to the economy through neuroscience, i.e. "brain economy". This would be "an approach for thinking about the economy and how it works in new ways and […] laying some of the groundwork, looking at relevant metrics and building up a network of interested actors in the medical field, neuroscience, philanthropy and business". According to the OECD, the specific targets of this approach would be "the application of ideas from neuroscience and medicine to economic and social policy including topics such as productivity, gender equality, mental health and education" and "investments in brain health and brain skills [which] are critical for post-COVID economic renewal, re-imagination, and long-term economic resilience".[24] The OECD has underlined how neuroscience and productivity are connected because "depression, anxiety and neurodegeneration" are a cost for the global economy and neuroscience can contribute to productivity in the "knowledge economy".[25] The EU has referred to neuroscience as a research field in connection to artificial intelligence

21. See, for example, the 2020 Report 'Towards Regulation of AI Systems' of the Ad hoc Committee on Artificial Intelligence of the Council of Europe. As to the human rights implications of neuroscience, see in particular the 2021 report 'Common human rights challenges raised by different applications of neurotechnologies in the biomedical field'.
22. See, among others, https://solportal.ibe-unesco.org/articles/democratizing-neuroscience-for-education/; https://www.gcedclearinghouse.org/resources/early-childhood-neuroscience-and-child-development; https://www.unesco.org/en/articles/neuroscience-schools-between-mirage-and-miracle; https://solportal.ibe-unesco.org/articles/education-2030-agenda-targets-implementing-neuroscience-findings/. Research on the human brain is meant to contribute to brain health/integrity and enhance "fluid abilities", such as memory, reasoning, speed of thought and problem-solving ability.
23. See, among others, https://www.worldbank.org/en/programs/embed
24. For further information, see https://www.oecd.org/naec/
25. See, in particular, https://www.oecd.org/naec/brain-capital/

and machine learning, interactions between algorithms, technological developments, neural networks and deep learning processes. The EU has provided financial assistance to establish specific research centres based on networking, open innovation and clusters between scientists, people and corporations from different Member States.[26] This way, the EU has facilitated the search for a balance of interests among the various groups that contribute to technical innovation. However, neuroscience does not appear to be a specific subject of policy and legal considerations within the EU action. The focus has been on neurotechnology as a research field and a medical device, from the standpoint of the functioning of the single market rather than of a common governance.

As to lessons that can be learned from all these developments, neuroscience is conceptualized both as an enhancement and as a risk. From the former perspective, neuroscience is a tool for human health, innovation and human development. Brain capital, that is brain health and brain skills, is the reference concept, and the distinction between rational and emotional intelligence is important in understanding both how the human brain learns and "brain complexity". From the latter perspective, transparency, fairness, participation and safe usage are recommended, as brain data are sensitive personal data. A precautionary approach is an option because of the risks arising from scientific uncertainty and the idea of neurotechnology as a dual-use technology. Policy concerns for human societies are also at stake as neuroscience can influence social behaviour and democracy.

As to what research lines can be proposed from an international law perspective,

regulatory gaps on a number of issues related to the impact of neuroscience/ neurotechnology on people encourage negotiations on specific international rules through international organizations. With respect to the kinds of international rules that might be designed, binding rules are unlikely, whereas the enhancement of international cooperation and coordination might support the adoption by international organizations of special non-binding rules, such as guidelines, codes and/or principles of conduct. Differences between States, due to different levels of economic and social development, and thus nationalism, in other words, unilateral interests in research, scientific progress and technical innovation, could be mitigated. This would facilitate harmonization and equality through linkages between neuroscience, health, education, economics, policy, technology and psychology.

References

Abadzi, H. (2006). *Efficient Learning for the Poor: Insights from the Frontier of Cognitive Neuroscience.* Washington, DC: The World Bank.

Chapko, D. (2015). *Early Childhood Development and Skills across the Life-course through the Lens of the Developing Brain*. Washington, DC: The World Bank.

Narváez Mora, M. (2019). How Law and Neuroscience Became a New Field of Study. *Bioethics Update*. pp. 75-88.

Spain Bradley, A. (2021). Advancing Neuroscience in International Law. Grant Cohen, H. and Meyer, T. (eds.), *International Law as Behaviour*, Cambridge University Press. pp. 191–229.

26. See, among others, https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/brain-research_en

13. Ethics issues and global governance of neurotechnology.

Hervé Chneiweiss, Research Director at Centre National de la Recherche Scientifique (CNRS), Head of Neuroscience Paris Seine Sorbonne University, CNRS INSERM Paris France, former Chairperson of the International Bioethics Committee at UNESCO.

The history of neuroscience can be traced back to antiquity, for example the famous school of Alexandria in Egypt in the third century B.C.E. with Ptolemy II's scholars such as Straton of Lamsachus, Erasistratus and Herophilus. However, the birth of a technology capable of recording brain activity dates from 1929 when Hans Berger demonstrated that it was possible to record changes in the electrical potential of the human brain using an electroencephalography (EEG) machine, leading to important advances, such as the accurate diagnosis and treatment of many forms of epilepsy. In the last 20 years, with the convergence of neuroscience discoveries, more and more precise brain imaging combining brain architecture and the analysis of neural functions, micro- and nanotechnologies, allowing the simultaneous detection of the activity of hundreds and thousands of neurons, and computing allowed the rapid development of multiple forms of neurotechnologies, already applied for the benefit of numerous patients. However, because of the central role the brain plays in our ability to be human and to exercise our rights and duties, an ethical and normative reflection is needed on the rapidly developing field of neurotechnologies, which the Organisation for Economic Co-operation and Development (OECD) defines as *"devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural system of natural persons"* (OECD 2019).

It is not simply a question of health that is at stake here, but rather our view of the human person, of our dignity and of the full capacity to exercise our rights in a context of tension between health needs and market aims. On the one hand we have major health needs, since diseases of the nervous system, neurological diseases and mental illnesses represent one third of our health care expenditure. These are huge needs, estimated in 2014 at more than 800 billion euros each year in the European Union. We often think of Alzheimer's disease, which will have an approximate annual global cost of 2,000 billion by 2030, but multiple sclerosis is the first cause of disability in young people and 13% of the population is affected by migraines. Strokes are the second cause, perhaps even now the number one cause of death. On the other hand, the consumer market, "neural data" (also called "brain data"[27]), are becoming a sought-after data type and commodity beyond the medical sector including digital phenotyping,[28] affective computing,[29] neurogaming[30] and neuromarketing.[31]

27. Personal brain data: data relating to the functioning or structure of the human brain of an identified or identifiable individual that includes unique information about their physiology, health or mental states (OECD, 2019). In this report we define neural data as personal brain data. See also Ienca M. et al. (2022). Towards a Governance Framework for Brain Data. *Neuroethics* 15:20 https://doi.org/10.1007/s12152-022-09498-8
28. Digital phenotyping was defined by Jukka-Pekka Onnela as the "moment-by-moment quantification of the individual-level human phenotype *in situ* using data from personal digital devices".
29. Affective computing is the study and development of systems and devices that can recognize, interpret, process and simulate human affects.
30. Neurogaming is a novel form of gaming that involves the use of brain-computer interfaces such as EEG helmets so that users can interact with the game without using a traditional controller.
31. Neuromarketing is the study of the cerebral mechanisms likely to intervene in consumer behaviour.

Among the tensions raised by neurotechnologies we should also mention public trust, respect for mental privacy, rapid technological and economic development, and the fact that such developments face little or poorly supervised uses. These latter considerations and the risk of a backlash blocking the necessary development of neurotechnology led the OECD to launch a reflection in 2015, allowing its Council to adopt, in December 2019, the Recommendation on Responsible Innovation in Neurotechnology as the first international standard in this domain. The Recommendation aims to guide governments and innovators to anticipate and address the ethical, legal and social challenges raised by novel neurotechnologies while promoting innovation in the field.
The Recommendation embodies nine principles, which focus on:

1. promoting responsible innovation;
2. prioritizing safety assessment;
3. promoting inclusivity;
4. fostering scientific collaboration;
5. enabling societal deliberation;
6. enabling the 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 seeks to provide guidance at each step of the innovation process so that benefits are maximized and risks minimized. It articulates the importance of:

1. high-level values such as stewardship, trust, safety and privacy in this technological context;
2. building the capacity of key institutions, such as foresight, oversight and advisory bodies;
3. processes of societal deliberation, inclusive innovation and collaboration.

Indeed, the question arises today as to whether current human rights sufficiently protect the individual with regard to the potential intrusions of neurotechnologies into his or her brain activity. The International Bioethics Committee (IBC) of UNESCO has highlighted in its report on the ethical, legal and social issues of neurotechnologies, published in December 2021, the benefits that may result from the development of neurotechnologies, but also some fundamental human rights that could be jeopardized by this technology. These include:

a. human dignity by respecting the integrity of each individual's brain;
b. personal identity, the ability to think and feel for ourselves;
c. freedom of thought and free will if devices interfere with our judgement and decision-making abilities;
d. privacy/confidentiality of our thoughts and the inference that can be made from an analysis of brain data to predict an individual's behaviour with the risk of neuro-surveillance;
e. equal access/distributive justice if their availability and accessibility lead to increased inequality;
f. the risk of discrimination if there is bias in the algorithms used;
g. the risk of misuse, unauthorized or coercive use for malicious purposes;
h. the issue of augmentation and enhancement;
i. informed consent: given the potential for influence regarding perceived personal identity and cognitive abilities;
j. the specific issue of the best interests of the child, a period of development when the brain is rapidly changing and determining the life of the individual.

To feed its reflection, the IBC mapped the existing literature, organized hearings on the main players and open and closed deliberation. A main topic at stake is the question of whether we need novel rights, increasingly named neurorights. We can cite Marcelo Ienca and Roberto Andorno who identified four new rights in the face of the development of neurotechnologies: the right to cognitive freedom, to privacy, to mental integrity and to psychological continuity (Ienca and Andorno 2017). We can mention the Neuro-Rights initiative, led by Rafael Yuste, who proposed five neurorights: mental privacy, personal identity, free will, fair access to mental augmentation and protection from bias.[32] The legal impact of this reflection is already visible. An amendment to the Chilean Constitution now protects mental identity as a fundamental right. In France, within the framework of the revision of the bioethics law in 2021, Articles 18 and 19 of the bill protect against the abusive use of neural data.[33]

In its 2021 report, the IBC considers that we should take great care with the proliferation of new rights, and we should first examine the application of existing human rights and how neurotechnology challenges them. IBC considers that the 'neurorights' called for to protect our brains from the risks identified in the report encompass certain human rights that are already recognized in international law. These rights are based on the recognition of the fundamental rights of all individuals to physical and mental integrity, mental privacy, freedom of thought and free will; and the right to enjoy the benefits of scientific progress; and the recognition of the need to protect and promote these rights with respect to the application of neurotechnology. They also include the right to decide freely and responsibly on matters related to the use of neurotechnology, free from any form of discrimination, coercion and violence.

To this end, the IBC calls on UNESCO to use its unique global mandate in the ethics of science and technology, and its multifaceted expertise, to address the challenges highlighted by this report:

a. to provide new insights into the interpretation and application of existing human rights instruments by legislative bodies and courts in relation to the new challenges;
b. to propose the adaptation of existing human rights instruments and the proclamation of new human rights;
c. to organize global dialogues in the field of human rights towards building a consensus on the nature and substance of neurorights.

UNESCO could convene a multidisciplinary group of experts to develop a policy-oriented governance model, to monitor progress in the field and to examine whether the issues raised are effectively covered by the existing legal frameworks. This governance model would build on the existing human rights architecture and incorporate the relevant principles identified in this report, paving the way towards the eventual elaboration of a new normative instrument on neurorights.

32. https://neurorightsfoundation.org/mission
33. Article 18 I. – The first sentence of Article 16-14 of the Civil Code: 'Brain imaging techniques may only be used for medical or scientific research purposes or in the context of forensic examinations excluding, in this context, functional brain imaging.'

The meeting at Milano-Bicocca is one of these multiple steps to raise awareness about these questions and pave the way to investigations and elaborations called by the IBC. A process is also ongoing at the United Nations level in the context of the 75th anniversary of the Charter in 2023. In the meantime, the IBC encourages Member States to guarantee neurorights. Granting neurorights a positive status will empower citizens to claim respect for these rights as well as empowering Member States to provide appropriate legal frameworks for the production and use of neurotechnology.

References

Ienca, M. and Roberto A. (2017). Towards New Human Rights in the Age of Neuroscience and Neurotechnology. *Life Sciences, Society and Policy* 13(1):5.

OECD (2019). *Recommendation of the Council on Responsible Innovation in Neurotechnology.* Paris, OECD. Available at https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457

THE RISKS AND CHALLENGES OF NEUROTECHNOLOGIES FOR HUMAN RIGHTS

In line with the Report of the International Bioethics Committee of UNESCO (IBC) on the ethical issues of neurotechnology (December 2021), this publication builds on the efforts made by the international community to raise awareness on the risks resulting from the uses of neurotechnologies for human rights.

This interdisciplinary publication is the result of two-days of enlightening and thought-provoking discussions among neuroscientists, engineers, computer scientists, philosophers, legal scholars and experts in neuroethics. It provides an updated picture of the state of art of neurotechnology both from a scientific, regulatory and human rights perspective. The issues are presented in a concise and readable fashion. The publication aims to inform and engage the general public in the global debate about the human rights risks and challenges relating to the uses of neurotechnology.

9 789231 005671