UK Parliament POST

POSTNOTE

Number 614 January 2020

Brain-Computer Interfaces

Overview

- Brain-computer interfaces (BCIs) connect the brain to an external computer and are typically used to control electronic devices.
- Development has focused primarily on medical uses with some applications in defence, entertainment and marketing.
- Use has been largely limited to research settings due to technical challenges, but BCIs are attracting sizeable investment.
- BCIs raise ethical questions about privacy, fair access, assessing risks versus benefits, and attributing responsibility for actions involving BCIs.
- New regulatory approaches may be needed to stimulate innovation and ensure privacy, safety and the effectiveness of BCI devices.

Brain-computer interfaces allow people to use brain activity to control equipment such as protheses. Beyond medicine, they are being investigated for gaming, marketing, defence and for improving cognitive functions. This briefing looks at the technology, its uses and associated ethical and regulatory challenges.

Background

Neural interfaces (NIs) are devices that interact with the brain or other parts of the nervous system.[1] NIs can replace, alter or enhance nervous system processes that are impaired.[2] They may record data, stimulate the nervous system to modify its activity, or in some cases do both (Box 1). Brain-computer interfaces (BCIs) are a type of NI. BCIs generally refers to devices that record the electrical signals from neurons (nerve cells) in the brain and transmit them to an external computer for interpretation. This information can be used to operate computer-controlled devices, such as speech synthesis software or computer games.[3] There is no universally-agreed definition for BCIs.[4–6] For instance, some researchers use BCI to describe devices that only record data from the nervous system, while others also use it for devices that stimulate activity (sometimes in response to the recorded data).[6–8] In this note we use BCIs to mean devices that only record data from the brain and NIs to mean devices that stimulate, record or do both.

The term BCIs was first used in 1973.[9] Since then, development has mainly focused on researching brain function and medical applications,[10] such as assisting a patient with paralysis to communicate or control a prosthetic such as a limb or a wheelchair.[11,12] BCIs have been highlighted by the Chief Medical Officer as an emerging technology with therapeutic potential.[13] Other sectors, such as entertainment and defence, are also developing BCIs, while companies and entrepreneurs are investing in heavily in BCIs and other NIs.[14–19]

BCIs present ethical challenges that may require new approaches to regulation. Many of these challenges also apply more widely to other types of NI. In September 2019, a report by the Royal Society suggested that the UK could lead in developing responsible regulation and new applications for NIs.[1]

BCI Technology

BCI systems typically comprise:[3,20]

- **A sensing element** to detect brain activity
- **A computational element** to decode that activity into meaningful information
- **A control element** that uses this information to operate a computer-controlled device.

In one recent research study, a BCI system enabled a paralysed patient to control a tablet computer.[12,21] Brain signals detected from a patient thinking about moving a cursor on a screen were decoded and sent to software to control the tablet in the same way as a mouse.[21]

Typically, BCIs use electrodes to measure the electrical signals generated by the brain.[3,22] However, alternative sensing elements can be used to measure other aspects of brain activity, such as magnetic fields or blood flow.[23–26]

BCIs may be categorised according to where the sensors are placed:[27]

- **Invasive** – electrodes are implanted during a surgical procedure.[3,4,28] These sit on the outermost layer of the brain or penetrate this layer (Box 1).[29]
- **Non-invasive** – sensors are located outside the skull. When a BCI uses electroencephalography (EEG), electrodes are worn on the scalp in a headset.[27] When magnetoencephalography (MEG) is used, a patient's head is placed in a scanner to measure magnetic fields produced by electrical activity in the brain.[23,26] BCIs may also use other non-invasive imaging techniques, such as functional magnetic resonance imaging[24,30] and functional ultrasound, which can measure blood flow in the brain.[25]

EEG is the most widely used sensing method for non-invasive BCIs due to its low cost and portability.[27,31] Invasive systems provide better signal quality by making direct contact with the brain.[3,28] In theory, this could give users greater control of BCI-enabled devices.[12,32] In practice, a range of technical challenges and risks associated with surgery currently limit the use of invasive BCIs (Box 2).[27,28,32]

Box 1: Neural Interfaces
The Royal Society defines NIs as devices placed in or on the brain or other parts of the nervous system.[1] They can act to:

- **Stimulate** a region of the nervous system, for example by applying electric or magnetic pulses (known as neurostimulation). For instance, cochlear implants translate sounds into electrical signals and send them to the auditory nerve.[33] Deep-brain stimulators involve implanting electrodes deep in the brain to deliver electrical pulses,[34] to alleviate the symptoms of movement disorders such as Parkinson's disease.[35]
- **Record** and interpret nervous system activity. For example, BrainGate's BCI involves implanting an array of electrodes in the area of the brain that controls movement.[36] This detects activating neurons when someone intends to move,[20] and has been used to allow immobile patients to control devices such as computer cursors and robotic arms.[37–39]
- **Record and stimulate** part of the nervous system.[40] For example, one stroke rehabilitation device under development aims to detect when a patient intends to move their arm and then stimulates the muscle to assist movement.[41] Combining recording and stimulation functions in the same device is a key focus of current research.[8,42–44]

Medical Applications

Control of Assistive Equipment

BCIs are being developed to assist patients who have lost motor and sensory function, for example as a result of stroke or spinal cord injury, resulting in paralysis.[12,43,45–47] These include systems that allow patients to control assistive equipment, such as exoskeletons, mechanised limbs or wheelchairs.[46,48–51] BCIs are also being developed for people who have lost the ability to speak. These work by translating brain activity intentionally generated by the patient into synthesised speech or text (Box 3).[52–55] However, the use of decoded brain activity to enable control of assistive equipment has been largely limited to research settings.[43,56,57] Future developments are likely to require further innovation (Box 2).[1]

Box 2: Technical Challenges of BCIs
EEG records brain signals from electrodes placed on the scalp. For non-invasive BCIs the skull and tissue between the electrodes and the brain result in weaker signals and slower transfer of information to the computer.[11,28] This limits how well the user can control the device they are connected to (such as a prosthetic limb).[58] EEG also has lower spatial resolution so it is less accurate at pinpointing the location where a signal is generated.[59] Researchers are trying to overcome these limitations to improve EEG's utility for both medical and non-medical applications.[60,61]

MEG may be a promising alternative since the magnetic fields it detects are not weakened by the skull. It can also determine the location of brain activity more accurately than EEG.[23,62,63] MEG has been less explored as it is expensive and requires people to lie still inside a scanner.[1] Researchers have demonstrated the feasibility of a wearable MEG system, based on quantum technology,[64] to address these issues.[26]

Invasive BCIs also face challenges. These include intrusive wiring (which carries an infection risk) and the body's immune response can compromise electrode function over time.[32,65,66] As a result, only a limited number of patients have been fitted with them in research settings, although attempts to commercialise implantable BCI systems continue.[20] For invasive BCIs to become more widely used, they are likely to require a number of innovations:[1]

- Miniaturisation of implanted devices
- Capacity to measure far larger volumes of data
- Wireless recharging of device batteries
- Wireless data transfer between device and computer
- Longer device lifetime following implantation
- New surgical methods for implantation[67,68]
- Reduction of scarring around implanted electrodes.

BCIs for Improved Neurostimulation

BCI technology has the potential to make established therapies more effective, because of its ability to transfer information from the brain to an external computer for analysis. For example, implantable deep-brain stimulators apply an electric current to the brain (Box 1).[34,69] They are available on the NHS to treat movement disorders like drug-resistant Parkinson's.[70] However, the current is delivered in a pre-programmed way that doesn't change according to the patient's symptoms. This can lead to adverse side effects, such as speech or balance impairment.[42,71–74]

BCIs can be used to make treatments more responsive by providing greater insight into brain function. They can sense abnormal brain activity, using it to identify the onset of symptoms. Treatment could then be tailored to a specific patient, reducing the need for clinicians to re-programme devices regularly.[72] The NeuroPace RNS[75] is one example of a responsive implantable device (approved for clinical use in the US) that applies brain stimulation to prevent epileptic seizures from occurring.[76] BCIs could also help to make neurostimulation treatments for mental health disorders, like depression,[77]responsive to the person's mental state.[20,78–84]

Non-Medical Applications

BCI technology is attracting interest in a number of non-medical areas, with some products being marketed directly to consumers.[3,85,86] Examples include:

- **Entertainment**: Companies are developing non-invasive BCI headsets to play computer games.[87,88] These would allow users to control actions within the game via thought.[89–91] NeuroSky[92] and MyndPlay[93] are among the small number of companies currently offering BCI-enabled gaming products to consumers.[94]
- **Training**: NeuroSky, MyndPlay, Emotiv[95] and other companies also market EEG headsets for enhancing cognitive abilities such as concentration.[94,96] These systems work by neurofeedback, the process of learning to control your brain activity by becoming visually aware of it on a computer screen.[97,98,99] This may help people with attention deficit disorders to focus[94] and patients with chronic pain to manage their symptoms.[1]
- **Marketing**: BCI technology is being developed for market research studies (neuromarketing).[100] This involves collecting data from the brain to gain insight into consumer decision-making.[101,102] BCIs might be used, for example, to measure the reaction of a consumer to an advertising campaign.[103]
- **Defence**: The MoD is investigating how BCIs can enhance different cognitive abilities, including decision-making and sensory processing (such as sight, hearing and touch).[104] In the US, the Defense Advanced Research Projects Agency is funding an extensive programme of NI projects.[12] For example, the Next-Generation Nonsurgical Neurotechnology programme aims to develop non-invasive BCIs for service personnel.[105,106] Potential applications could include control of unmanned aerial vehicles or cyber-defence systems.[105,107,108]

BCI technology is also under development for other applications that are further from being realised.[109] For example, Facebook is working on non-invasive BCIs to enable hands-free communication with smartphones at a faster rate than typing.[16,110] Meanwhile, Neuralink recently reported it had developed a laboratory prototype of an implantable BCI.[67] This BCI is initially intended for medical applications, with the ultimate goal of merging human intelligence with artificial intelligence.[17,111] Estimates suggest that invasive BCIs could be available for medical use within 5–10 years.[66] However, for non-medical use, the timeframe is likely to be much greater.[1]

Ethical Challenges

In 2013, the Nuffield Council on Bioethics published an ethical framework for technologies that interface with the brain.[3] Since then, the Royal Society (2019)[1], the OECD (2019)[112] and academics [4,113,114] have all highlighted the importance of addressing the ethics of NI use.

Safety of BCIs

Safety concerns primarily focus on invasive types of BCI. As these are implanted in brain tissue, they can cause localised damage to nerve cells and blood vessels, and an increased infection risk.[3] The Nuffield Council concluded that the pivotal role of the brain (including in the functioning of mind and body, and sense of self), requires the risks and benefits of interventions to be carefully assessed.

Weighing up the risk of using a device against the benefits it offers may be easier for medical applications. Their benefits can be more directly measured by the effectiveness of the treatment whereas, for non-medical applications, benefits may be harder to define or be more subjective.[3,115,116] The Council also concluded that non-invasive BCIs systems, such as EEG devices for gaming, are unlikely to cause serious health risks. However, extended use may lead to changes in the brain that occur as a result of the brain's inherent plasticity,[3,117] which the Council highlighted as a particular risk to children.[3] There has been no systematic research on the long-term effects of EEG for recreational purposes.[118]

Privacy and Security

Current understanding of brain function is limited, which means that brain activity data cannot be used to 'read' a person's thoughts.[3] Theoretically, it might be possible to infer certain personal information from BCI data, such as a person's emotional state, sexual preferences, religious and political beliefs, and cognitive health.[119–121] However, some academics have questioned whether currently available BCIs can reveal this kind of information.[122]

Brain activity data may be captured in increasing volumes as the consumer market for BCI technology grows.[121,123] Some academics have expressed concern that companies developing or using BCIs could seek to use this data for profit, for example by targeting advertising to specific individuals.[124,125] They also speculate that governments may seek to obtain brain activity data from BCI companies for security and law enforcement.[124] Other academics suggest that connecting BCI systems to the internet may open up the possibility of them being hacked to steal data or to hijack the devices under their control.[113,126]

Equality of Access

New technologies may often be costly (particularly initially), limiting use to those who can afford them. Unequal access to BCIs and other NIs for human enhancement applications could widen already existing societal inequalities.[115,127] In a recent public dialogue that canvassed the views of a small sample of the UK population, participants felt that NIs for medical applications should be available to all those in need, regardless of wealth (Box 4).[128] NICE provides recommendations to the NHS on the adoption of new technologies,[129,130] based on how well the treatment works and whether it is value for money.

Accurately Communicating the Risks and Benefits

According to the Nuffield Council, publicising the more speculative uses and benefits of BCIs may help to attract investment and shape future research.[3] However, exaggerated claims or inaccurate communication risks and benefits may affect patients' understanding and expectations, and jeopardise informed consent. Unsubstantiated or misleading marketing may undermine wider public trust in the technology.[3,96]

Agency & Autonomy

The use of BCI-enabled equipment involves the user sharing control of that equipment with the BCI, especially when it includes automated decision-making.[113,131] This raises questions regarding agency.[58,132,133] An example is the extent to which responsibility for an action facilitated by a BCI-enabled device, such as a prosthetic limb or speech synthesiser (Box 3), can be attributed to the user.[4] Such questions may raise challenges for attributing legal responsibility when actions or speech have been executed by a BCI-enabled device.[134,135,136]

Box 3: Decoding Speech from the Brain
BrainCom is one example of a research project aiming to develop invasive BCIs for patients who are unable to verbalise speech.[53] The separate processes of: (1) thinking about saying specific words and (2) speaking, produce similar activity patterns within the brain. BrainCom's BCI implant would record electrical brain activity generated by a patient who has lost the ability to verbalise their speech but can still imagine speaking. These recordings would then be decoded to identify specific sounds that can be stitched together to form words delivered by a speech synthesiser.[53,54] This process has been compared to lip reading using measurements from the brain.

Regulating BCIs

In the UK, there is no regulation specific to BCI technology. However, BCI systems may fall within the scope of the EU Medical Devices Regulation (MDR) if they are intended for medical use.[137,138] The MDR came into force in 2017 and will apply fully in the UK in May 2020.[138] It sets out the safety, quality and performance requirements that must be met for any medical device marketed in the EU. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating medical devices to ensure they meet the standards of the MDR and will continue to have this role after Brexit.[139]

From May 2020, the MDR scope will be extended to certain products that work in a similar way, or have similar risks, to a medical device. The extension aims to strengthen their safety, quality assurance and market surveillance.[137] It includes non-invasive brain stimulation equipment that applies electrical currents, magnetic or electromagnetic fields that penetrate the skull and modify brain activity.[140–142] The MDR will therefore apply to some commercially available devices, such as headsets intended to enhance memory and focus through brain stimulation.[140,143] Non-invasive BCIs that measure brain activity, such as some computer game headsets using EEG, will remain outside the scope of the MDR. However, there has been some debate between academics about whether neurofeedback equipment should be more strictly regulated.[117,142] BCI devices that fall outside the scope of the MDR will still be governed by consumer protection laws, such as the Consumer Rights Act 2015.[144,145]

Regulatory Challenges

The Royal Society recently reported clinicians' concerns that regulatory restrictions limit access to new medical innovations. It also suggested that NIs are being used by some consumers with little regulatory constraint, despite a limited understanding of their safety or effectiveness.[1]

Effectiveness of Consumer BCIs

Some academics have questioned the effectiveness of consumer BCIs that use EEG.[146–148] For example, it is unclear whether the benefits of EEG neurofeedback are real or a placebo effect.[146,149] In addition, some have contended that companies marketing these devices and other products for enhancing cognitive functions are making exaggerated claims without adequate evidence.[96,150,151] In the UK, consumer BCI products not covered by the MDR are subject to lower levels of oversight. This makes it very difficult for consumers to assess whether devices will work as advertised.[96]

Data Governance

The use of personal information in the UK is governed by data protection laws, including the EU General Data Protection Regulation (GDPR).[153] Under the Regulation, health data are subject to stricter access requirements than some other personal data.[154] Academics have raised concerns that brain data from commercially available BCIs that are not classed as medical devices may not have these additional protections.[155] The Morningside Group (an international collaboration of neuroscientists, neurotechnologists, ethicists and engineers) have also made recommendations for the regulation of BCIs and other technologies that interface with the nervous sytem.[1,113] These include suggestions for data governance, including that users give explicit consent before their brain data can be shared.[113] Research on brain activity data may provide new insights and tools for enhancing the health and well-being of individual patients and wider society.[156,157]

Box 4: Public Opinion on NI technology
In 2019, the Royal Society commissioned a public dialogue to identify public attitudes towards NIs.[128,152] It involved 73 participants from a "broadly representative demographic of society" with varying tendencies to adopt new technologies. Nearly all participants approved of using NIs for medical purposes. Non-medical uses were met with greater caution, but some were considered positive developments for society (such as enhancing experiences of entertainment).

Data derived from brain activity were considered more personal than data generated by using social media or smartphones, leading to the view that more caution is required with NIs than other technologies. Participants expressed a variety of other concerns such as equality of access, control and transparency of BCI data use, and a potential future in which their minds could be read, or their behaviour controlled without prior consent.

New Approaches to Regulation

The Royal Society has suggested that NIs could be used as a test case for new approaches to technology regulation.[1] For example, allowing new medical devices to be temporarily tested in a controlled environment with limited regulation (a sandbox). Sandboxes have also been used to support innovation in other sectors, such as financial technologies.[158] They also recommended that the public be given a clear voice in shaping future NI regulation.[1]

In June 2019, the UK Government said that it is working with the NHS and regulators to develop guidance for innovators looking to bring novel medical technologies to market.[159] Through the Regulators' Pioneer Fund, it has invested £10m in projects to make regulation more supportive of innovation. The MHRA and NHS Digital are developing datasets enabling the validation of AI-based software used in medical devices.[160]

In the US, the FDA has published draft, non-binding, regulatory guidance for implantable BCIs to help accelerate medical uses of the technology.[161,162] This is the first example of a regulatory agency focusing explicitly on BCIs. The FDA says that it intends to update this guidance as invasive BCI technology develops.[163]

POST is an office of both Houses of Parliament, charged with providing independent and balanced analysis of policy issues that have a basis in science and technology. POST is grateful to Michael Potter for researching this briefing, to the EPSRC for funding his parliamentary fellowship, and to all contributors and reviewers. For further information on this subject, please contact the co-author, Dr Lydia Harriss.

Endnotes

1. Royal Society (2019). *iHuman Perspective: Neural Interfaces.* Royal Society.
2. Jackson, P. A. (2019). *iHuman Perspective: Neural Interfaces - The Science of Neural Interfaces.* Royal Society.
3. Nuffield Council on Bioethics (2013). *What are Novel Neurotechnologies?* Nuffield Council on Bioethics.
4. Burwell, S. *et al.* (2017). Ethical aspects of brain computer interfaces: a scoping review. *BMC Medical Ethics*, Vol 18, 60.
5. Brunner, C. *et al.* (2015). BNCI Horizon 2020: towards a roadmap for the BCI community. *Brain-Computer Interfaces*, Vol 2, 1–10.
6. Nijboer, F. *et al.* (2013). The Asilomar Survey: Stakeholders' Opinions on Ethical Issues Related to Brain-Computer Interfacing. *Neuroethics*, Vol 6, 541–578.
7. Wander, J. D. *et al.* (2014). Brain–computer interfaces: a powerful tool for scientific inquiry. *Current Opinion in Neurobiology*, Vol 25, 70–75.
8. Starr, P. A. (2018). Totally Implantable Bidirectional Neural Prostheses: A Flexible Platform for Innovation in Neuromodulation. *Front. Neurosci.*, Vol 12, 1–5.
9. Vidal, J. J. (1973). Toward Direct Brain-Computer Communication. *Annual Review of Biophysics and Bioengineering*, Vol 2, 157–180.
10. Mak, J. N. *et al.* (2009). Clinical Applications of Brain-Computer Interfaces: Current State and Future Prospects. *IEEE Reviews in Biomedical Engineering*, Vol 2, 187–199.
11. Tingley, A. Next Generation Neural Implants. *Imperial Innovations*.
12. Smalley, E. (2019). The business of brain–computer interfaces. *Nat Biotechnol*, Vol 37, 978–982.
13. Chief Medical Officer (2018). *Annual Report of the Chief Medical Officer, 2018. 'Health 2040 - Better Health Within Reach'.* Department of Health and Social Care.
14. Fields, R. D. Wristband Lets the Brain Control a Computer with a Thought and a Twitch. *Scientific American*.
15. Dodds, L. (2019). Facebook buys brain tech start-up as it bets on a future of mind-reading computers. *The Telegraph*.
16. Tech@Facebook (2019). Imagining a new interface: Hands-free communication without saying a word. *Facebook Technology*.
17. Urban, T. (2017). Neuralink and the Brain's Magical Future. *Wait But Why*.
18. Grand View Research (2018). Brain Computer Interface Market Size | BCI Industry Report, 2012-2022.
19. Mitrasinovic, S. *et al.* (2018). Silicon Valley new focus on brain computer interface: hype or hope for new applications? *F1000Res*, Vol 7, 1327.
20. Palmer, A. (2018). Thought experiments. *The Economist*.
21. Nuyujukian, P. *et al.* (2018). Cortical control of a tablet computer by people with paralysis. *PLOS ONE*, Vol 13, e0204566.
22. Utrecht NeuroProsthesis. *About Brain Computer Interface.*
23. Mellinger, J. *et al.* (2007). An MEG-based brain–computer interface (BCI). *NeuroImage*, Vol 36, 581–593.
24. Ekanayake, J. *et al.* (2018). Real-time decoding of covert attention in higher-order visual areas. *NeuroImage*, Vol 169, 462–472.
25. Khalaf, A. *et al.* (2018). A brain-computer interface based on functional transcranial doppler ultrasound using wavelet transform and support vector machines. *Journal of Neuroscience Methods*, Vol 293, 174–182.
26. Boto, E. *et al.* (2018). Moving magnetoencephalography towards real-world applications with a wearable system. *Nature*, Vol 555, 657–661.
27. Abiri, R. *et al.* (2019). A comprehensive review of EEG-based brain–computer interface paradigms. *J. Neural Eng.*, Vol 16, 011001.
28. Waldert, S. (2016). Invasive vs. Non-Invasive Neuronal Signals for Brain-Machine Interfaces: Will One Prevail? *Front. Neurosci.*, Vol 10,
29. Homer, M. L. *et al.* (2013). Sensors and Decoding for Intracortical Brain Computer Interfaces. *Annual Review of Biomedical Engineering*, Vol 15, 383–405.
30. Wang, Y. *et al.* (2018). Real-time fMRI-based Brain Computer Interface: A Review. *arXiv:1808.05852 [cs]*,
31. Nicolas-Alonso, L. F. *et al.* (2012). Brain Computer Interfaces, a Review. *Sensors*, Vol 12, 1211–1279.
32. Baranauskas, G. (2014). What limits the performance of current invasive brain machine interfaces? *Front. Syst. Neurosci.*, Vol 8.
33. Overstreet, E. *et al.* (2018). Cochlear Implants: Considerations Regarding the Relationship between Cognitive Load Management and Outcome. *Hearing Review*.
34. Mayo Clinic Deep brain stimulation - Mayo Clinic.
35. Parkinsons Disease Surgery, DBS Surgery, Deep Brain Stimulation surgery | Mayfield Brain & Spine Cincinnati. *Mayfield Brain & Spine*.
36. Duncan, D. E. Implanting Hope. *MIT Technology Review*.
37. Bacher, D. *et al.* (2015). Neural Point-and-Click Communication by a Person With Incomplete Locked-In Syndrome. *Neurorehabil Neural Repair*, Vol 29, 462–471.
38. Hochberg, L. R. *et al.* (2006). Neuronal ensemble control of prosthetic devices by a human with tetraplegia. *Nature*, Vol 442, 164–171.
39. Collinger, J. L. *et al.* (2013). High-performance neuroprosthetic control by an individual with tetraplegia. *The Lancet*, Vol 381, 557–564.
40. Jackson, A. *et al.* (2012). Neural interfaces for the brain and spinal cord—restoring motor function. *Nat Rev Neurol*, Vol 8, 690–699.
41. Adama, S. (2018). Stroke Rehabilitation and Parkinson's Disease Tremor Reduction Using BCIs Combined With FES. *Int. J. Priv. Heal. Info. Manag.*, Vol 6, 20–36.
42. Sun, F. T. *et al.* (2014). Closed-loop Neurostimulation: The Clinical Experience. *Neurotherapeutics*, Vol 11, 553–563.
43. Bensmaia, S. J. *et al.* (2014). Restoring sensorimotor function through intracortical interfaces: progress and looming challenges. *Nature Reviews Neuroscience*, Vol 15, 313–325.
44. Zhou, A. *et al.* (2019). A wireless and artefact-free 128-channel neuromodulation device for closed-loop stimulation and recording in non-human primates. *Nat Biomed Eng*, Vol 3, 15–26.
45. McFarland, D. J. *et al.* (2017). Therapeutic Applications of BCI Technologies. *Brain Comput Interfaces (Abingdon)*, Vol 47, 37–52.
46. Shih, J. J. *et al.* (2012). Brain-Computer Interfaces in Medicine. *Mayo Clinic Proceedings*, Vol 87, 268–279.
47. Remsik, A. *et al.* (2016). A review of the progression and future implications of brain-computer interface therapies for restoration of distal upper extremity motor function after stroke. *Expert Review of Medical Devices*, Vol 13, 445–454.
48. Gallagher, J. (2019). Paralysed man moves in mind-reading exoskeleton. *BBC News*.
49. Science Daily (2018). Brain-computer interface advances improve prosthetics, therapies: Advances offer help for quadriplegic, stroke, amputee, and blind patients. *ScienceDaily*.

50. Sczesny-Kaiser, M. *et al.* (2015). HAL® exoskeleton training improves walking parameters and normalizes cortical excitability in primary somatosensory cortex in spinal cord injury patients. *Journal of NeuroEngineering and Rehabilitation*, Vol 12, 68.
51. Tanaka, K. *et al.* (2005). Electroencephalogram-based control of an electric wheelchair. *IEEE Transactions on Robotics*, Vol 21, 762–766.
52. Moses, D. A. *et al.* (2019). Real-time decoding of question-and-answer speech dialogue using human cortical activity. *Nat Commun*, Vol 10, 1–14.
53. BrainCom BrainCom.
54. Anumanchipalli, G. K. *et al.* (2019). Speech synthesis from neural decoding of spoken sentences. *Nature*, Vol 568, 493–498.
55. Akbari, H. *et al.* (2019). Towards reconstructing intelligible speech from the human auditory cortex. *Sci Rep*, Vol 9, 1–12.
56. Murphy, M. D. *et al.* (2016). Current Challenges Facing the Translation of Brain Computer Interfaces from Preclinical Trials to Use in Human Patients. *Front. Cell. Neurosci.*, Vol 9,
57. Rabbani, Q. *et al.* (2019). The Potential for a Speech Brain–Computer Interface Using Chronic Electrocorticography. *Neurotherapeutics*, Vol 16, 144–165.
58. Haselager, P. (2013). Did I Do That? Brain–Computer Interfacing and the Sense of Agency. *Minds & Machines*, Vol 23, 405–418.
59. Deshpande, G. *et al.* (2017). A New Generation of Brain-Computer Interfaces Driven by Discovery of Latent EEG-fMRI Linkages Using Tensor Decomposition. *Front. Neurosci.*, Vol 11,
60. TechnologyNetworks (2019). First Ever Non-invasive Brain-Computer Interface Developed. *Technology Networks*.
61. Edelman, B. J. *et al.* (2019). Noninvasive neuroimaging enhances continuous neural tracking for robotic device control. *Science Robotics*, Vol 4, eaaw6844.
62. Baillet, S. (2017). Magnetoencephalography for brain electrophysiology and imaging. *Nat Neurosci*, Vol 20, 327–339.
63. Kosmyna, N. *et al.* (2019). A conceptual space for EEG-based brain-computer interfaces. *PLOS ONE*, Vol 14, e0210145.
64. Parliamentary Office of Science and Technology (2017). Quantum Technologies.
65. Morales, J. M. H. *et al.* (2018). Technical Challenges of Active Implantable Medical Devices for Neurotechnology. in *2018 IEEE CPMT Symposium Japan (ICSJ)*. 77–80.
66. Corbyn, Z. (2019). Are brain implants the future of thinking? *The Observer*.
67. Musk, E. *et al.* (2019). An integrated brain-machine interface platform with thousands of channels. *bioRxiv*, 703801.
68. RehabPub Stentrode Brain-Computer Interface Implanted Successfully for the First Time - Rehab Managment.
69. Parkinson's UK Deep brain stimulation | Parkinson's UK.
70. NHS Commissioning Board *Clinical Commissioning Policy: Deep Brain Stimulation (DBS) In Movement Disorders (Parkinson's Disease, Tremor, Dystonia).*
71. Rouse, A. G. *et al.* (2011). A chronic generalized bi-directional brain–machine interface. *J. Neural Eng.*, Vol 8, 036018.
72. Hoang, K. B. *et al.* (2019). The Emerging Role of Biomarkers in Adaptive Modulation of Clinical Brain Stimulation. *Neurosurgery*, Vol 85, E430–E439.
73. Parastarfeizabadi, M. *et al.* (2017). Advances in closed-loop deep brain stimulation devices. *J NeuroEngineering Rehabil*, Vol 14, 79.
74. Afshar, P. *et al.* (2013). A translational platform for prototyping closed-loop neuromodulation systems. *Front. Neural Circuits*, Vol 6,
75. Premarket Approval (PMA) - FDA Regulation for NeuroPace.
76. NP-9823479 (2018). NeuroPace Announces Final Results from the Largest Prospective Clinical Study in the Field of Neuromodulation with 9-Year Follow-Up at the 2018 American Epilepsy Society Annual Meeting. *NeuroPace, Inc.*
77. Crowell, A. L. *et al.* (2019). Long-Term Outcomes of Subcallosal Cingulate Deep Brain Stimulation for Treatment-Resistant Depression. *AJP*, Vol 176, 949–956.
78. Shanechi, M. M. (2019). Brain–machine interfaces from motor to mood. *Nat Neurosci*, Vol 22, 1554–1564.
79. Kirkby, L. A. *et al.* (2018). An Amygdala-Hippocampus Subnetwork that Encodes Variation in Human Mood. *Cell*, Vol 175, 1688-1700.e14.
80. Widge, A. S. *et al.* (2018). Closing the Loop on Deep Brain Stimulation for Treatment-Resistant Depression. *Front. Neurosci.*, Vol 12,
81. Bouthour, W. *et al.* (2019). Biomarkers for closed-loop deep brain stimulation in Parkinson disease and beyond. *Nat Rev Neurol*, Vol 15, 343–352.
82. Emondi, A. Systems-Based Neurotechnology for Emerging Therapies (SUBNETS). *DARPA*.
83. Phillips, N. (2018). Brain-stimulation trials get personal to lift depression. *Nature*,
84. Janicak, P. *et al.* (2015). Transcranial magnetic stimulation for the treatment of major depression. *NDT*, 1549.
85. Abdulkader, S. N. *et al.* (2015). Brain computer interfacing: Applications and challenges. *Egyptian Informatics Journal*, Vol 16, 213–230.
86. van Erp, J. *et al.* (2012). Brain-Computer Interfaces: Beyond Medical Applications. *Computer*, Vol 45, 26–34.
87. Zhang, B. *et al.* (2010). A review of the commercial brain-computer interface technology from perspective of industrial robotics. in *2010 IEEE International Conference on Automation and Logistics*. 379–384.
88. Vasiljevic, G. A. M. *et al.* (2019). Brain–Computer Interface Games Based on Consumer-Grade EEG Devices: A Systematic Literature Review. *International Journal of Human–Computer Interaction*, 1–38.
89. michaelthompson (2017). A Game You Can Control With Your Mind. *Neurable INC*.
90. Valve Corporation (2019). Valve psychologist explores controlling games directly with your brain. *VentureBeat*.
91. Metz, R. Get ready to throw toys with your mind (in VR, at least). *MIT Technology Review*.
92. EEG Headsets | NeuroSky Store.
93. MyndPlay.
94. Frost & Sullivan Frost and Sullivan: BCI Opportunities.
95. Emotiv. *EMOTIV*.
96. Wexler, A. *et al.* (2019). Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications. *J Cogn Enhanc*, Vol 3, 131–137.
97. Sitaram, R. *et al.* (2017). Closed-loop brain training: the science of neurofeedback. *Nat Rev Neurosci*, Vol 18, 86–100.
98. Fawkes, J. (2019). Can EEG Headsets Supercharge Your Brain? *Medium*.
99. Hammond, D. C. (2007). What Is Neurofeedback? *Journal of Neurotherapy*, Vol 10, 25–36.

100. Agarwal, S. *et al.* (2015). Neuromarketing and consumer neuroscience: current understanding and the way forward. *Decision*, Vol 42, 457–462.
101. Yadava, M. *et al.* (2017). Analysis of EEG signals and its application to neuromarketing. *Multimed Tools Appl*, Vol 76, 19087–19111.
102. Harvard Business School Neuromarketing: What You Need to Know.
103. BitBrain (2019). All you need to know about neuromarketing. *Bitbrain*.
104. Cinel, C. *et al.* (2019). Neurotechnologies for Human Cognitive Augmentation: Current State of the Art and Future Prospects. *Front. Hum. Neurosci.*, Vol 13,
105. DARPA and the Brain Initiative - thinkhumm - Medium.
106. Tullis, P. The US military is trying to read minds. *MIT Technology Review*.
107. DARPA Next-Generation Nonsurgical Neurotechnology.
108. Darpa funds brain-machine interface project for controlling weapons via thoughts | E&T Magazine.
109. Forbes Brain-Computer Interfaces And Mind Control Move One Step Closer To Becoming Reality.
110. Facebook F8 2017: AI, Building 8 and More Technology Updates From Day Two | Facebook Newsroom.
111. How Elon Musk's Neuralink Plans to Unify the Brain with AI. *Psychology Today*.
112. OECD (2019). *Responsible innovation in neurotechnology enterprises.*
113. Yuste, R. *et al.* (2017). Four ethical priorities for neurotechnologies and AI. *Nature News*, Vol 551, 159.
114. Goering, S. *et al.* (2016). On the Necessity of Ethical Guidelines for Novel Neurotechnologies. *Cell*, Vol 167, 882–885.
115. Sarah Chan Neural Interface Technologies: ethical and social dimensions. 10.
116. Maslen, H. Intervening in the brain: with what benefit?
117. Kuersten, A. *et al.* (2014). The brain, cognitive enhancement devices, and European regulation. *J Law Biosci*, Vol 1, 340–347.
118. Vlek, R. J. *et al.* (2012). Ethical Issues in Brain–Computer Interface Research, Development, and Dissemination: *Journal of Neurologic Physical Therapy*, Vol 36, 94–99.
119. Agarwal, A. *et al.* (2019). Protecting Privacy of Users in Brain-Computer Interface Applications. *arXiv:1907.01586 [cs]*,
120. Schwartz Mind-reading tech? How private companies could gain access to our brains | Technology | The Guardian.
121. Bonaci, T. *et al.* (2014). App stores for the brain: Privacy security in Brain-Computer Interfaces. in *2014 IEEE International Symposium on Ethics in Science, Technology and Engineering*. 1–7.
122. Wexler, A. (2019). Separating neuroethics from neurohype. *Nat Biotechnol*, Vol 37, 988–990.
123. Tilburg University *Brain Computer Interface: A Data Protection Perspective.*
124. Ienca, M. *et al.* (2018). Brain leaks and consumer neurotechnology. *Nature Biotechnology*, Vol 36, 805–810.
125. Bridle, J. (2019). The Age of Surveillance Capitalism by Shoshana Zuboff review – we are the pawns. *The Guardian*.
126. Ienca, M. *et al.* (2016). Hacking the brain: brain–computer interfacing technology and the ethics of neurosecurity. *Ethics Inf Technol*, Vol 18, 117–129.
127. Inglesant, P. *et al.* Thinking Ahead to a World with Quantum Computers. 107.
128. van Mil, A. *et al.* A public dialogue research programme conducted on behalf of the Royal Society Executive Summary. 11.
129. Charlton, V. *et al.* (2019). Innovation as a value in healthcare priority-setting: the UK experience. *Soc Just Res*, Vol 32, 208–238.
130. NICE technology appraisal guidance | NICE guidance | Our programmes | What we do | About. *NICE*.
131. Glannon, W. (2014). Neuromodulation, Agency and Autonomy. *Brain Topogr*, Vol 27, 46–54.
132. Drew, L. (2019). The ethics of brain–computer interfaces. *Nature*, Vol 571, S19–S21.
133. Steinert, S. *et al.* (2019). Doing Things with Thoughts: Brain-Computer Interfaces and Disembodied Agency. *Philos. Technol.*, Vol 32, 457–482.
134. Rainey, S. (2018). "A STEADYING HAND": ASCRIBING SPEECH ACTS TO USERS OF PREDICTIVE SPEECH ASSISTIVE TECHNOLOGIES. 10.
135. Tamburrini, G. (2009). Brain to Computer Communication: Ethical Perspectives on Interaction Models. *Neuroethics*, Vol 2, 137–149.
136. O'Brolchain, F. *et al.* (2014). Brain–Computer Interfaces and User Responsibility. in *Brain-Computer-Interfaces in their ethical, social and cultural contexts.* (eds. Grübler, G. et al.) 163–182. Springer Netherlands.
137. (2017). *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.). OJ L.* Vol 117,
138. European Medical Agency (2018). Medical Devices. *European Medicines Agency*.
139. MHRA Regulating medical devices in the event of a no-deal Brexit. *GOV.UK*.
140. MHRA *Guidance_leaflet_on_Annex_XVI_products_.pdf.*
141. Carter, O. *et al.* (2016). Regulate devices for brain stimulation. *Nature*, Vol 533, 179–179.
142. Maslen, H. *et al.* (2014). The regulation of cognitive enhancement devices: extending the medical model. *J Law Biosci*, Vol 1, 68–93.
143. Best of The Neuroethics Blog: Intervening in the Brain: With What Benefit?
144. Consumer Rights Act 2015.
145. Which? Consumer Rights Act 2015. *Which? Consumer Rights*.
146. Wexler, A. *et al.* (2019). Oversight of direct-to-consumer neurotechnologies. *Science*, Vol 363, 234–235.
147. Grush, L. (2016). Those 'mind-reading' EEG headsets definitely can't read your thoughts. *The Verge*.
148. Maskeliunas, R. *et al.* (2016). Consumer-grade EEG devices: are they usable for control tasks? *PeerJ*, Vol 4, e1746.
149. Thibault, R. T. *et al.* (2017). The psychology of neurofeedback: Clinical intervention even if applied placebo. *American Psychologist*, Vol 72, 679–688.
150. Mishra, J. *et al.* (2016). Video Games for Neuro-Cognitive Optimization. *Neuron*, Vol 90, 214–218.
151. Coates McCall, I. *et al.* (2019). Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies. *Neuron*, Vol 102, 728–731.
152. van Mil, A. *et al.* A public dialogue research programme conducted on behalf of the Royal Society Findings Report. 77.
153. ICO (2019). Guide to the General Data Protection Regulation (GDPR).
154. Rohatgi, J. (2018). GDPR and healthcare: Understanding health data and consent.
155. Rainey, S. *et al.* Brain data regulation | Practical Ethics.
156. Horvitz, E. *et al.* (2015). Data, privacy, and the greater good. *Science*, Vol 349, 253–255.
157. Border, P. (2014). Big Data and Public Health.
158. BBVA What is a regulatory sandbox? | BBVA.

159. Department for Business, Energy & Industrial Strategy *Regulation for the Fourth Industrial Revolution.*
160. MHRA *CEOs_Report_September_2018.pdf.*
161. FDA FDA Draft Guidelines 2019 - Implantable BCIs.
162. Commissioner, O. of the (2019). Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to spur development of innovative devices, including new advancements in novel brain implants, that can help patients with paralysis or amputation gain mobility. *FDA*.
163. Draft Guidance 'Leapfrogs' FDA into Regulation of Brain–Computer Interfaces - Association for the Advancement of Medical Instrumentation.