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A Review of Ethical Considerations in the Clinical Application of Brain-Computer Interfaces

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Abstract. Brain-Computer Interfaces (BCIs) are transforming clinical neuroscience with direct brain device interaction, with unprecedented potential for restoring motor function and neurological rehabilitation. BCIs in clinical practice, however, present challenging ethical issues that need to be critically assessed. This paper addresses the pressing ethical implications associated with the use of BCIs in clinical settings. Key issues include informed consent, particularly for those with cognitive impairments; privacy and data security due to the personal nature of neural data and the potential impact on personal identity and autonomy. Moreover, justice and equitable access to BCI technologies are critical considerations, such as inequalities in availability and affordability. In addition, this paper evaluates existing regulatory frameworks, like the General Data Protection Regulation (GDPR), to determine their effectiveness in addressing these emerging ethical issues. This analysis stresses the necessity of an interdisciplinary cooperation between clinicians, ethicists, engineers, and policymakers for creating successful ethical guidelines and governance mechanisms. By integrating novel research and regulatory advances, this review seeks to inform stakeholders of the ethical issues of BCIs and chart ways toward their responsible translation into clinical practice.

Keywords: Neurotechnology, Brain-computer interfaces, Bioethics, Clinics

1. Introduction

Brain-Computer Interfaces (BCIs) are an emerging neurotechnology that enables humans to communicate with external devices through direct brain signal interaction. It is a neuroscience and biomedical engineering multidisciplinary innovation where the largest proportion is medical. They were originally constructed as assistive devices for motor disorders, but now also encompass therapeutic, rehabilitative, and even entertainment purposes. Such accelerated technological evolution has given rise to a diversity of ethical dilemmas testing well-established bioethical principles like autonomy, beneficence, and justice [1].

BCIs, according to Zhang et al.'s definition, are categorized into invasive, non-invasive, and semi-invasive systems, where invasive BCIs offer greater signal fidelity through direct cortical electrode implantation but at the cost of surgical risk [2]. Non-invasive alternatives like scalp electroencephalography (EEG) and functional near-infrared spectroscopy (fNIRS), though safer and more convenient, are encumbered with lower signal accuracy and susceptibility to noise, which

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means the trade-offs between efficacy and safety in clinical applications [2-4]. Granted, BCIs have consequences that extend beyond the clinic and are present in consumer markets today—the boundary between therapeutic intervention and enhancement is ever more diffuse. Such developments are accompanying urgent ethical concerns of user permission, safety, equity, and data privacy.

This paper aims to critically evaluate the bioethical concerns of the clinical use of BCIs. It looks at how the conventional bioethical principles can be applied to the new technology and identifies the limits of current ethical regulation. Integrating technological background and ethical concern, the review seeks to identify whether current frameworks are sufficient or must evolve to address the unique concerns of BCIs.

2. Progresses of bioethics in BCI

2.1. Key ethical principles

First and foremost, autonomy, or the ability of self-determination, is among the principles of bioethics. Zhang et al. highlight that BCIs add complexity to the traditional notion of autonomy by directly engaging with neural activity [2]. Livanis et al. and Canny et al. note that while BCIs can reinstate autonomy in individuals with impairment, it is doubtful whether BCI-mediated actions constitute cases of autonomous agency. This also highlights the utmost importance of individuals being in control of their mental states and information acquired therein [3, 5].

The principle of non-maleficence compels healthcare practitioners to “not harm”. While many BCIs remain experimental, there is also the possibility of unforeseen side effects, for example, psychological damage or neurological damage. Based on Peksa and Mamchur's team, the ethical impact of invasive techniques such as electrocorticography (ECoG) should be considered while formulating clinical BCIs due to their risk factors of infection and neurological injury [6].

Bioethics justice explains justice in the allocation of healthcare resources and access to healthcare technologies. Access disparities—observable with technologies like deep brain stimulation—will be transplanted onto BCIs due to socioeconomic and educational inequalities, expanding already present health divides [4, 7]. According to Zhang et al., equitable access must be a principle driving BCI development and implementation so that benefits do not accrue to privileged minorities [2].

2.2. Existing legal and ethical frameworks for BCI

The European Union's General Data Protection Regulation (GDPR) offers a legal framework for the safeguarding of personal data, such as sensitive health data. According to Kosal et al., Livanis et al., and Zhang et al., the ethics of BCIs entail thought privacy, particularly with noninvasive neuroimaging that can be abused for surveillance or interrogation. This aligns with the need for strong protection for neural data because neurodata generated by BCI is extremely intimate personal data that needs GDPR-strength protection [2, 5, 8]. Zhang et al. mention the importance of robust privacy protection in BCI usage, for example, in GDPR data minimization and consent requirements. The call in their paper for robust ethical guidelines recognizes the vulnerability of neural data, which, without regulation, would represent unparalleled invasions of cognitive privacy [2]. Therefore, the ability to withdraw consent and remove stored data is critical to preserving user control and barring misuse or commodification of neural data.

Yet, the majority of the existing privacy legislation was not written with neural data in mind, and thus, there is a pressing demand for new laws specifically considering the unique aspects of brain

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data. Institutional Review Boards (IRBs) have a central role in upholding ethical standards. They evaluate the risk-benefit ratio of BCI trials, obtain informed consent from participants, and oversee the interventions' continued safety and effectiveness [9]. However, according to the Chinese Academy of Medical Sciences team of Jin and Zhai, specialized ethical review outside regular IRB processes is required for ensuring ethical control of invasive BCI studies, facilitating dynamic informed consent, proportional risk-benefit analysis, and privacy protection measures in the distinct field of neurology [9].

3. Ethical controversies in clinical BCI use

3.1. Informed consent in vulnerable populations

Neurologically impaired candidates' vulnerability, together with media-generated hype, renders informed consent procedures ineffective, a phenomenon parallel to Kosal et al.'s necessity for iterative explanation and third-party observation to combat such therapeutic misconception. Such is particularly necessary in paediatric or locked-in patients, where surrogate decision-makers and assent procedures must be balanced against hope versus realistic prognostics [4, 8]. Moreover, according to Vansteensel et al. and Livanis et al., the most challenging aspect is to ensure effective communication of risk and benefit to individuals with severe motor impairments, involving repeated cycles of consent and procedures allowing participants to view or withdraw consent at any time, especially during locked-in states [5, 7].

3.2. Identity and personhood

BCIs, particularly with children, can disrupt social identity and self-awareness by masking human and machine agency divides, in alignment with Robb, Kiel-Chisholm, and Sun's thesis. The possibility of stigma or "cyborg" otherness underscores the need for psychosocial support, as well as open design, to preserve users' sense of personhood [4, 5, 10, 11]. Chandler et al. also caution that AI-driven BCIs can introduce uncertainty regarding whether decoded speech reflects user intention, echoing Vansteensel et al.'s concern with agency. This calls for transparency on the behalf of BCI systems, especially in high-stakes applications like legal testimony, where confusion would have catastrophic consequences [7, 12]. This question is especially relevant in legal situations, such as determining responsibility or "thought-reading" in criminal activity [10, 13]. Those concerns serve to highlight the need to treat personal identity with respect and make sure users of BCIs possess a unified sense of self. Ethically informed BCI development would emphasize user experience and feedback, e.g., psychological assessment and ethical consultation, as integral to clinical practice.

3.3. Enhancement or therapy

Kosal et al.'s framework identifies BCIs as paradigmatic dual-use technologies, blurring lines between therapeutic and enhancement applications. Their argument about military-civilian crossover vulnerabilities bolsters the ethical imperative to draw lines, as cognitive enhancement in healthy individuals can be leveraged to exacerbate inequalities or to enable coercive social pressures [8]. There is an ethical distinction between the two applications: the therapeutic applications, in principle, are justified on the basis of beneficence and medical necessity, but not for enhancement when considering equity, societal pressure, and altering human nature [7]. There are opportunities for those who are able to pay to access enhancement BCIs, decode interspecies communication, or enable "digital immortality" [14]. Secondly, Livanis et al. comment that the commercialization of

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BCIs has the potential to alter social norms and stigmatize users, especially with overt use of devices. The observation aligns with the criticism that enhancement normalization will lead to coercive pressures in competitive domains like employment and education [5]. Good standards, therefore, need to respond to such potential harms and promote good innovation that is in alignment with societal values.

3.4. Long-term effects and unknown

Bergeron et al. warn that exponential technology may render pediatric BCI implants obsolete, necessitating repeated surgeries and raising the question of ethical longitudinal risk-benefit ratios. This is akin to Kosal and Zhang et al.'s biocompatibility and exit strategy issues, only with attention to the need for flexible regulatory frameworks to promote device durability and user reliance [2, 4, 8]. Vansteensel et al. highlight the necessity for longitudinal studies to address the dynamic requirements, like disease progression and neural adaptation, so that BCIs can continue to be effective and ethically sound in the long term [7]. Malfunction, obsolescence, or removal of the device must be tackled by researchers, especially where individuals are reliant on the technology for essential functions. Exit strategies following ethical BCI design, where users are able to wean themselves from the technology without loss of quality of life or dignity, are required.

4. Ethical governance and future perspectives

4.1. Integrating ethics into BCI design

Mridha et al. note how more recent technologies like PET have been created in a cycle of ongoing clinical use, demanding "ethics by design." Their focus on tracking real-time brain function underlines the need for prospective ethical frameworks in tandem with technological advances [1]. Designers and engineers must collaborate with ethicists, clinicians, and end-users to define potential harms and incorporate safeguards. For example, to meet the needs of non-maleficence, Canny et al. emphasize the need for longitudinal studies to assess the long-term impacts of Brain Computer Interface-Functional Electrical Stimulation (BCI-FES) Systems, particularly in addressing user adaptation and disease progression [3]. Chandler et al. advocate an inclusive, user-centred design (UCD) approach in BCI development, emphasizing effectiveness, efficiency, and user satisfaction. Their perspective aligns with the trajectory of this paper by prioritizing the integration of ethics from the outset. By involving end-users, particularly individuals with disabilities, in the design process, their approach seeks to address real-world needs and ethical concerns [12].

4.2. International collaboration and policy development

Since the advancement of technology is a global phenomenon, Kosal et al. stress the inadequacy of current global frameworks to address neurotechnology's unique risks, calling for visionary policymaking. Their call for multilateralism is supported in this essay's proposal to enshrine neuro-rights (e.g., cognitive liberty) in UNESCO or WHO, for equitable regulation as BCIs traverse national borders [8]. Standards, if formulated, must address issues of universality, i.e., confidentiality of information, equal access, and safeguarding of human rights. In addition, neuro-rights must be institutionalized in international law to shield people from abuse or exploitation [11]. Policymakers must be nimble and sensitive because the pace at which BCI innovation is happening will create a demand for ongoing ethical and legal renewal.

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4.3. Public engagement and education

Successful and ethical public introduction of BCIs depends not just on expert regulation but on public consultation and education. Misinformation, fear, or overexpectation threatens to erode confidence and preclude responsible adoption. Huang Yongzhen's critical reflection on these informational limitations in BCIs emphasizes public education to prevent falsehood. Public discussion of neural data ownership has the possibility of allowing users to guide BCI adoption without sacrificing control, demystifying BCI technology, offering the pros and cons of the technology, and eliciting a variety of opinions, especially from less heard or marginalized communities [15]. In forming an enlightened public, society can better confront the complex ethics of neurotechnology and chart the future of its own.

5. Conclusion

The clinical use of Brain-Computer Interfaces (BCIs) raises profound ethical issues that must be addressed very seriously. Essential ethical principles—autonomy, non-maleficence, beneficence, and justice—were highlighted in this review, including excessive worries regarding informed consent, identity, privacy of personal data, and access equity. Specific attention has been paid to vulnerable populations, most importantly those with compromised cognitive capacity, whose conventional consent models fail. New prospects such as dynamic consent systems and multilateral ethical oversight, proposed by Jin and Zhai, are more situational. Similarly, dual-use and potential for enhancement have ended therapeutic lines, and more precise lines must now be established in ethics and in law.

Existing regulatory measures, like the GDPR, are a beginning but lack any ability to address neurodata specificity. In addition, Institutional Review Boards may not be optimally equipped to address BCI-specific risks and should be ethical focus-regulated. The report is also making a point on behalf of public engagement, as urged by Huang and others, to fight disinformation and demystify neurotechnology terminology.

However, this review is limited in scope, primarily drawing from sources in the developed world, which introduces a risk of cultural and geographical bias. Methodologically, the review is largely cynical of second-order literature and does not have patient experience or concordance among stakeholders as a result of empirical research. In addition, the dynamic and interdisciplinary nature of BCI ethics involves the risk that much progress has been made since this review's time frame.

Future studies should prioritize empirical research involving BCI users, take into account multicultural ethical perspectives, and explore practical applications of ethical methodologies. Without this integrative approach, ethical innovation may lag behind the rapid technological developments in BCIs.

References

[1] Mridha, M. F. , Das, S. C. , Kabir, M. M. , Lima, A. A. , Islam, M. R. , & Watanobe, Y. (2021). Brain-Computer Interface: Advancement and Challenges. Sensors, 21(17), 5746. https://doi. org/10. 3390/s21175746

[2] Zhang, H. , Jiao, L. , Yang, S. , Li, H. , Jiang, X. , Feng, J. , Zou, S. , Xu, Q. , Gu, J. , Wang, X. , & Wei, B. (2024). Brain-computer interfaces: the innovative key to unlocking neurological conditions. International journal of surgery (London, England), 110(9), 5745–5762. https://doi. org/10. 1097/JS9. 0000000000002022

[3] Canny, E. , Vansteensel, M. J. , van der Salm, S. M. A. , Müller-Putz, G. R. , & Berezutskaya, J. (2023). Boosting brain-computer interfaces with functional electrical stimulation: potential applications in people with locked-in syndrome. Journal of neuroengineering and rehabilitation, 20(1), 157. https://doi. org/10. 1186/s12984-023-01272-y

DOI: 10.54254/2753-8818/2025.AU24432

[4] Bergeron, D. , Iorio-Morin, C. , Bonizzato, M. , et al. (2023). Use of Invasive Brain-Computer Interfaces in Pediatric Neurosurgery: Technical and Ethical Considerations. Journal of Child Neurology, 38(3-4), 223-238. doi:10. 1177/08830738231167736

[5] Livanis, E. , Voultsos, P. , Vadikolias, K. , Pantazakos, P. , & Tsaroucha, A. (2024). Understanding the Ethical Issues of Brain-Computer Interfaces (BCIs): A Blessing or the Beginning of a Dystopian Future?. Cureus, 16(4), e58243. https://doi. org/10. 7759/cureus. 58243

[6] Peksa, J. , & Mamchur, D. (2023). State-of-the-Art on Brain-Computer Interface Technology. Sensors, 23(13), 6001. https://doi. org/10. 3390/s23136001

[7] Vansteensel, M. J. , Klein, E. , van Thiel, G. et al. (2023). Towards clinical application of implantable brain–computer interfaces for people with late-stage ALS: medical and ethical considerations. J Neurol 270, 1323–1336. https://doi. org/10. 1007/s00415-022-11464-6

[8] Kosal, M. , & Putney, J. (2023). Neurotechnology and international security: Predicting commercial and military adoption of brain-computer interfaces (BCIs) in the United States and China. Politics and the Life Sciences, 42(1), 81–103. doi:10. 1017/pls. 2022. 2

[9] Jin, S. R. , & Zhai, X. M. (2025). Ethical considerations in clinical trials of invasive brain-computer interface technology. Medicine and Philosophy, 46(2), 6-11.

[10] Robb, L. , & Kiel-Chisholm, S. (2024). Person, or property? Brain-Computer Interface technology and the law. Alternative Law Journal, 49(1), 19-25. https://doi. org/10. 1177/1037969X241233349

[11] Sun, X. Y. , & Ye, B. (2023). The functional differentiation of brain–computer interfaces (BCIs) and its ethical implications. Humanit Soc Sci Commun 10, 878. https://doi. org/10. 1057/s41599-023-02419-x

[12] Chandler, J. A. , Van der Loos, K. I. , Boehnke, S. , Beaudry, J. S. , Buchman, D. Z. , & Illes, J. (2022). Brain Computer Interfaces and Communication Disabilities: Ethical, Legal, and Social Aspects of Decoding Speech From the Brain. Frontiers in Human Neuroscience, 16, Article 841035. https://doi. org/10. 3389/fnhum. 2022. 841035

[13] Zhang, H. (2025). Protection of personality rights in the development of brain-computer interface technology. Chinese Jurisprudence, (02), 107-126. https://doi. org/10. 14111/j. cnki. zgfx. 2025. 02. 004

[14] Yao, G. (2025). Progress and case studies in the development of brain-computer interfaces. Journal of Nanjing Medical University (Social Science Edition), 25(02), 105-112.

[15] Huang, Y. (2025). Application risks of brain-computer interface technology and its legal regulations. Journal of South China University of Technology (Social Science Edition), 27(01), 24-36. https://doi. org/10. 19366/j. cnki. 1009-055X. 2025. 01. 003