Legal Issues and Countermeasures in Transcranial Magnetic Stimulation Treatment for Mental Disorders from a Neuroscience Perspective (post-print)

Authors: Ren Jing, Li Xiaoyong, Liang Hengyu, Zhao Yifan, Wu Jiaoyue, Xiaoyong Li

Date: 2023-10-07T00:00:00+00:00

Abstract

Against the backdrop of China' s brain research strategy, transcranial magnetic stimulation (TMS) technology, as an input-type brain-computer interface technology, can ameliorate the pathological states of patients with mental disorders through non-invasive approaches. Nevertheless, the novel risks engendered by this emerging technology have been neglected in legislation, with patients' brain neural data presenting privacy leakage risks. Legal issues including physicians' failure to disclose risks of personality changes and the off-label use of TMS devices urgently warrant investigation. This study employs literature research and case analysis methodologies to retrieve and examine multi-disciplinary literature on the balance between the right to health and privacy protection, the principle of informed consent, privacy protection and data utilization, and off-label application of medical devices. By summarizing key points from judicial decisions concerning disputes over off-label TMS device use and informed consent, it is found that legal interpretation and value balancing should be achieved through clarifying the right to health while accommodating privacy protection, reconciling physicians' diagnostic and therapeutic authority with patients' right to informed consent, and balancing medical device accessibility and safety. Furthermore, it is necessary to improve full disclosure of novel risks in new technology applications; specify that physicians and medical institutions should respect patient privacy and fulfill obligations for securing neural data, expand the scope of risk disclosure, clarify the risk of personality changes, prohibit off-scope device usage, and establish mechanisms for risk analysis, dynamic monitoring, and adverse reaction reporting.

Full Text

Legal Issues and Countermeasures of Transcranial Magnetic Stimulation for Mental Disorders from the Perspective of Brain Science

REN Jing[1], **LI Xiaoyong**[1]*, **LIANG Hengyu**[1], **ZHAO Yifan**[2], **WU Jiaoyue**[1]

[1]School of Law, China University of Political Science and Law, Beijing 100088, China

*Corresponding author: LI Xiaoyong, Professor/Doctoral supervisor; E-mail: lixiaoyong@ccmu.edu.cn

Abstract

In the context of China' s brain science research strategy, transcranial magnetic stimulation (TMS), as an input-type brain-computer interface technology, can non-invasively improve the pathological status of patients with mental disorders. However, legislation has overlooked the new risks arising from this emerging technology. There are urgent concerns regarding the risk of privacy leakage from patients' neural data, physicians' failure to inform patients about the risk of personality changes, and the legal issues surrounding off-label use of TMS devices. This study employs literature review and case analysis methods to examine multidisciplinary literature on the trade-off between the right to health and privacy protection, the principle of informed consent, data utilization, and off-label device use. By summarizing key points from judicial decisions on TMS device off-label use and informed consent disputes, we find that legal interpretation and value balancing should be clarified between the right to health and privacy protection, between physicians' diagnostic and treatment rights and patients' informed consent rights, and between device accessibility and safety. Improvements should be made in fully disclosing new risks in emerging technology applications. Physicians and medical institutions should respect patient privacy and fulfill their obligations to ensure neural data security, expand the scope of risk disclosure to specifically include personality change risks, prohibit off-label device use, and establish mechanisms for risk analysis and dynamic monitoring of adverse reactions.

Keywords: Transcranial magnetic stimulation; Therapeutics; Brain-computer interface; Brain privacy; Legal liability; Informed consent; Devices off label use

1. Legal Issues in TMS Treatment of Mental Disorders

Against the backdrop of brain science being designated as a national strategic frontier technology and research direction, the development of neurotechnology

is unstoppable. Correspondingly, risks that were once merely speculative are rapidly becoming reality, yet relevant legislation remains quite limited. In TMS technology applications, the risk of patient brain privacy leakage, physicians' inadequate disclosure of personality change risks, and off-label device application urgently require legislative response and improvement.

1.1 Risk of Patient Brain Privacy Leakage Hippocrates once stated: "Men ought to know that from the brain, and from the brain only, arise our pleasures, joys, laughter and jests, as well as our sorrows, pains, griefs and tears ···And by the same organ we become mad and delirious, and fears and terrors assail us" [4]. TMS technology monitors, filters, and analyzes brain electrical signals in real time, then amplifies and decodes them to extract biologically identifiable information with specific meaning, which is subsequently converted into corresponding signals or instructions to personalize treatment plans by adjusting adaptive thresholds [5]. The neural data obtained through this technology produces electroencephalograms as unique as fingerprints, forming biometric "brainprints" [6]. In 2015, ARMSTRONG et al. [7] recorded brain electrical signals when individuals silently read texts, using computer systems to analyze their different responses. The study demonstrated that collected electrical signals could identify individuals with 94% accuracy, and remarkably, this was achieved using only three electrodes placed on the scalp. Similarly, Chinese research has shown that by collecting neurophysiological signals from mental disorders, it is possible to analyze abnormal cognitive characteristics from early to late clinical stages and identify a series of valuable objective EEG biomarkers [8].

As the carrier of neural data, readable and usable brain information containing an individual' s most intimate and private information can reflect their deepest personality preferences and thought patterns—information closely related to dignity and existential value—constituting what is known as "brain privacy." Since this technology relies on data processing and analysis, patients must bear attendant privacy risks in addition to the health benefits from medical services. Physicians can use neural decoding technology to assign directional meaning to EEG data, enabling them to read patients' physiological states, emotions, and even analyze their intentions, preferences, and tendencies [9]. This activity exposes brain information—the deepest thoughts of the human mind—to machines, placing individuals in a "panopticon" [10]. As *Nineteen Eighty-Four* states: "Nothing was your own except the few cubic centimetres inside your skull." People should be grateful that at least these "few cubic centimetres" remain private. However, brain-computer interface technology can materialize previously elusive, intangible, and inaccessible mental states, making the brain readable and controllable to some extent.

Research shows that by delivering imperceptible direct current stimulation, subjects' reactions are significantly slowed when attempting to lie, enabling high-precision lie detection [11]. This means the brain—the final sanctuary of human

privacy—may ultimately be breached. Patients' brain privacy may also be compromised due to security vulnerabilities in neural data transmission and storage. As technology becomes more widespread, complex hacking programs may emerge, allowing clinical data to be hijacked for marketing purposes or used for malicious intervention, manipulation, or coercion, constituting manipulation of psychological experience [4]. During transmission and storage, patients' neural data is stored locally or on web-based servers or repositories, creating risks of data leakage due to technical failures or mixing multiple patients' data in data pools [12]. When TMS devices are connected to the internet, this issue transforms into a cloud-based cybersecurity threat. Particularly when TMS (electrotherapy) devices are registered abroad or produced by foreign enterprises, vigilance is required regarding cross-border data flow and illegal use to prevent threats to national security. Patients should have the right to be informed about and decide on the use of their data during diagnosis and treatment, and their neural data should not be illegally provided to others without consent. Otherwise, this would not only create a crisis of data leakage but also cause secondary psychological distress to patients, violating the original intention of promoting patient welfare.

1.2 Inadequate Physician Disclosure of Personality Change Risks from TMS TMS technology is a powerful emerging neuroregulation technique that directly stimulates the brain to alter neural excitability and modulate neurotransmitters, potentially producing fundamental and irreversible effects on patients' brain function. As the highest-level neural center, the brain physiologically governs human emotions, personality, and even affections. A study tracking the prognosis of patients receiving input-type brain-computer interface technology treatment confirmed that personality changes can indeed result from treatment. Among 27 treated patients, 21 exhibited emotional shifts, including both more positive attitudes compared to pre-surgery and the emergence of indifference or anxiety [13].

In practice, although TMS technology is treated as a special therapy, disclosure obligations are only considered from the physical dimension, thereby ignoring the risk of emotional or personality changes the technology may cause [14]. Specifically, during diagnosis and treatment, physicians only inform patients about absolute contraindications and some common adverse reactions. TMS absolute contraindications require ensuring the exclusion of magnetic metals implanted near the head or in the brain, and confirming patients' history of traumatic brain injury or other organic brain diseases and seizures before treatment. Common adverse reactions include headaches and head discomfort that can resolve spontaneously, but the risk of personality change is completely omitted. To some extent, "consent" has become a risk-avoidance tool in the face of new technology. Generally, physicians can exempt themselves from legal liability for corresponding risks simply by obtaining a signed "informed consent form." This "blanket consent" approach effectively forces patients to grant broad authorization, directly blocking their access to treatment if they refuse, which

in practice deprives patients of their autonomy. Patients' consent to personality changes cannot be presumed based on the establishment of a medical contract and therefore cannot absolve physicians of fault liability for failing to obtain patient consent.

1.3 Risks of Off-Label Device Application in TMS Treatment for Mental Disorders China' s National Medical Products Administration has only approved the "transcranial magnetic stimulation (electrotherapy) device" for use as adjunctive therapy and research in ischemic cerebrovascular disease, neurological disorders, limb dysfunction in stroke patients, and insomnia. However, the disease spectrum treated by TMS technology is expanding [15]. In practice, for mental disorders such as schizophrenia where drug efficacy is poor or ineffective, physicians attempt to improve therapeutic outcomes through off-label clinical recommended treatments combined with non-pharmacological interventions. Yet, due to the lack of high-quality evidence-based medical evidence, the effectiveness and safety of such treatments remain to be verified.

Off-label medical device use refers to use that exceeds the "product scope of application" registered for the medical device, which defines the device' s indications, applicable population, and usage settings [16]. China regulates TMS devices through a Class II medical device filing model, including domestic and imported devices. Article 48 of the *Regulations on Supervision and Administration of Medical Devices*, Article 16 of the *Measures for Quality Management of Medical Device Use*, and Article 33 of the *Measures for Clinical Use of Medical Devices* all stipulate that "medical device users shall use medical devices in accordance with the instructions," without establishing any exemption clauses. In addition to its intended regulatory effects, TMS may trigger very minor side effects (SE), adverse events (AE), and serious adverse events (SAE) [3]. Once off-label use causes harm to patients, physicians and medical institutions will inevitably face litigation. As in the case of Yang v. Chongqing Beida Yangguang Hospital, the medical institution violated medical device usage instructions by using adult devices on children and exceeding the time requirements specified in the instructions for prolonged TMS treatment. Although multiple appraisal institutions could not accurately determine the causal relationship between the harm and off-label device use, the court ultimately determined that Beida Yangguang Hospital was indeed at fault in its use of the TMS treatment device and concluded that it should "bear corresponding tort liability" [17].

2. Value Foundations for Legal Responses to Clinical Application of TMS Technology

Neuroscience not only challenges assumptions about the brain' s position in the natural world but also urges people to reconsider its role in the normative world. The principle of balancing the right to health with privacy protection establishes the fundamental content and value orientation of TMS technology application. Under the framework of informed consent principles and the trade-off between

accessibility and safety of off-label device use, the primary issue becomes how to balance the tension between new medical technologies and legislative lag, and to clarify the discourse logic between regulation and development.

2.1 Promoting Balance Between Right to Health and Privacy Protection The right to health has rich connotations, with its structural framework referring to "the right of natural persons to maintain normal bodily functions and protect health interests according to law, which shall not be infringed upon by any organization or individual." The right to health also includes equal access to optimal health systems and access to essential medicines [18]. Most mental disorders are characterized by high prevalence and recurrence rates, with complex etiology and pathogenesis that remain incompletely understood [19]. Consequently, corresponding treatment measures often require lifelong medication to control conditions. TMS technology, when used in conjunction with drug therapy, is undoubtedly an effective means to enhance patient health and well-being and alleviate pathological symptoms. When physicians conduct medical service activities, patients delegate certain rights based on the medical service contract, making neural data collection, decoding, and analysis for condition assessment unavoidable. In this sense, patient consent to physicians' diagnostic and treatment actions is essentially a voluntary authorization regarding privacy rights intervention, granting physicians legitimate access to patients' neural data and brain information. However, due to potential cognitive impairment, mental disorder patients' personality rights are more vulnerable to violation. The secretive, non-public, and private nature of privacy rights means they are inherently related to the most vulnerable and sensitive core of human dignity. Based on this characteristic, physicians should provide timely treatment while simultaneously protecting patient privacy rights, including not only physical and informational privacy but also brain privacy.

2.2 Balancing Physicians' Diagnostic and Treatment Rights with Patients' Informed Consent Rights Article 22 of the *Physicians Law* establishes physicians' independent diagnostic and treatment rights, enabling them to conduct medical examinations and treatments within their practice scope according to standards and to select reasonable medical and preventive plans. Physicians' fulfillment of full disclosure obligations is a necessary condition for truly realizing patient self-determination. Patient autonomy is not merely a single right to autonomous decision-making but a collection of specific rights, centrally manifested in active participation in medical decision-making aimed at protecting patients' best interests [20]. Assuming a medical institution fails to fulfill the disclosure obligation regarding "personality change risk" before TMS treatment, and post-treatment personality changes cause patients to lose enthusiasm for life, courts will face interpretive dilemmas in legal selection and application if patients seek legal remedy. At the normative level, based on patient autonomy, physicians should fully disclose all significant risks that would affect a reasonable patient' s judgment, treating patients as the subjects of

information assessment—that is, various risks that a reasonable person in the patient' s position might value under specific circumstances [21]. Only when patients make decisions with access to all important information is their consent valid. In such cases, physicians' disclosure obligations should be determined by patient rights rather than medical convention [22]. As a special treatment modality, TMS requires physicians to explain medical risks and alternative options to patients according to Article 1219 of the *Civil Code*. During diagnosis and treatment, physicians must propose personalized treatment plans and provide full, detailed explanations of risks and alternative treatments. Whether to accept treatment or which treatment plan to choose should be decided by the patient themselves. Regarding medical risks, particular attention should be paid to enhancing disclosure of unknown safety risks to reach consensus with patients. To improve disclosure effectiveness, physicians should use understandable expressions, communicate patiently with patients, answer their questions, and help them fully comprehend the disclosed information.

2.3 Promoting Balance Between Accessibility and Safety of Off-Label Device Use A major purpose of off-label medical device use is to promote accessibility of medical resources. The requirement for medical device accessibility is essential to achieving the United Nations"2030 Sustainable Development Goals" of promoting "health and well-being for all ages" [23]. However, WHO notes that global medical device accessibility is poor [24]. WHO' s 2025 global non-communicable disease targets include achieving 80% availability of affordable basic technologies and essential medicines [25]. In special circumstances, applying off-label TMS technology based on evidence-based medical evidence helps promote the accessibility of medical devices and technology. However, the issue of TMS technology continuously introducing new stimulation modes cannot be ignored, as safety data for these new modes are very limited and standardized protocols have not been established. How to regulate potential risks while maximizing safety on the basis of promoting accessibility urgently requires legal and technical standard responses.

Off-label device application is essentially an exploratory treatment lacking sufficient evidence-based medical evidence and accompanied by high risks. While ensuring device accessibility for patients under special circumstances, necessary regulation of this exploratory treatment is required from the perspectives of applicable conditions and evidence standards.

3. Recommendations for Addressing Legal Issues in Clinical Application of TMS Technology

The governance of emerging brain sciences requires, on the one hand, that "upstream" design elements such as legal principles have guiding functions to promote deeper integration of law and medical ethics in technology application processes, ensuring consideration of not only the instrumental value of risk-benefit ratios but also the underlying legal foundations and medical ethics. On the other

hand, the formulation of specific application issues also demands "downstream" legal regulation of technology-related behaviors and corresponding countermeasures to promote continuous dialogue between technology' s instrumental value and social value systems.

3.1 Strengthening Security Obligations of Medical Institutions Regarding Brain Privacy Based on the principle of balancing privacy protection with the right to health, physicians, medical institutions, and even device manufacturers should fully respect patient privacy. Thought reading or so-called "brain reading" through neural signal monitoring is gradually making privacy in the human mind transparent [25], particularly by detecting psychological responses to visual and other stimuli that individuals are exposed to—some of which are automatic, unconscious, uncontrollable, and directly reflect an individual' s irreplaceable physical essence [26]. Identifiable neural data is often essential to ensure recording integrity and accuracy, but for clinical research and treatment purposes, neural data is difficult to truly anonymize. Even when "anonymized," the high-precision individual identification characteristics of new technology persist, creating data protection challenges for medical institutions during data processing.

At the physical level, patients have the right to physical access and control over privacy information generated by their brains; at the psychological level, they have the right to oppose any involuntary brain privacy intervention. TMS devices can collect brain neural data without physical contact with patients. Due to their unique biometric characteristics and reflection of an individual' s unique personality profile regarding emotions and cognition, this information exceeds the protection limits of traditional personal information and cannot be illegally collected, decoded, analyzed, or disseminated by others. The possibilities opened by neurotechnology development and its application in all aspects of human life will force people to reconsider certain rights. Law must establish "normative boundaries" around privacy because "neurotechnology promises to enable people to transcend natural boundaries (the skull) and regulate the internal workings of thought."

As the primary data processing entity for brain neural data, medical institutions should address security vulnerabilities in software and hardware during data processing and establish full-process data security management systems. First, medical institutions should sign confidentiality agreements with neural device manufacturers and establish assessment mechanisms for neural data processing and cross-border flow based on the cybersecurity multi-level protection system, providing data traceability and accountability support to prevent security threats to domestic and cross-border data. Second, medical institutions should implement encryption and authentication operations during data transmission, develop data access control plans, establish verification security questions between data senders and recipients, reject malicious access requests, and provide feedback on permitted information streams filtered by threat detection

software to improve data access security [27]. Additionally, patients should have the right to be forgotten regarding their neural data, with the right to request deletion of neural data and exit neural databases when certain conditions are met, completing data erasure operations.

3.2 Expanding Risk Disclosure Scope and Fully Informing About Personality Change Risks The multiple and uncertain risks of TMS technology treatment require expanded risk disclosure. The cutting-edge and complex nature of TMS technology creates an even greater information gap between physicians and patients. Physicians should abandon "blanket" overview consent and instead provide itemized disclosure of different types of medical risks required for specific purposes, fulfilling disclosure obligations as fully as possible and obtaining patients' explicit separate consent to maximize protection of patient self-determination. Risk disclosure scope should include three aspects: first, disclosure of all neural data processing stages, including the time span for collecting and decoding patients' brain privacy and risks of potential data leakage; second, disclosure of TMS risks of personality changes, including possible emotional or personality alterations; and third, if off-label medical device use is involved, clear disclosure of potential safety risks and uncertain factors in application.

Furthermore, while mental disorders may affect patients' cognitive abilities, this is not an "all-or-nothing" relationship and does not necessarily lead to complete loss of cognitive capacity. When patients retain the capacity to understand treatment plans, physicians should maximize explanations and assist patients in independently understanding and making medical decisions that serve their best interests. Only when cognitive capacity is completely lost should guardians have limited rights to make substitute decisions for patients.

After determining the scope of risk disclosure, the importance of disclosure depth must be emphasized. Since most clinical recipients of this technology suffer from diseases like epilepsy, depression, and anxiety that may impair cognitive function, their cognitive capacity and comprehension during disclosure are already compromised, further testing physicians' communication abilities. In clinical TMS application, physicians should enhance disclosure depth, including three main aspects: first, diagnostic and basic condition assessment results; second, basic treatment information, including treatment procedures, postoperative efficacy, treatment success rates, disease prognosis, alternative treatment plans, and whether the application is off-label; third, medical risks, including complications and adverse reactions, particularly data leakage and personality change risks.

3.3 Standardizing Treatment Processes and Prohibiting Off-Label Application of TMS Technology Off-label application of TMS technology still presents real-world risks. On one hand, due to neural plasticity, long-term, multi-session stimulation may cause the central nervous system to undergo po-

tentially harmful adaptive changes to accommodate the machine, leading to serious consequences [28]. On the other hand, insufficient encryption protection and prudent regulation of brain-computer interface hardware devices mean that internet-connected neural devices provide opportunities for individuals or organizations to track or even manipulate personal psychological experiences—so-called "brainjacking"—such as maliciously altering regulatory thresholds and parameters, expanding subjects' mental and psychological impacts, potentially causing emotional changes, depression, or even suicidal intentions. In view of this, off-label use of TMS devices should be strictly prohibited to protect patients' neural activities from harmful manipulation through technology abuse. When involving experimental treatments such as clinical trials and other medical research, the "off-label device use" requirement cannot provide exemption. Such research must strictly comply with medical ethics norms, undergo ethical review according to law, and obtain written informed consent.

First, the regulatory level for non-invasive brain-computer interface devices should be elevated. In the *Medical Device Classification Catalogue*, implantable brain-computer interface devices are primarily managed as Class III (higher risk) devices. The risk level of non-invasive brain-computer interface devices is determined by measuring intended use or degree of invasiveness. Based on the aforementioned risks, brain-computer interface devices involving brain stimulation and influence should all be regulated as Class III devices, strengthening supervision of device safety, effectiveness, and registrants' quality management capabilities to ensure device safety.

Second, a risk analysis management system and dynamic monitoring mechanism for adverse reaction reporting should be established. In 2014, the International Federation of Clinical Neurophysiology (IFCN) published *Evidence-Based Guidelines on the Therapeutic Use of TMS*, indicating that TMS technology can be widely applied in various neuropsychiatric disorders. Whenever TMS devices or usage methods change, including hardware and software configurations or patient population changes, resulting in potential new risks, risk analysis is required. Even if risk analysis indicates unchanged or low risk, caution should still be exercised when operating new methods. For example, children, adolescents, and pregnant women are special populations requiring safe and effective alternative antidepressant treatments. The lack of systematic reporting of TMS-related adverse reactions and accurate data leads to insufficient information on risk-benefit ratios during technology application [29]. Therefore, standardized reporting models for SE, AE, and SAE should be established to assess any events during treatment that may affect TMS safety or efficacy, such as local pain, mental state changes, and seizures at different severity levels.

References

[1] LEBEDEV M A, NICOLELIS M A. Brain-machine interfaces: from basic

science to neuroprostheses and neurorehabilitation[J]. Physiol Rev, 2017, 97(2): 767-837. DOI: 10.1152/physrev.00027.2016.

[2] RAO R P N. Introduction to Brain-Computer Interfaces[M]. Translated by ZHANG L, CHEN M Y. Beijing: China Machine Press, 2016: 23-25.

[3] GIUSTINIANI A, VALLESI A, OLIVERI M, et al. A questionnaire to collect unintended effects of transcranial magnetic stimulation: a consensus based approach[J]. Clin Neurophysiol, 2022, 141: 101-108. DOI: 10.1016/j.clinph.2022.06.008.

[4] BREITENFELD T, JURASIC M J, BREITENFELD D. Hippocrates: the forefather of neurology[J]. Neurol Sci, 2014, 35(9): 1349-1352. DOI: 10.1007/s10072-014-1869-3.

[5] XU W Q, CHEN L, SUI X F, et al. Brain-computer interface—brain information reading and brain activity regulation technology[J]. Chin Sci Bull, 2023, 68(8): 927-943.

[6] ZHANG M. Legal concept construction of brain privacy: path, characteristics and contributions[J]. Oriental Law, 2022(5): 60-73. DOI: 10.19404/j.cnki.dffx.20220824.004.

[7] ARMSTRONG B C, RUIZ-BLONDET M V, KHALIFIAN N, et al. Brainprint: assessing the uniqueness, collectability, and permanence of a novel method for ERP biometrics[J]. Neurocomputing, 2015, 167: 242-251. DOI: 10.1016/j.neucom.2015.04.025.

[8] TANG X R, WANG X G, CHEN T L, et al. Evidence-based neurophysiological evidence for mental disorders[J]. Prog Biochem Biophys, 2021, 48(10): 1157-1176. DOI: 10.16476/j.pibb.2020.0399.

[9] FOLGIERI R. Brain computer interface and transcranial magnetic stimulation in legal practice and regulations[M]//D' ALOIA A, ERRIGO M C. Neuroscience and Law. Cham: Springer, 2020: 273-290. DOI: 10.1007/978-3-030-38840-9_{14}.

[10] XIAO F. Ethical challenges and principles of brain-computer interface technology[J]. Acad J Zhongzhou, 2022(7): 95-102. DOI: 10.3969/j.issn.1003-0751.2022.07.014.

[11] BONACI T, HERRON J, MATLACK C, et al. Securing the exocortex: a twenty-first century cybernetics challenge[C]//Norbert Wiener in the 21st Century. IEEE, 2014. DOI: 10.1109/NORBERT.2014.6893912.

[12] WU J Y, ZHANG B Y, REN J, et al. Legal regulation of input-type brain-computer interface technology in clinical application[J]. Med Philos, 2023, 44(4): 62-66. DOI: 10.12014/j.issn.1002-0772.2023.04.13.

[13] LEWIS C J, MAIER F, HORSTKÖTTER N, et al. Subjectively perceived personality and mood changes associated with subthalamic stimulation in pa-

tients with Parkinson' s disease[J]. Psychol Med, 2015, 45(3): 493-502. DOI: 10.1017/S0033291714001081.

[14] Chongqing No. 1 Intermediate People' s Court. Second-instance civil judgment on medical malpractice liability dispute between Yang Xiaohang and Chongqing Beida Yangguang Hospital Co., Ltd. (2021) Yu 01 Min Zhong 9237[EB/OL]. (2021-02-22)[2023-03-18]. https://wenshu.court.gov.cn/website/wenshu/181107ANFZ0BXSK4/

[15] XU Y, LI D, TAN L W, et al. Expert consensus on repetitive transcranial magnetic stimulation therapy[J]. Transl Med J, 2018, 7(1): 4-9.

[16] YIN X F, YANG B, ZHANG H H. Control strategies for off-label use of medical devices[J]. China Med Devices, 2016, 31(5): 142-143, 148. DOI: 10.3969/j.issn.1674-1633.2016.05.042.

[17] Chongqing No. 1 Intermediate People' s Court. Second-instance civil judgment on medical malpractice liability dispute between Yang and Chongqing Beida Yangguang Hospital. (2017) Yu 01 Min Zhong 2178[EB/OL]. (2017-09-30)[2023-03-18]. https://wenshu.court.gov.cn/website/wenshu/181107ANFZ0BXSK4/index.html?docId=XpN

[18] WANG C G. The Cornerstone of Health Rule of Law: The Origin, Theory and System of the Right to Health[M]. Beijing: Peking University Press, 2020: 12-14.

[19] YAO J, YANG Y T, AI Q D, et al. Research progress on neurotransmitter function and depression pathogenesis[J]. Chin Pharmacol Bull, 2023, 39(7): 1217-1221. DOI: 10.12356/CPB202204076.

[20] LIU J K. Patient autonomy, dignified death and the best interest principle[J]. Chin Foreign Law, 2022, 34(4): 904-923. DOI: 10.3969/j.issn.1002-4875.2022.04.005.

[21] CHAUHAN R S, CHAUHAN S P. Montgomery v Lanarkshire Health Board: a paradigm shift[J]. BJOG, 2017, 124(8): 1152. DOI: 10.1111/1471-0528.14501.

[22] CHEN H. Ethical Interpretation and Legal Construction of Informed Consent[M]. Beijing: People' s Publishing House, 2019.

[23] LI H L, XU P P, ZENG L N, et al. Health technology assessment: an important tool for scientific regulation of medical devices[J]. Chin J Evid Based Med, 2021, 21(1): 2-7.

[24] World Health Organization. Access to medical devices for Universal Health Coverage and achievement of SDGs, 2017[EB/OL]. [2023-02-06]. https://www.who.int/medical_{devices}/October_{{{2017}}{{*Medical*}}}{{{Devices}}_{{English}}}.pdf?u

[25] GU X Y, CHEN S F. Research on ethical issues of brain-computer interfaces[J]. Stud Philos Sci Technol, 2021, 38(4): 79-85.

[26] RAN K P. On personal biometric information and its legal protection[J]. Soc Sci J, 2020(6): 111-120.

[27] ZHAO J X, YUE X H, FENG C P, et al. Overview of data privacy security based on General Data Protection Regulation[J]. J Comput Res Dev, 2022, 59(10): 2130-2163. DOI: 10.7544/issn1000-1239.20220800.

[28] JENS C, NEIL L. Handbook of Neuroethics[M]. Dordrecht: Springer, 2015.

[29] MCCLINTOCK S M, RETI I M, CARPENTER L L, et al. Consensus recommendations for the clinical application of repetitive transcranial magnetic stimulation (rTMS) in the treatment of depression[J]. J Clin Psychiatry, 2018, 79(1): 16cs10905. DOI: 10.4088/JCP.16cs10905.

Author Contributions: REN Jing and LI Xiaoyong conceived the research, designed the study, and developed the article structure. REN Jing and LIANG Hengyu conducted literature retrieval and organization and drafted the manuscript. LI Xiaoyong, LIANG Hengyu, ZHAO Yifan, and WU Jiaoyue provided suggestions and ideas for revision. REN Jing and LI Xiaoyong revised the manuscript. LI Xiaoyong was responsible for quality control and review, overall responsibility for the article, and supervision.

Conflict of Interest Statement: The authors declare no conflict of interest.

Received: 2023-07-23
Revised: 2023-09-12
Edited by: MAO Yamin

Note: Figure translations are in progress. See original paper for figures.