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LEGAL REGULATION OF CROSS-BORDER FLOW OF HEALTH AND MEDICAL DATA: A SYSTEMATIC LITERATURE REVIEW

Abstract. This article is a systematic literature review on the legal regulation of cross-border flow of health and medical data. Primarily employing a systematic literature review approach, this study systematically identifies, screens, and comprehensively analyzes relevant academic literature in this field. Based on a comprehensive review of representative research findings, this study summarizes the main viewpoints, research context, and development trends of existing research. Furthermore, this study conducts a targeted analysis of the literature focusing on core issues such as the legal definition and attributes of health and medical data, the connotation and impact of cross-border data flow, and the legal regulation of cross-border flow of health and medical data. This analysis reveals that while current scholarship has established foundational frameworks for defining health and medical data, identifying core regulatory tensions, and addressing related issues, it remains fragmented along jurisdictional lines and predominantly focused on static institutional comparisons rather than dynamic implementation challenges. Building upon this foundation, this study comprehensively reviews the main viewpoints, existing controversies, and shortcomings of existing research, thereby revealing current research gaps and future development directions and highlighting the important theoretical value and practical significance of research on the legal regulation of cross-border flow of health and medical data in the current context.

Key words: literature review, health and medical data, cross-border data flow, legal regulation, data security, data freedom, international cooperation.

Introduction

In recent years, with the rapid development of the digital economy, artificial intelligence, and global data governance frameworks, “health and medical data” (the terms “health and medical data”, “health data”, “medical data”, and “healthcare big data” are used interchangeably in parts of the existing literature. Unless otherwise specified, this article will use the term “health and medical data” throughout) have increasingly become a fundamental strategic resource for nations and a critical element in global digital competition [1]. Compared to general data, health and medical data possess multiple sensitive characteristics – including strong personality rights attributes, public interest implications, and

economic value [2][3][4]. These data not only concern individuals' health, privacy, dignity, and personal interests but also directly impact national public health governance capabilities, medical innovation capacity, and digital economy competitiveness. However, the global utilization of health and medical data necessitates cross-border flow, which represent an inevitable outcome of globalization in the digital era [5]. Particularly amid advancements in AI-assisted diagnostics, big data analytics, telemedicine, and international collaborative medical research, “cross-border data flow” (the terms “cross-border data flow” and “transborder data flow” are used interchangeably in parts of the existing literature. Unless otherwise specified, this article will use the term “cross-border data flow” throughout) has exhibited nonlinear growth. On one hand,

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international medical research, pharmaceutical and medical device development, disease prediction and control, as well as AI training models all rely heavily on vast, diverse, and geographically distributed health and medical data resources. For instance, during the COVID-19 pandemic, international collaboration on data sharing regarding virus transmission, vaccine development, and epidemic forecasting vividly demonstrated the critical importance of cross-border flow of health and medical data for global public health governance [6]. Conversely, given the high sensitivity of health and medical data, its cross-border transfer may give rise to a range of issues including personal privacy breaches, data misuse, algorithmic discrimination, national security risks, and conflicts over data sovereignty [7][8][9]. Consequently, legal regulation of cross-border flow of health and medical data has increasingly become a central issue within the international data governance framework.

Research on the legal regulation of cross-border flow of health and medical data encompasses numerous interconnected issues, including the legal definition and attributes of such data, the conceptual delineation of cross-border data flow, and corresponding regulatory frameworks – all of which represent current research focal points.

Materials and Methods

This study employs a research methodology that combines a systematic literature review with comparative legal analysis. First, through a systematic literature review, relevant academic publications on the legal regulation of cross-border flow of health and medical data are identified, screened, and synthesized to provide a comprehensive overview of existing scholarship. Second, a comparative legal analysis is conducted to examine the regulatory frameworks adopted by major jurisdictions, including the United States, the European Union, and China, highlighting their similarities, differences, and underlying regulatory rationales. Third, the collected

literature is critically analyzed to identify the principal legal issues, theoretical debates, and emerging trends concerning cross-border health and medical data governance. Finally, based on the findings of the literature review and comparative analysis, this study evaluates current regulatory approaches and proposes directions for future legal research and policy development. Data sources include relevant international legal instruments, health and medical data legislation of major jurisdictions, publicly accessible journal articles, books, and official policy documents.

Results and Discussion

1. Research on the Legal Definition of Health and Medical Data

The most authoritative definition of health and medical data in the United States derives from the “Health Insurance Portability and Accountability Act” (HIPAA). According to Section 160.103 of the “HIPAA Privacy Rule”¹: “Protected health information” means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. The European Union's definition of health and medical data is primarily set forth in the “European Health Data Space Regulation”²(EHDS). According to Article 2 of EHDS: “Electronic health data” means data concerning health and genetic data processed in electronic form, as well as non-personal electronic data that were originally collected in relation to natural persons for the provision of healthcare services, public health, research, innovation, policy-making, statistics or regulatory activities.

The legal definition of health and medical data in China is primarily reflected in two major aspects.

Firstly, there exists a terminological dilemma at the legal level. In 2018, the “Administrative Measures on Standards, Security and Services of National Healthcare Big Data (for Trial Implementation)”³ issued by the National

¹ Health Insurance Portability and Accountability Act (HIPAA Privacy Rule), Section 160.103, Definitions. URL: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160?toc=1> (accessed: 09.03.2026).

² European Health Data Space Regulation, Article 2, Definitions. URL: <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng> (accessed: 09.03.2026).

³ Administrative Measures on Standards, Security and Services of National Healthcare Big Data (for Trial Implementation), Article 4, Definition. URL: <https://www.pkulaw.com/chl/7b14867195b5b4e6bdfb.html> (accessed: 09.03.2026).



Health Commission of the People's Republic of China defined “healthcare big data” in Article 4 as “data related to healthcare generated during processes such as disease prevention, treatment, and health management”. However, this definition only describes the generation scenarios and source domains of health and medical data from a macro perspective, without addressing its specific content composition or boundary scope. Subsequently, although Article 49 of the “Basic Healthcare and Health Promotion Law of the People's Republic of China”⁴ enacted in 2020 mentioned terms such as “health and medical big data” or “health and medical data”, these were only briefly referenced without further legal definition. It was not until the implementation of China's national standard the “Information Security Technology – Guide for Health Data Security”⁵ (GB/T 39725-2020) in 2021 that a relatively clear definition was provided. This standard first defines “personal health data” as “electronic data that, alone or in combination with other information, can identify a specific natural person or reflect their physiological or mental health status”. Furthermore, it specifies: “Health data includes both personal health data and health-related electronic data derived from the processing of personal health data”. While this definition possesses certain normative and legal significance, it fails to adequately address key dimensions such as data sources, application scenarios, and lifecycle [10]. Moreover, although the “Personal Information Protection Law of the People's Republic of China”⁶ does not explicitly use or define the concept of “health and medical data”, it nonetheless includes “medical and health information” within the scope of protected sensitive personal information. Thus, the concept of health and medical data exhibits dual discrepancies in both terminology and substantive meaning within the current regulatory framework (see table 1).

⁴ Basic Healthcare and Health Promotion Law of the People's Republic of China, Article 49. URL: https://www.pkulaw.com/en_chl/22a006a09f3565e4bdfb.html (accessed: 09.03.2026).

⁵ Information security technology—Guide for health data security, Article 3, Definitions. URL:

Table 1. Comparison of Legal Definitions of Health and Medical Data in the United States, the European Union, and China

Jurisdiction	Legal Basis	Definition of Health and Medical Data
United States	Health Insurance Portability and Accountability Act (HIPAA Privacy Rule) Section 160.103	“Protected health information” means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.
European Union	European Health Data Space Regulation Article 2	“Electronic health data” means data concerning health and genetic data processed in electronic form, as well as non-personal electronic data that were originally collected in relation to natural persons for the provision of healthcare services, public health, research, innovation, policy-making, statistics or regulatory activities.
China	Information security technology – Guide for health data security (GB/T 39725 – 2020) Article 3.2	“Health data” includes personal health data and health-related electronic data formed by processing personal health data. Personal health data refers to electronic data that, alone or in combination with other information, can identify a specific natural person or reflect the physical or mental health of a specific natural person.

Note: The table is self-created by the author

Secondly, there exists conceptual differentiation at the academic level. The discussion of the concept of health and medical data in China's academic circles primarily focuses on distinguishing between “data” and “information”. Chen and Lv traced the evolution of this relationship, noting that there has long been a consensus in academia that “data is form,

<https://openstd.samr.gov.cn/bzgk/std/newGbInfo?hcno=239351905E7B62A7DF537856738247CE> (accessed: 10.03.2026).

⁶ Personal Information Protection Law of the People's Republic of China, Article 28. URL: https://www.pkulaw.com/en_chl/d653ed619d0961c0bdfb.html (accessed: 10.03.2026).



while information is content”, meaning that information and data describe the same object from the perspectives of content and form, respectively. They also attempted to provide a precise definition of health and medical data as “information generated during the provision of medical services, recorded electronically, related to identified or identifiable data subjects, and capable of directly or indirectly revealing their physical and mental health status” [10]. Wu adopted a broader perspective, encompassing all aspects of health and medical research and agreeing with the definitional scope outlined in the “GB/T 39725-2020” [11]. Scholars such as Deng and Liu, Hu et al., and Chen similarly argue that the scope of health and medical data is extensive, including but not limited to medical data generated during diagnosis and treatment processes [12][13][14].

2. Research on the Legal Attributes of Health and Medical Data

Research on the legal nature of health and medical data can be traced back to the fields of patient privacy protection and medical ethics. As early as the 1890s, Brandeis and Warren emphasized in their article “The Right to Privacy”: “With political, economic, and social changes, law must evolve and create new rights – the right to be left alone, i.e., the right to privacy” [15]. Since the mid-20th century, advancements in technologies such as electronic information have led to a renewed interpretation of the right to privacy, specifically the right to protect personal data (privacy) within information and communication technologies [16]. Concurrently, academic discourse has progressively incorporated “medical data” into the framework of personal data protection. Within the European Union legal context, health and medical data are generally classified as one of the “special categories of personal data”. Since the “Convention on the Protection of Individuals with regard to Automatic Processing of Personal Data”⁷, adopted by the Council of Europe in 1981 (also known as Convention 108), which classified personal health data under “special categories of data” in Article 6, and up to the “General Data Protection Regulation”⁸ (GDPR) formally implemented in 2018, which explicitly

categorizes personal health data as a special category of personal data in Article 9 – where processing is generally prohibited except in specific circumstances such as public health or scientific research – personal health data should therefore receive heightened protection compared to general personal information.

Health and medical data not only embodies personal interests related to dignity and health, but also exhibits long-term identifiability – particularly genetic data, biological samples, and electronic medical records – which, if improperly disclosed, could cause irreversible harm to individuals [17][18]. In response, Adebayo et al. advocated adopting a human rights-based approach to managing health and medical data in digital public health [19]. Additionally, scholars have increasingly examined the property rights aspects and data entitlements associated with health and medical data [20][21][22], while recognizing the substantial economic value of such data in artificial intelligence training and precision medicine. Although Roach et al. did not explicitly employ civil law terms like “personality rights” or “property rights”, their study clearly delineated the dual legal attributes of health and medical data. Regarding property attributes, it stipulates that the physical carriers of medical records (data) belong to healthcare institutions, while patients hold legal interests in the information contained therein; HIPAA further grants patients control over such information. In terms of personality rights, it emphasizes that health and medical data are protected by constitutional privacy rights, as they pertain to personal dignity and autonomous decision-making, and unauthorized disclosure constitutes a privacy infringement [23]. In summary, concerning control over health and medical data, its utilization benefits, and data sharing mechanisms, the academic community has gradually developed a research approach that concurrently addresses both “personality rights protection” and “data value utilization”.

In current research on the legal attributes of health and medical data within China's academic community, three representative viewpoints have primarily emerged.

⁷ Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, Article 6. URL: <https://rm.coe.int/1680078b37> (accessed: 10.03.2026).

⁸ General Data Protection Regulation, Article 9. URL: <https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng> (accessed: 10.03.2026).



Firstly, the personality rights attribute theory. This theory emphasizes the close connection between health and medical data and personal dignity as well as privacy, advocating protection centered on the right to privacy or autonomous control over personal information. For example, patients enjoy the rights to freely dispose of, control, and prevent unauthorized access to their health and medical data [24]. Wei argues that the protection of personal information in medical practices under big data technologies should return to a normative approach oriented toward the protection of privacy rights [25]. Guo, from a legal perspective, contends that health and medical data possess greater privacy value compared to other types of data, and this privacy value essentially falls within the scope of extended protection of personality rights [26].

Secondly, the property interest attribute theory. This theory does not deny the personality rights nature of health and medical data but acknowledges its role as a production factor, emphasizing the recognition of data handlers' property interests to incentivize the exploitation of data value. Li, from a practical perspective on data assetization, argued for the property rights attributes of health and medical data based on the principle of “who invests, who contributes, who benefits” outlined in the “Pilot Program for the Entire-Process Management of Data Assets” issued by the Ministry of Finance of the People's Republic of China in December 2024 [27]. Gao also emphasized that medical institutions have made long-term investments in human, financial, and intellectual resources, and according to labor theory, they naturally possess ownership over the outcomes of these investments (i.e., resource-based health and medical data). Therefore, granting data property rights to the producers of health and medical data is both necessary and justified [28].

Thirdly, the composite rights attributes theory. This theory has gained considerable support among scholars. It posits that a single attribute cannot fully capture the complexity of medical data, advocating for a multi-dimensional rights framework or innovative rights structures. Wu proposed establishing a “dual-rights architecture” incentive mechanism, where the

“portability right of medical data” stems from civil law protections of health rights and personal rights, while the “usage right of medical data” arises from safeguards for property interests [29]. Shen and Bao argue that health and medical data possesses three fundamental characteristics: co-creation, sensitivity, and public accessibility, which collectively form the normative basis for its rights allocation. Based on a contribution-oriented distribution principle, they propose that medical data rights should be separately allocated between patients and healthcare institutions. For instance, as data sources, patients enjoy primary rights – including ownership, usage, benefit derivation, and disposal authority – along with secondary rights such as access, reproduction, and transfer; whereas healthcare institutions, as data processors, hold rights to ownership, usage, and commercial utilization of the data [30]. Zhu emphasizes that health and medical data differs from general data due to its strong personal and public attributes, necessitating a balanced approach in governing it to reconcile conflicts between personality interests and property interests, as well as private interests and public interests [31].

3. Research on the Connotation and Impact of Cross-Border Data Flow

To conduct in-depth research on cross-border flow of health and medical data, the primary task is to clarify the concept of “cross-border data flow”. The discussion of this concept originated in the Western world, where it has been interpreted and defined from diverse disciplinary perspectives and theoretical frameworks. From an international regulatory and academic historical perspective, the earliest systematic definition of this concept can be traced to the “Guidelines on the Protection of Privacy and Transborder Flows of Personal Data”⁹ issued by the Organisation for Economic Cooperation and Development (OECD) in the 1980s. This document first systematically established at the international level that “transborder flows of personal data” refer to “the movement of personal data across national borders”, which remains widely regarded as one of the foundational institutional sources for the contemporary academic understanding of this concept. Subsequently, Fishman adopted a

⁹ Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, Part 1, Definitions. URL:

<https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0188> (accessed: 10.03.2026).



macroscopic perspective and broadly defined cross-border data flow as the electronic movement of data between nations [32]. Concurrently, Kirby acutely identified the potential negative impacts of such flows, noting that while their surge has brought significant benefits to humanity by facilitating global information exchange and economic development, this irreversible trend also poses serious challenges to personal privacy protection [33]. Jussawalla and Cheah conducted an in-depth analysis of the concept and nature of cross-border data flow from a political economy perspective, not only highlighting its profound impact on international economic cooperation but also emphasizing the critical importance of establishing robust regulatory frameworks for trade development [34]. This perspective provided essential theoretical foundations for later efforts to incorporate data flow regulations into Free Trade Agreements. Estadella-Yuste defined cross-border data flow narrowly as the transmission of data and/or information across national borders in machine-readable formats, typically facilitated through complex networks of computers spanning multiple countries [35].

Since the dawn of the 21st century, continuous advancements in computer and internet technologies have significantly increased the frequency of cross-border data flow, leading to profound transformations in both their definition and societal implications. Meltzer noted that the rapid development of the internet has enabled data to flow across borders in a networked and dynamic manner in real time. In fact, data may cross national boundaries during transmission without the knowledge of either sender or recipient. The widespread utilization of cross-border data flow further enhances economic efficiency and productivity levels, ultimately contributing to improved social welfare and living standards [36]. The McKinsey Global Institute (MGI) describes cross-border data flow as the “core hallmark” driving 21st-century business globalization and the “connective tissue” linking the global economy [37]. This metaphor underscores the pivotal role of data flow within the global economic system, functioning like connective tissue that provides a solid foundation for interconnections and collaborative development among economies. Additionally, Mercurio and Yu define cross-border data flow as

the movement or transmission of information between computer servers across different countries, emphasizing that the lack of globally recognized regulatory standards – despite efforts by international organizations to establish principles and best practices – has significantly increased the complexity of governance challenges in this area [38].

In terms of conceptual definition, Chinese scholars began exploring cross-border data flow slightly later than their international counterparts. However, with the rapid development of China's digital economy and the continuous improvement of its data governance framework, Chinese researchers have gradually caught up in this field, making unique theoretical contributions and demonstrating significant practical value. The earliest research on cross-border data flow in China dates back to the late 1990s. Cheng defined cross-border data flow as point-to-point transmission of digital data across national and political boundaries, noting that with ongoing advancements in computer technology, future data flow will exhibit broader reach, richer content, faster speeds, and more profound impacts [39]. With the advent of the 21st century, continuous innovations in computing and internet technologies have made cross-border data transmission increasingly frequent. Concurrently, the scope and implications of cross-border data flow have undergone profound transformations. To gain a comprehensive and nuanced understanding of this phenomenon, Chinese scholars have provided detailed interpretations from diverse perspectives. Chen and Jia argue that cross-border data flow essentially represents a dynamic process where data traverses sovereign borders via communication systems, primarily manifested today through efficient transmission across countries via internet platforms, accompanied by complex storage and processing procedures [40]. Zhang and Song emphasize that cross-border data flow generally refers to the movement of data between different legal jurisdictions [41]. Tan defines cross-border data flow as activities involving the reading, storage, and processing of data across national borders, encompassing both outbound and inbound transfers [42]. Most scholars have interpreted this concept primarily through the lens of data transmission, processing, and storage across borders.



However, Shi argues that cross-border data flow should not be confined to physical border crossings alone; it can also be understood from the perspective where data may not physically cross borders but remains accessible to third countries or foreign entities [43]. Zhang similarly contends that even when data is not physically exported, its accessibility to foreign entities should still fall under the category of cross-border data flow [44]. In summary, cross-border data flow can be defined as the act of transferring data across national boundaries (both physical and virtual) between countries, including the processing of machine-readable data stored on hardware devices (such as computers and servers) within a country [45].

4. Research on Legal Regulation of Cross-Border Flow of Health and Medical Data

In recent years, with the rapid advancement of digital healthcare, artificial intelligence, telemedicine, and the development of healthcare informatization systems worldwide, “health and medical data” has gradually become a key research focus in the fields of law, medical informatics, and public governance. The nonlinear growth in cross-border healthcare services such as international telemedicine and clinical trials has made the cross-border flow of health and medical data an irreversible trend. How to promote the development of the healthcare industry while safeguarding national data sovereignty, mitigating cross-border data risks, and protecting personal medical privacy remains a prominent issue of ongoing academic interest.

In the era of digital globalization, the cross-border flow of health and medical data has evolved beyond merely a technical issue to encompass a complex interplay of data protection, data sovereignty, national security, research ethics, and international cooperation. The academic community has produced substantial research on this topic, gradually establishing a research framework centered on institutional comparisons, regulatory model analysis, and practical framework development. To date, the World Health Organization (WHO) has not established a dedicated international treaty specifically addressing “health and medical data”

or “cross-border flow of health and medical data”. Its legal regulatory system primarily consists of one legally binding international treaty – the “International Health Regulations”, alongside a series of internal policy frameworks such as the “WHO Data Policy,” the “WHO Personal Data Protection Policy,” and the “WHO Data Principles”, as well as a new instrument currently under negotiation. Xia et al., from a comparative regulatory perspective, identified three prevailing regulatory paradigms for global cross-border flow of health and medical data: first, the “rights-based” paradigm represented by the EU's GDPR, which emphasizes personal data rights and strictly restricts the cross-border transfer of health data; second, the U.S. – centric paradigm; The third approach emphasizes a “market-oriented” model that promotes the free flow of health and medical data trade and services; the third approach is represented by China. It adopts a “sovereign security-based” model that regulates the export of health and medical data under a framework prioritizing data security. Furthermore, it is noted that such policy differences have substantially hindered international medical research collaboration, undermined the effectiveness of telemedicine, and created barriers for healthcare providers when sharing patient information [46].

In research on practical framework development, the European Union undoubtedly holds a central position. With the official publication and phased implementation of the EHDS in March 2025, academic focus has shifted from a one-sided examination of the GDPR to an analysis of the synergistic operation between EHDS and the GDPR. For the first time at the EU level, EHDS establishes a unified legal framework covering both “primary use” and “secondary use” of health and medical data. Regarding primary use, EHDS grants individuals stronger access rights and cross-border sharing rights to their electronic health data; for secondary use, it establishes mechanisms for structured data acquisition through “Health Data Access Bodies”, applicable to specific purposes such as scientific research, innovation, and policy-making ¹⁰. However, some scholars argue that by relying on robust legal frameworks such as internal markets,

¹⁰ Moreno N. The European Health Data Space is in Force : Implications for Healthcare, Medtech and Life Sciences. URL: <https://www.kennedyslaw.com/en/thought-leadership/article/2026/the-european-health-data-space-is-in->

[force-implications-for-healthcare-medtech-and-life-sciences/](https://www.kennedyslaw.com/en/thought-leadership/article/2026/the-european-health-data-space-is-in-force-implications-for-healthcare-medtech-and-life-sciences/) (accessed: 25.03.2026).



the EHDS effectively expands the EU's influence and control in public health – a domain originally falling within its supplementary competencies. While this approach objectively advances EU healthcare integration, it leads to “competency erosion” and creates tensions with the EU's constitutional boundaries, raising legal concerns about the EHDS's practical implementation [47][48]. Furthermore, Bradford et al. emphasize that the exchange of patient and population health-related data across regions is crucial for sustained innovation in healthcare and public health. Standard contractual clauses can provide a relatively straightforward, “safe-haven-like mechanism” for the cross-border flow of regulated health data [49].

In recent years, the Chinese academic community has conducted relatively systematic research on this topic, forming a research framework centered on institutional examination, international comparisons, and pathway construction. Regarding China's current legal framework, scholars generally agree that a preliminary regulatory system for cross-border data flow has been established, with the “Cybersecurity Law of the People's Republic of China”, the “Data Security Law of the People's Republic of China”, and the “Personal Information Protection Law of the People's Republic of China” serving as its pillars, supplemented by specialized regulations such as the “Measures on Security Assessment of Data Export” and the “Provisions on Promoting and Regulating Cross-Border Data Flow”. However, existing studies have also revealed multiple challenges at the institutional level. Guan and Wang systematically pointed out that currently, China faces three major practical challenges in regulating the cross-border flow of health and medical data: a logically conservative design of the legal framework; insufficient compliance assurance capabilities among data managers (primarily healthcare institutions); and inadequate international cooperation mechanisms [5]. He and Zhang argued that China's existing regulatory rules for cross-border health and medical data are ill-suited to the industry's evolving needs, emphasizing the need to strike an “optimal balance” between “risk control” and “industry promotion” [50]. Feng, based on the realities of sensitive health-related personal data flow, proposed shifting regulatory approaches from

inclusive oversight to prudent regulation when such data transitions from private to public information [51].

Given the absence of specialized legislation in this area in China, many scholars have turned to foreign regulatory frameworks for guidance. Ao and Pan conducted a comprehensive analysis of the EU's institutional practices across governance objectives, rule formulation, and technological safeguards, detailing the “dual-track” framework established by the GDPR and EHDS, and recommending that China establish differentiated governance goals for various scenarios involving cross-border personal health data flow while continuously improving regulatory frameworks and strengthening technical support platforms [52]. Other studies have also drawn insights from more focused country-specific comparisons. Chen and Meng focused on the regulation of cross-border flow of health and medical data in Australia, analyzing the special protections afforded to health information under Australia's the “Privacy Act” and the specific rules governing its cross-border transfer, while also exploring the implications for improving relevant institutional frameworks in China [53]. These comparative law studies provide valuable references for China to establish a regulatory model that aligns with international norms yet suits local realities amid globalization.

Furthermore, given the distinctive features of the Guangdong-Hong Kong-Macao Greater Bay Area – characterized by “one country, two systems, and three legal jurisdictions” – as well as practical challenges such as significant disparities in regulations regarding the export of domain-specific data (particularly health and medical data) among the three regions and the lack of comprehensive legal guidance, Lv and Sun propose four approaches: adapting the informed consent principle, enhancing data interoperability, leveraging interregional administrative agreements, and utilizing legislative authorization lists. These measures could fully unlock the societal value of health and medical data and facilitate the standardized cross-border flow of such data across the three regions [54].



Conclusion

A systematic review of current research trends and developments in the academic field reveals three distinct strengths. First, rigorous research methodology. Academic studies consistently trace international discussions on legal regulation of health and medical data and its cross-border flow – from single-perspective analyses to multi-dimensional approaches, from foundational theories to practical applications, and from domestic regulations to global standards, whether examined directly or indirectly.

Second, diverse research methods. Scholars employ a variety of techniques – including literature reviews, case studies, comparative analyses, and interdisciplinary approaches – to investigate health and medical data issues, demonstrating both methodological diversity and scientific rigor.

Third, strong alignment with contemporary contexts. Research on legal regulation of cross-border flow of health and medical data has emerged prominently in the digital age; as globalization accelerates digital transformation, data mobility has become a critical resource fiercely contested globally. Thus, this research topic exhibits both timeliness and innovative value.

However, several critical shortcomings in academic research warrant attention. First, there is a tendency toward homogenization in analytical frameworks. Most studies adhere to a four-step structure – “current situation description → problem diagnosis → international experience → policy recommendations”. While logically sound and practical, this approach leads to limited differentiation and repetition across studies regarding problem identification and argumentation approaches. Some recommendations (e.g., “improve legislation” or “enhance international cooperation”) lack rigorous derivation from problem analysis, diminishing their practical applicability.

Second, excessive emphasis is placed on static institutional analysis at the expense of implementation effectiveness. Existing research predominantly focuses on normative legal text analysis, with insufficient attention to actual implementation outcomes. Key questions remain

unanswered: What are the compliance costs associated with cross-border flow of health and medical data? Do small and medium-sized medical institutions abandon international collaborations due to compliance barriers? How can operational challenges of informed consent protocols be addressed in global research? These implementation-related issues rarely receive systematic empirical examination. Research divorced from implementation effects fails to address fundamental questions such as whether regulations are excessive or ineffective.

Third, coverage of specialized fields and emerging topics remains inadequate. The regulation of human genetic resource data exports exhibits particular sensitivity given its implications for national biosecurity, yet dedicated literature in this area remains scarce. Similarly, cross-border data sharing in rare disease research – due to small patient populations and data scarcity – has received limited thematic discussion. Furthermore, legal analyses regarding whether and to what extent emerging technologies such as privacy-preserving computing and federated learning can alleviate the tension between health and medical data flow and security protection remain in their early stages.

By addressing the contentious issues discussed above, this study underscores its significance and timeliness in examining legal regulation of cross-border flow of health and medical data. Consequently, finding a balance between law and technology represents a novel approach for academic exploration. The tension between data protection and data utilization remains only the tip of the iceberg; driven by rapid digital technological advancements, cross-border data collection will give rise to numerous additional challenges. Undoubtedly, the conflict between law and technology will be a fierce and prolonged struggle that requires continuous human effort to address.

Funding information

This work was supported by the China Scholarship Council (No. 202507010005) and the Xinjiang University Outstanding Graduate Student Innovation Project (No. XJDX2025YJS024).



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МЕДИЦИНАЛЫҚ ДЕРЕКТЕРДІҢ ШЕКАРААРАЛЫҚ АҒЫНЫН ҚҰҚЫҚТЫҚ РЕТТЕУ: ЖҮЙЕЛІ ӘДЕБИЕТТЕРГЕ ШОЛУ

Аңдатпа. Бұл мақала медициналық деректердің трансшекаралық ағынын құқықтық реттеу бойынша жүйелі әдебиетке шолу болып табылады. Негізінен жүйелі әдебиетке шолу тәсілін қолдана отырып, бұл зерттеу осы саладағы тиісті академиялық әдебиеттерді жүйелі түрде



анықтайды, іріктейді және жан-жақты талдайды. Өкілдік зерттеу нәтижелерін жан-жақты шолуға негізделген бұл зерттеу қолданыстағы зерттеулердің негізгі көзқарастарын, зерттеу контекстін және даму үрдістерін қорытындылайды. Сонымен қатар, бұл зерттеу медициналық деректердің құқықтық анықтамасы мен атрибуттары, трансшекаралық деректер ағынының мағынасы мен әсері және медициналық деректердің трансшекаралық ағынын құқықтық реттеу сияқты негізгі мәселелерге бағытталған әдебиеттерге мақсатты талдау жүргізеді. Бұл талдау қазіргі ғылыми зерттеулер медициналық деректерді анықтау, негізгі реттеуші шиеленістерді анықтау және онымен байланысты мәселелерді шешу үшін негізгі негіздерді белгілегенімен, ол юрисдикциялық бағыттар бойынша фрагменттелген күйінде қалатынын және негізінен динамикалық енгізу қиындықтарына емес, статикалық институционалдық салыстыруларға бағытталғанын көрсетеді. Осы негізге сүйене отырып, бұл зерттеу қолданыстағы зерттеулердің негізгі көзқарастарын, қолданыстағы дауларды және кемшіліктерін жан-жақты қарастырады, осылайша қазіргі зерттеудегі олқылықтар мен болашақ даму бағыттарын анықтайды және қазіргі жағдайда медициналық деректердің трансшекаралық ағынын құқықтық реттеу бойынша зерттеулердің маңызды теориялық құндылығы мен практикалық маңыздылығын көрсетеді.

Тірек сөздер: әдебиеттерге шолу, медициналық деректер, трансшекаралық деректер ағыны, құқықтық реттеу, деректер қауіпсіздігі, деректер бостандығы, халықаралық ынтымақтастық.

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ПРАВОВОЕ РЕГУЛИРОВАНИЕ ТРАНСГРАНИЧНОГО ПОТОКА МЕДИЦИНСКИХ ДАННЫХ: СИСТЕМАТИЧЕСКИЙ ОБЗОР ЛИТЕРАТУРЫ

Аннотация. Данная статья представляет собой систематический обзор литературы по правовому регулированию трансграничного потока медицинских данных. В основном, используя подход систематического обзора литературы, это исследование систематически выявляет, отбирает и всесторонне анализирует соответствующую академическую литературу в этой области. На основе всестороннего обзора репрезентативных результатов исследований, данное исследование обобщает основные точки зрения, контекст исследований и тенденции развития существующих исследований. Кроме того, в этом исследовании проводится целенаправленный анализ литературы, сфокусированный на ключевых вопросах, таких как правовое определение и атрибуты медицинских данных, смысл и влияние трансграничного потока данных, а также правовое регулирование трансграничного потока медицинских данных. Этот анализ показывает, что, хотя современные исследования создали основополагающие рамки для определения медицинских данных, выявления основных регуляторных противоречий и решения связанных с этим вопросов, они остаются фрагментированными по юрисдикционным признакам и преимущественно сосредоточены на статических институциональных сравнениях, а не на динамических проблемах реализации. Опираясь на эту основу, данное исследование всесторонне рассматривает основные точки зрения, существующие противоречия и недостатки существующих исследований, выявляя тем самым пробелы в текущих исследованиях и будущие направления развития, а также подчеркивая важную теоретическую ценность и практическую значимость исследований по правовому регулированию трансграничного потока медицинских данных в современном контексте.

Ключевые слова: обзор литературы, медицинские данные, трансграничный поток данных, правовое регулирование, безопасность данных, свобода данных, международное сотрудничество.