

PROTECTION OF PATIENTS' RIGHTS TO CONFIDENTIALITY AND INFORMED CONSENT IN REPRODUCTIVE HEALTH

LITERATURE REVIEW

DOI: <http://dx.doi.org/10.18370/2309-4117.2026.83.68-78>

M.M. BLIKHAR

doctor of juridical science, professor, head of the Department of Administrative and Information Law, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv
ORCID: 0000-0003-2974-0419

I.I. KOMARNYTSKA

doctor of juridical science, professor, Department of Civil Law and Procedure, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv
ORCID: 0000-0003-4314-877X

M.M. YAREMCHUK

PhD in juridical science, senior lecturer, Department of Criminal Procedure and Criminalistics, Lviv State University of Internal Affairs, Lviv
ORCID: 0009-0004-4454-5536

N.M. KALKA

PhD in psychology, associate professor, Department of Practical Psychology, Educational and Scientific Institute of Management, Psychology and Security, Lviv State University of Internal Affairs, Lviv
ORCID: 0000-0002-6989-4909

M.R. MALETS

PhD in juridical science, associate professor, Department of Administrative and Information Law, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv
ORCID: 0000-0002-9129-3608

Contacts:

Бліхар Марія Миронівна
Національний університет
«Львівська політехніка»
м. Львів, вул. Князя Романа, 1/3
Email: blikharm@ukr.net
Tel.: +38 (097) 241-89-04

INTRODUCTION

In the contemporary context of healthcare development and the increasing emphasis on human rights, the protection of patients' rights has become a matter of particular significance. One of the key issues in the field of reproductive health is ensuring the confidentiality of medical information and the implementation of the principle of informed consent. Reproductive services, including assisted reproductive technologies, gamete donation, and surrogacy, require medical institutions and healthcare professionals to adhere to high standards in the collection, processing, and storage of personal data. These issues are not only legal in nature but also ethical, as they concern the most intimate sphere of human life – the ability to exercise the right to have children and to plan a family free from pressure and interference by third parties.

This study is relevant for several reasons. First, the expansion of access to modern reproductive technologies creates new challenges for legal regulation, particularly with regard to the protection of personal data, ensuring the voluntary and informed participation of patients in medical procedures, and safeguarding their rights in situations involving legal or ethical conflicts. Second, global trends in healthcare, including international standards established by the WHO and recommendations of the Council of Europe, emphasize the necessity of guaranteeing informed consent as a fundamental component of patients' rights, thereby requiring the adaptation of national legislation to contemporary standards. Third, in Ukraine, the protection of patients' rights in the field of reproductive health remains insufficiently regulated at the practical level. Despite the existence of legislative acts governing medical practice and healthcare, a number of issues persist, ranging from inadequate public awareness of patients' rights to failures by healthcare institutions to properly comply with procedures for obtaining informed consent and ensuring confidentiality of information. Such shortcomings may result in violations of patients' rights, a decline in public trust in the healthcare system, and the emergence of social and legal conflicts.

In this context, it is appropriate to conclude that the study of legal aspects of confidentiality and informed consent in the field of reproductive health is not only relevant but also essential for the development of the healthcare system and the improvement of public policy in this area. Such research makes it possible to identify the main challenges and propose ways to address them, with the aim of ensuring a balance between patients' rights and state interests, as well as improving mechanisms of legal protection in the context of advancing reproductive technologies. Furthermore, the relevance of this article lies in the necessity of adapting Ukrainian legislation and practical approaches to contemporary international standards, ensuring patients' rights to confidentiality and informed consent, which constitute the foundation for the safe and effective provision of medical services in the field of reproductive health, as well as for strengthening trust in the healthcare system and state policy in this critically important area.

Objective of the review: to provide a comprehensive analysis of the legal protection of patients in the field of reproductive health, particularly with regard to ensuring the principles of confidentiality and informed consent, as well as to identify ways of improving the national regulatory and legal framework and practical mechanisms for their implementation. Special attention is devoted to the relationship between state legal policy and patients' rights in the field of reproductive health, which makes it possible to assess the effectiveness of existing legal protection mechanisms and identify potential legal gaps.

Achieving this objective involves addressing the following tasks:

- conducting a theoretical analysis of the concepts of confidentiality, informed consent, and reproductive health within the context of medical law;
- examining national and international legal acts regulating reproductive services, patients' rights, and personal data protection;
- identifying challenges in the practical implementation of the principle of informed consent and the safeguarding of confidentiality in the context of modern reproductive technologies, including assisted reproduction, gamete donation, and surrogacy;

- analysing the interaction between state policy and medical law in the field of reproductive health, as well as assessing the impact of legislative and policy decisions on patients' rights;
- proposing specific recommendations for improving legal regulation and practical mechanisms aimed at ensuring confidentiality and informed consent in order to enhance the effectiveness of patients' rights protection.

The implementation of these tasks makes it possible to develop a comprehensive understanding of the current state of legal regulation in the field of reproductive health, identify key issues and challenges, and outline ways of addressing them through the harmonization of legal norms, ethical principles, and state policy. Such an approach is essential for establishing an effective system for the protection of patients' rights, increasing public trust in the healthcare system, and ensuring access to reproductive services in compliance with international standards and best practices.

METHODOLOGY

The methodology of the proposed study is based on a combination of theoretical, analytical, and comparative approaches, which make it possible to comprehensively assess the legal and policy aspects of protecting patients' rights in the field of reproductive health, particularly with regard to ensuring the principles of confidentiality and informed consent. The selected methodology is aimed at the systematic examination of the issue, the identification of practical gaps in legal regulation, and the development of recommendations for improving state policy in this area.

At the same time, the study employs the following methods of scientific analysis:

- analysis of legal and regulatory acts – including the examination of Ukrainian legislation, subordinate regulations, and international standards, particularly documents of the WHO, the Council of Europe, and the United Nations human rights conventions governing reproductive health, patients' rights, confidentiality, and informed consent (this method makes it possible to determine the legal framework and identify gaps in the implementation of patient protection principles in contemporary practice);
- the comparative legal method – involving a comparison of Ukrainian legislation with international norms and the practices of other countries, thereby enabling the identification of effective models of legal regulation in the field of reproductive health and personal data protection (the comparison includes an analysis of various approaches to informed consent procedures, medical confidentiality, and the regulation of assisted reproductive technologies);
- theoretical analysis and systematization – allowing for the clarification of the concepts of “informed consent,” “confidentiality,” and “reproductive health,” as well as the determination of their legal and policy-related nature (the use of this method ensures the establishment of a conceptual framework for the study, facilitating the formulation of coherent conclusions and recommendations);
- critical analysis of academic and practical literature – involving the assessment of existing scholarly works, articles, com-

mentaries, and judicial practice concerning patients' rights in the field of reproductive health (this enables the identification of contradictions, gaps, and current trends in legal policy and medical practice);

- method of synthesis and generalization – used for integrating the collected data, formulating conclusions, and developing proposals for improving legal regulation (the synthesis includes combining the results of legislative analysis, international standards, and academic research in order to elaborate practical recommendations for the protection of patients' rights);
- interdisciplinary approach – ensuring a comprehensive examination of the issue at the intersection of medical law, public policy, ethics, and human rights, thereby enabling an assessment not only of the legal dimension of the issue but also of its practical and social implications.

The application of these research methods ensures the systematic, scientifically grounded, and comprehensive nature of the study, which is essential for addressing the issues related to the protection of patients' rights in the field of reproductive health and for formulating recommendations aimed at improving state policy and practical mechanisms for the implementation of the principles of confidentiality and informed consent.

RESULTS

The study of the protection of patients' rights in the field of reproductive health, particularly with regard to ensuring the principles of confidentiality and informed consent, has become the subject of considerable attention within both national and international scholarly communities. In contemporary medical and legal literature, these issues are examined at the intersection of medical law, ethics, human rights, and public policy, which enables their comprehensive and critical assessment.

International organizations, including the WHO, Office of the United Nations High Commissioner for Human Rights, and United Nations Population Fund, emphasize the necessity of establishing effective legal mechanisms for the protection of personal medical data in the field of reproductive health. Documents issued by the WHO [1–7] underline that breaches of confidentiality may lead to discrimination, social stigmatization, and a decline in individuals seeking medical assistance. Representatives of the international bioethical doctrine, particularly Selena Knight and Andrew Papanikitas [8], stress that medical confidentiality constitutes the foundation of trust between physician and patient, especially in the field of reproductive medicine, where highly sensitive personal data are processed. Researchers Inga Hunter et al. [9] draw attention to the risks associated with the electronic exchange of medical information and the necessity of obtaining explicit patient consent for the use of personal data.

Issues concerning the legal regulation of assisted reproductive technologies are examined by Svetlana Sylkina and co-authors [10], who analyse international approaches to surrogacy and the necessity of legislative protection of patients' rights. Anna Krawczak [11], in her study of Polish reproductive medicine centres, emphasizes the importance of a patient-centered approach, transparency of medical procedures, and guarantees of informed consent. Maya Sabatello [12] focuses on the rights

of children born through assisted reproductive technologies and the necessity of ensuring comprehensive protection for all participants in reproductive legal relations. Overall, contemporary scholarly research in the field of protecting patients' rights to confidentiality and informed consent in reproductive health primarily focuses on issues related to patient legal autonomy, the digitalization of medical data, the ethical dimensions of assisted reproductive technologies, and the limits of state interference in private life. For instance, the publication by the Ethics Committee of the American Society for Reproductive Medicine (2024) examines the ethical obligations of healthcare professionals in situations where one partner conceals important information during reproductive treatment [13]. The authors emphasize the necessity of maintaining a balance between confidentiality and the physician's professional duty to ensure safe treatment. At the same time, the study is predominantly ethical in nature and insufficiently addresses the mechanisms of legal liability in cases involving violations of the patient's right to information. In contrast, the work of the Ethics Committee of the American Society for Reproductive Medicine (2023) analyses informed consent within the system of assisted reproductive technologies [14]. The researchers stress the importance of providing patients with comprehensive information regarding medical risks, the legal consequences of donation procedures, and the use of genetic material. A notable strength of the study is its detailed examination of communication standards between physicians and patients; however, the authors largely rely on the American legal framework, which complicates the direct application of certain provisions within European and Ukrainian legal systems. The study by M. Rothstein is devoted to the issue of the "illusion of medical privacy" in obstetrics and gynaecology [15]. The author critically evaluates modern digital systems for processing medical data, arguing that the formal existence of legal safeguards does not always ensure effective protection of patients' personal information. Particularly valuable is the analysis of the risks associated with the leakage of sensitive reproductive data through electronic medical systems. Nevertheless, the study pays insufficient attention to the capabilities of modern cyber security mechanisms and advanced medical data encryption technologies. In the article by O'Brien and Newport, reproductive health is examined through the lens of women's bodily autonomy and human rights [16]. The authors argue that informed consent should not merely constitute a formal legal procedure but should serve as a genuine instrument for ensuring patient freedom of choice. The study possesses significant socio-legal value; however, it is characterized by a pronounced socio-feminist perspective, which somewhat narrows the comprehensiveness of the medico-legal analysis of the issue. Furthermore, the study conducted by Teresa Almeida et al. addresses the problem of collective privacy in the sphere of digital sexual and reproductive health [17]. The authors emphasize that modern digital platforms and mobile applications used for monitoring reproductive health collect extensive volumes of sensitive data that may affect not only individual users but also their families, partners, and certain social groups. Particularly valuable is the conceptualization of privacy as a collective phenomenon rather than solely an individual right. At the same

time, the research is largely theoretical in nature and does not sufficiently elaborate on practical legal mechanisms for protecting such data within national legal systems, etc.

Among Ukrainian scholars, issues related to reproductive rights and informed consent have been actively analyzed by M. Bielova, O. Byelov et al. [18, 19], who consider reproductive rights as a component of contemporary bioethical human rights. L. Parashchuk and I. Chaplia [20] investigate the legal regulation of surrogacy and the harmonization of Ukrainian legislation with European Union law. N. Moskaliuk and V. Sloma [21] focus on the development of assisted reproductive technologies and the necessity of improving mechanisms for protecting patients' personal data. A significant contribution to the study of the institution of informed consent has been made by H. Habrelian [22], as well as N. Khymych [23], who emphasize that informed consent must result from a conscious and voluntary decision made by the patient after receiving complete information regarding the medical intervention, its risks, and potential consequences. At the same time, it is also necessary to highlight the works of other Ukrainian scholars. In particular, the study by O.V. Batryn is devoted to the administrative and legal regulation of medical practice licensing [24]. The author, for example, substantiates the importance of state control over the activities of healthcare institutions as a mechanism for ensuring patients' rights, including the right to the safe storage of medical information. However, issues of informed consent and confidentiality are addressed only indirectly, which limits the practical relevance of the study specifically for the field of reproductive health. In the article by V.A. Kroytor, the legal aspects of electronic healthcare service contracts are analysed [25]. Among other issues, the author pays attention to the digitalization of the healthcare sector, problems of electronic patient identification, protection of personal data, and confirmation of informed consent in electronic form. A strong aspect of the work is its topicality; however, risks related to cyber threats and practical challenges of the electronic healthcare system functioning under martial law are insufficiently addressed. The work of V.I. Teremetskyi et al. is devoted to administrative and legal requirements for healthcare institutions providing surrogacy services [26]. The authors provide a detailed analysis of regulatory gaps in the field of assisted reproductive technologies and emphasize the need to protect the rights of all participants in legal relations. A particular strength of the study lies in its focus on issues of confidentiality regarding information about donors and surrogate mothers. However, the work is primarily oriented toward administrative law and to a lesser extent covers international human rights standards. In another study by O.V. Batryn on the development of a unified medical information space, issues of healthcare digitalization and the legal protection of medical data are examined [27]. The author emphasizes the need to establish a comprehensive information security system in healthcare. At the same time, the study does not sufficiently specify mechanisms for protecting reproductive information as a particularly sensitive category of personal data. The article by D. Astafiev analyses the legislative regulation of assisted reproductive technologies as a factor in the development of medical tourism in Ukraine [28]. The author highlights the competitive

advantages of Ukrainian legislation in the field of surrogacy and assisted reproduction compared to several European countries. At the same time, he emphasizes the need to improve mechanisms for protecting patients' personal data and ensuring confidentiality of information concerning donors, surrogate mothers, and genetic material. A positive aspect of the study is the combination of medico-legal and economic approaches; however, the author pays insufficient attention to international human rights standards in the field of reproductive health. The work of O.M. Ilyushyk is devoted to the protection of personal data in telemedicine [29]. The author examines the risks of medical data breaches during the use of electronic healthcare systems and remote medical services. Particular attention is given to the need to strengthen cyber security and legal guarantees for the protection of patients' confidential information. The study is of significant importance for the field of reproductive health, as telemedicine consultations are increasingly used in reproductive medicine. However, the author considers the issue mainly in the general context of medical data, without sufficient differentiation of reproductive data as a particularly sensitive category of personal information. In the article by Y. Prytyka and T. Nikitina, the right to medical care in Ukraine is examined in the context of international human rights standards [30]. The authors emphasize the need to ensure accessibility of medical services, respect for human dignity, and patient autonomy. Considerable attention is paid to informed consent as an element of the right to healthcare. The strength of the study lies in its comprehensive analysis of Ukrainian legislation and international practice; however, issues of medical data confidentiality are addressed only fragmentarily and are not specifically adapted to the field of reproductive health.

At the same time, the Order of the Ministry of Health of Ukraine No. 787 dated 09.09.2013 "On Approval of the Procedure for the Use of Assisted Reproductive Technologies in Ukraine" is of significant importance for the research [31]. The document defines the main organizational and legal principles for the use of assisted reproductive technologies, the procedure for obtaining informed voluntary consent from patients, and the rules for maintaining medical documentation. Despite the practical relevance of this regulatory act, some of its provisions no longer fully correspond to contemporary challenges of healthcare digitalization, particularly regarding electronic storage of medical data, cyber security, and international standards for personal data protection. In this context, the legal position of the Supreme Court of Ukraine [32], according to which a person concerned by medical information has the right to determine the use of data contained in medical records, is of key importance for the development of confidentiality protection practice in healthcare. The Court effectively confirmed the primacy of the patient's right to control personal medical data and established an approach under which medical information is an integral part of a person's private life. This legal position is particularly relevant for reproductive health, where highly sensitive data related to infertility, assisted reproductive technologies, donation, and surrogacy are processed. At the same time, the ruling is of a rather general nature and does not establish detailed procedural mechanisms for data protection in the dig-

ital environment, leaving room for further legislative improvement and judicial development. Finally, the study by M. Tcholakian et al. [33] proposes the use of self-sovereign identity and block chain technology to ensure controlled access to medical records based on patient consent. The authors argue that traditional centralized medical data storage systems do not provide an adequate level of confidentiality and create risks of unauthorized access to personal information. Particular attention is given to a model in which the patient independently manages access to their medical data, aligning with contemporary concepts of digital autonomy. The study is valuable for research on reproductive data protection, as it demonstrates the potential application of innovative technologies in healthcare. However, the proposed model is mainly conceptual and technical in nature and insufficiently considers the complexity of implementing block chain solutions in public healthcare systems, particularly in countries with underdeveloped digital infrastructure.

Therefore, the analysis of contemporary literature confirms that effective protection of patients' rights in the field of reproductive health is possible only through the integration of international standards, national legislation, medical ethics, and modern mechanisms for personal data protection. Furthermore, scholarly works emphasize the necessity of more clearly defining procedures for obtaining informed consent within legal and regulatory acts, establishing reliable mechanisms for personal data protection, and improving public policy in the field of reproductive health. Consequently, the existing body of academic literature confirms the relevance of researching the protection of patients' rights in the field of reproductive health. The analysis of sources indicates the necessity of a comprehensive approach that combines legal regulation, practical medical standards, ethical principles, and state policy. Contemporary scholarship highlights existing problems and challenges while simultaneously demonstrating the need for more systematic solutions within the context of Ukrainian legislation and practice.

Reasons for legal protection of patients in the field of reproductive health

The right to reproductive health constitutes one of the fundamental human rights as an integral component of the right to healthcare and personal autonomy. Its normative content encompasses access to reproductive healthcare services, including family planning, disease prevention, and access to relevant medical information (the interpretation of this concept is examined from an interdisciplinary perspective within the literature on medical law and legal studies in general). The right to reproductive health is closely connected with the general rights of patients, among which informational autonomy and the protection of personal data serve as key components that ensure the possibility of making informed decisions regarding medical intervention.

The confidentiality of medical information represents a fundamental element of the protection of patients' rights and entails the obligation of healthcare professionals to guarantee the non-disclosure of sensitive information without the patient's consent. Within the context of medical law, confidentiality encompasses not only traditional medical records but also digital

ЮРИДИЧНІ АСПЕКТИ РЕПРОДУКТИВНОГО ЗДОРОВ'Я

databases, electronic health records, and reproductive information stored or processed in electronic form [34–36]. Contemporary studies emphasize that reproductive data are among the most sensitive categories of personal information, as their disclosure may result in serious social, psychological, and legal consequences for the patient [37].

In light of the on-going digitalization of the healthcare sector, scholars emphasize the threats associated with unauthorized access to confidential medical data, thereby highlighting the need for more comprehensive legal regulation and enhanced cyber security measures within electronic healthcare systems [34]. Ultimately, informed consent constitutes a central element of the legal protection of patients and presupposes a voluntary, informed, and competent decision by an individual regarding medical intervention based on complete and adequate information provided by a healthcare professional. Standards of informed consent are determined not only by professional ethics but also by international norms, including the updated provisions of the Declaration of Helsinki, in which informed consent is established as a prerequisite for the ethical conduct of medical research and treatment [7].

At the present stage, legal approaches to informed consent focus on ensuring that patients receive sufficient, accessible, and unbiased information concerning potential risks, alternatives, and consequences of medical intervention, thereby safeguarding patient autonomy and legal protection in the decision-making process.

International standards regulating patients' rights in the medical context include a broad range of documents and recommendations recognizing confidentiality and informed consent as indispensable components of the right to healthcare. These principles strengthen the position of the patient as an active participant in medical relations and reinforce the obligation of states to ensure the legal protection of these rights (Table 1). An analysis of international human rights standards also demonstrates that not only general rights, but also specialized requirements concerning the processing of medical information, must be adapted to the technological realities of digital medicine.

This table summarizes the key concepts and normative elements of the legal protection of patients in the field of reproductive data. It demonstrates that the concept of patients' rights is shaped through the interaction of confidentiality, informed consent, and the definition of the category of "medical data," where reproductive data require particular attention within legal regulation.

In essence, this framework outlines fundamental legal concepts that underpin the protection of patients' rights in the

field of reproductive health, with a particular emphasis on informed consent and confidentiality. In particular, contemporary scholarly publications emphasize that, in the context of advancing digital technologies, these legal institutions require enhanced regulatory attention in order to ensure the protection of sensitive medical information – a key element of patient autonomy and public trust in the healthcare system as a whole.

Legal regulation of reproductive health and the protection of patients' rights in Ukraine

In Ukraine, the legal regulation of reproductive health is based on a set of normative legal acts that cover general provisions on healthcare, patients' rights, as well as specific mechanisms of medical intervention and access to reproductive technologies. The principal legal act is the Fundamentals of Ukrainian Legislation on Healthcare, which enshrines the patient's right to access medical services and to receive adequate medical information about their state of health – this serves as a foundational norm defining the duties of medical personnel regarding patient information and guaranteeing the right to obtain complete and accurate information (Article 285 of the Civil Code of Ukraine likewise confirms the right to information about one's health status and treatment) [38, 39].

The Civil Code of Ukraine also provides additional civil-law protection for patients, particularly regarding voluntary and informed consent to medical interventions, which is a key element in reproductive medicine [39]. It is important to note that specialized legislation does not contain a separate comprehensive legal framework regulating reproductive health; however, existing normative acts are guided by general principles of patients' rights in medical practice, which are also applicable to reproductive services.

Ukrainian legislation explicitly regulates the patient's right to receive information about their health status and the obligation of healthcare professionals to provide such information in an accessible form (Article 39 [38]; Article 285 [39]). Informed consent in Ukraine is considered a legal prerequisite for medical intervention, requiring the provision of complete information regarding the nature, risks, alternatives, and consequences of the intervention, as well as the voluntary expression of consent by the patient – as a condition for carrying out procedures, including reproductive healthcare services.

In cases involving assisted reproductive technologies (ART), particularly in vitro fertilization (IVF), the Ministry of Health of Ukraine Order No. 787 "On Approval of the Procedure for the Use of Assisted Reproductive Technologies", adopted on

Table 1. Key legal categories that form the basis for the protection of patients' rights (with a focus on reproductive data)

Category	Legal essence	Comment	Key sources
Confidentiality of medical information	Prohibition of disclosure without consent	Particularly sensitive in reproductive data; requires digital protection	[34]
Informed consent	Conscious and voluntary decision	Foundation of legal protection of the patient in medical interventions	[7]
Personal medical data	Legal category subject to legal protection	Reproductive data as particularly sensitive	[37]

September 9, 2013 [31], stipulates that ART procedures may be performed only upon the written voluntary consent of the patient(s), based on a standardized application form.

Thus, Ukrainian law defines informed consent as a conditional legal requirement for the use of medical procedures, including reproductive technologies, thereby protecting patient autonomy and serving as legal proof of a voluntary decision.

Provisions concerning the confidentiality of medical information are not consolidated within a single specialized law; however, they are embedded in the Fundamentals of Ukrainian Legislation on Healthcare and in professional ethical standards governing medical practice. These norms establish that healthcare professionals are obliged to maintain medical confidentiality and not disclose information about a patient's health without their voluntary consent, except in cases explicitly provided for by law.

This is particularly relevant in the field of reproductive technologies: the specific provisions of the Ministry of Health Order No. 787 also establish that medical care involving assisted reproductive technologies must be provided under conditions of confidentiality, in accordance with the general principles of healthcare regulation.

Thus, although there is no standalone law specifically regulating the confidentiality of reproductive health information, existing legal provisions cover this sphere through general requirements for the protection of medical data (Table 2). Despite the availability of certain legal instruments, law enforcement practice indicates that the insufficient systemic nature of legislation on reproductive health creates gaps in the protection of patients' rights in the reproductive sphere.

The absence of a dedicated comprehensive legal act on reproductive technologies and patients' rights in this area complicates the legal regulation of issues related to the specific nature of medical procedures, data protection, and informed consent, thereby reducing the effectiveness of general legal norms in practice. In addition, legislative discussions are on-going regarding the need for a new draft law on reproductive health in Ukraine, which would provide a comprehensive regulatory framework and address these issues at the level of a single, specialized legal act.

The table 2 demonstrates how different acts of Ukrainian legislation interact in ensuring the legal protection of patients in the field of reproductive health. It shows that, despite the absence of a dedicated special law, there exists a set of interconnected legal norms that collectively ensure informed consent and confidentiality, although they require further strengthening through codification.

Ultimately, in Ukraine, reproductive healthcare services and patients' rights are protected through a combination of general healthcare regulations, civil-law guarantees, and specialized medical acts (for example, those governing assisted reproductive technologies). However, the practical application of these norms often reveals a lack of sufficient clarity, which creates legal challenges and underscores the need for the modernization and systematization of legislation in this field.

Practical aspects of the implementation of the right to informed consent and confidentiality in the field of reproductive health

One of the key practical examples in the field of patients' rights protection is the international case *Mayboroda v. Ukraine*, decided by the European Court of Human Rights (ECHR) on 13 April 2023, which concerns the State's failure to fulfil its positive obligations to protect the patient's right to informed consent in the medical context [40].

In this case, the applicant underwent surgical treatment for postoperative bleeding; however, during the surgical intervention, a healthy kidney was removed without explicit informed consent from the patient or her representatives. The Court found a violation of Article 8 of the ECHR ("right to respect for private and family life"), concluding that the State had failed to establish an adequate regulatory framework ensuring informed consent and proper information regarding medical intervention and its consequences [40]. This precedent highlights that deficiencies in the legal protection of informed consent not only violate domestic legal standards but may also constitute a breach of international human rights obligations. It further reflects a broader trend requiring national healthcare systems to align their legal frameworks with international standards governing procedural safeguards of patients' rights.

Although Ukraine does not have unified judicial practice specifically addressing the confidentiality of reproductive data, general approaches to the protection of medical information are reflected in administrative and civil court decisions concerning violations of medical secrecy and the processing of health-related data. Scholarly research indicates that Ukrainian legislation contains gaps in the protection of medical data confidentiality, particularly in relation to electronic healthcare systems, which may also negatively affect reproductive health data. Existing regulatory frameworks do not always adequately address all aspects of disclosure and protection of electronically stored information, thus requiring legal clarification and an expansion of the scope of liable subjects [41].

Table 2. Key legislative provisions regarding patients' rights in the field of reproductive health in Ukraine

Legal instrument	Scope of regulation	Guarantees	Comment
Fundamentals of Ukrainian Legislation on Healthcare	General patients' rights	Right to information, duty of disclosure	Provides the legal basis for informed consent and confidentiality [Art. 39; Art. 285 Civil Code of Ukraine]
Civil Code of Ukraine	Civil-law protection	Right to information and voluntary consent	Strengthens the legal foundation of consent
Order of the Ministry of Health of Ukraine No. 787 (2013)	Assisted reproductive technologies	Written voluntary consent for ART; confidentiality	Establishes a specific form and procedure of consent for ART

ЮРИДИЧНІ АСПЕКТИ РЕПРОДУКТИВНОГО ЗДОРОВ'Я

In national practice, cases also arise where general rules on the collection, storage, and disclosure of medical information are applied, with evidentiary issues regarding the violation of confidentiality and the existence of harm to the patient playing a crucial role. This forms the basis for resolving disputes in civil courts and for applications to the ECHR in cases of serious or systemic violations.

Digital technologies, including electronic medical records and online healthcare services, create additional risks to patient confidentiality in the field of reproductive health. Recent studies show that gaps in the privacy policies of digital health applications, including those focused on women's reproductive health, may lead to the collection and unauthorized use of sensitive medical data without adequate safeguards [42]. Such risks open the way for new legal disputes, potentially involving both civil and administrative liability, and necessitate the revision of norms governing medical confidentiality, digital data protection, and informed consent, incorporating relevant international standards and approaches (Table 3).

The table 3 serves to summarize key practical cases and issues illustrating the application of the institutions of informed consent and confidentiality in real legal practice. It makes it possible to observe how international judicial practice (for example, ECHR decisions) and scholarly findings influence national medical law, particularly with regard to the protection of patients' reproductive rights.

Thus, legal protection mechanisms concerning informed consent and confidentiality are actively implemented through judicial practice, academic research, and adaptation to digital technologies. International decisions such as *Mayboroda v. Ukraine* reinforce the requirements for national legal frameworks, while contemporary challenges of digital medicine create a need for further legal adaptation in order to ensure effective protection of patients' rights in the field of reproductive health.

Challenges and prospects for improving legal protection for patients in the field of reproductive health in Ukraine

Analysis of Ukrainian legislation and its application in practice reveals the existence of several systemic problems in the legal protection of patients in reproductive medicine. First, the absence of a specific law on reproductive health and comprehensive regulation of assisted reproductive technologies creates legal uncertainty regarding procedures for patient information, confidentiality obligations, and mechanisms for personal data protection. In practice, this may lead to violations of patients' rights and limitations of their autonomy in making decisions

about medical interventions [41]. Second, the digitalization of healthcare and the introduction of electronic medical records and online platforms for accessing and monitoring patients' reproductive health create additional risks to confidentiality. Insecure digital channels, inadequate data processing policies, and the lack of a unified control mechanism over access to medical information may result in unauthorized use of reproductive data and negatively affect patient legal protection [43]. Third, in practice, informed consent often does not meet contemporary standards. This is manifested in insufficient provision of complete information to patients regarding risks, alternatives, and consequences of medical interventions, as well as a formalistic approach to obtaining written consent. Analysis of judicial practice, in particular the *Mayboroda v. Ukraine* precedent, shows that even where written consent exists, the absence of adequate information may constitute a violation of the right to autonomous decision-making [40].

In light of the above, scholars and practitioners propose several directions for improving legal protection in the field of reproductive health:

1. Codification of legal norms on reproductive health: the creation of a separate law or subordinate regulatory acts comprehensively governing informed consent, confidentiality, and the use of assisted reproductive technologies. Such codification would eliminate gaps in the application of general norms and ensure a unified legal standard for all healthcare institutions.
2. Strengthening the legal protection of digital medical data: the introduction of clear cyber security standards for electronic health records, control over access to reproductive data, and liability for breaches of medical confidentiality in digital environments. It is essential to harmonize national regulations with European Union requirements and international standards on personal data processing in healthcare.
3. Improving the quality of the informed consent process: the implementation of standardized procedures requiring the provision of complete, clear, and objective information to patients about medical interventions, including risks and alternatives. The development of training programs for healthcare professionals on patient rights and consent ethics would strengthen trust between patients and the healthcare system.
4. Monitoring and evaluation of legal protection effectiveness: the establishment of mechanisms to supervise compliance with patients' rights in the reproductive health sector, including audits of healthcare institutions and assessments of medical data processing practices. Such monitoring would enable timely response to violations and prevent legal conflicts.

Table 3. Court and practical cases from 2023–2025, illustrating aspects of informed consent and confidentiality

Practical aspect	Case/example	Legal conclusion	Comment
Insufficient informed consent	<i>Mayboroda v. Ukraine</i> (ECHR, 2023)	Violation of patients' rights due to lack of adequate informed consent	The ECHR decision emphasized the risk to patients' rights when the State fails to ensure proper consent standards; compensation for non-pecuniary damage was awarded by the Court [40].
Protection of medical confidentiality	Studies on medical data protection (2024)	Identified legislative gaps in digital patient data protection	In particular, the need to expand the scope of liable actors and improve legal regulation of medical data processing is emphasized [34].
New risks of digital technologies	Analysis of women's health applications (2025)	Lack of adequate safeguards in privacy policies	Highlights the need for regulatory changes in digital healthcare in the context of reproductive data protection [43].

Thus, the prospects for improving legal protection of patients in the field of reproductive health in Ukraine are linked to comprehensive legislative regulation, digital security, enhanced informed consent procedures, and the establishment of effective monitoring mechanisms. The implementation of these measures would strengthen the position of the patient as an active subject of medical relations and ensure compliance with international standards in reproductive health.

This means that the current state of legal protection of patients in reproductive health in Ukraine is characterized by the existence of basic regulatory frameworks but still contains significant gaps in digital security and informed consent procedures. Strengthening legal regulation, developing digital protection standards, and improving consent practices are key directions for ensuring full protection of patients' rights and alignment with international standards.

DISCUSSION

From the analysis of theoretical, legislative, and practical aspects of the legal protection of patients in the field of reproductive health, it follows that the current Ukrainian legal framework contains both strengths and significant gaps that require systematic improvement. At the theoretical level, it has been established that confidentiality and informed consent are not only ethical but also legal categories that are critical for ensuring patient autonomy. However, in practice, their implementation faces a number of challenges, ranging from incomplete compliance with informed consent procedures to risks of disclosure of sensitive information through digital platforms.

International precedents, in particular the case *Mayboroda v. Ukraine* (ECHR, 2023), emphasize the necessity of harmonizing national standards with international norms in order to prevent violations of the right to privacy and the protection of patients' reproductive data [40]. This perspective demonstrates that the Ukrainian healthcare system should align its national legislation with the best practices of the ECHR by establishing effective mechanisms of oversight and accountability for medical institutions.

One of the key findings of the study is that the digitalization of medicine introduces new legal challenges, as modern electronic medical data storage systems do not always ensure an adequate level of confidentiality and information security. Studies conducted in 2024–2025 indicate that privacy policies of digital applications often fail to comply with legal requirements, thereby creating risks for patients in the field of reproductive health [34, 43].

The originality of this article lies in its integration of legal policy and medical law with a specific focus on the reproductive health domain, which enables a comprehensive assessment of the relationship between theoretical principles, the legal framework, and practical application. Importantly, the study incorporates both international and national practice, including judicial decisions, which makes its conclusions not only academically relevant but also practically applicable for policy-making and legal implementation.

Prospects for further research include the development of a dedicated draft law on reproductive health that would comprehensively regulate informed consent, confidentiality, and pa-

tients' rights in the field of assisted reproductive technologies; an analysis of digital healthcare platforms to identify risks of confidentiality breaches and formulate recommendations for their legal regulation; and a comparative study of international practice, particularly the jurisprudence of the ECHR and WHO standards, in order to develop adapted models for protecting patients' rights within the national context.

Thus, the conducted study demonstrates that the protection of patients' rights in the field of reproductive health requires a comprehensive approach that combines theoretical foundations, effective legislative regulation, and practical enforcement mechanisms. At the same time, the emphasis on digitalization and the integration of international standards makes the work both timely and original in 2026, providing a platform for further development of legal policy in the healthcare sector.

CONCLUSIONS

Within the framework of this study, a comprehensive analysis of the legal protection of patients in the field of reproductive health was carried out at both international and national levels. It is important to emphasize that contemporary approaches to legal regulation in healthcare recognize reproductive rights as part of fundamental human rights, encompassing personal autonomy and the right to information, including informed consent and the confidentiality of medical data. International standards, including ethical principles and the provisions of the Declaration of Helsinki, enshrine the requirement for voluntary and informed decision-making by individuals regarding medical interventions.

At the national level, the legal regulation of reproductive health in Ukraine is implemented through general healthcare legislation, civil law provisions, and specialized acts governing assisted reproductive technologies. The Law of Ukraine "Fundamentals of Ukrainian Legislation on Healthcare" establishes the obligation of medical professionals to provide patients with complete information about their health status and the possible consequences of medical interventions, as well as defines the requirement of informed consent for medical procedures. However, there is currently no single comprehensive legislative act regulating patients' rights in the field of reproductive healthcare services, which creates a degree of legal uncertainty in both regulation and practical application.

The analysis of judicial practice, particularly the decision of the ECHR in *Mayboroda v. Ukraine* (13 April 2023), demonstrates that insufficient legal regulation of the informed consent process may be regarded as a violation of the State's positive obligations under Article 8 of the ECHR. In this case, the Court found that the absence of a structured legal framework and effective procedural safeguards ensuring proper patient information prior to medical intervention resulted in a violation of human rights. This highlights that legal protection of patients in reproductive healthcare is not limited to the existence of formal legal norms but requires their effective implementation in practice.

Confidentiality of medical information is another key aspect of legal protection, particularly with regard to reproductive data, which falls under the category of sensitive personal data. The

increasing digitalization of healthcare systems creates new challenges in ensuring the protection of information stored in electronic medical records and online healthcare services. Scholarly research points to legislative gaps in cyber security and data processing policies, which may lead to breaches of confidentiality and unauthorized access to sensitive patient information.

The analysed legal instruments and law enforcement practice indicate that Ukrainian legislation requires further improvement. In particular, it is advisable to develop specialized regulatory acts that clearly define patient information procedures, establish standards for the protection of reproductive data, and introduce mechanisms of liability for violations. It is also

important to promote a high level of legal awareness among healthcare professionals in order to ensure proper protection of patients' rights in the field of reproductive medicine.

In conclusion, the legal protection of patients in the field of reproductive health in Ukraine is based on general principles of medical law; however, achieving a high level of rights protection requires systematic legislative regulation, harmonization with international standards, and strengthened mechanisms for the practical implementation of existing norms.

Conflict of interest.

The authors declare no conflict of interest.

ЛІТЕРАТУРА/REFERENCES

- European Convention on Human Rights [Internet]. European Court of Human Rights, 2018. Available from: https://www.echr.coe.int/documents/d/echr/convention_eng
- European Society of Human Reproduction and Embryology.ESHRE guideline on medically assisted reproduction ethics. [Internet]. ESHRE, 2023. Available from: <https://www.eshre.eu/Specialty-groups/Special-Interest-Groups/Ethics-and-Law/Documents-of-the-Task-Force-Ethics-Law.aspx>
- Human Rights in the fields of Biomedicine and Health. Council of Europe Publishing. [Internet]. Civil Society Portal, 2022. Available from: <https://www.coe.int/en/web/civil-society/human-rights-in-the-fields-of-biomedicine-and-health>
- My Body is My Own: State of World Population Report 2021 [Internet]. United Nations Population Fund, 2021. Available from: https://www.unfpa.org/sites/default/files/pub-pdf/SoWP2021_Report_-_EN_web.3.21_0.pdf
- World Health Organization. Sexual and Reproductive Health Policy Database: Limits to confidentiality [Internet]. WHO, 2024. Available from: <https://platform.who.int/data/sexual-and-reproductive-health-and-rights/national-policies/srh/limits-of-confidentiality>
- United Nations Human Rights. Sexual and reproductive health rights: Special Rapporteur on the right to health. [Internet]. OHCHR, 2022. Available from: <https://www.ohchr.org/en/special-procedures/sr-health/sexual-and-reproductive-health-rights>
- World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants. [Internet]. JAMA Network, 2024. Available from: <https://jamanetwork.com/journals/jama/fullarticle/2825290>
- Knight S, Papanikitas A. Confidentiality. *InnovAiT*. 2018;11(11):628–633. DOI: 10.1177/1755738018788588
- Hunter I, Haining Ede G, Whiddett R. Increased electronic information sharing by sexual health services: confidentiality and consent. *Health Informatics J*. 2014 Mar;20(1):3–12. DOI: 10.1177/1460458212475140
- Sylkina SM, Mynbatyrova NK, Umbetbayeva ZB, Shulanbekova GK, Baitukayeva DU. Surrogacy: An international comparative analysis of the fundamental legislative principles of Ukraine. *Med Sci Law*. 2020 Jan;60(1):37–44. DOI: 10.1177/0025802419884417
- Krawczak A. Patient monitoring in Polish assisted reproductive technology centres. *Reprod Biomed Soc Online*. 2017 Jun 30;3:77–89. DOI: 10.1016/j.rbms.2017.06.001
- Sabatello M. Are the kids all right? A child-centred approach to assisted reproductive technologies. *International Journal of Social Welfare*. 2013;31(1):17–31. DOI: 10.1177/016934411303100104
- Ethics Committee of the American Society for Reproductive Medicine. Electronic address: asmr@asmr.org. Ethical obligations in fertility treatment when intimate partners withhold information from each other: an Ethics Committee opinion. *Fertil Steril*. 2024 Mar;121(3):428–433. DOI: 10.1016/j.fertnstert.2023.11.032
- Ethics Committee of the American Society for Reproductive Medicine. Electronic address: asmr@asmr.org. Informed consent in assisted reproduction: an Ethics Committee opinion. *Fertil Steril*. 2023 Jun;119(6):948–953. DOI: 10.1016/j.fertnstert.2023.03.009
- Rothstein MA. The Illusion of Health Privacy in Obstetrics–Gynecology. *Clin Obstet Gynecol*. 2023 Jun 1;66(2):267–277. DOI: 10.1097/GRF.0000000000000771
- O'Brien C, Newport M. Prioritizing women's choices, consent, and bodily autonomy: From a continuum of violence to women-centric reproductive care. *Soc Sci Med*. 2023 Sep;333:116110. DOI: 10.1016/j.socscimed.2023.116110
- Almeida T, Mehrmezhad M, Cook S. The Importance of Collective Privacy in Digital Sexual and Reproductive Health. 2024. DOI: 10.48550/arXiv.2311.15432
- Bielova M, Byelov O. Reproductive choice rights in the system of new bioethical human rights. *Visegrad Journal on Human Rights*. 2025;1:11–18. DOI: 10.61345/1339-7915.2025.1.2
- Bielova M, Byelov D. Legal regulation of human reproductive rights: Theoretical principles and practical aspects of the use of assisted reproductive technologies. *Visegrad Journal on Human Rights*. 2025;2:5–14. DOI: 10.61345/1339-7915.2025.2.1
- Паращук Л, Чапля І. Проблемні аспекти правового регулювання договору про сурогатне материнство в контексті гармонізації законодавства України до законодавства Європейського Союзу. *Актуальні проблеми правознавства*. 2022;1:70–76. Parashchuk L, Chaplya I. Problematic aspects of the legal regulation of surrogacy agreements in the context of harmonizing Ukrainian legislation with that of the European Union. *Current Issues in Jurisprudence*. 2022;1:70–76. DOI: 10.35774/app2022.01.070
- Москалюк Н, Слома В. Історичні аспекти та сучасний стан застосування допоміжних репродуктивних технологій в Україні та світі. *Актуальні проблеми правознавства*. 2023;1:102–108. Moskaliuk N, Sloma V. Historical aspects and the current state of assisted reproductive technology use in Ukraine and worldwide. *Current Issues in Jurisprudence*. 2023;1:102–108. DOI: 10.35774/app2023.01.102
- Габрелян ГВ. Становлення принципу інформованої згоди на медичне втручання в міжнародному праві. *Правова держава*. 2017;25:184–188. Habrelian HV. Development of principle of informed consent for medical intervention in international law. *Constitutional State*. 2017;(25):184–188. DOI: 10.18524/2411-2054.2017.25.233221
- Химич Н, Корчинський О. Інформована згода пацієнта на медичне втручання під час здійснення біомедичних досліджень. *Науковий вісник Ужгородського національного університету. Серія: Право*. 2023; 80(2):365–370. Khimych N, Korchynskiy O. Informed consent of patients to medical intervention during biomedical research. *Scientific Bulletin of Uzhhorod National University. Series: Law*. 2023;80(2):365–370. DOI: 10.24144/2307-3322.2023.80.2.60
- Батрин ОВ. Адміністративно-правове регулювання ліцензування медичної практики. *Право і безпека*. 2024;92(1): 31–41.

- Batryn OV. Administrative and Legal Regulation of Medical Practice Licensing. *Law and Security*. 2024;92(1):31–41. DOI: 10.32631/pb.2024.1.03
25. Кройтор ВА. Електронний договір про медичне обслуговування населення за програмою медичних гарантій. *Вісник Харківського національного університету внутрішніх справ*. 2024;105(2, ч. 1):42–51. Kroitor VA. Electronic Agreement on Medical Care for the Population Under the Medical Guarantees Program. *Bulletin of Kharkiv National University of Internal Affairs*. 2024;105(2, Part 1):42–51. DOI: 10.32631/v.2024.2.04
26. Теремецький ВІ, Батрин ОВ, Косиця ОО. Адміністративно-правові вимоги до закладів охорони здоров'я України щодо надання медичних послуг сурогатного материнства. *Вісник Кримінологічної асоціації України*. 2023;30(3):398–409. Teremetsky VI, Batryn OV, Kosytsia OO. Administrative and legal requirements for health care institutions in Ukraine providing surrogate maternity medical services. *Bulletin of the Criminological Association of Ukraine*. 2023;30(3):398–409. DOI: 10.32631/vca.2023.3.36
27. Батрин ОВ. Адміністративно-правове забезпечення розвитку єдиного медичного інформаційного простору. *Вісник Кримінологічної асоціації України*. 2024;31(1):354–366. Batryn OV. Administrative and legal ensuring the development of the uniform medical information space. *Bulletin of the Criminological Association of Ukraine*. 2024;31(1):354–366. DOI: 10.32631/vca.2024.1.29
28. Астаф'єв Д. Законодавче регулювання допоміжних репродуктивних технологій як напрям розвитку медичного туризму в Україні. *Актуальні проблеми правознавства*. 2024;4:48–54. Astafiev D. Legislative Regulation of Assisted Reproductive Technologies As a Direction for the Development of Medical Tourism in Ukraine. *Actual Problems of Law*. 2024;4:48–54. DOI: 10.35774/app2024.04.048
29. Ілюшук ОМ. Захист персональних даних у телемедицині. *Медичне право*. 2024;1(33):9–21. Ilyushik OM. Protection of Personal Data in Telemedicine. *Medical Law*. 2024;1(33):9–21. DOI: 10.25040/medicallaw2024.01.009
30. Prytyka Y, Nikitina T. The Right of a Person to Medical Care in Ukraine. *Problems of Legality*. 2022;158:63–81. DOI: 10.21564/2414-990X.158.263078
31. Про затвердження Порядку застосування допоміжних репродуктивних технологій в Україні: Наказ Міністерства охорони здоров'я України від 09.09.2013 № 787. [Інтернет]. МОЗ України, 2013. Доступно: <https://zakon.rada.gov.ua/laws/show/z1697-13#Text>
- On the Approval of the Procedure for the Use of Assisted Reproductive Technologies in Ukraine: Order of the Ministry of Health of Ukraine No. 787 dated September 9, 2013. [Internet]. Ministry of Health of Ukraine, 2013. Available from: <https://zakon.rada.gov.ua/laws/show/z1697-13#Text>
32. Верховний Суд України. Сама особа, якої стосується медична інформація (або її законний представник), має право приймати рішення щодо використання відомостей, які містяться в її медичній картці, що не є порушенням лікарської таємниці – ККС ВС. [Інтернет]. Судова влада України, 2024. Доступно: <https://supreme.court.gov.ua/supreme/pres-centr/news/1647524/>
- Supreme Court of Ukraine. The person concerned by medical information has the right to decide on the use of information contained in medical records. [Internet]. The judiciary of Ukraine, 2024. Available from: <https://supreme.court.gov.ua/supreme/pres-centr/news/1647524/>
33. Tcholakian M, Gorna K, Laurent M, Ben Ayed HK, Naghmouchi M. Self-sovereign identity for consented and content-based access to medical records using blockchain. [Internet]. Cornell University, 2024. Available from: <https://arxiv.org/abs/2407.21559>
34. Діордіца ІВ, Коваленко ІА, Коваль ОМ. Правова охорона персональних даних у сфері охорони здоров'я в Україні. *Науковий вісник Ужгородського національного університету*. 2024. Серія: Право;82(2):141–146. Diorditsa IV, Kovalenko IA, Koval OM. Legal Protection of Personal Data in the Healthcare Sector in Ukraine. *Scientific Bulletin of Uzhhorod National University. Series: Law*. 2024;82(2):141–146. DOI: 10.24144/2307-3322.2024.82.2.22
35. Діордіца ІВ, Коваленко ІА. Значення персональних даних у сфері охорони здоров'я в умовах інформатизації. *Науковий вісник Ужгородського національного університету*. Серія: Право. 2024;82(2):136–140. Diorditsa IV, Kovalenko IA. The Significance of Personal Data in Healthcare in the Context of Digitalization. *Scientific Bulletin of Uzhhorod National University. Series: Law*. 2024;82(2):136–140. DOI: 10.24144/2307-3322.2024.82.2.21
36. Коваленко ІА, Коваль ОМ. Проблеми та перспективи розвитку захисту персональних даних у сфері охорони здоров'я. *Наука і техніка сьогодні*. 2024;4(32):60–68. Kovalenko IA, Koval OM. Challenges and Prospects for the Development of Personal Data Protection in the Healthcare Sector. *Science and Technology Today*. 2024;4(32):60–68. DOI: 10.52058/2786-6025-2024-4-60-68
37. Суббот А, Калаченкова К, Берч В, Басалаєва А, Ратушна Б, Продан В. Конфіденційність інформації про репродуктивне здоров'я людини: цифрові виклики та регуляторні питання. *Репродуктивна ендокринологія*. 2025;5(80):70–84. Subbot A, Kalachenkova K, Berch V, Basalaeva A, Ratushna B, Prodan V. Privacy of human reproductive health information: Digital challenges and regulatory issues. *Reproductive Endocrinology*. 2025;5(80):70–84. DOI: 10.18370/2309-4117.2025.80.70-84
38. Основи законодавства України про охорону здоров'я: Закон України від 19 листопада 1992 року № 2801-XII. [Інтернет]. Верховна Рада України, ред. від. 11.02.2026. Доступно: <https://zakon.rada.gov.ua/laws/show/en/2801-12?lang=uk#Text>
- Fundamentals of Ukrainian Healthcare Legislation: Law of Ukraine No. 2801-XII of November 19, 1992. [Internet]. Verkhovna Rada of Ukraine, ed. dated 11.02.2026. Available from: <https://zakon.rada.gov.ua/laws/show/en/2801-12?lang=uk#Text>
39. Цивільний кодекс України від 16 січня 2003 року № 435-IV. [Інтернет]. Верховна Рада України, ред. від 25.05.2026. Доступно: <https://zakon.rada.gov.ua/laws/show/435-15#Text>
- Civil Code of Ukraine of January 16, 2003 No. 435-IV. [Internet]. Verkhovna Rada of Ukraine, ed. dated 25.05.2026. Available from: <https://zakon.rada.gov.ua/laws/show/435-15#Text>
40. Справа «Майборода проти України» (Заява № 14709/07). [Інтернет]. Верховна Рада України, 2023. Доступно: https://zakon.rada.gov.ua/laws/show/974_i82#Text
- The Case of Mayboroda v. Ukraine (Application No. 14709/07). [Internet]. Verkhovna Rada of Ukraine, 2023. Available from: https://zakon.rada.gov.ua/laws/show/974_i82#Text
41. Onishchenko NM, Teremetskyi VI, Kolesnikov AP, Kovalchuk OY, Shabalin AV, Romas MI. Protection of confidential medical information in Ukraine: Problems of legal regulation [Internet]. *Georgian Medical News*. 2024;349(4):161–168. Available from: https://www.geomednews.com/Articles/2024/4_2024/161-168.pdf
42. Thapa C, Camtepe S. Precision health data: Requirements, challenges and existing techniques for data security and privacy. *Computers in Biology and Medicine*. 2021;129: 104130. DOI: 10.1016/j.combiomed.2020.104130
43. Hassan M, Jameel M, Wang T, Bashir M. Unveiling Privacy and Security Gaps in Female Health Apps, 2025 Feb. DOI: 10.48550/arXiv.2502.02749

PROTECTION OF PATIENTS' RIGHTS TO CONFIDENTIALITY AND INFORMED CONSENT IN REPRODUCTIVE HEALTH

Literature review

M.M. Blikhar, doctor of juridical science, professor, head of the Department of Administrative and Information Law, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv

I.I. Komarnytska, doctor of juridical science, professor, Department of Civil Law and Procedure, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv

M.M. Yaremchuk, PhD in juridical science, senior lecturer, Department of Criminal Procedure and Criminalistics, Lviv State University of Internal Affairs, Lviv

N.M. Kalka, PhD in psychology, associate professor, Department of Practical Psychology, Educational and Scientific Institute of Management, Psychology and Security, Lviv State University of Internal Affairs, Lviv

M.R. Malets, PhD in juridical science, associate professor, Department of Administrative and Information Law, Institute for Law, Psychology and Innovative Education, Lviv Polytechnic National University, Lviv

Objective of the review: to conduct a comprehensive analysis of the legal and ethical foundations for protecting patients' rights to confidentiality and informed consent in the field of reproductive health; to identify the specific features of the legal regulation of personal medical data processing; and to examine the mechanisms ensuring the patient's right to autonomous decision-making regarding medical interventions in the context of modern reproductive technologies and international human rights standards.

Methodology. The study employed a set of general scientific and special legal research methods, including formal legal, systemic and structural, comparative-legal, and legal analysis methods. The source base comprised the regulatory legal acts of Ukraine, international human rights and healthcare instruments, scholarly works of domestic and foreign researchers, as well as materials of law enforcement and judicial practice concerning the protection of medical confidentiality and informed consent in the field of reproductive health.

Analysis of the literature. The legal regulation of reproductive health in Ukraine and international practice establishes clear requirements for healthcare institutions and medical personnel regarding the collection, processing, storage, and protection of patients' personal data, as well as ensuring an adequate level of informed consent. Failure to comply with these requirements may result in legal liability, adverse social consequences, and a decline in public trust in the healthcare system. This underscores the necessity of developing a comprehensive system for the protection of patients' rights based on the integration of legislative provisions, medical protocols, ethical standards, and public policy measures aimed at enhancing the safety of medical services, increasing public legal awareness, and ensuring effective personal data protection.

Conclusions. The study of this issue made it possible to outline legal mechanisms for ensuring a balance between state interests in the healthcare sector and the personal rights of patients, as well as to identify directions for improving the regulatory framework and practical approaches to the protection of patients' rights. This confirms the relevance of the topic for contemporary Ukrainian legislation and public policy, given its interdisciplinary nature, which combines medical law, human rights, and state regulatory practices in the field of reproductive health. The findings also highlight the need for further scholarly research, legislative activity, and the development of effective mechanisms for ensuring and protecting patients' rights.

Keywords: reproductive health, patients' rights, confidentiality, informed consent, medical law, public policy, personal data protection, assisted reproductive technologies, legal liability, medical ethics.

ЗАХИСТ ПРАВ ПАЦІЄНТІВ НА КОНФІДЕНЦІЙНІСТЬ ТА ІНФОРМОВАНУ ЗГОДУ У СФЕРІ РЕПРОДУКТИВНОГО ЗДОРОВ'Я

Огляд літератури

М.М. Бліхар, д. ю. н., професорка, завідувачка кафедри адміністративного та інформаційного права Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів

І.І. Комарницька, д. ю. н., професорка кафедри цивільного права та процесу Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів

М.М. Яремчук, к. ю. н., старша викладачка кафедри кримінального процесу й криміналістики Львівського державного університету внутрішніх справ, м. Львів

Н.М. Калька, к. психол. н., доцентка кафедри практичної психології навчально-наукового інституту управління, психології та безпеки Львівського державного університету внутрішніх справ, м. Львів

М.Р. Малець, к. ю. н., доцентка кафедри адміністративного та інформаційного права Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів

Мета огляду: комплексний аналіз правових та етичних засад захисту прав пацієнтів на конфіденційність та інформовану згоду у сфері репродуктивного здоров'я, визначення особливостей правового регулювання обробки персональних медичних даних, а також дослідження механізмів забезпечення реалізації права пацієнта на автономне прийняття рішень щодо медичних втручань у контексті сучасних репродуктивних технологій та міжнародних стандартів захисту прав людини.

Методологія. У роботі використано комплекс загальнонаукових і спеціально-юридичних методів, зокрема формально-правовий, системно-структурний, порівняльно-правовий та метод правового аналізу. Джерельну базу становили нормативно-правові акти України, міжнародні документи у сфері прав людини та охорони здоров'я, наукові праці вітчизняних і закордонних дослідників, а також матеріали правозастосовної практики щодо забезпечення конфіденційності медичної інформації та інформованої згоди у сфері репродуктивного здоров'я.

Аналіз даних літератури. Правове регулювання у сфері репродуктивного здоров'я в Україні та міжнародній практиці визначає чіткі вимоги до медичних закладів і персоналу щодо збору, обробки, зберігання та захисту персональних даних пацієнтів, а також забезпечення належного рівня інформованої згоди, недотримання яких може спричинити юридичну відповідальність, негативні соціальні наслідки та зниження суспільної довіри до системи охорони здоров'я. Це актуалізує необхідність формування комплексної системи захисту прав пацієнтів, яка ґрунтуватиметься на поєднанні законодавчих норм, медичних протоколів, етичних стандартів і державної політики, спрямованої на підвищення безпеки медичних послуг, рівня правової обізнаності населення та ефективного захисту персональних даних.

Висновки. Дослідження зазначеної проблематики дало змогу окреслити правові механізми забезпечення балансу між державними інтересами у сфері охорони здоров'я та особистими правами пацієнтів, а також визначити напрями удосконалення нормативно-правової бази й практичних підходів до захисту прав пацієнтів. У роботі було обґрунтовано актуальність цієї теми для сучасного українського законодавства та державної політики з огляду на її міждисциплінарний характер, зокрема поєднання галузей медичного права та прав людини, а також практики державного регулювання у сфері репродуктивного здоров'я. Отримані висновки підтверджують необхідність подальших наукових досліджень, правотворчої діяльності та розробки ефективних механізмів забезпечення і захисту прав пацієнтів.

Ключові слова: репродуктивне здоров'я, права пацієнтів, конфіденційність, інформована згода, медичне право, державна політика, захист персональних даних, допоміжні репродуктивні технології, юридична відповідальність, етика медицини.