STATE LEGAL REGULATION AND PATIENT AUTONOMY IN THE FIELD OF REPRODUCTIVE HEALTH

DOI: http://dx.doi.org/10.18370/2309-4117.2024.74.73-79

M.M. BLIKHAR
doctor of juridical sciences, professor, head of the Department of Administrative and Informational Law, Institute of Jurisprudence, Psychology and Innovative Education of the National University «Lviv Polytechnic», Lviv
ORCID ID: 0000-0003-2974-0419

I.O. LYCHENKO
doctor of juridical sciences, professor, head of the Civil Law and Procedure Department, Institute of Jurisprudence, Psychology and Innovative Education of National University «Lviv Polytechnic», Lviv
ORCID ID: 0000-0002-4838-3579

Y.S. OLIINYK
doctor of juridical sciences, professor, Department of Legal Theory and Constitutionalism, Institute of Jurisprudence, Psychology and Innovative Education of National University «Lviv Polytechnic», Lviv
ORCID ID: 0000-0002-5906-4565

M.Y. SHCHYRBA
doctor of law, professor, Department of Theory and History of State and Law, Lesya Ukrainka Volyn National University, Lutsk
ORCID ID: 0000-0002-6579-6893

I.I. SHULHAN
PhD, associate professor, Department of Administrative and Informational Law, Institute of Jurisprudence, Psychology and Innovative Education of the National University «Lviv Polytechnic», Lviv
ORCID ID: 0000-0002-9623-3495

Contacts:
Blikhar Maria Myronivna
National University «Lviv Polytechnic»
Lviv, Kniazya Romana st, 1/3
tel.: +38 (097) 241-89-04
E-mail: blikharm@ukr.net

INTRODUCTION

The reproductive and sexual health of the nation and the individual is essential for social development and future generations. The importance of this area is acknowledged at the international level. Goal 5 of the Millennium Development Goals aims to "achieve gender equality and empower all women and girls" and addresses factors such as discrimination, violence against women, and access to sexual health and reproductive rights [1]. Also, the Goal of Health Strategy 3.7, which aims to: access to sexual and reproductive health services, pays prominent attention to sexual and reproductive health; knowledge of sexual and reproductive health and rights; respectful care and human rights in sexual and reproductive health information and service delivery [1]. The international community places the obligation to create guarantees for the proper implementation of reproductive rights on the state. The main means of establishing social relations in any area is through legal regulation, and the reproductive sphere is no exception, so it is important to examine doctrinally how the state fulfills its obligations.

The rule of law, justice, and protection of human and civil rights and freedoms are the axiological values of modern state power. However, the issues of reproduction, maternity, family relations, and medical information are often of a sensitive private nature, so the welfare of the nation and the continuation of the species depend on the chosen method of legal regulation.

General theoretical jurisprudence has two methods of state influence on society: imperative (compulsory) and dispositive (providing for the right to choose behaviour by the subject of law). Medical activity, the healthcare sector, and the relationship between a patient and a doctor are among the areas where a balanced approach is needed, which would provide for a significant amount of patient autonomy. However, we cannot say that this area is devoid of legitimate state coercion, because national interests, public health, the value of human life and other aspects require state legal regulation.

The issue of reproductive health has been the subject of consideration by many scholars. Their works are devoted to the following groups of problems. Firstly, the inconsistency of legal regulation with social demands, in particular, the fundamental discrepancy between the existing indicators and the stated goals of family planning in terms of supporting reproductive health and rights (L. Senderowicz) [2]; the desired freedom and restrictions caused by law, so G. Cavaliere analyses the ethics of procreation based on an individual-oriented structure and points to the inadmissibility of third-party interference [3]. Secondly, the developments related to state positive legal guarantees for human reproductive function. In particular V. Kantorová identified countries that have succeeded in reducing the number of unwanted pregnancies and unsafe abortions in order to gain knowledge of these achievements [4]. Thirdly, a group of scholars who studied the meaning and role of reproduction and the legal regulation of this right for adolescents and young people (F. Ashley) [5] proposed a scale of sexual and reproductive empowerment for adolescents and young people [6], and the specifics of education in this area (Villalobos A. et al.) [7]. Fourthly, the issue of women's rights and autonomous will in relation to reproductive health was studied by scholars based on the legal norms of India [8], Pakistan [9], Ethiopia [10], and the United Kingdom [11], but in most cases, gender inequality in the exercise of the right to reproduction was pointed out. Some researchers (J. Chalmers et al.) even argued that the right to autonomous reproduction for women exists formally, in contrast to men's reproductive autonomy [12]. Sixthly, a group of works that have a special understanding of patient autonomy in the field of reproduction, in particular Burke H. et al. consider contraceptive services to improve reproductive health through the ability of people to achieve their reproductive goals to be the basis of autonomy, rather than voluntary consent [13]. A. Athan [14] develops the concept of reproductive autonomy much more broadly, bringing it to the level of "reproductive identity", which is understood as a conscious right to sexuality and parenthood.

However, the issue of interaction between the legal sphere, the impact of the state and public authorities on the reproductive autonomy of an individual and the reproductive health of the nation has rarely been the subject of scholarly attention, and therefore such an analysis requires additional attention.

Objective of the study: to find the optimal combination of state, public and private legal interests in the exercise of the right to reproductive health and to establish the legal nature of patient autonomy in this area. Technologies and methods of assisted reproduction raise complex questions about how to better understand, respect and promote autonomy, and this issue should also be analysed in this paper.

MATERIALS AND METHODS

To achieve these aims, we use a comprehensive methodology that includes a dual research agenda in the synergy of medicine and law, focusing on the context, processes, interests, systems of law and clinical practice, behaviour of the participants involved in this process, and relationships embedded in a public health perspective. The results will only be valid if they are aligned with the tradition of policy analysis that exists in the field of public health and health policy. Policy analysis aims to understand, describe and explain what is defined as a public problem that deserves the attention of academics and policy makers. The defined paradigm requires a combination of the third area of science – cultural studies, morality and ethics, since mental and orthological intentions, social stereotypes and practices, and religious norms affect the praxeological aspect of the right to reproduction. The adopted multidimensional framework is important for public health.

The method of humanism is used to highlight the essence and importance of human rights, personal freedom, dignity of the individual in a state governed by the rule of law and the right to privacy in making personal reproductive health decisions. However, the rights of an individual end where the legitimate interests of other subjects of law begin, so it is appropriate to analyse the legitimate possibility of restricting the human right to reproductive choice. The method of gender analysis is appropriate for identifying the level of autonomy of women and men in reproductive medicine, as gender factors have a significant impact on equality, non-discrimination, barriers and legal regulation of policy in the field under study.

The research materials become substantiated and representative when they are based on a broad empirical and research methodology. Several data collection tools were used, including document analysis, interviews conducted by the author at various stages of the study on public attitudes towards the state's reproductive policy, published statistics and research, and reports of casual state and legal situations. The documents under consideration include government reports, legal statutes, other official documents, and professional recommendations.

The authors conducted a survey using the author's questionnaires in Lviv, Zakarpattia and Kyiv regions (Ukraine) and Podkarpackie Voivodeship in the cities of Przemysl and Rzeszów (Republic of Poland). The selected regions are quite representative because they represent different levels of access to medical infrastructure within the country, allow for heterogeneity of rural and urban populations, and have their own cultural and mental characteristics that may represent attitudes towards reproductive health. The number of respondents was 402 women who had given birth at least once, who personally gave permission to participate and were of legal age. The purpose of the survey was to obtain information about women's personal experiences and opinions in order to form a position based on the public ideology prevailing in the country, assess the level of approval of legal regulation in the field of reproduction and identify gaps in clinical practice. The survey was conducted through personal interviews and the results are presented in graphical form for clarity, the number of Ukrainian women surveyed was 206, and the number of Polish women surveyed was 196. The margin of error is about 2%. The survey was conducted from March 2023 to September 2024.

This methodological approach allowed us to identify problematic aspects of the interaction between legal regulation, government influence, and patient autonomy in the field of reproductive health.

RESULTS AND DISCUSSION

Approaches to state regulation of reproductive autonomy

The role of the state authorities in a democratic society is to protect and defend the human right to reproduction, and the modern medical and legal paradigm should develop in the area of influence of state institutions and policies on the personal sphere of a person.

There are two practices in this regard. The first approach is rights-based and emphasises individual autonomy; it will not allow state regulation that interferes with personal autonomy in decision-making, at least not without a good reason. The basis of the relationship in the state-person-healthcare system is the value of the position, opinion, and "free will" of the individual, who has the right to make his or her own choices within the scope of the law and the doctor "coordinates the position with the patient" [15]. In the light of reproductive health, such autonomy means the right of a person of any gender to make decisions about the specifics of sexual life, the number of children, refusal to have children, positioning of their sexual identity, etc. A person's autonomy is determined by his or her human dignity and the ability to reflect on personal goals and the ability to act on the basis of this reflection.

The principle of patient autonomy is formed from the autonomy of a person's free will, which is key in modern medicine, but according to R. Alam and A. Rasheed, it entails many unresolved dilemmas [16]. This approach is the basis of modern medical practice, provides for a departure from the paternalistic ideology, when the patient does not have the right to choose a doctor, a method of treatment, and in the modern autonomous principle, mandatory consent to medical intervention and medical procedures of an adult plays a significant role. Josephine Johnston and Rachel Zacharias prove that the right of autonomy to reproductive rights is thus seen primarily as a negative right – the right of individuals to be free from unwanted or unauthorised medical intervention. However, it also extends to the right to be free from obstacles to accessing affordable health care, if such health care includes contraception, abortion, prenatal testing and fertility preservation [17].

The second approach adopts regulation that affects individual decision-making for the public good. In a modern democratic society, we can no longer talk about the existence of state coercion in the field of reproductive health. Usually, the state uses

incentives and stimulating measures to correlate the reproductive health of the nation. Here, the state acts as a proactive institution. The literature proves that in a state governed by the rule of law, the main policy is preconception care, which is an intervention before pregnancy to improve the short- and long-term health and well-being outcomes of people of reproductive age and any future children they may have [18, 19]. However, the role of the state still remains significant, and the second approach still imposes restrictions on the right to reproduction, but with a legitimate purpose. What this purpose is should be further defined.

In our opinion, it is possible to distinguish two legitimate groups of restrictive legal phenomena in the field of the right to exercise the human reproductive function. The first group includes general legal restrictions relating to human rights in general. The Convention for the Protection of Human Rights and Fundamental Freedoms [20] is a key document that defines the European values of a democratic state, and Article 8 provides for the right to respect for family and private life. It forms the basis of autonomy, as a person has the right to determine his or her own life, including in the area of reproduction. Part two of Article 8 states that public authorities may not interfere with the exercise of this right, except for the cases provided by law and necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others. Thus, the quoted standard indicates those areas of state and public interest for which human rights restrictions may occur.

The second group of rights concerns the legitimate restriction of reproductive rights. In our opinion, these include: protection of women's health, fetal health in late pregnancy, ethical and religious norms of society, and the public interest in birth control. While the first two are perceived as absolutes, the latter are subject to debate and each state determines its own regulation, but in some cases, state influence is quite categorical and authoritarian.

We can consider an example of this kind of state influence on patient autonomy by the legislation of Poland, where an almost complete ban on abortion was recently enforced by the ruling party with the support of Catholic Church leaders and lay people after the previous adoption of one of the most restrictive abortion laws in Europe [21]. The Polish case highlights the consequences of drastic restrictions on access to safe and legal abortion that can arise in a relatively high-income country in the context of moral and religious requirements of the state [22]. Nationally representative polls consistently show a sharp polarisation of opinion and a lack of public consensus in favour of strict restrictions or accessibility on request, and in 2016–2020, general protests, street brawls and mass actions swept Poland. Abortion remains a widely recognised phenomenon on a massive scale, despite further tightening of legislation and a lack of meaningful documentation. It is estimated that around 150,000 Polish women terminate their pregnancies every year, and the actual number is now even more difficult to estimate due to the increase in the number of medical abortions (performed with medication instead of surgery) [23]. Women having late-term abortions can be sent to the Netherlands or the UK, where abortion is actually allowed up to 24 weeks [24]. In the pre-war period, the Ukrainian borderlands also served as a hub for Polish women to exercise their right to decide on their own bodies.

The survey we conducted, among other things, focused on women's experiences of being granted autonomy in the medical field in relation to reproductive rights. The survey data are presented in Fig. 1.

We see a significant discrepancy between the positions of

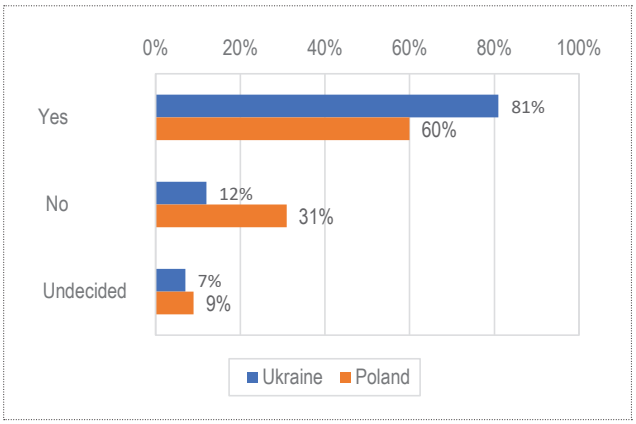

Fig. 1. Did you have autonomy in deciding on reproductive health issues? (results of the author's survey, 2023–2024)

Polish and Ukrainian women in that the former did not have a significant right to autonomy, as the legal regulation of the right to abortion in Poland is much less than in Ukraine, where a woman decides on her own and exercises this right until the appropriate time.

Another example is found in US law. On 24 June 2022, the United States Supreme Court ruled in the case of Dobbs v. Jackson Women's Health Organisation, where Judge Alito wrote a majority opinion that "abortion is not a fundamental constitutional right because such a right has no basis in the text of the Constitution or in the history of our nation" [25]. Thus, the law defining the right to abortion was cancelled.

Although this legal decision directly affected women's reproductive rights and bodily autonomy, it also had a strong impact on men. Scientists point out that as a result of this state legal regulation, the number of requests for vasectomy counselling increased by 35.0%. However, the problem is not exhausted by this, but only exacerbated, as vasectomised men were much younger (35 vs. 38 years old before the decision was made) and much more likely to be under 30 years old (23.9% vs. 10.3%) [26]. Previously, the average age of men undergoing vasectomy was approximately 37 years old [27]. This surge in young men choosing permanent contraception half a decade earlier than historical rates should not be dismissed as a negative temporal change. The younger generation is now significantly influenced by the legal climate, and the consequences of this decision for the population will continue to manifest themselves in various ways over the coming decades.

Experts point out that the myth that American women have full autonomy over their reproductive choices needs to be dis-

pelled. Kimport K. in her book "No Real Choice", which has gained worldwide popularity, points out that structural, cultural and empirical factor can make the choice of abortion impossible [28].

Such a state incident demonstrates that the lack of a coordinated reproductive policy with the public is ineffective and causes public resistance and the search for other, not always legitimate, ways to solve the problem.

Synergies of reproductive autonomy with the use of new reproductive technologies

Modern reproductive technologies pose significant uncertainties in terms of the choice of dominance of the first or second approaches discussed earlier. Respect for autonomy is a central value in reproductive ethics, but it can be challenging to implement in practice. This primarily concerns the number of embryos used in embryo transfer *in vitro* fertilisation (IVF). The state policy does not answer the question of what a doctor should do if a patient requests a large number of embryos to be transferred and how to determine whether such a request is autonomous or due to other factors, including the high cost of the medical procedure, the woman's age, social pressure, etc. The problem does not end there – there is no legal regulation of actions on the part of a doctor if he or she has reasonable doubts about the autonomous will of a person, and no algorithm for further actions is provided.

The closely related concepts of reproductive autonomy and reproductive rights developed along with the emergence in the twentieth century of new medical technologies that could first safely prevent or terminate pregnancy, and later safely create it.

Let us turn to medical law in this area. In most developed countries, the number of embryos transferred is regulated by medical protocols. Table presents the general conditions for embryo transfer in IVF.

So, for the most part, the number of embryos transferred depends on the woman's age, the number of attempts, and the quality of the embryos. Most legislation prohibits the transfer of more than three embryos. In most cases, IVF treatment is rarely performed before the age of 35; a UK report found that the average age of women starting IVF treatment for the first time exceeded 35 years old [29], so most women fall into the second or third groups presented in the table, therefore the patient's autonomy in terms of the number of embryos transferred should be taken into account. Respect for autonomy is necessary where people have the opportunity to make a fully informed and voluntary choice, the right to self-determination.

Let's analyse the current national legislation. The only document and it should be noted that it is intellectually outdate, is the subordinate legislation issued by the Ministry of Health of Ukraine "On Approval of the Procedure for the Use of Assisted Reproductive Technologies in Ukraine" of 2013. Paragraph 3.8 of this Order states the following: it is recommended to transfer no more than 1–2 embryos into the uterine cavity. However, with a predicted reduced probability of implantation, it is possible to transfer a greater number of embryos – 3 (with clinical justification and with the patient's consent) [30].

This approach is not fully consistent with modern global medical approaches. Age is one of the main determining factors, so according to the statistics available to us, patients aged 18–34 years old have the highest rate of pregnancy on fresh embryo transfer – 42%, which decreases sharply over the years and at 40–42 years old is 16% [29], so the age approach determined by international practice is justified by clinical practice.

A significant legal and medical problem is that the approach specified in the national regulatory framework determines the substantial discretion of the physician, which is not always justified, since it is a challenge to be responsible for the professionalism of each physician and medical errors occur quite often. Regarding the latter, the data is diverse, depending on the country and research methodology. English scientists indicate that 237 million medical errors occur annually in this country at some stage of the treatment process, 38.4% of which occur in primary care; 72% have a small/unsecured potential, and 66 million of them are potentially clinically significant [31]. According to analytical data from Chinese scientists, they account for up to 5% in the reproductive sphere [32], while other data indicate that more than 800 women and adolescent girls die every day due to complications during pregnancy and childbirth [33]. Of course, they can be of a different nature – "multidisciplinary organisational and legal, forensic pharmaceutical, clinical and pharmacological, forensic medical, criminal law" [34], but they are all significant because they affect the sphere of human life and health, and in the case of reproductive health, additionally the fetus.

The author's survey analysed how often women encountered medical errors in order to determine whether legal regulation could allow for significant medical discretion. The results are presented graphically (Fig. 2).

The survey data and field experiments of other scientists indi-

Table. The recommended number of embryos in IVF according to global medical protocols (data generated by the authors, 2024)

Organization protocols	Allowed number of embryos according to the woman's age		
	Up to 35 years old	35–40 years old	Over 40 years old
American Society for Reproductive Medicine	1–2	2– 3	More than 3 with the agreement of the doctor and the patient
European Society of Human Reproduction and Embryology	1	2	2
National Institute for Health and Care Excellence, UK	1	After 37 years old – 2	2
Canadian Society of Reproductive Medicine	1	1–2	Up to 3
Fertility Society of Australia and New Zealand	1	After 38 – 2	2

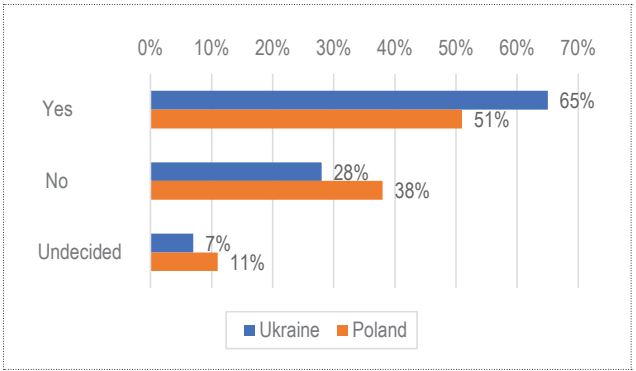

Fig. 2. Have you encountered doctors' mistakes in the field of reproductive health? (results of the author's survey, 2023–2024)

cate that a clear establishment of clinical practice requirements in protocols is appropriate and justified.

Given the above arguments, we propose to state paragraph 8.8 of the Order of the Ministry of Health of Ukraine "On Approval of the Procedure for the Use of Assisted Reproductive Technologies in Ukraine" in the following wording: "It is recommended to transfer to the uterine cavity: one embryo for women under 35 years of age, from 35 to 40 – up to two embryos, up to two embryos (if care is provided for the first time) and up to three embryos – over 40 years of age."

Another dilemma in the field of patient autonomy is the issue of the latest opportunities in the field of reproductive and genetic medicine.

Emerging reprogenetic technologies may radically change the way people reproduce in the near future [35]. One of the anticipated consequences of disruptive innovations in childbearing is the increased reproductive autonomy of future parents. Regarding the future parental freedom to enhance the non-health traits of their offspring, as well as the child's physical features. Not only is there a moral and religious controversy, but there is also disagreement about the threat to the child's future personal autonomy.

The idea of genome modification has now revolutionized the era of modern therapeutic research [36]. At the time of writing this article, perhaps the most talked about of these technologies have been the new gene-editing tools, including CRISPR–associated protein 9 (Cas9), which have sparked a debate about whether future parents should be allowed to help modify the genes of their future children. The gene editing technology of clustered regularly intervals of short palindromic repeats (CRISPR/CRISPR-Cas9) is an ideal tool for the future to treat diseases by permanently correcting harmful base mutations or destroying disease-causing genes with high precision and efficiency [37]. Particularly positive results are expected in the field of combating cancer cells [38; 39]. Today, the technology can determine the chromosomal composition of the fetus and detect hundreds of diseases and predispositions to diseases during pregnancy. In addition, in vitro analysis of embryos using preimplantation genetic diagnosis has made it possible to predict to some extent the health status of the child even before pregnancy is established.

Autonomy in the context of legal humanism has demonstrated openness to germ line modification for the treatment or prevention of diseases, crossing what many previously considered a hard ethical line. Given the potential impact of such manipulations on children born several generations into the future, the ethical implications of current actions may not be realized for many years. Medical science is inherently aimed at preserving health and eliminating disease. Although the development of diagnostic methods to predict the health of unborn children was a fundamental goal underlying research into prenatal and preimplantation diagnostics, the knowledge gained has in some cases been used for non-medical purposes. The issues of the use of enhancement raise serious concerns about eugenics and the value of designer children. We agree with a number of scientists [40, 41] that this technology requires safeguards to avoid misuse or ethical problems.

Our survey demonstrated the negative attitude of Ukrainian and Polish society towards genetic modifications in the reproductive sphere. The amplitude between Ukrainian and Polish women is insignificant, which can be explained by the more persistent religious stereotypes of Polish women. The results are shown in Fig. 3.

Before embryo gene editing moves from theory and research

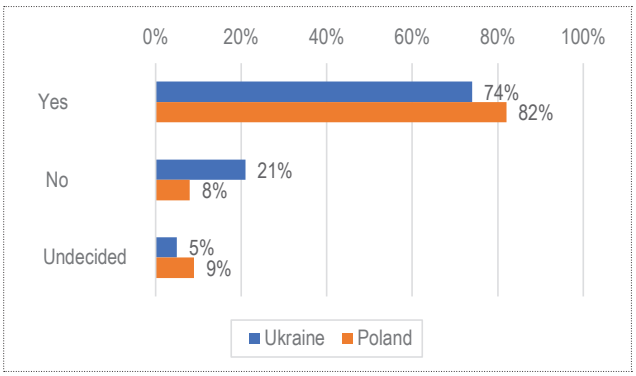

Fig. 3. What is your opinion on the legal prohibition of gender engineering to enhance intelligence and physical characteristics? (results of the author's survey, 2023–2024)

to clinical practice – which is rapidly approaching reality – stakeholders must discuss and develop mechanisms that will allow access to those who will benefit from avoiding diseases in their children, while setting limits on experimental use that most of society considers unethical.

CONCLUSIONS

The modern medical and legal reality provides for two approaches to state regulation of reproductive autonomy, the first limits legal regulation and state intervention by prioritizing individual autonomy, the second indicates a legitimate broad, but legitimate possibility of interference in the patient's autonomous decision in the field of reproductive health. The authors distinguish two legitimate groups of restrictive legal phenomena in the sphere of the right to exercise human reproductive function: general legal restrictions (interests of national security, public safety, economic well-being of the country, prevention of riots or crimes, protection of health, morality, rights and freedoms of other persons) and special ones – relating exclusively to the human right to reproduction (protection of wom-

en's health, health of the fetus in the late stages of pregnancy, ethical and religious norms of society, public interest in the sphere of birth control).

Using the example of the policy on patient autonomy in the sphere of reproductive health of the USA and Poland, it is proven that state restrictive policy contributes to a number of negative consequences: public measures of national resistance, the search for alternative ways to resolve the issue of reproduction (abortion tourism, vasectomy, etc.).

The synergy of reproductive autonomy when using the latest reproductive technologies is manifested through the possibility of devaluation of a real independent decision during the IVF procedure and this applies to the number of embryos used in embryo transfer. It is motivated that the high cost of the procedure, age, number of attempts deprive a woman of autonomy of choice. The need to update the legislation by specifying clearer medical protocols regarding the number of embryos and their dependence on the patient's age is indicated. The problem of an ethical and medical nature is identified as the latest possibilities of gene editing and the public fear of the specified area is proven, which requires additional legal regulation.

Conflict of interest

The authors declare the absence of a conflict of interest.

ЛІТЕРАТУРА/REFERENCES

1. Logie C. H.
Sexual rights and sexual pleasure: Sustainable Development Goals and the omitted dimensions of the leave no one behind sexual health agenda. Global Public Health. 2021. 18(1). DOI: 10.1080/17441692.2021.1953559
2. Senderowicz L.
Contraceptive Autonomy: Conceptions and Measurement of a Novel Family Planning Indicator. Studies in Family Planning, 2020;51(2):161–176
DOI: 10.1111/sifp.12114
3. Cavaliere G.
The problem with reproductive freedom. Procreation beyond procreators' interests. Med Health Care and Philos 2020; 23:131–140 DOI: 10.1007/s11019-019-09917-3
4. Kantorová, V.
Unintended pregnancy and abortion: what does it tell us about reproductive health and autonomy? The Lancet Global Health, 2020; 8 (9):e1106 – e1107
5. Ashley F.
Adolescent Medical Transition is Ethical: An Analogy with Reproductive Health. Kennedy Institute of Ethics Journal, 2022;32 (2):127–171 DOI:10.1353/ken.2022.0010
6. Upadhyay U, Danza P, Torsten N, et al.
Development and Validation of the Sexual and Reproductive Empowerment Scale for Adolescents and Young Adults. Journal of Adolescent Health. 2021; 68(1): 86-94
DOI: 10.1016/j.jadohealth.2020.05.031
7. Villalobos A, Estrada F., Hubert C., Torres-Ibarra L., et al.
Sexual and reproductive health among adolescents in vulnerable contexts in Mexico: Needs, knowledge, and rights. PLOS Glob Public Health. 2023;3(11): e0002396.
DOI: 10.1371/journal.pgph.0002396
8. Mondal D, Karmakar S, Banerjee A.
Women's autonomy and utilization of maternal healthcare in India: Evidence from a recent national survey. PLoS ONE. 2020;15(12): e0243553. DOI: 10.1371/journal.pone.0243553
9. Nadeem M, Malik MI, Anwar M, et al.
Women Decision Making Autonomy as a Facilitating Factor for Contraceptive Use for Family Planning in Pakistan. Soc Indic Res. 2021;156: 71–89. DOI: 10.1007/s11205-021-02633-7
10. Kebede AA., Cherkos EA, Taye EB, et al.
Married women's decision-making autonomy in the household and maternal and neonatal healthcare utilization and associated factors in Debretabor, northwest Ethiopia. PLoS ONE. 2021; 16(9): e0255021. DOI: journal.pone.0255021
11. Riche E, Barrett, G, Hall JA.
Evaluation of the psychometric properties of the Reproductive Autonomy Scale for use in the UK. BMJ Sexual & Reproductive Health. 2023;49:151–157. DOI: 10.1136/bmjsrh-2022-201685
12. Chalmers J, Petterson A, Woodford L, Sutton, R.
The Rights of Man: Libertarian Concern for Men's, But Not Women's, Reproductive Autonomy. Political Psychology. 2023; 44(3):603–625 DOI: 10.1111/pops.12867
13. Burke HM, Ridgeway K, Murray K, et al.
Reproductive empowerment and contraceptive self-care: a systematic review. Sexual and Reproductive Health Matters, 2022;29(3). DOI: 10.1080/26410397.2022.2090057
14. Athan AM.
Reproductive identity: An emerging concept. American Psychologist, 2020. 75(4): 445–456. DOI: 10.1037/amp0000623
15. Hwan K, Lee A.
How patient autonomy drives the legal liabilities of medical practitioners and the practical ways to mitigate and resolve them, Postgraduate Medical Journal. 2023; 99(1168):83–88. DOI: 10.1093/postmj/qgad003
16. Alam R, Abdul Rasheed F.
Patient autonomy and decision-making capacity; ethical dilemmas in clinical practice. [Internet]. Pakistan Journal of Ethics. 2024;4(1):7–12. Available from: https://www.kgpublisher.com/index.php/pje/article/view/138
17. Johnston J, Zacharias R.
The Future of Reproductive Autonomy. Supplement: Just Reproduction: Reimagining Autonomy in Reproductive Medicine, 2017;47:S6–S11 DOI: 10.1002/hast.789
18. Hall J, Chawla M, Watson D, et al.
Addressing reproductive health needs across the life course: an integrated, community-based model combining contraception and preconception care. The Lancet Public Health, 2023; 8(1): e76 – e84 DOI: 10.1016/S2468-2667(22)00254-7
19. Watson D, Jacob C, Giles G, et al.
A scoping review of nutritional interventions and policy guidelines in the interconception period for prevention of noncommunicable diseases. Reprod Female Child Health. 2022; 1:18–41 DOI:10.1002/rfc2.8
20. Convention for the Protection of Human Rights and Fundamental Freedoms Rome. 4.XI.1950.
[Internet]. Available from: https://www.echr.coe.int/documents/d/echr/convention_ENG
21. Kulczycki A.
Between a Rock and a Hard Place: Abortion, Catholicism, the Populist Right and Public Health Threats in Poland. Religions, 2023;14;1271. DOI: 10.3390/rel14101271
22. Kehmová S.
Towards a total ban on abortion? The factors shaping Polish perception of the right to abortion and reproductive injustice in Poland. SN Soc Sci/ 2023;3:153. DOI: 10.1007/s43545-023-00742-3
23. Strek K., Brady K., Parker C.
Polish court convicts activist of providing abortion pills in landmark case. Washington Post, 2023; March 14.
24. Sussman A.
What the U.S. Could Learn from Abortion Without Borders. [Internet]. The New Yorker, 2022; May 17. Available from: https://www.newyorker.com/news/news-desk/what-the-us-could-learn-from-abortion-without-borders
25. United States Reports. Dobbs, State Health Officer of the Mississippi Department of Health et al.
[Internet]. Jackson Women's Health Organization et al. 2022;597. Available from: https://www.supremecourt.gov/opinions/21pdf/19-1392_6j37.pdf
26. Bole R., Lundy S.D., Pei E, et al.
Rising vasectomy volume following reversal of federal protections for abortion rights in the United States. Int J Impot Res, 2024;36:265–268
DOI: 10.1038/s41443-023-00672-x
27. Velez D, Pagani, R, Mima, M, Ohlander S.
Vasectomy: a guidelines-based approach to male surgical contraception. Fertil Steril. 2021;115:1365–8. DOI: 10.1016/j.fertnstert.2021.03.045
28. Kimport K.
No Real Choice: How Culture and Politics Matter for Reproductive Autonomy, 2021; DOI:10.36019/9781978817951
29. Fertility treatment 2022: preliminary trends and figures. Preliminary UK statistics for IVF and DI treatment, storage, and donation. [Internet]. 2024 Available from: https://www.hfea.gov.uk/about-us/publications/research-and-data/fertility-treatment-2022-preliminary-trends-and-figures/
30. Наказ МОЗ України від 09.09.2013 № 787 «Про затвердження Порядку застосування допоміжних репродуктивних технологій в Україні» [Інтернет]. Міністерство охорони здоров'я України. 2013. Available from: https://zakon.rada.gov.ua/laws/show/z1697-13#Text ;
Order of the Ministry of Health of Ukraine 09.09.2013 № 787 «Pro zatverdzhennia Poriadku zastosuvannia dopomizhnykh reproduktyvnykh tekhnolohii v Ukraini». [Internet]. Order of the Ministry of Health of Ukraine. 2013. Available from: https://zakon.rada.gov.ua/laws/show/z1697-13#Text
31. Elliott RA, Camacho E., Jankovic D, et al
Economic analysis of the prevalence and clinical and economic burden of medication error in England. BMJ Quality & Safety 2021;30:96–105. DOI: 10.1136/bmjqs-2019-010206
32. Zhu J, Pu S, He J, et al.
Processing imbalanced medical data at the data level with assisted-reproduction data as an example. BioData Mining, 2024; 17, 29 DOI: 10.1186/s13040-024-00384-y
33. Global health. UnFoundation. 26.03.2023.
[Internet]. 2023. Available from: https://unfoundation.org/what-we-do/issues/global-health/?gclid=Cj0KCQjw2v-gBhC1ARIsAOQdKY1Ll4chY_Qy6j6j0Aj46VL4o_Oeblp--
34. Shapovalov V.
Multidisciplinary Study of Medical Errors in the System of Legal Relations Between «Doctor-Patient-Pharmacist-Advocate» During the Circulation of Drugs. SSP Modern Pharmacy and Medicine. 2023;3(2):1–10. DOI: 10.53933/sspmpm.v3i2.88
35. Rueda J.
From Self-Determination to Offspring-Determination? Reproductive Autonomy, Procrustean Parenting, and Genetic Enhancement. 2022;88(6):1086–110
DOI: 10.1111/theo.12349
36. Sharma G, Sharma AR, Bhattacharya M. et al.
CRISPR-Cas9: A Preclinical and Clinical Perspective for the Treatment of Human Diseases. Molecular Therapy, Volume 29, Issue 2, 571 –86 DOI: 10.1016/j.ymthe.2020.09.028
37. Li T, Yang Y, QiH, et al.
CRISPR/Cas9 therapeutics: progress and prospects. Sig Transduct Target Ther 2023; 8, 36 DOI: 10.1038/s41392-023-01309-7
38. Zhang H, Qin C, An C, et al.
Application of the CRISPR/Cas9-based gene editing technique in basic research, diagnosis, and therapy of cancer. Mol Cancer, 2021; 20, 126.
DOI: 10.1186/s12943-021-01431-6
39. Wang, S.W., Gao, C., Zheng, Y.M. et al.
Current applications and future perspective of CRISPR/Cas9 gene editing in cancer. Mol Cancer, 2022; 21, 57
DOI: 10.1186/s12943-022-01518-8
40. Barman A, Deb B, Chakraborty S.
A glance at genome editing with CRISPR–Cas9 technology. Curr Genet 2020; 66: 447–462
DOI: 10.1007/s00294-019-01040-3
41. Janik, E, Niemcewicz M., Ceremuga M, et al.
Various Aspects of a Gene Editing System—CRISPR–Cas9. Int. J. Mol. Sci. 2020; 21, 9604.
DOI: 10.3390/ijms21249604

STATE LEGAL REGULATION AND PATIENT AUTONOMY IN THE FIELD OF REPRODUCTIVE HEALTH

M.M. Blikhar, doctor of juridical sciences, professor, head of the Department of Administrative and Informational Law, Institute of Jurisprudence, Psychology and Innovative Education of the National University «Lviv Polytechnic», Lviv
I.O. Lychenko, doctor of juridical sciences, professor, head of the Civil Law and Procedure Department, Institute of Jurisprudence, Psychology and Innovative Education of National University «Lviv Polytechnic», Lviv
Y.S. Oliinyk, doctor of juridical sciences, professor, Department of Legal Theory and Constitutionalism, Institute of Jurisprudence, Psychology and Innovative Education of National University «Lviv Polytechnic», Lviv
M.Y. Shchyrba, doctor of law, professor, Department of Theory and History of State and Law, Lesya Ukrainka Volyn National University, Lutsk
I.I. Shulhan, PhD, associate professor, Department of Administrative and Informational Law, Institute of Jurisprudence, Psychology and Innovative Education of the National University «Lviv Polytechnic», Lviv

Background. The article analyses the interaction between the state's mandatory regulation of the human right to reproductive health and its coordination with the patient's autonomous will. The main emphasis is placed on the latest reproductive procedures and methods and possible problems in their implementation in relation to human autonomy are pointed out.

Objective of the study: to find the optimal combination of state, public and private legal interests in the exercise of the right to reproductive health and to establish the legal nature of patient autonomy in this area.

Materials and methods. A comprehensive methodological approach was used, including a combination of legal, medical knowledge and cultural and ethical norms of society. The humanistic method was used to establish the priority of human rights and will in the regulation of reproductive rights, and the method of gender analysis was used to understand the differences in the level of autonomy of women and men in reproductive medicine. The empirical method was used in the author's survey of 402 women in the Republic of Poland and Ukraine on their personal and state legal attitudes to reproductive health.

Results. Two approaches to state regulation of reproductive autonomy are envisaged: the first one limits legal regulation and state intervention, giving priority to individual autonomy, the second one indicates a legitimate broad, but legitimate possibility of interfering with the patient's autonomous decision in the field of reproductive health. The author distinguishes legitimate groups of restrictive legal phenomena in the field of the right to exercise the human reproductive function: general legal restrictions and special restrictions relating exclusively to the human right to reproduction.

Conclusions. It is need to update national legislation by specifying clearer medical protocols regarding the number of embryos during embryo transfer and their dependence on the patient's age. The author identifies the newest possibilities of gene editing as an ethical and medical problem and proves the public fear in this area, which requires additional legal regulation.

Keywords: reproductive health, reproductive rights, patient's right to autonomy, women's right, public health, governmental influence, legal policy, legal regulation.

ДЕРЖАВНО-ПРАВОВЕ РЕГУЛЮВАННЯ ТА АВТОНОМІЯ ПАЦІЄНТА У СФЕРІ РЕПРОДУКТИВНОГО ЗДОРОВ'Я

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.О. Личенко, д. ю. н., професорка, завідувачка кафедри Цивільного права та процесу Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів
Я.С. Олійник, д. ю. н., доцентка, професорка кафедри теорії права та конституціоналізму Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів
М.Ю. Щирба, д. ю. н., доцентка, професорка кафедри теорії та історії держави і права Волинського національного університету ім. Лесі Українки, м. Луцьк
І.І. Шульган, к. ю. н., доцентка кафедри адміністративного та інформаційного права Інституту права, психології та інноваційної освіти Національного університету «Львівська політехніка», м. Львів

Обґрунтування. У статті проаналізовано взаємозв'язок державного імперативного регулювання права людини на репродуктивне здоров'я та його узгодження з автономною волею пацієнта. Основний акцент робиться на новітніх репродуктивних процедурах і методах та зазначаються можливі проблеми у їхній реалізації щодо автономності людини.

Мета дослідження: визначення оптимального поєднання державно-громадських та приватноправових інтересів для реалізації права на репродуктивне здоров'я та встановлення правової природи автономії пацієнта в цій сфері.

Матеріали та методи. Використано комплексний методичний підхід, що охоплює юридичні, медичні знання та культурно-етичні норми суспільства. Застосовано гуманістичний метод для встановлення пріоритету прав та волі людини в регулюванні її репродуктивних прав, а також метод гендерного аналізу для розуміння розбіжностей у рівнях автономії жінки та чоловіка в репродуктивній медицині. Емпіричний метод використано в процесі авторського опитування 402 жінок Республіки Польщі та України щодо особистого та державно-правового ставлення до репродуктивного здоров'я.

Результати. Передбачено два підходи державного регулювання репродуктивної автономії: перший – обмежує правове регулювання та державне втручання, надаючи пріоритет індивідуальній автономії, другий – вказує на широку, проте легітимну можливість втручання в автономне рішення пацієнта у сфері репродуктивного здоров'я. Виокремлено легітимні групи обмежувальних правових явищ у сфері права на реалізацію репродуктивної функції людини: загальноправові обмеження та спеціальні, що стосуються виключно права людини на репродукцію.

Висновки. Існує потреба оновлення національного законодавства через визначення більш чітких медичних протоколів щодо кількості ембріонів за ембріотрансферу та її залежності від віку пацієнтки. Новітні можливості редагування генів визначено як проблему етико-медичного характеру та доведено суспільний острах щодо цієї сфери, що вимагає додаткового правового регулювання.

Ключові слова: репродуктивне здоров'я, репродуктивні права, право пацієнта на автономію, право жінки, громадське здоров'я, державно-владний вплив, правова політика, правове регулювання.