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Regulation of Assisted Reproduction in Hungary[1]

JÁNOS ZÁDORI[2] – KATALIN SZOBOSZLAI-KISS[3]

Following the implementation of state oversight of human reproductive procedures in 2020, several regulations have been introduced to mitigate potential issues. To enhance patient care and alleviate the workload of IVF centers, a network of specialized infertility outpatient clinics will be established alongside existing centers of assisted reproduction. These changes aim to address the challenges faced by infertility centers and improve the chances of patients having children. The policy currently allows for up to five insurance-funded treatment cycles, while cryopreserved embryo transfers are not subject to a specific limit. Furthermore, the previous three-month waiting period between treatment cycles has been eliminated, and restrictions on the number of embryos that can be implanted have been implemented. Limiting the number of embryos transferred during IVF procedures is a common practice aimed at reducing the risks associated with multiple pregnancies. By allowing only one embryo for the first transfer up to the age of 36, especially when transferred on day five of embryonic development, this initiative prioritizes the health and safety of both the mother and potential offspring. It helps to minimize the chances of complications such as preterm birth and low birth weight, which are more common with multiple pregnancies. Additionally, it can improve the overall success rates of IVF by focusing on the quality of the transferred embryo rather than the quantity. The Hungarian government anticipates that these measures will enhance the success rates of IVF treatments, consequently leading to a rise in future childbirths and a decrease in the number of frozen embryos. This study aims to delineate the effectiveness of the introduced changes in 2023 and provide recommendations accordingly.

Keywords: in vitro fertilisation, human reproductive rights, ethics of artificial insemination, infertility care, embryo donation

1 Special thanks to János Zádori, MD for his expert advice and consultation on evolving this manuscript.

2 Head of the Institute of Reproductive Medicine at the University of Szeged; Head of the Infertility Centre of the former Kaáli Institute, now the Institute of Reproductive Medicine of the University of Szeged.

3 Habilitated Associate Professor, Lecturer, University of Győr, Faculty of Law and Political Sciences; philosopher, classical philologist, editor-in-chief of the journal *Jog–Állam–Politika.*

Introduction

Infertility is an important social phenomenon that needs much more attention due to demographic decline than earlier. These days, fertility and reproductive capacity itself are declining, even at a young age. It is also an important issue for the electorate, because regarding medical treatments, there is an exemplary state-subsidised programme in Hungary. IVF has a very high level of social acceptance,[4] while the number of opponents, although low, is also relevant. The main opponents are leaders of the Roman Catholic Church. According to the Catholic doctrine, the artificial human reproduction should be prohibited because it is regarded as the same method as abortion due to the fact that some embryos die during the procedure.

"In vitro fertilisation" (IVF) is one of the most significant medical advancements of the 20th century.[5] Robert G. Edwards was awarded the Nobel Prize for his contributions to this field. Since the birth of the first IVF baby in 1978, nearly eight million people have been born through this procedure and have lived happy, healthy, and fulfilling lives.

The incredible number of couples struggling with infertility addresses a complex problem as the accelerated world, the challenges of women's integration into the labour market, the tendency to delay starting a family, modern lifestyles, stress, environmental factors and different diseases are not conducive to delayed childbearing, in addition to other factors which are also behind this phenomenon. Infertility is not just a medical but also a growing social problem that requires attention.

Infertility affects approximately 9-10% of the global population, making it a widespread phenomenon. In 2015, a report estimated that 48.5 million couples worldwide

4 Infertility is a medical condition, and its treatment can be costly and complex. One of the most effective medical techniques for treating infertility is in vitro fertilisation (IVF). IVF involves the fusion of the gametes of the two prospective parents outside the body in a flask, under artificial conditions. The procedure is preceded by a lengthy preparation phase involving both members of the parental couple. The maturation and retrieval of the eggs from the body is a significant process. To produce more than one egg per cycle, drugs are injected into the woman's body. These cells are then surgically removed, a procedure known as puncture. On the day of the puncture, the male gametes are thawed in a petri dish and, if necessary, injected by a biologist into the oocytes to trigger cell division. IVF can result in the production of multiple embryos. Typically, a single embryo is implanted into the womb after being cultured for three to five days. The embryos are kept outside the body in a special incubator and are either transferred to the womb or frozen during their development. Embryos that are not yet ready for implantation but viable are also frozen. This medical procedure is strictly regulated by law.

5 In vitro fertilisation (IVF) is carried out using different medical methods. Some use medication, while others undergo insemination, where sperm is transferred into the womb using a device. In certain cases, neither of these methods can be used, and IVF or intracytoplasmic sperm injection (ICSI) may be the most appropriate option. The gametes of the parents are fused outside the body, and the resulting embryos are kept in a laboratory environment. The pre-embryos are transferred back to the womb (uterus) on the most ideal day for natural conception. The other embryos, twins, are 'anaesthetised' in a protective solution (vitrification, also known as freezing) to give them a chance of life in the future. The debate should focus on protecting human embryos that do not survive the process.

were infertile. The growing demand for treatments is predicted by market analysts regarding a $50 billion healthcare market in this area by 2030.[6]

There is only limited public data available on the period following the phased introduction of state funding of infertility clinics in 2020. Prior to the legislation, the state acquired the clinics belonging to the Kaáli Institute system by sale. As a result, only public health centres are allowed to provide fombicide treatment.[7] The clinics have been placed under the control of the Directorate of Human Reproduction of the National Directorate General of Hospitals. In parallel with this provision, the use of medication in care has also become 100% subsidised. Since 2020, screening tests and related diagnostic services have also become publicly funded. Thanks to the changes, screening and treatment are free of charge for women aged 45 and over in Hungary. A complex system has been created, accessible to all free of charge. However, the resulting increase in demand requires the involvement of additional specialists. Currently, seven clinics in Budapest and six in the countryside provide assisted reproductive services.

Since the introduction of state supervision in 2020, a number of (mitigating) relief regulations have been launched.[8] The amending provisions cover three broad areas: patient care (access to and retention of those eligible for treatment, establishment of specialised outpatient clinics); financing (making treatment free of charge); and the creation of a legal framework to support further steps to achieve certain pregnancies (single embryo implantation for mothers under 36).

6 According to the latest statistics, infertility is a global epidemic, affecting 9-10% of the population, and according to a 2015 report, around 48.5 million couples globally were infertile. The growing demand for treatments is also indicated by the fact that market analysts forecast a $50 billion healthcare market in this area by 2030. Lovászy 2020b: 8.

7 In vitro fertilisation (IVF) is a medical procedure in which the gametes of the intended parents are fused by professionals outside the body in an artificial environment. There are various methods, including fusion and injection. It is a technical term for a specific technique. The intervention for fombicide is a drastic measure. Participants undergo a thorough examination and various methods, including insemination, before the medical intervention. During insemination, a sperm cell is injected into the mother's womb, resulting in pregnancy and the birth of a child. However, the fusion of cells from outside the body may raise ethical or psychological concerns for many individuals. Some opponents of IVF argue that it can damage marriage because fertilisation takes place outside the body. Additionally, the extraction of gametes, such as eggs retrieved by a surgical procedure called puncture for women or donated eggs from a clinic in the case of men, is prohibited by religious Catholic morality; and therefore, the procedure is not allowed for religious individuals. The same applies to those of the Jewish faith. Both arguments can be refuted by the practice itself. The doctor, as a specialist, is involved in the process of fertilisation.

8 The amendments were published in July and October 2023. The most recent amending rules were released for public consultation in October 2023 and are available on the website of the Government of Hungary under Ministerial Decrees, see: https://kormany.hu/dokumentumtar/egyes-eu-es-egeszsegbizt-t-min-rend-humanrepr-elj-osszef-mod-min-rend

Changes in patient care

Retaining people in treatment, reducing drop-outs

As data before 2020 is not publicly available, a comparative analysis cannot be made. However, published data on the number of patients treated between 2020 and 2021 is accessible in an article entitled *The Development Concept of Infertility Care in Hungary*[9] The paper was published in the April 2023 issue of the *Review on Gynaecological and Obstetric Training,* published by the Institute of Human Reproduction of the National Directorate General of Hospitals and the Urology Clinic of Semmelweis University. According to the study 7091 IVF treatments were carried out during the period examined.[10] The success rate of the interventions was 25%. This is the twinning rate for many years. It can be concluded that 1772 children were born from IVF treatments carried out in the period under review. It is not clear from the article how the number of children born was distributed among the 13 infertility centres. The authors of that article did not investigate the success rates but focused their analysis on the causes of patient drop-out. Their analysis reveals that patients often give up on ART after two unsuccessful treatments without taking advantage of the additional opportunities offered by public funding. The NDGH Institute of Human Reproduction aims to keep couples who drop out of treatment in the system through positive measures.[11] These modifications should positively influence the patient's attitudes: "a significant proportion of patients are therefore unlikely to take advantage of the amount of fombicide treatment that would give them a realistic chance to become family."[12] The published high drop-out rate is indeed shocking. It is well known that the biggest difficulty an infertile couple faces is getting into the clinic. The question arises as to what might be the explanation for the fact that they stop treatment after the second or third unsuccessful treatment. The 2023 amendment abolished the time limit between treatments. The waiting period between two implantations was a minimum of three months until 2023. This change raises a number of questions. Can the abolition of the three-month waiting period have the retention effect that would encourage patients to take advantage of all the funded treatments? Can we predict whether the abolition of the waiting time limit will have a positive effect on the increase in the number of

9 Vesztergom et al. 2023b: 45–50.

10 "The NDGH 2022 study shows that of the 7,091 cases treated in Hungary in 2020 and 2021, the survival rate of patients who underwent four cycles of treatment for infertility was 25%. The first treatment resulted in a relapse in 11% of the patients. Each unsuccessful attempt is associated with a significant drop-out rate, leading to a steady decline in the number of treatment cycles. After the first intervention, 15.5% of patients (1101) give up or take a longer break from treatment, and more than half of the patients (3981, 56.1%) give up or take a longer break from treatment after three unsuccessful attempts." Vesztergom et al. 2023b: 49.

11 "After the first intervention, 15.5% of patients (1101), and after three unsuccessful attempts, more than half of the patients (3981, 56.1%) give up or take a longer break from treatment." Vesztergom et al. 2023b: 49.

12 Vesztergom et al. 2023b: 49.

people seeking treatment? Abolishing the time limit alone cannot eliminate drop-outs. It helps give couples a clearer vision of the future of treatment. If we also take into account the new provision that the number of embryo transfers is not limited, it is now up to the time available to couples and the capacity of the reproduction centres to transfer frozen embryos. This significantly reduces stress and greatly shortens the time needed to achieve pregnancy; it helps to move on.

On patient-friendly and embryo-friendly funding changes[13]

Over the past twenty years, the date of the first child's birth has been delayed. According to the Central Statistical Office, in 1998, 13% of women aged 30 were childless, while in 2018, this figure rose to 56%.[14] The postponement of the first childbirth date reduces the chances of having a child later. It is also noteworthy that, according to the data of the Hungarian Central Statistical Office, while in 1998 the average number of children per 100 women aged 30 was 156, in 2018 this fell to 76, indicating a reduction in the rate of twin pregnancies which is considered the main risk of the treatment. This change in trend will also increase the workload of the centres. However, the implementation of the planned multi-tiered, rural-focused improvements may enable the new system to operate efficiently and in a patient-centred way. The 2023 changes are also intended to mitigate the negative demographic trend, as more people will use the five treatments funded by the state than those who would have done so if they had remained self-funded. The number of subsidised treatments has been increased from the previous three to five, meaning that five embryo implantations will be eligible for free funding. State funding covers the cost of medication, screening and implantation. It is expected that the increase in the number of free implantations will lead to more children being born. At the same time, the measure could lead to a reduction in the number of cryopreserved embryos in the future. This change will have a positive impact not only on patients but also on embryos. It will also speed up the use of frozen embryos. [15] The costs of keeping embryos stored in clinics are also covered by the state, incurring considerable expenses on storage and resources.[16] Can such a measure increase the chances of a live birth at the same time? It is likely to have a positive impact on the number of births. [17]

13 Legislation should be implemented to determine the fate of these embryos after the storage period to ensure ethical practices and inform prospective parents of their responsibilities. Embryos can be stored by freezing for up to ten years.

14 Lilla Szijártó examined the demographic data for the period 1998–2018 based on the data of the Hungarian Central Statistical Office (KSH). Szijártó 2023: 122.

15 Szijártó 2023: 121.

16 Szijártó 2023: 121.

17 "It is generally accepted that there is no difference in reproductive potential between 'fresh' and frozen embryos, and therefore, except in some cases, there is no justification for new stimulation treatments." Veszтergom 2023a: 45.

The measure financed by the state is also justified in terms of speeding up the turnaround time for patients awaiting treatment, and it is an important change given the age of the patient population, as fertility rates are effectively decreasing month by month over time. According to NEAK[18] data, the age of women presenting for infertility treatment in 2022 was 35.5 years.[19]

The measure also reduces the number of embryos frozen by preventing the start of new IVF treatments in case embryos from previous stimulations are awaiting implantation.[20]

Under the new rules, if a couple has six embryos from one stimulation, a patient under 36 can claim these six embryos free of charge, in that case with five implantations, which means that they will get back one embryo per implantation. However, birth chances of cryopreserved embryos could be influenced even more effectively by allowing embryo donation in our country. This is not addressed in this article. This is a sensitive issue, as embryo donation is not regulated by law in Hungary. However, in the European Union, donation without precedent is allowed in the Czech Republic. Various non-scientific forums have reported that infertile couples in Hungary are using embryo donation in this neighbouring country, which is banned in Hungary. This phenomenon has been going on for years. If we look at the issue from the point of view of these frozen embryos, which are awaiting implantation but not used, donation can be considered a life-saving intervention, and its introduction is also a matter of moral consideration. The prohibition of donation is primarily based on religious and moral grounds.

Conclusion

A number of relaxed regulations have been introduced since the introduction of Government of Hungary oversight of human reproductive procedures in 2020. These changes aim to reduce the burden on fertility centres and improve patients' chances of having children. The number of state-funded implantations following a given IVF treatment was made free of charge. The three-month waiting period between implantations has also been abolished and the number of embryos that can be implanted has been limited, to one per implantation. To improve patient care and reduce the workload of IVF centres, a network of specialised clinics was set up alongside

18 National Health Insurance Fund in Hungary.

19 "The issue of bringing forward the age of childbearing – according to the age of possibility – is of paramount importance from a health and population policy point of view. Women's fertility declines gradually with age (30-35 years) and this decline accelerates after the age of 35. In recent years, the similar trend of male age on reproduction has become evidence-based. In 2021 the average age at childbearing was increasing, rising to 29.08, while the average age at the birth of a woman's first child, and the average age at which women undergo assisted reproductive treatment was at 35.5 in 2022 (HRI survey based on NEAK data)." Veszтergom et al. 2023b: 48.

20 "From a bioethical point of view, it is appropriate to regulate that a new embryo treatment can only be started if the embryos already created have been used, i.e. implanted." Veszтergom et al. 2023b: 46.

infertility clinics. These clinics mainly provide fertility counselling. The Government of Hungary expects that these measures will lead to an increase in the success rate of IVF treatments, leading to a rise in the number of children born. The Government of Hungary expects the changes to improve the demographic deficit and ensure that all desired children are born.

In Hungary, IVF is gaining ground and the Government of Hungary is providing a lot of support, promising that within three years there will be testing centres in every county, while assisted reproductive technologies and IVF will only be available in existing and licensed state clinics.

References

Bernárd, Artúr (2018): A meddőségről általában [About Infertility in General]. In Kaáli, Steven G. (ed.): *A meddőség korszerű diagnosztikája és kezelése* [Modern Diagnosis and Treatment of Infertility]. Budapest: Medicina, 13–23.

Kaáli, Steven G. ed. (2018): *A meddőség korszerű diagnosztikája és kezelése* [Modern Diagnosis and Treatment of Infertility]. Budapest: Medicina.

Kovács, Gábor (2020): Jogi és etikai kihívások a vér- és plazmadonációnál [Legal and Ethical Challenges in Blood and Plasma Donation]. *Jog–Állam–Politika,* 12(Különszám), 69.

Kőrösi, Alexandra (2016): Jogvédelem az élet kezdetén – A méhmagzat jogalanyi státusza [Legal Protection at the Beginning of Life – The Legal Status of the Fetus]. *Jog–Állam–Politika,* (2), 135–150.

Kőrösi, Tamás (2009): *Lombikcsodák. A mesterséges megtermékenyítésről orvos-, pszichológus- és páciens szemmel* [Fetuses. On Artificial Insemination from the Doctor's, Psychologist's and Patient's Point of View]. Győr: Lilli.

Kőrösi, Tamás (2018): Stimulációs protokollok [Stimulation Protocols]. In Kaáli, Steven G. (ed.): *A meddőség korszerű diagnosztikája és kezelése* [Modern Diagnosis and Treatment of Infertility]. Budapest: Medicina, 199–238.

Kőrösi, Tamás (2020): Legyen több a bölcső, mint a koporsó [Let There Be More Cradles than Coffins]. *Magyar Nemzet,* 9 January, 2020. Online: https://magyarnemzet.hu/velemeny/legyen-tobb-a-bolcso-mint-a-koporso-7644173

Lovászy, László (2010): Rövid elmélkedés a modern abortusz-paradoxonról a magyar alkotmányozás fényében az állam életvédelmi kötelezettsége szempontjából [A Brief Reflection on the Modern Abortion Paradox in the Light of the Hungarian Constitution in Terms of the State's Duty to Protect Life]. *Európai Jog,* 10(5), 3–12.

Lovászy, László (2019): A biozsák, ami megmentheti a világot [The Bio-Bag that Could Save the World]. *Portfolio,* 19 August, 2019. Online: www.portfolio.hu/prof/20190819/a-biozsak-ami-megmentheti-a-vilagot-334343

Lovászy, László (2020a): Lombik: áldás és békesség – Már lehet etikai szempontokat érvényesíteni a szűken vett profitszemlélet rovására [Flask: Blessing and Peace – Ethical Considerations Can Now be Applied to the Detriment of a Narrow Profit Motive]. *Magyar Nemzet,* 24 November, 2020. Online: https://magyarnemzet.hu/velemeny/lombik-aldas-es-bekesseg-8996354

Lovászy, László (2020b): Nyolcmillió új élet [Eight Million New Lives]. *Figyelő,* 63(5), 8.

Lovászy, László – Szalay Máté Gerzson (2015): Genetikailag háromszülős gyermekektől az eugenika polgári jogiasításáig [From Children with Genetically Three Parents to the Civil Legalisation of Eugenics]. *Európai Jog,* 15(5), 1–6.

Lovászy, László Gábor – Szoboszlai-Kiss, Katalin (2021): A mesterséges megtermékenyítésről mint az élethez való jog lehetőségéről és az ebből származó etikai dilemmákról [On the Possibility of Artificial Insemination as a Right to Life and the Ethical Dilemmas it Raises]. *Jog–Állam–Politika,* 13(2), 61–96.

Meixner, Zoltán (2022): Minden nőnek tudnia kell, hogy a terhesség időpontjának kitolásával mit kockáztat [Every Woman Should Know What she is Risking by Postponing her Pregnancy]. 27 May, 2022. Online: www.hazipatika.com/napi_egeszseg/orvosnal/cikkek/minden-nonek-tudnia-kell-hogy-a-terhesseg-idopontjanak-kitolasaval-mit-kockaztat

Serdült, Viktória (2023a): Változtat a kormány a meddőségi kezelések szabályain, de a legfontosabb kérdéshez még nem mert nyúlni [The Government is Changing the Rules on Infertility Treatment, but Has Not Yet Dared to Touch the Most Important Issue]. *HVG.hu,* 7 June, 2023. Online: https://hvg.hu/itthon/20230607_kormany_meddosegi_kezelesek_finanszirozas_valtozas

Serdült, Viktória (2023b): Új tervezet az állami lombikkezelésről: 36 év alatt csak egy embriót ültetnek be, 45 év marad a korhatár és kijelölték a szakambulanciákat [New Draft on State-Run IVF: Only One Embryo Implantation under 36, the Age Limit Remains 45 and Specialised Outpatient Clinics have been Designated]. *HVG.hu,* 26 October, 2023. Online: https://hvg.hu/itthon/20231026_igy_modositana_tovabb_a_lombikkezelesek_szabalyait_a_kormany

Szijártó, Lilla (2023): A humán reprodukciós eljárások etikai és jogi dilemmái a XXI. századi Magyarországon [Ethical and Legal Dilemmas of Human Reproductive Procedures in 21st Century Hungary]. *Jog–Állam–Politika,* (1), 111–144. Online: https://doi.org/10.58528/JAP.2023.15-1.111

SZTE (2023): *A Szegedi Tudományegyetem Dél-alföldi Demográfiai Program keretében több száz párnak ad esélyt a családalapításra az SZTE Reprodukciós Medicina Intézet* [The Institute of Reproductive Medicine of the University of Szeged Gives Hundreds of Couples the Chance to Start a Family within the Framework of the South Great Plain Demographic Programme of the University of Szeged]. 10 July, 2023. Online: https://u-szeged.hu/sztehirek/2023-julius/szegedi-tudomanyegyetem

Vesztergom, Dóra – Téglás, Gyöngyvér – Fónyad, Gábor – Szomszéd, Orsolya – Szöllősi, Katalin – Krádi, Anna – Kopa, Zsolt – Nánássy, László (2023a): A hazai meddőségi ellátás helyzete [The Situation of Infertility Care in Hungary]. *Nőgyógyászati és Szülészeti Továbbképző Szemle,* February 25(1), 5–11.

Vesztergom, Dóra – Téglás, Gyöngyvér – Fónyad, Gábor – Szomszéd, Orsolya – Szöllősi, Katalin – Krádi, Anna – Kopa, Zsolt – Nánássy, László (2023b): A hazai meddőségi ellátás fejlesztési koncepciója [The Development Concept of Infertility Care in Hungary]. *Nőgyógyászati és Szülészeti Továbbképző Szemle,* 25(2), 45–50.

Legal sources

1997. évi CLIV. törvény az egészségügyről [Act CLIV of 1997 on healthcare]

30/1998. (VI. 24.) NM rendelet az emberi reprodukcióra irányuló különleges eljárások végzésére vonatkozó, valamint az ivarsejtekkel és embriókkal való rendelkezésre és azok fagyasztva tárolására vonatkozó részletes szabályokról [NM Decree 30/1998 (24.VI.) on the detailed rules for the performance of special procedures for human reproduction, the disposal of gametes and embryos and their frozen storage]