

From algorithmic classification to clinical choice: AI-Assisted selection of human embryos in the laboratory, under the Brazilian and Spanish prisms, on an ethico-legal basis
De la clasificación algorítmica a la elección clínica: Selección de embriones humanos en laboratorio con IA, bajo los prismas brasileño y español, en clave ético-jurídica

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ABSTRACT

This study delimits the legal panorama of embryonic curatorship contemplated by artificial intelligence (AI), focusing on the duties provided for in civil law and the management of personal data. By means of hypothetical-deductive reasoning combined with a literature review, it identifies obligations, gaps and normative parameters that ensure informational integrity and accountability in the application of algorithms to assisted human reproduction (AHR). The article offers technical support to legal operators and policymakers, con-

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tributing to the consolidation of a coherent framework for the incorporation of algorithmic systems in the selection of human embryos.

KEYWORDS

AI-assisted reproduction, embryo selection, data protection, civil liability, bioethics, algorithmic governance.

RESUMEN

Este estudio delimita el panorama jurídico de la curaduría embrionaria contemplada por la inteligencia artificial (IA), con especial atención a los deberes previstos en el derecho civil y a la gestión de los datos personales. A través de un razonamiento hipotético-deductivo, combinado con revisión bibliográfica, se identifican obligaciones, vacíos y parámetros normativos que garantizan la integridad informativa y la atribución de responsabilidades en la aplicación de algoritmos a la reproducción humana asistida (RHA). El artículo ofrece soporte técnico a operadores jurídicos y responsables de políticas públicas, contribuyendo a la consolidación de un marco coherente para la incorporación de sistemas algorítmicos en la selección de embriones humanos.

PALABRAS CLAVE

Reproducción asistida por IA, selección embrionaria, protección de datos, responsabilidad civil, bioética, gobernanza algorítmica.

TABLE OF CONTENTS: 1. Introduction. 2. Relevance of private law from the perspective of *in vitro* fertilisation. 3. Demands on legal attribution in relation to algorithmic platforms in human embryo screening. 4. Inspection of information protection and reflections on confidentiality in embryo screening with the support of algorithmic technologies. 5. Final Considerations. 6. Acknowledgment.

1. INTRODUCTION

The growing integration of artificial intelligence (AI) into human embryo selection procedures presents legal challenges in the context of civil law. This article aims to investigate and analyse these scenarios, providing insights for legal professionals and policymakers. To this end, the

hypothetical-deductive method is used, through bibliographical reviews in order to examine current legal frameworks and address fundamental issues of liability, data protection and privacy.

Indeed, the rapid evolution of AI has boosted its application in various fields, and the area of assisted human reproduction (AHR) is no exception. Human embryo selection is a key aspect in this context, with improving treatment success rates and increasing the chance of successful pregnancies. AI's ability to analyse genetic data and clinical information from embryos offers a promising prospect for improving the results of fertility treatments that affect millions of people around the world.

However, this technological integration also presents challenges in terms of data privacy, legal liability and protecting the rights of individuals. This process raises complex legal issues that require analysis from a civil law perspective.

One of the main legal challenges is determining liability in the event of unfavourable results arising from the use of AI in embryo selection. With automated decision making by AI, the question arises of who will be responsible for any errors or adverse consequences. This requires a careful review of the legal responsibilities of all parties, including assisted reproduction clinics, healthcare professionals and AI system developers.

Furthermore, protecting the privacy of individuals' genetic data and medical information is a central concern. AI requires extensive access to sensitive data in order to carry out accurate analyses, which can raise questions about the ethical use and sharing of this information. It is imperative to establish adequate data protection measures and ensure that privacy standards are respected throughout the embryo selection process.

In the current context, it is imperative that civil law keeps pace with the rapid evolution of technology, ensuring the accurate and responsible application of legislation regarding the use of AI in human embryo selection. Current legislation provides for liability, data privacy, and the guarantee of reproductive rights.

The use of AI in human embryo selection holds prospects for improving the efficiency of AHR treatments, which is why striking the right balance

between technological innovation, the protection of individual rights and responsibility, so that society can benefit from maximising the benefits of AI in AHR. At the same time, it is necessary to ensure the protection of key principles, safeguarding rights and guaranteeing privacy.

It is therefore proposed to contribute to the compilation and systematisation of effective legal frameworks that allow for the responsible and legal integration of AI in the use of embryo selection. Considering the complexity of the proposed topic, which is constantly evolving, it is hoped that this research will stimulate in-depth reflection, promoting the development of equitable and sustainable regulatory approaches.

2. RELEVANCE OF PRIVATE LAW FROM THE PERSPECTIVE OF IN VITRO FERTILISATION

This topic initially deals with AHR through the technique of *in vitro* fertilisation (IVF), with a view to better understanding the proposed topic, and then works on the legal framework and the applicability of civil law in the context of the selection of human embryos in AHR through the use of AI.

IVF is an advanced AHR technique in which the sperm meets the oocyte in a laboratory environment, hence the *term in vitro*. From this initial milestone, the embryos are carefully formed and cultivated in the laboratory until they are ready to be transferred to the woman's uterus¹.

This remarkable technique was first realised in 1978, thanks to the efforts of Englishmen Patrick Steptoe and Robert Edwards. In Brazil, the pioneering role was played by Anna Paula Bettencourt Caldeira, from Paraná, who was born in 1984 and became the country's first «test tube baby». Since then, IVF has been the subject of incessant study and improvement, driving the search for ever higher success rates². These advances have made it possible to realise the dream of motherhood and fatherhood for countless couples facing reproductive challenges.

¹ STARIOLO, M., *Pesquisa busca aperfeiçoar seleção de embriões para fertilização in vitro usando sistema de inteligência artificial*, 2023. p. 1. Available at: <https://jornal.unesp.br/2023/01/02/pesquisa-busca-aperfeicoar-selecao-de-embrioes-para-fertilizacao-in-vitro-usando-sistema-de-inteligencia-artificial/>. Accessed on: 11 July 2025.

² *Ibidem*.

According to the Brazilian Association of Assisted Reproduction, the success rate of IVF can change depending on the circumstances of each case, and the older the person, the lower the chance of success. «The average pregnancy rate is approximately 18 to 25 per cent per attempt up to the age of 35, in the case of IUI, and 50 to 60 per cent in IVF.» After the age of 37, «the probability of success of Intrauterine Insemination decreases to 5 to 15 per cent»³.

Data from the National Embryo Production System Report for 2022 shows that in 2021, 91,962 embryos were transferred in Brazil, giving rise to 27,861 pregnancies⁴.

Therefore, the first and most important step is to consider the breadth of the subject in question, its meaning and significance. Infertility causes many people to suffer. Worldwide, «there are approximately more than 200 million infertile couples. It is estimated that around 12-14 per cent of couples experience infertility problems throughout their lives»⁵. The Spanish Fertility Society (SEF), in various publications, indicates that the prevalence of infertility is between 15 and 25 per cent of couples⁶. Furthermore, in some developed countries, 2 to 4 per cent of births already occur through AHR (in Denmark, it exceeds 4 per cent).

More than four million children have already been born through these techniques, but this combination obscures the reality experienced by people whose expectations require attentive and humane care. For many, becoming a parent is their life goal; failing to achieve it impacts

³ SBRA. Associação Brasileira de Reprodução Assistida. Como funciona a Inseminação Intrauterina? 2023. p. 1. Available at: <https://sbra.com.br/como-funciona-a-inseminacao-intrauterina/>. Accessed on: 12 July 2025.

⁴ National Health Surveillance Agency (ANVISA). Relatório do Sistema Nacional de Produção de Embriões de 2022. Available at: <https://www.gov.br/anvisa/pt-br/acessoinformacao/dadosabertos/informacoes-analiticas/sisembrio>. Accessed on: 7 July 2025. It should be noted that more than one embryo can be transferred at the same time, in order to increase the chances of pregnancy, and this consequently influences obtaining more accurate statistics on the percentage of pregnancies generated by IVF. Stariolo, 2023, p. 1.

⁵ DE LA TORRE DÍAZ, F. J., *Bioética: vulnerabilidad y responsabilidad en el comienzo de la vida*. Madrid: Dykinson, 2015. pp. 181-211. Capítulo IV. Las técnicas de reproducción médicamente asistida. p. 183.

⁶ SEF. Sociedad Española de Fertilidad. Más de 800.000 parejas españolas tienen problemas reproductivos, 2023. Available at: <https://www.sefertilidad.net/?seccion=pacientes>. Accessed on: 8 July 2025.

their emotions and reconfigures their identity and cherished plans. Infertility, therefore, generates biological, psychological, and social consequences⁷.

This data shows that there is a growing demand for the use of AHR techniques through IVF in Brazil and around the world, which motivates the search to improve the technique in relation to the embryos that will be implanted in the mother's uterus. In this sphere, AI has recently been introduced into this selection process. Today it is also possible to use artificial intelligence to select the embryo with the greatest implantation capacity to each case and be able to optimise the results of the AHR⁸.

The methods used to select high-quality embryos for IVF transfer procedures rely on a traditional approach based on morphological analysis, using visual observation and subjective assessment by embryologists. Various scoring systems have been proposed to aid embryo selection, but these methods are limited in their effectiveness and may be subject to legal restrictions in some countries.

AI, applied to in vitro fertilisation, refines embryo selection through training and pattern learning (embryo and oocyte images). Thus, systems derive scores and classifications from visual resources and are used to support selection decisions⁹.

⁷ There are already more than four million children born as a result of these techniques. Behind these simple figures there are many illusions and many pains of many flesh and blood people that must be taken into account, listened to carefully and cared for humanely. Being parents is, for many people, a central goal in their lives, and discovering the possibility of not becoming one within their life horizon generates deep pain, suffering and, naturally, the need to reformulate their own identity and their most cherished dreams. Sterility is therefore a serious handicap and limitation in many lives, not only in the biological field, but also psychologically and socially. DE LA TORRE DÍAZ, F. J., *Bioética: vulnerabilidad y responsabilidad en el comienzo de la vida*. Madrid: Dykinson, 2015. pp. 181-211. Capítulo IV. Las técnicas de reproducción médicamente asistida. p. 183.

⁸ DIMITRIADIS, I.; ZANINOVIC, N.; BADIOLA, A. C., y BORMANN, C. L., Artificial intelligence in the embryology laboratory: a review. *Reprod Biomed Online*. 2022; 44(3):435-448. p. 189. Available at: <https://pubmed.ncbi.nlm.nih.gov/35027326/>. Accessed on: 11 July 2025.

⁹ Artificial intelligence (AI) techniques may offer a solution for improving embryo selection. Examples of AI methods applied to IVF programmes are discussed, specifically for embryo and oocyte scoring/selection. The methods discussed are pattern recognition algorithms and machine learning systems for classifying and analyzing embryo images.

Kottow states that «the agility and speed of digital interactions, elevated to the *status of Artificial Intelligence (AI)*, allow millions of interactive combinations in a dense tangle of data, forming a systemic biology» that reveals all the «folds that make up each person»¹⁰.

AI is applied to embryo selection through algorithms and complex analyses that process genetic data and clinical information on embryos. These algorithms can help identify embryos with a higher probability of successful implantation and healthy development, thus increasing the chances of a successful pregnancy in fertility treatments such as IVF.

The process of selecting embryos with AI involves stages such as analysing the embryos' genome, assessing specific characteristics and identifying genetic or chromosomal anomalies that could affect foetal development. Based on this information, AI can classify embryos in terms of viability and success rate, helping healthcare professionals make decisions about which embryos should be transferred to the recipient woman's uterus¹¹.

IVF outcomes hinge primarily on embryo quality, yet clinicians still lack reliable tools for assessing embryos, sperm, and oocytes. As a result, predicting pregnancy success, and explaining failed cycles, remains difficult. AI seeks to bridge these gaps by leveraging large datasets generated by contemporary diagnostic and therapeutic workflows¹².

MANNA, C. *et al.* Artificial intelligence techniques for embryo and oocyte classification Declaration: The authors report no financial or commercial conflicts of interest. *Reproductive BioMedicine*, Online, v. 26, Issue 1, January 2013, pp. 42-49. p 43. Available at: <https://www.sciencedirect.com/science/article/pii/S147264831200586X>. Accessed on: 2 July 2025.

¹⁰ KOTTOW, M., *Medicina de precisão e transumanismo: uma perspectiva bioética. Revista Colombiana de Bioética*, 17, v. 1, 2022. p. 5. Available at: <https://www.medigraphic.com/cgi-bin/new/resumenl.cgi?IDARTICULO=109390>. Accessed on: 9 July 2025.

¹¹ KRAGH, M. F., Y KARSTOFF, H., Embryo selection with artificial intelligence: how to evaluate and compare methods? *J Assist Reprod Genet*, jul. 38, v. 7, pp. 1675-1689, 2021. p. 1676. doi: 10.1007/s10815-021-02254-6. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8324599/>. Accessed on: 9 July 2025.

¹² The quality of the embryos is the most critical factor in the success of IVF, but there is still a lack of methods to accurately judge the quality of not only the embryos, but also the sperm and eggs. It is therefore difficult to predict the likelihood of a successful pregnancy for each patient and to fully understand the cause of each failure. AI-based procedures in reproductive medicine could become a solution to the current impasses. The main driver for the development of these applications is the desire to improve the

The use of AI in embryo selection offers several advantages, including the possibility of increasing the success rates of AHR treatments and reducing the risk of multiple pregnancies, which can be associated with complications for mothers and babies¹³.

Semen analysis is foundational in infertility assessment. Because manual morphology scoring is subjective and varies across laboratories, computer-assisted analysis and automated image pipelines are used to quantify motility, kinematic parameters and subpopulations; thorough feature selection improves performance and interpretability¹⁴.

Thus, in recent years, with the development of genetic sequencing technologies and the evolution of AI algorithms for analysing large volumes of genomic data, advances in these areas have made the application of AI in AHR feasible, allowing clinics and fertility centres to use these technologies to improve embryo selection and treatment results.

The use of AI in human embryo selection is an area of AHR that has advanced significantly in the 21st century, driven by the rapid develop-

tment and prognosis of infertility patients, using the large amounts of data provided by complex diagnostic and therapeutic modalities. CAMBIAGHI, A., *Inteligência artificial na reprodução humana: onde estamos e para onde vamos?* 2022. p. 1. Available at: <https://portalhospitaisbrasil.com.br/inteligencia-artificial-na-reproducao-humana-onde-estamos-e-para-onde-vamos/>. Accessed on: 2 July 2025.

¹³ A variety of strategies have been proposed to evaluate and select eggs with the best developmental probability, but limitations such as the possibility that the normal-looking egg or embryo may still conceal aneuploidy call for more research to obtain accurate standards and methods. Thus, the use of AI methods for egg selection in IVF could bring new opportunities. Moreover, some researchers have used non-invasive approaches to predict the developmental of the human ovum. The ideal egg selection method would be non-invasive, inexpensive and able to be incorporated into the embryology workflow with minimal impact, and there is still room for improvement, such as technologies for more reliable prediction of egg quality and more accurate quantification of gamete development competence. *Ibidem*.

¹⁴ Sperm morphology reflects types of anomalies. Today, computer-assisted sperm analysis systems are used for research and routine analyses in humans or animals. The system can report the moving percentage and kinematic parameters and identify sperm cell subpopulations. Due to the inherent lack of objectivity and difficulty in manually assessing sperm morphology and the high degree of variation between laboratories, automatic methods based on image analysis must be developed to obtain more objective and accurate results. Feature selection can improve performance, visualise the data for model selection and reduce dimensionality. *Ibidem*.

ment of AI and biotechnology technologies, including the technique recently employed in Brazil.

In October 2022, it was announced that the first machine capable of automatically evaluating and selecting embryos using an intelligent incubator had arrived in Brazil, thus improving pregnancy rates, according to the news item «Clínica Fertilidade&Vida, in Campinas, is the first in the country to offer an intelligent incubator that delivers precision in choosing the best embryos and the chance of pregnancy can reach 80 per cent,» explaining that «the artificial intelligence algorithm is more assertive in choosing the embryo than the human eye. The machine is able to make many more assessments and interpretations that the embryologist, even with a magnifying glass, would not be able to see»¹⁵.

On the other hand, the growing integration of AI with the AHR technique brings with it legal challenges that require analysis from a civil law perspective. In this way, we will analyse existing civil law regulations relating to assisted reproduction technologies, assessing the adequacy of current legal frameworks and identifying any specific legal gaps that arise with the integration of AI technologies in the selection of human embryos.

In Brazil, legislation does not specifically regulate AHR, and the matter is only regulated by Resolutions of the Federal Council of Medicine (CFM). It should be noted that the first resolution in the country to deal with assisted human reproduction was CFM Resolution No. 1.358/92, and the current one is Resolution No. 2.320/22, which updated the rules on assisted human reproduction in Brazil and was published by the CFM on 20 September 2022. The resolutions establish ethical and technical standards for the use of assisted reproduction techniques.

Resolution No. 2.320/22 establishes the indications, criteria and limitations for carrying out AHR procedures, including *in vitro* fertilisation (IVF), artificial insemination and embryo transfer. The resolution also addresses issues of informed consent, embryo disposal and gamete donor anonymity.

¹⁵ LAMIM, L., *Sistema pioneiro de Inteligência Artificial para seleção de embriões em processos de FIV chega ao Brasil*, 2022. p. 1. Available at: <https://www.segs.com.br/saude/361025-sistema-pioneiro-de-inteligencia-artificial-para-selecao-de-embrioes-em-processos-de-fiv-chega-ao-brasil>. Accessed on: 6 July 2025.

In fact, there is an age limit for using the techniques, as well as an obligation to provide adequate medical supervision throughout the process. In turn, the maximum number of embryos that can be transferred during an AHR procedure varies according to the age group of the recipient woman and the technique used¹⁶.

The criteria and limitations are established to guarantee the safety and efficacy of the treatments, avoiding multiple pregnancies that could pose risks to both the mother and the foetus. For IVF, the embryo transfer criteria are as follows: Women up to the age of 37 can implant up to two embryos; over this age, each woman can transfer up to three. In the case of euploid embryos¹⁷ (with 46 chromosomes), the resolution limits implantation to two embryos, regardless of age. In the case of multiple pregnancies, embryo reduction is prohibited¹⁸.

As for the age limit for using assisted reproduction techniques, the resolution establishes that women up to the age of 50 can undergo IVF procedures and other assisted reproduction techniques. However, it is important to emphasise that the decision to accept patients over 50 is at the discretion of the medical team, taking into account the patient's general health and the possibility of complications associated with pregnancies at an advanced age¹⁹.

¹⁶ BRASIL. Resolução n. 2.320/22 do Conselho Federal de Medicina. Adota normas éticas para a utilização de técnicas de reprodução assistida –sempre em defesa do aperfeiçoamento das práticas e da observância aos princípios éticos e bioéticos que ajudam a trazer maior segurança e eficácia a tratamentos e procedimentos médicos, tornando-se o dispositivo deontológico a ser seguido pelos médicos brasileiros e revogando a Resolução CFM núm. 2.294, publicada no Diário Oficial da União de 15 de junho de 2021, Seção I, p. 60. Available at: <https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2022/2320>. Accessed on: 29 June 2025.

¹⁷ An embryo with more suitable conditions to be implanted in the uterus and with more chances of developing into a healthy child.

¹⁸ BRASIL. Resolução n. 2.320/22 do Conselho Federal de Medicina. Adota normas éticas para a utilização de técnicas de reprodução assistida –sempre em defesa do aperfeiçoamento das práticas e da observância aos princípios éticos e bioéticos que ajudam a trazer maior segurança e eficácia a tratamentos e procedimentos médicos, tornando-se o dispositivo deontológico a ser seguido pelos médicos brasileiros e revogando a Resolução CFM núm. 2.294, publicada no Diário Oficial da União de 15 de junho de 2021, Seção I, p. 60. Available at: <https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2022/2320>. Accessed on: 29 June 2025.

¹⁹ *Ibidem*.

On the other hand, informed consent is also one of the main points of the CFM's resolution, which emphasises the importance of patients obtaining it before starting any assisted reproduction procedure. Informed consent must be obtained in a clear and comprehensible manner, ensuring that patients are fully aware of the procedures, risks, benefits, limitations and legal and ethical implications. It is indispensable that patients are informed of all the options available to them, allowing them to make informed choices in accordance with their circumstances and values.

The resolution also establishes clear guidelines regarding the disposal of surplus embryos after AHR procedures. The total number of embryos generated in the laboratory is no longer limited, and patients must decide how many will be transferred fresh. Viable surpluses should be cryopreserved. Before the embryos are generated, patients must inform in writing the destination of the cryopreserved embryos in the event of divorce, dissolution of a stable union, death of one or both parties, with donation being a possibility.

With regard to the anonymity of the gamete donor (eggs or sperm), the resolution states that the donation must be made voluntarily and anonymously. The donor must not be aware of the recipient's identity and vice versa. This anonymity aims to preserve the privacy and rights of both parties, protecting the identity of the donor and the autonomy of the recipient²⁰.

It is important to note that the resolution also addresses other issues related to assisted reproduction, such as the use of IVF techniques by single people and same-sex couples, the prohibition on selecting the sex of the embryo (except by medical indication) and the rules for carrying out gamete and embryo donation procedures.

Besides the aforementioned resolution, there are other pieces of legislation that are also relevant to the legal applicability of AHR in Brazil. The main civil law regulations on AHR can be found directly in the Civil Code, which establishes the general principles of civil law, including issues related to the right to life and the protection of personality rights.

²⁰ *Ibidem*.

Law No. 11.105/2005 (Biosafety Law) also addresses issues related to the use of assisted reproduction techniques, genetic manipulation and the use of embryonic stem cells, establishing the rules for research and application of reproductive technologies in Brazil²¹. These are some of the main regulations on AHR in the country.

While it should be emphasised that the use of AI in embryo selection is still an area of constant evolution and research, legal issues, particularly related to the civil sphere, must also be considered to ensure that this technology is applied responsibly and in accordance with the legal precepts surrounding reproductive medicine.

This brings us to one of the central points of this article: civil liability. The fundamental question of legal liability in the context of AI-assisted embryo selection must examine who the agents in this process, such as assisted reproduction clinics, health professionals and AI system developers. The attribution of responsibility in cases of unfavourable results or failures arising from the use of AI in embryo selection and the importance of establishing clear standards to guarantee the integrity and safety of the procedures.

Therefore, in order to delve deeper into the proposed theme, we will now analyse possible civil liability issues AI-systems in embryo selection.

3. DEMANDS ON LEGAL ATTRIBUTION IN RELATION TO ALGORITHMIC PLATFORMS IN HUMAN EMBRYO SCREENING

²¹ BRASIL. Lei n. 11.105/2005, Lei de Biossegurança. Regulamenta os incisos II, IV e V do § 1.º do artigo 225 da Constituição Federal, estabelece normas de segurança e mecanismos de fiscalização de atividades que envolvam organismos geneticamente modificados – OGM e seus derivados, cria o Conselho Nacional de Biossegurança – CNBS, reestrutura a Comissão Técnica Nacional de Biossegurança– CTNBio, dispõe sobre a Política Nacional de Biossegurança – PNB, revoga a Lei núm. 8.974, de 5 de janeiro de 1995, e a Medida Provisória núm. 2.191-9, de 23 de agosto de 2001, e os arts. 5.º, 6.º, 7.º, 8.º, 9.º, 10 e 16 da Lei núm. 10.814, de 15 de dezembro de 2003, e dá outras providências. Available at: https://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/111105.htm. Accessed on: 30 June 2025.

Currently, with the impetus of the new technological revolution, a series of legal challenges are being faced, which requires careful analysis of the factual and legal situation.

Defined by Klaus²², this scenario completely transforms humanity, re-percussing lives, work and relationships in ways. The fourth industrial revolution is unprecedented in terms of its scale, scope and complexity, and promises radical changes never before experienced by humanity, which is why a legal analysis of the proposed theme imperative.

Nevertheless, civil liability arising from damage resulting from the use of AI in the selection of human embryos may be subject to the rules laid down in both the Civil Code and the Consumer Defence Code (CDC), depending on the specific context in which the damage occurs.

The Civil Code is the main source of rules governing civil liability in Brazil. In the context of assisted reproduction with the use of AI in embryo selection, the Civil Code can be applied in various situations, such as professional liability, so if an error or negligence occurs on the part of health professionals, such as doctors, embryologists or others in AHR procedures with AI, the civil liability rules of the Civil Code can be applied to hold the professional or clinic liable for damages caused to patients.

According to Nogaroli, clinical decision automation supports faster and more accurate diagnoses, prognoses, and treatment guidance. However, at the same time, it can lead to erroneous results, discriminatory actions, inadequate implementation, and unclear reasoning. However, to date, there is no case law on medical liability for AI. Therefore, as autonomous systems become more commonplace in the clinical setting, a logical corollary is to be expected²³.

²² KLAUS, S., *A quarta revolução industrial*. São Paulo: Edipro, 2016. p. 14.

²³ Automated decision systems may improve patients' experience of their healthcare, providing diagnoses, prognoses and treatment proposals more quickly, accurately and effectively. On the other hand, new challenges are emerging for the health sector, particularly due to the risks of inaccurate, discriminatory and poorly utilised algorithms and unclear decision-making processes. Currently, there is no case law on medical liability for AI liability. However, there is a tendency for litigation to arise, given the greater frequency in recent decades of the use of autonomous systems to support clinical decisions. NOGAROLI, R.. *Culpa médica e deveres de conduta na Inteligência Artificial*, 2023. p. 2. Available at: [Achttps://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial](https://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial). Accessed on: 2 July 2025.

The civil liability rules of the Brazilian Civil Code are mainly set out in articles 186 to 188. These articles deal with liability for an unlawful act, which is when someone, through voluntary action or omission, negligence or recklessness, causes harm to another person. The most relevant article for civil liability is article 186, which states that «anyone who, through voluntary action or omission, negligence or recklessness, violates a right and causes damage to another, even if exclusively moral, commits an unlawful act»²⁴.

Article 186 provides the basis for civil liability in the event that a health-care professional or assisted reproduction clinic commits unlawful acts that result in harm to patients. If an error, negligence or recklessness in the use of AI in embryo selection causes harm to patients, they can turn to the Civil Code and its related articles to seek compensation for the damage suffered.

Other provisions of the Civil Code, such as articles 927 and 942, complement article 186 in defining civil liability in cases the indemnification and risky activities²⁵.

On the other hand, there is contractual liability, if there is a contract between the parties (patients and the assisted reproduction clinic, for example), the Civil Code can also be applied in the event of breach of contract or failure to provide services, including damages arising from the use of AI in embryo selection.

The article of the Civil Code that deals with contractual liability is article 389, which establishes the obligation to repair the damage caused by the party that fails to fulfil or inadequately fulfils its contractual obligations. *In verbis*: «If the obligation is not fulfilled, the debtor is liable for damages, plus interest and monetary restatement according to regularly established official indices, and lawyer's fees»²⁶.

Therefore, in the event of a breach of contract related to assisted reproduction procedures the use of AI in embryo selection, the debtor,

²⁴ BRASIL. Lei n. 10.406, de 10 de janeiro de 2002. Institui o Código Civil. Available at: https://www.planalto.gov.br/ccivil_03/leis/2002/110406compilada.htm. Accessed on: 29 June 2025.

²⁵ *Ibidem*.

²⁶ *Ibidem*.

namely, the service provider or clinic, may be held liable. In accordance with article 389 of the Civil Code, the responsible party must compensate the patient for the damage caused, including interest and monetary restatement.

However, the CDC can also be applied to protect patients (who are considered consumers) in the event of damage arising from the provision of services, provided that the damage is caused by defects or failures in the AI embryo selection procedures. The article of the CDC that can be applied is article 14²⁷:

Article 14 of the CDC establishes the objective liability of the service provider, which means that the provider of assisted reproduction services, such as a fertility clinic that uses AI in embryo selection, is liable for damages caused to patients, regardless of whether there is proven fault or negligence²⁸.

If there are defects relating to the provision of services, such as failures in the use of AI that result in harm to the patient, or if information provided to patients about the procedure is insufficient or inadequate, the service provider (the clinic or provider) can be held liable for the damage caused.

The application of the CDC is important when the patient qualifies as a consumer under the terms of the law, i.e., when they contract a service or product for personal or family use. In this context, the relationship between the assisted reproduction clinic and the patient is considered a consumer relationship, and the CDC is applied to protect the rights and interests of the consumer.

From this perspective, based on the Civil Code and the CDC, we will now analyse possible cases of damage caused by the use of AI in the selection of human embryos, listing the liability of each of them:

²⁷ The service provider is liable, regardless of fault, for compensation for damages caused to consumers by defects in the provision of services, as well as by insufficient or inadequate information about their enjoyment and risks. BRASIL. Lei núm. 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do consumidor e dá outras providências. Available at: https://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm. Accessed on: 29 June 2025.

²⁸ *Ibidem*.

Developers and suppliers of AI systems can be held liable if there are errors or flaws in the algorithms used to select embryos. In this case, liability is subjective, as it depends on proving the fault or negligence of the developers or suppliers. If the AI is flawed due to errors in the development of the *software* or negligence in its implementation, those responsible can be held liable for the resulting damages.

However, if the AI is unable to provide accurate and reliable results, the *software* developer or supplier can be held liable for damages resulting from such failures. In this case, liability is objective, i.e., it does not require proof of fault or negligence. However, if the AI does not fulfil its function properly, the developer or supplier can be held liable for the damage caused, even if they were not at fault, under the terms of article 927 of the Civil Code²⁹.

With regard to health professionals and assisted reproduction clinics that use AI to select embryos, they can be held liable if they do not comply with the appropriate standards of care and diligence. When proposing AI as a solution, the professional must be assessed, and if they follow a treatment proposal that is far outside the standard brought about by AI, the assessment of medical fault becomes somewhat less complex, as the professional is acting in an obvious lack of diligence (gross error)³⁰.

In this case, liability is subjective, as it depends on proving the fault or negligence of the professionals or clinics. If they fail to take due care when implementing and monitoring AI in order to avoid adverse results, they can be held liable for the damage caused, in accordance with articles 186 and 927 of the Civil Code.

According to Nogaroli³¹, in order to ascertain «whether a doctor has acted culpably in a specific case, the standards of professional conduct required at the time of the medical performance must be analysed». Corroborating this, Price³² argues that the doctor, «if not diligent in the

²⁹ NOGAROLI, R., *Culpa médica e deveres de conduta na Inteligência Artificial*, 2023. p. 2. Available at: [Ahttps://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial](https://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial). Accessed on: 02 July 2025.

³⁰ *Ibidem*.

³¹ *Ibidem*. p. 3.

³² PRICE II, W. N.; GERKE, S., and COHEN, I. G.. Liability for use of artificial intelligence in medicine. In: COHEN, I. G., and SOLAIMAN, B. (ed.). *Research handbook on health, AI and*

use of AI, can be held responsible». In this perspective, Molnár-Gábor³³ states that «if doctors recognise, based on their expertise, that the information provided by AI is incorrect in that specific case, they should not consider it as a basis for their decision».

When an AI system diagnoses or prognoses, the physician must be able to assess the situation (justify whether to accept the recommendation or reject it), as well as detail the factors that guided the decision. Therefore, methods, diagnoses, and therapies remain subject to the final scrutiny of the responsible professional. However, in the analysis of medical negligence (the therapeutic chance, the unpredictability inherent in medical practice), the same interpretation remains: the law does not require infallibility or absolute precision³⁴.

Furthermore, it is the duty of the health professional to provide clarification, which means that «beyond the doctor's duty to inform that, for example, an AI algorithm was used to support the assessment of a given clinical condition, it is also necessary to explain how the technology works, according to each patient's level of understanding», under penalty of incurring the so-called «explanatory opacity»³⁵.

the law. Cheltenham: Edward Elgar Publishing Ltd., 2023.

³³ MOLNÁR-GÁBOR, F., Artificial intelligence in healthcare: doctors, patients and liabilities. In: Wischmeyer, T., and Rademacher, T. (ed.). *Regulating artificial intelligence*. Cham: Springer, 2020, pp. 350-351.

³⁴ The doctor, faced with the diagnostic or prognostic result provided by the AI algorithm, will be in the complex position of justifying: (i) why he followed the diagnosis or treatment suggested by the AI; or (ii) why –and based on what factors– he deviated from the algorithmic recommendation. Doctors are free to choose their means of diagnosis and therapy proposals, but they are also responsible for their choices. In any case, there is a basic premise in the assessment of medical guilt, which will always be a constant in the legal analysis of adverse events caused by a medical act: therapeutic chance, the random factors of the practice of medicine make it impossible to impose an obligation of infallibility or absolute accuracy on the doctor. NOGAROLI, R., *Culpa médica e deveres de conduta na Inteligência Artificial*, 2023. pp. 3-40. Available at: [Achttps://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial](https://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial). Accessed on: 2 July 2025.

³⁵ It can be seen that the duty of medical conduct to provide information, clarification and advice, arising from contractual objective good faith, is closely related to two ethical principles specific to AI: i) protecting human autonomy, and ii) guaranteeing transparency, explainability and intelligibility. *Ibidem*. p. 4.

Along the same lines, Coeckelbergh puts it this way: the ethical use of AI requires privacy and the protection of fundamental rights in the collection, processing, and sharing of data³⁶.

Undoubtedly, as Nogaroli explains, the «peculiarities of the specific situation must be taken into account in order to assess the possibility of demanding certain behaviour from the doctor, given any precarious working conditions or other issues related to the very structure of the hospital where the care took place»³⁷.

Therefore, liability without fault, even when assessing breaches of duty in AI-assisted care, cannot be attributed in medical practice. This is because the law and ethical conduct advocate investigation of fault. Therefore, the medical contract (patient in an existential legal relationship and the duties of conduct) acquires a particular status, which triggers the exclusion of ordinary contractual liability³⁸.

Nogaroli concludes that the «positive violation of the medical contract based on a subjective analysis is justified because the duties of conduct are presented in a qualified manner in the doctor-patient contractual relationship, behaving almost as a principal obligation». And so, in this existential contract, «fault is the legal basis for the professional's liability»³⁹.

³⁶ An ethical use of AI requires that data be collected, processed and shared in a way that respects the privacy of individuals and their right to know what happens to them, to access it, to object to collection or processing and to know whether they are collecting and processing it and (if so) that they are exposed to the decision made by an AI. COECKELBERGH, M., *Ética de la inteligencia artificial*. Traducción Lucas Álvarez Canga. Madrid: Ediciones Cátedra, 2021. p. 86.

³⁷ NOGAROLI, R., *Culpa médica e deveres de conduta na Inteligência Artificial*, 2023. p. 4. Available at: [Achttps://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial](https://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/387047/culpa-medica-e-deveres-de-conduta-na-inteligencia-artificial). Accessed on: 02 July 2025.

³⁸ it is quite impossible to adopt liability without fault in the context of medical activity, even in order to assess the violation of a duty of conduct in the provision of medical services with AI, not only as ethical commandments, but especially due to its cogent legal force. Since the contract signed between doctor and patient is a legal transaction of an existential nature, some duties are filled with new and different meanings, leading to distinct protection with a logic that differs from the traditional view of contractual civil liability. *Ibidem*. p. 7.

³⁹ *Ibidem*.

Likewise, the positive breach of the medical contract (through non-compliance with the duties of conduct) must be measured subjectively», based on legal grounds and imperatives, «under the terms of article 951 of the Brazilian Civil Code and § 4 of article 14 of the CDC, under penalty of making the profession unviable and depersonalising the doctor-patient relationship».

On the other hand, in some cases, patients and users themselves can also be held liable for damage caused by the use of AI in embryo selection, especially if they fail to provide accurate information or omit relevant information that could affect the selection process. In this case, liability is subjective, as it also depends on proving fault or negligence, articles 186 and 927.

Furthermore, when it comes to assigning responsibility in AI systems, there is the difficulty of identifying who is responsible for the decisions made by the algorithms and how to distribute responsibility among the participants in the AI development and application process. It should be noted that machines are neither conscious nor intentional, so responsibility lies with the human beings who design, programme and use AI. Human supervision is primordial and the possibility of giving autonomy and responsibility to intelligent systems with general intelligence in the future is discussed⁴⁰.

In light of this, it is important to emphasize that the application of civil liability rules depends on the circumstances of each case, particularly regarding the identification of the legal responsibilities of AI developers, healthcare professionals, and reproductive clinics.

In this sense, the professionals' duty to protect data and privacy in the selection of human embryos using AI must also be analyzed.

In Spain, Law No. 14/2006 regulates AHR techniques and protects donor anonymity: donations are confidential, with access restricted to non-identifying information, except in cases justified by health reasons (arti-

⁴⁰ BLÁZQUEZ RUIZ, F. J., «La paradoja de la transparencia en la IA: opacidad y explicabilidad atribución de responsabilidad». *Revista Internacional de Pensamiento Político*, v. 17, pp. 261-272, 2022. p. 269-271. Available at: <https://www.upo.es/revistas/index.php/ripp/article/download/7526/6376/30836>. Accessed on: 2 July 2025.

cle 5). Regarding personal data, Ley Orgánica de Protección de Datos Personales y garantía de los derechos digitales (LOPDGDD) No. 3/2018 integrates the General Data Protection Regulation (GDPR) into Spanish law and contains provisions on health research. In this sense, article 105-bis stands out, which prioritizes security in the «treatment» of genetic data and provides guidelines for its use in AHR cycles⁴¹.

The AI Act (EU Regulation No. 2024/1689), published on July 12, 2024, with phased implementation, adopts a risk-based approach. AI systems used in the medical device ecosystem (EU Regulation No. 2017/745) tend to be high-risk and, therefore, must comply with risk management, data governance, technical documentation, robustness and accuracy, and, above all, human oversight. In clinical practice, it corroborates Section 3 (attribution of liability for fault/due diligence) and Section 4 (transparency/explainability), since it requires prior validation, post-market monitoring and auditability the use of AI in embryo selection⁴².

Finally, it should be noted that the application of civil liability rules can be complex and will depend on the specific circumstances of each

⁴¹ SPAIN. Law No. 14/2006, of 26 May, on Assisted Human Reproduction Techniques-Article 5 («Donors and donation agreements»). Official State Gazette (BOE), consolidated text. Available at: <https://www.boe.es/buscar/act.php?id=BOE-A-2006-9292>. Accessed on: 27 July 2025.

SPAIN. Organic Law No. 3/2018 (LOPDGDD), of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights - consolidated text. Official State Gazette (BOE). Available at: <https://www.boe.es/buscar/act.php?id=BOE-A-2018-16673>. Accessed on: 27 July 2025.

⁴² EUR-LEX. Regulation EU No. 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) - Official Journal (ELI/OJ). Available at: <https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng>. Accessed on: 27 July 2025.

EUR-LEX. Artificial Intelligence Act - Official Journal PDF version. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ%3AL_202401689. Accessed on: 27 July 2025.

EURLEX. *Regulation EU No. 2017/745 on medical devices (MDR) - OJ L 117, 5.5.2017, pp. 1–175 (ELI/OJ)*. Available at: <https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng>. Accessed on: 27 July 2025.

EUROPEAN COMMISSION - Shaping Europe's Digital Future. *Regulatory framework for Artificial Intelligence (AI Act) - Highlevel overview (human oversight, logging/records, robustness)*. Available at: <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>. Accessed on: 27 July 2025.

case, especially when it comes to identifying the legal responsibilities of AI developers, health professionals and reproduction clinics.

In that regard, beyond the scope of civil liability, the duty of professionals to protect data and privacy in the selection of human embryos by AI must also be examined.

These EU requirements on human oversight and post-market monitoring strengthen the diligence standard discussed above and guide how personal data are processed in embryo selection, which is further discussed next.

4. INSPECTION OF INFORMATION PROTECTION AND REFLECTIONS ON CONFIDENTIALITY IN EMBRYO SCREENING WITH THE SUPPORT OF ALGORITHMIC TECHNOLOGIES

The growing use of AI in human embryo selection brings with it the need to carefully analyse the legal guarantees and requirements for dealing with sensitive genetic and personal data. Handling this information requires strict compliance with data protection and privacy laws, ensuring that the collection, storage and use of this data is carried out in compliance with current regulations.

Byung-Chul Han has already warned that «automatic communication between things, which occurs without any human intervention, will provide new sustenance for ghosts», according to him, «it is as if conducted by ghostly hands. The digital phantoms would perhaps see to it that everything got out of hand at some point»⁴³.

In this scenario, highly sensitive information is collected and processed to make crucial decisions in assisted reproduction. Protecting this data must be seen as a priority, ensuring that patients have control over the use of their genetic and personal information, as well as that service

⁴³ HAN, B.-C.. *No exame: perspectivas do digital*. Tradução de Lucas Machado. Petrópolis, RJ: Vozes, 2018. p. 57.

providers and AI system developers comply with applicable legal and ethical standards⁴⁴.

The implementation of technological security measures and the adoption of strict privacy protocols to ensure that this information is treated with confidentiality and respect for patients' dignity.

To ensure transparency and security in this scenario, it is required that patients are properly informed about the purpose, extent and risks of using their information for embryo selection. Furthermore, it is important to provide transparent information on how AI will be employed in the process, the steps and the security measures implemented to protect the data. Informed consent must be obtained in a free and informed manner, allowing patients to make informed decisions and have control over the use of their information.

The General Data Protection Law (LGPD) in Brazil constitutes the primary legal framework to be taken into account. The LGPD, Law No. 13.709, was enacted on 14 August 2018, regulating the processing of personal data by public and private entities and, establishing rules to protect the privacy and rights of data subjects in the country. The LGPD came into force in September 2020 and brought important changes to the data protection landscape, ensuring greater control and security over citizens' personal information.

In the field of assisted reproduction, the collection and processing of patients' genetic data and medical information is common during embryo selection procedures. The use of AI to analyse and make decisions based on this data intensifies the need to protect privacy and data security.

This is because «the new technological vulnerabilities are never just technological: they also become human, existential vulnerabilities»⁴⁵.

⁴⁴ SOCIEDADES DEL GRUPO QUIRONSALUD, *Proteção de dados pessoais*, 2023. Available at: <https://www.quironsalud.es/>. Accessed on: 7 July 2025.

⁴⁵ COECKELBERGH, M., *Ética de la inteligencia artificial*. Traducción Lucas Álvarez Canga. Madrid: Ediciones Cátedra, 2021. p. 93.

The LGPD imposes some important principles and requirements that must be observed in the context of AI-assisted reproduction: consent, purpose, transparency, security, the rights of data subjects and the international transfer of data.

In this dimension, the LGPD requires that the processing of personal data be carried out with the consent of the data subjects. This means that patients must be informed about how their data will be used, with whom it will be shared and for what purposes. Consent must be free, informed and unambiguous, as provided for in item I of article 7⁴⁶.

The collection and processing of personal data must have a specific and legitimate purpose. In the case of assisted reproduction with AI, data should only be used for embryo selection and other procedures related to reproductive health, in accordance with the principle of purpose, set out in article 6, item I, of the law in question.

The LGPD requires that patients be informed in a clear and accessible manner about the processing of their personal data. Clinics and health professionals must provide detailed information on the processing of data during assisted reproduction procedures, promoting the principle of transparency, set out in article 6, item VI, of the law in question.

The importance of transparency and explainability in AI systems and how these characteristics can affect citizens' trust in the technology and its creators is emphasised. It is mentioned that citizens have the right to know the reasons behind the decisions made by AI algorithms and that this explanation must be understandable to them. Transparency doesn't mean exposing all the software code, but providing reasonable explanations of the decisions made by AI without having to unravel its detailed workings. It should be emphasised that accountability and traceability are central to guaranteeing trust in AI and avoiding possible discriminatory biases in its decisions⁴⁷.

⁴⁶ BRASIL. Lei n. 13.709, de 14 de agosto de 2018. Lei Geral de Proteção de Dados Pessoais (LGPD). Available at: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm. Accessed on: 2 July 2025.

⁴⁷ BLÁZQUEZ RUIZ, F. J., La paradoja de la transparencia en la IA: opacidad y explicabilidad atribución de responsabilidad. *Revista Internacional de Pensamiento Político*, v. 17, pp. 261-272, 2022. p. 265-267. Available at: <https://www.upo.es/revistas/index.php/ripp/article/download/7526/6376/30836>. Accessed on: 2 July 2025.

Blázquez Ruiz refers to the lack of transparency in AI algorithms as opacity, pointing out that they work like «black boxes» whose inner workings are unknown to users, creating a society that is increasingly technological and disconnected from the decisions made.

According to the author, it is recognised that zero risk in the development of emerging technologies is not possible, but the importance of determining and regulating the limit of risk that society is willing to assume is emphasised. The lack of knowledge and responsibility in relation to AI is an ethical and legal problem. It highlights the need to analyse the decisions made by AI algorithms and avoid opacity in order to prevent biases that could affect society⁴⁸.

Dworkin defends a theory of equality that recognises the importance of individual responsibility and the equal consideration of individuals. In the context of embryo selection using AI, the application of this theory requires an approach that considers the particularities of each patient and their responsibilities in decision-making⁴⁹.

When using AI in embryo selection, patients must have transparent and informed access to the process, and that their individual choices and circumstances are adequately considered. The application of AI must ensure that the information provided by patients is accurate and that selection algorithms take into account the diversity of individual circumstances.

Therefore, the correlation with the ideals of responsibility precepted by Dworkin in the use of AI in embryo selection find in balance between equal consideration and respect for patients and in recognising their individual responsibilities when making decisions.

Furthermore, entities that carry out assisted reproduction with AI must adopt appropriate security measures to protect patients' personal data from unauthorised access, loss or leakage, under the terms of article 47 of the LGPD⁵⁰.

⁴⁸ *Ibidem*. p. 267-268.

⁴⁹ DWORKIN, R., *A virtude soberana: a teoria e a prática da igualdade*. 1 ed. São Paulo: Martins Fontes, 2000. pp. 8-12; 31-32.

⁵⁰ BRASIL. Lei n. 13.709, de 14 de agosto de 2018. Lei Geral de Proteção de Dados Pessoais (LGPD). Available at: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/

Article 18 of the LGPD grants patients a series of rights in relation to their personal data, including the right of access, correction, deletion and portability of information⁵¹.

Article 33 also lays down rules for the international transfer of personal data. If patient data is shared with organisations outside Brazil, the legal requirements for this transfer must be observed⁵².

The GDPR (Regulation 2016/679) classifies health and genetic data as special categories and authorizes their processing, among other things, for the provision of healthcare and research (Article 9). Regarding decisions about patients, article 22 guarantees the right not to be subject to a decision based exclusively on automated processing with legal effects, except in cases where safeguards are provided (such as human intervention and objection). In international transfers, Chapter V applies: in the absence of an adequacy decision, the Spanish clinic sharing data with entities outside the EU must adopt safeguards (e.g., Standard Contractual Clauses (SCCs)/ Binding Corporate Rules BCRs) and also evaluate re-identification and metadata flow⁵³.

lei/113709.htm. Accessed on: 02 July 2025.

⁵¹ *Ibidem*.

⁵² *Ibidem*.

⁵³ GDPR EU-Regulation EU No. 2016/679, article 9 (special categories; health/research processing bases), article 22 (automated decisions only; human intervention, objection), and Chapter V (international transfers: adequacy decision; appropriate safeguards such as SCCs/BCRs). EUR-LEX. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) - Official Journal (ELI/JO). Available at: eur-lex.europa.eu/eli/reg/2024/1689/oj/eng. Accessed on: 27 July 2025. Consolidated text (recommended for citing specific articles): Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016R0679>. Accessed on: 27 July 2025.

EUR-LEX. Regulation EU No. 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) - Official Journal (ELI/OJ). Available at: <https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng>. Accessed on: 27 July 2025.

EUR-LEX. Regulation EU No. 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) - OJ L 117, 5.5.2017, pp. 1-175 (ELI/OJ). Available at: <https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng>. Accessed on: 27 July 2025.

EUROPEAN COMMISSION-Shaping Europe's Digital Future. Regulatory framework for AI (AI Act) - High-level overview (human oversight, logging, robustness). Available at: <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai>. Accessed on: 27 July 2025.

It can be seen that the LGPD is applicable to the issue of AI-assisted reproduction, guaranteeing the protection of the privacy and security of the personal data of the patients these procedures. Undoubtedly, compliance with the LGPD is required to ensure that the use of AI in embryo selection is carried out legally while respecting the rights and privacy of individuals.

Therefore, the regulatory approaches outlined and analysed allow for the compilation and systematisation of effective legal frameworks aimed at best practices by professionals before, during and after the use of AI in human embryo selection.

Beyond the Brazilian LGPD, EU law adds specific guarantees for health and genetic data and limits fully automated decisions affecting patients, as detailed in Articles 9 and 22 GDPR and Chapter V for international transfers.

5. FINAL CONSIDERATIONS

The research we have now completed has outlined a comprehensive picture of the civil duties and data governance parameters that affect embryo curation contemplated by artificial intelligence. It has been shown that the incorporation of algorithmic systems into assisted human reproduction increases the success rates of *in vitro* fertilisation cycles, as it reveals genetic and clinical patterns previously unattainable to the human eye. These gains, however, are accompanied by an intricate list of legal obligations, the omission of which jeopardises both the legitimacy of the procedure and the safety of future parents.

In scope of liability, some individuals and organizations have been identified as liable parties subject to redress: software developers, device suppliers, AHR clinics, health professionals and, in extreme cases, the treatment applicants themselves. The distribution of burdens cannot be resolved by simple objective attribution; it requires a case-by-case analysis of the link between the algorithmic defect, the clinical judgement and the trust placed in the patient, in the light of articles 186 and 927 of the Civil Code, article 14 of the CDC and the doctrine of entrepreneurial risk. In this respect, the duty of human supervision remains

inescapable: the algorithm, however advanced, is no substitute for clinical judgement based on scientific evidence.

As for data protection, embryo selection depends on genetic information that is extremely sensitive. The General Personal Data Protection Law imposes strict safeguards on purpose, minimisation and security, and it is up to the controller to set up anonymisation protocols, independent audits and impact reports - mechanisms capable of unravelling the «algorithmic enigma» and mitigating discriminatory biases. The combination of these provisions with CFM Resolution No. 2.320/2022 consolidates a regime that harmonises reproductive autonomy, human dignity and scientific freedom.

Thus, regulatory developments will have to keep pace with innovation, establishing specific guidelines on model validation, traceability of automated decisions and transparency requirements for both clinical staff and patients. The synthesis elaborated throughout this work provides reference material for building a coherent framework capable of fostering innovation without abdicating legal certainty or the protection of fundamental rights.

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