Artificial Intelligence and Human Embryos: A Comparative Dialogue between Italy, Spain and Brazil (2004-2025)

Bruna Ghezzo Scarmagnan Pavelski*

ABSTRACT: This article examines artificial intelligence in embryo assessment through a functional comparison of Italy, Spain and Brazil between 2004 and 2025. It analyses legislation, case law and scholarship concerning clinical validation, patient information, human oversight and responsibility. The Italian debate illustrates tensions between health protection, reproductive autonomy and legislative discretion. Spanish data protection safeguards and Brazilian professional rules reveal distinct institutional approaches. The article proposes a governance model comprising documented data practices, local validation, patient information, recorded clinical review and allocated responsibility. Algorithmic ranking must remain distinguishable from genetic diagnosis and from separate decisions about embryo storage, research or disposal.

KEYWORDS: artificial intelligence; assisted reproduction; comparative biolaw; embryo selection; data protection

SUMMARY: 1. Introduction – 2. AI in the Embryology Laboratory – 3. Italy: Law no. 40/2004, Constitutional Adjudication and EU Digital Regulation – 4. Spain: Statutory Permissibility, Biomedical Research and Clinical Governance – 5. Brazil: Biosafety, Professional Regulation and Fragmented Oversight – 6. Comparative Findings: Convergence, Divergence and Functional Equivalence – 7. A Governance Model for Clinical Deployment – 8. Concluding Remarks.

1. Introduction

Artificial intelligence is changing assisted reproductive technology (ART) at the point where biological uncertainty, clinical judgment and legally protected interests intersect. Machine-learning systems can process static or time-lapse images, identify morphokinetic patterns and assign scores intended to predict blastocyst formation, implantation or live birth. Their output may influence which embryo is transferred first, which remains cryopreserved and which is not selected for a particular transfer. Although the system does not itself create a legal status for the embryo, it modifies the informational environment in which decisions about embryos are made.[1]

The legal problem is therefore narrower, and more concrete, than the general debate over 'AI in medicine'. It concerns the conditions under which probabilistic classification may enter a decision involving prospective parents, health professionals, clinics, software manufacturers and embryos that receive dif-

* *Universidad Pública de Navarra. Mail: bruna.guesso@unavarra.es.* *This article was subject to a double-blind peer review process.*

[1] I. DIMITRIADIS, N. ZANINOVIC, A. CHÁVEZ-BADIOLA, C.L. BORMANN, *Artificial intelligence in the embryology laboratory: a review*, in *Reproductive BioMedicine Online*, 44(3), 2022, 435-448.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

ferent forms of protection in different legal systems. A model may perform well in its training environment and still produce unreliable results when applied to another patient population, laboratory protocol or imaging device. A score may appear objective while concealing the selection of outcomes, labels and thresholds made by developers and clinicians. In this field, technical performance and normative legitimacy cannot be separated.[2]

This article asks how Italy, Spain and Brazil regulate AI-assisted embryo assessment and what common governance standard can be derived from their differences. These jurisdictions were selected because they combine civil-law traditions with markedly different approaches to ART and embryo protection. Italy has a restrictive statute that has been repeatedly reshaped by constitutional adjudication. Spain has a detailed statutory framework that generally permits a broader range of reproductive techniques and biomedical research under administrative control. Brazil lacks a comprehensive ART statute and relies on constitutional norms, the Biosafety Law, professional resolutions, health-surveillance rules, consumer law and data-protection legislation.[3]

The study uses a functional comparative-law method and examines developments between 2004 and 2025, while retaining earlier background legislation where necessary. Its legal account is a snapshot at 31 December 2025, rather than a statement of the law applicable on the date of publication. The corpus comprises the ART and biomedical-research legislation of the three jurisdictions, relevant judgments, professional and regulatory instruments, and EU legislation on medical devices, personal data and AI. Instruments adopted within the period are distinguished from provisions already applicable at its end; later amendments fall outside this historical scope. The comparison asks how each system validates technology, informs patients, preserves clinical judgment and allocates responsibility. The literature review is selective and doctrinal, not a systematic review of every publication on ART or AI.[4]

The article's normative claim is that the legitimacy of AI in embryo selection should be assessed through functional equivalence rather than formal labels. Whether a product is marketed as a 'decision-support tool', a 'score' or an 'automated assessment', the decisive question is what it does in clinical practice. If its output materially affects the order of transfer or a decision not to transfer an embryo, safeguards must correspond to that influence. This is a proposed comparative standard, not a claim that national rules are identical. The article accordingly proposes a five-part governance model: a data dossier; local and periodic validation; patient-facing algorithmic information; a documented human decision; and an *ex ante* responsibility matrix.

[2] C. CASONATO, *Biodiritto. Oggetto, fonti, modelli, metodo*, Torino, 2023.

[3] Italy, Legge 19 febbraio 2004, n. 40, *Norme in materia di procreazione medicalmente assistita*; Spain, Ley 14/2006, de 26 de mayo, *sobre técnicas de reproducción humana asistida*; Spain, Ley 14/2007, de 3 de julio, *de Investigación biomédica*; Brazil, Lei n. 11.105, de 24 de março de 2005; Conselho Federal de Medicina, Resolução CFM n. 2.320, de 1 de setembro de 2022, *Normas éticas para a utilização das técnicas de reprodução assistida*, published 20 September 2022.

[4] European Union, Regulation (EU) 2017/745 of 5 April 2017 on medical devices; European Union, Regulation (EU) 2016/679 of 27 April 2016 (*General Data Protection Regulation*); European Union, Regulation (EU) 2024/1689 of 13 June 2024 (*Artificial Intelligence Act*).

Downloaded from https://teseo.unitn.it/biolaw
ISSN 2284-4503

2. AI in the Embryology Laboratory

Embryo assessment has traditionally relied on visual examination of morphology at selected stages of development. Embryologists consider factors such as cell number, fragmentation, symmetry and blastocyst expansion. Time-lapse incubators add continuous imaging and permit the observation of developmental timing without repeatedly removing embryos from controlled conditions. Machine-learning models can then process a large set of images and variables, detect patterns and generate rankings.[5]

The relevant systems do not all perform the same task. Some predict development to the blastocyst stage; others estimate implantation potential, fetal heartbeat or live birth. Some use only images; others combine images with maternal age, treatment history, genetic data or laboratory parameters. A model may rank embryos within one cycle, classify them into categories, or recommend a transfer order. These distinctions matter because each intended purpose defines the clinical claim to be validated and may affect classification under medical-device law.[6]

Three activities must therefore be distinguished: image-based prioritisation for transfer, genetic testing for a specified condition, and decisions about the eventual disposition of embryos. An image-derived score is not, by itself, a genetic diagnosis. Nor does a low predicted chance of implantation establish a legal entitlement to destroy an embryo, donate it for research or discontinue cryopreservation. Those decisions require their own clinical assessment and legal justification.[7]

Published studies demonstrate promise but do not justify treating algorithmic scores as universal truths. Reported performance depends on the outcome selected, the prevalence of that outcome, image quality, laboratory practice and the composition of the dataset. The area under the receiver-operating-characteristic curve is frequently used, yet it does not by itself show calibration, clinical utility or fairness across subgroups. A tool may discriminate relatively well between cases while systematically overestimating probabilities. It may also reproduce the preferences embedded in historical decisions made by particular clinics.[8]

Clinical evidence also counsels restraint. In the 2024 multicentre trial reported by Illingworth and colleagues, involving 1,066 patients, deep-learning embryo selection did not demonstrate noninferiority to the study's morphology-based comparator for clinical pregnancy under the prespecified margin. This is not proof that every AI system is inferior. It does show why predictive performance and faster assessment cannot simply be equated with a demonstrated improvement in reproductive outcomes.[9]

External validity is especially important in reproductive medicine. Embryology laboratories differ in culture media, incubators, oxygen concentration, timing conventions, fertilisation techniques and grading practices. Patient populations differ in age, diagnosis and treatment history. A model trained in one centre may therefore lose performance elsewhere. In the governance model proposed here, assessment of

[5] M.F. KRAGH, H. KARSTOFT, *Embryo selection with artificial intelligence: how to evaluate and compare methods?*, in *Journal of Assisted Reproduction and Genetics*, 38(7), 2021, 1675-1689.

[6] Vitrolife A/S, *iDAScore: User Manual*, version 1, revision 10 February 2024, 4-5; I. DIMITRIADIS, N. ZANINOVIC, A. CHÁVEZ-BADIOLA, C.L. BORMANN, *Artificial intelligence in the embryology laboratory*, cit.

[7] Corte costituzionale, Judgment no. 229/2015; Spain, Ley 14/2006, arts 11-12; Brazil, Lei n. 11.105/2005, art. 5.

[8] M.F. KRAGH, H. KARSTOFT, *Embryo selection with artificial intelligence*, cit.; C. MANNA *et al.*, *Artificial intelligence techniques for embryo and oocyte classification*, in *Reproductive BioMedicine Online*, 26(1), 2013, 42-49.

[9] P.J. ILLINGWORTH *et al.*, *Deep learning versus manual morphology-based embryo selection in IVF: a randomized, double-blind noninferiority trial*, in *Nature Medicine*, 30(11), 2024, 3114-3120.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

performance in the intended local setting is a safeguard against deploying a tool on the strength of benefits demonstrated only elsewhere. Its design should be proportionate to the clinical claim, available evidence and applicable device obligations.[10]

Three risks organise the legal analysis. The first is opacity. A patient may be told that 'AI selected the best embryo' without receiving an intelligible explanation of what the tool predicts, what data it uses, its limitations or the role of the embryologist. The second is safety. Dataset shift, software updates, interface errors and automation bias can alter performance after deployment. The third is responsibility. When a score influences a choice, the clinic, professional, developer, manufacturer and data controller may each have different duties, but fragmented contracts can obscure who must monitor, explain and remedy failure.[11]

The response cannot be a fictional demand that every neural network disclose an intuitive causal narrative for each score. Legal transparency is broader than mathematical interpretability. It requires information proportionate to the decision: intended purpose, validated population, performance and uncertainty, relevant data sources, version, known limitations, human-review procedure and route for contesting or correcting information. Informed consent must be understood as an ongoing relational process rather than a single signature obtained before treatment. Tomasi's constitutional framing of genetics through equality, solidarity and responsibility helps locate patient information within relationships of care, rather than treating disclosure as a complete answer to vulnerability.[12]

Within the proposed model, human oversight must likewise be substantive. A professional who merely confirms the default output, lacks access to relevant documentation or cannot depart from the ranking does not provide meaningful oversight. The clinician or embryologist must be competent to evaluate whether the system applies to the patient, identify discordance with morphological or clinical evidence, record reasons for following or departing from the output, and suspend use when performance concerns arise. Human presence without authority, information and time is ceremonial rather than protective.

The ethical literature adds a different concern. Halsband argues that the combination of AI, embryo selection and changing reproductive practices may reshape reproductive choice and expectations about responsible parenthood. A governance model focused only on accuracy and liability would miss this social dimension. Its relevance here is not to equate every ranking exercise with genetic enhancement, but to ask whether patients remain free to assess the tool's limited purpose without pressure to treat its output as a guarantee of a preferred child.[13]

[10] M.F. KRAGH, H. KARSTOFT, *Embryo selection with artificial intelligence*, cit.; G. COTICCHIO *et al.*, *Time will tell: time-lapse technology and artificial intelligence to set time cut-offs indicating embryo incompetence*, in *Human Reproduction*, 39(12), 2024, 2663-2673.

[11] F.J. BLAZQUEZ RUIZ, *La paradoja de la transparencia en la IA: opacidad y explicabilidad. Atribución de responsabilidad*, in *Revista Internacional de Pensamiento Político*, 17, 2022, 261-272.

[12] M. TOMASI, *Genetica e Costituzione. Esercizi di eguaglianza, solidarietà e responsabilità*, Trento, 2019.

[13] A. HALSBAND, *Embryo selection, AI and reproductive choice*, in *AI and Ethics*, 5, 2025, 3115-3127.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

3. Italy: Law no. 40/2004, Constitutional Adjudication and EU Digital Regulation

Italian Law no. 40/2004 places medically assisted procreation within an expressly protective framework for all persons involved, including the conceived. Its original architecture restricted access to treatment, prohibited heterologous fertilisation and tightly constrained embryo production and cryopreservation. Constitutional adjudication subsequently altered specific restrictions. The legal significance of that trajectory is contested: it concerns both the substantive protection of health and reproductive choice and the respective roles of legislation, courts and clinical expertise.[14]

Judgment no. 151/2009 removed the statutory requirement limiting embryo creation to a maximum of three for a single simultaneous transfer and required the transfer framework to safeguard the woman's health. It restored room for individualised medical assessment within the statute's protective aims. Penasa's comparison of Italian substantive rigidity with Spanish procedural flexibility helps explain the instability of fixed numerical rules when they cannot accommodate clinical circumstances. This supports a distinction between regulating the conditions of medical judgment and prescribing the same outcome for every patient.[15]

Judgment no. 162/2014 invalidated the prohibition of heterologous fertilisation for couples otherwise eligible for ART who face absolute and irreversible sterility or infertility. The doctrinal debate is particularly instructive. Casonato reads the judgment through reasonableness and proportionality, stressing the inconsistency of excluding the very patients for whom the prohibited technique addresses the obstacle to reproduction. Violini instead questions aspects of the Court's reasoning and the space left for legislative balancing in a morally contested field. These positions should not be flattened into a single narrative of inevitable liberalisation: a favourable assessment of a rights-protecting outcome differs from an assessment of the institutional authority used to reach it.[16]

Judgment no. 96/2015 extended access to ART and preimplantation diagnosis to fertile couples carrying serious transmissible genetic diseases meeting the severity criteria identified by reference to Law no. 194/1978, ascertained by appropriate public facilities. Penasa's commentary distinguishes this health-based reasoning from recognition of an unrestricted right to a healthy child, and emphasises the continuing need for legislative specification. For AI, the implication advanced here is correspondingly limited: individualised assessment does not authorise developers or clinics to define desirable offspring through an unrestricted optimisation target.[17]

Judgment no. 229/2015 then removed the criminal prohibition of selection in the medically justified circumstances recognised in judgment no. 96/2015, while rejecting the challenge to the prohibition on destroying embryos affected by disease. The distinction is decisive: lawful diagnosis and a decision against

[14] Italy, Legge n. 40/2004, arts 1, 4 and 13-14.

[15] Corte costituzionale, Judgment no. 151/2009; S. PENASA, *La frágil rigidez de la ley italiana de reproducción asistida contra la rígida flexibilidad del modelo español: contenido vs. procedimiento*, in *Revista de Bioética y Derecho*, 18, 2010, 17-25.

[16] Corte costituzionale, Judgment no. 162/2014; C. CASONATO, *La fecondazione eterologa e la ragionevolezza della Corte*, in *Confronti costituzionali*, 2014, 1-3; L. VIOLINI, *La Corte e l'eterologa: i diritti enunciati e gli argomenti addotti a sostegno della decisione*, in *Osservatorio costituzionale*, 2014, 1-15.

[17] Corte costituzionale, Judgment no. 96/2015; S. PENASA, *L'insostenibile debolezza della legge 40: la sentenza n. 96 del 2015 della Corte costituzionale tra inevitabili illegittimità e moniti "rafforzati"*, in *Forum di Quaderni Costituzionali*, 2015, 1-4.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

transfer do not imply a general power of disposal. Molero Martín-Salas's account of the successive judgments likewise presents an unfinished regulatory reconstruction, rather than a comprehensive new code supplied by the Court. AI cannot fill that legislative space merely by producing a more detailed score.[18]

Dalla Costa examines the fate of supernumerary embryos as a problem of continuing institutional responsibility, not merely classification. Her account of embryos that will not be transferred and of abandonment links prolonged custody to financial and organisational burdens for clinics and uncertainty for patients. In her conclusions she calls for a coherent legislative response and European harmonisation, together with informed patient decisions about the possible destinations of surplus embryos. This reform-oriented position adds a practical question to the constitutional debate: how should the law organise care for embryos once there is no immediate transfer project? The present article draws a limited implication for AI: a low score cannot itself establish abandonment, legal nonviability or a power to terminate storage.[19]

Her comparative analysis also exposes limits to ready-made solutions. Reviewing the Italian Bioethics Committee's embryo-adoption proposal, she notes difficulties with extending the rules for adoption of minors to embryos. In the Spanish discussion, she raises a possible time limit followed by destruction when the selected destination cannot be implemented or consent has not been renewed. These are reform questions, not an existing Italian authorisation or a rule governing every stored embryo. They require separate consideration of consent, eligibility for donation and the legal conditions for ending conservation. Algorithmic rankings cannot settle those issues, and functional equivalence should not convert a proposal for legislative reform into a clinical permission.[20]

The limits of judicial reconstruction also appear at the European level. In Parrillo v. Italy, the European Court of Human Rights found no violation of Article 8 in the restriction on donating the applicant's cryopreserved embryos to scientific research, allowing Italy a wide margin of appreciation. This reinforces the need to avoid treating reproductive autonomy, control of medical data and authority over the research use of embryos as interchangeable legal entitlements.[21]

These debates support a more qualified application to algorithmic ranking than a simple appeal to technological flexibility. A score should not recreate an inflexible numerical command within clinical practice; at the same time, restoring medical judgment does not transfer legislative authority over permissible reproductive aims to software designers. Functional equivalence therefore concerns safeguards within the legally authorised activity. It cannot be used to erase substantive limits or to claim that constitutional judgments about ART already decided the legality of particular AI products.[22]

At the European level, the intended purpose and integration of the software determine whether it is regulated as a medical device under Regulation (EU) 2017/745. Software that provides information used

[18] Corte costituzionale, Judgment no. 229/2015; M.P. MOLERO MARTÍN-SALAS, *La reproducción asistida en Italia: una regulación (inacabada) a golpe de sentencia*, in *Revista Española de Derecho Constitucional*, 112, 2018, 315-344.

[19] S. DALLA COSTA, *Perspectiva legal del manejo de embriones supernumerarios en Italia. Soluciones prácticas de Derecho comparado*, in *Revista de Derecho y Genoma Humano. Genética, Biotecnología y Medicina Avanzada*, 58, 2023, 45-83, especially 56-63 and 78.

[20] S. DALLA COSTA, *Perspectiva legal del manejo de embriones supernumerarios en Italia*, cit., 63 and 76-78.

[21] European Court of Human Rights, *Parrillo v. Italy*, [GC], application no. 46470/11, 27 August 2015.

[22] S. PENASA, *La frágil rigidez*, cit.; L. VIOLINI, *La Corte e l'eterologa*, cit.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

for diagnostic or therapeutic decisions may fall within Rule 11, with classification depending on the potential impact of those decisions. Medical-device status brings obligations concerning risk management, clinical evaluation, technical documentation, quality systems, post-market surveillance and vigilance. For embryo-ranking software, the relevant claim must be precise: predicting blastocyst formation is not equivalent to predicting implantation or live birth.[23]

The AI Act introduces a further, phased regulatory layer. Under Article 6(1), the product route to high-risk classification requires both an AI product or safety component covered by Annex I legislation and a requirement for third-party conformity assessment. Medical relevance alone does not establish that classification. Under the original Article 113, relevant to this study's cutoff, the general application date was 2 August 2026 and the Article 6(1) product-related obligations were scheduled for 2 August 2027; some provisions already applied in 2025. The account here therefore distinguishes prospective duties from rules already applicable at the cutoff. The high-risk requirements address risk management, data, documentation, logging, transparency, oversight, accuracy, robustness and cybersecurity. Neither a future high-risk classification nor existing CE marking establishes local clinical utility by itself.[24]

The need to examine the particular product is illustrated by the manufacturer's February 2024 user manual for iDAScore version 1, which describes that version as a Class I medical device and assigns the final embryo decision to the user. This historical manufacturer statement is not an independent legal determination of classification, and it cannot establish the status of every later version or competing system. It does caution against assigning one regulatory category to all embryo-ranking software without examining intended purpose and the applicable conformity route.[25]

The GDPR applies where the information relates to identified or identifiable persons. Embryo images linked to a patient's reproductive care can reveal health information, but an image is not automatically genetic data merely because it depicts an embryo. Special-category processing requires an Article 6 basis and an Article 9 condition; purpose limitation, minimisation and security remain applicable. A data-protection impact assessment is required where processing is likely to create a high risk, assessed under Article 35. Article 22 concerns solely automated decisions with legal or similarly significant effects, not every use of a clinical score. Genuine professional assessment therefore matters, but nominal human involvement cannot settle the issue.[26]

Responsibility must also be allocated across healthcare facilities, professionals and manufacturers. Article 7 of Law no. 24/2017 differentiates institutional and professional civil liability; an internal allocation of tasks does not remove duties owed to patients. Directive (EU) 2024/2853 expressly includes software within the updated product-liability framework, but, at the study cutoff, it required national transposition by 9 December 2026 and applied to products placed on the market or put into service after that date. It is therefore discussed as an adopted reform, not as the liability regime already governing every clinical deployment in 2025.[27]

---

[23] European Union, Regulation (EU) 2017/745, art. 2, arts 10, 61 and 83, and Annex VIII, Rule 11.

[24] European Union, Regulation (EU) 2024/1689, art. 6(1), arts 8-15, Annex I and art. 113, original 2024 text.

[25] Vitrolife A/S, *iDAScore: User Manual*, 4-5.

[26] European Union, Regulation (EU) 2016/679, arts 4-6, 9, 22, 32 and 35.

[27] Italy, Legge 8 marzo 2017, n. 24, *Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie,* art. 7; European Union, Directive (EU) 2024/2853 of 23 October 2024 on liability for defective products, arts 2 and 22.

Downloaded from
https://teseo.unitn.it/biolaw
ISSN 2284-4503

The Italian model therefore combines a constitutionally sensitive ART framework with EU device and data regulation and an emerging, phased AI regime. Its main weakness is not absence of norms but coordination. The proposed governance model gives clinics a single operational protocol capable of translating overlapping regimes into a coherent record: why the tool was selected, how it was validated, which version was used, what the patient was told, how the professional reviewed the score and how incidents will be reported.

4. Spain: Statutory Permissibility, Biomedical Research and Clinical Governance

Spain regulates ART primarily through Law no. 14/2006 and biomedical research through Law no. 14/2007. The Spanish framework permits a comparatively broad range of reproductive techniques while maintaining controls on authorised centres, consent, confidentiality, preimplantation genetic testing, donation and research. This relative permissiveness does not create a technology-free zone. It makes procedural governance especially important because more clinical options can increase the number and complexity of decisions in which algorithmic systems intervene.[28]

Penasa's Italy-Spain comparison locates the Spanish model's flexibility in procedures and institutional controls, rather than the absence of legal constraints. Applied here, that distinction helps explain why a comparatively permissive ART statute still requires scrutiny of who authorises an AI-supported activity, on what evidence and with which limits. This is an analogy drawn from the earlier comparative debate, not an attribution to Penasa of a position on contemporary embryo-ranking AI.[29]

Law no. 14/2006 requires informed, free, conscious and express consent and regulates authorised reproductive practice. Article 12(1) permits preimplantation diagnosis for specified serious hereditary diseases and alterations compromising embryo viability; other applications require the additional authorisation and favourable commission assessment described in Article 12(2). Article 11 separately governs possible destinations of cryopreserved embryos, subject to its conditions. Research involving embryos must therefore be examined under the specific ART legislation as well as the relevant biomedical-research framework. Law no. 14/2007 addresses, among other matters, genetic analyses and biological samples; it does not make all embryo-related research interchangeable with ordinary clinical care.[30]

Dalla Costa's assessment of Spain qualifies the contrast with Italy: allowing several destinations does not ensure that a chosen use is available. She discusses difficulties in renewing consent and implementing research or reproductive donation. Those practical observations must be distinguished from the legal test in Article 11(6) of Law no. 14/2006. The provision links the centre's resulting authority to two consecutive unsuccessful consent-renewal procedures and demonstrable attempts to obtain a response, within the statutory framework of permitted destinations. It does not authorise disposition merely because a predicted implantation probability is low. For AI-supported care, the transfer record and any later decision about an embryo's destination must therefore remain distinct.[31]

[28] Spain, Ley 14/2006; Spain, Ley 14/2007.
[29] S. PENASA, *La frágil rigidez*, cit.
[30] Spain, Ley 14/2006, arts 3, 11-12 and 15-16; Spain, Ley 14/2007, Title V.
[31] S. DALLA COSTA, *Perspectiva legal del manejo de embriones supernumerarios en Italia*, cit., 76-78; Spain, Ley 14/2006, art. 11(3)-(6).

Downloaded from https://teseo.unitn.it/biolaw
ISSN 2284-4503

Spain's Organic Law no. 3/2018 on Personal Data Protection and the Guarantee of Digital Rights complements the GDPR and is directly relevant to secondary use of reproductive-health information. Treatment consent does not automatically authorise training a commercial model. The controller must identify the applicable legal basis and special-category condition, assess purpose compatibility where relevant, and distinguish personal-data processing from consent to the medical procedure. Pseudonymisation reduces identification risks but does not itself remove data from the GDPR's scope.[32]

Additional provision 17 of Organic Law no. 3/2018 specifies safeguards for health research. Its provisions on related secondary research uses, information and prior ethical assessment, and on pseudonymised research data, cannot be reduced to a general exemption. They include separation between research personnel and those holding reidentification information, confidentiality and security safeguards, prior ethics assessment for the specified pseudonymised uses, and an impact assessment where Article 35 GDPR requires one. A clinic developing an embryo-ranking model must establish which route actually applies; a research label alone does not legitimise unrestricted reuse or disclosure to a supplier.[33]

Spanish centres and manufacturers are also subject to the EU device and data frameworks, alongside the AI Act's phased architecture described in section 3. This permits a useful comparative insight: similar European product obligations can operate within different substantive boundaries for embryo creation, diagnosis, transfer and research. EU conformity does not establish that a particular use is permitted by Spanish ART law, just as a permitted reproductive technique does not establish that every supporting software product is suitable.[34]

For the proposed model, the Spanish approach underscores the importance of institutional responsibility. If AI affects embryo prioritisation, the clinical record should therefore identify the system and version, relevant input data, output, professional assessment and final decision. Without this record, neither the patient nor a regulator can reconstruct the causal and decisional chain.

Patient information should distinguish probability from certainty. The phrase 'best embryo' is scientifically and legally hazardous when a model predicts only a specified outcome under defined conditions. Information must state that the score is probabilistic, may not have been validated for every demographic or clinical subgroup, and does not determine the future health or moral worth of a child. Information and, where required, consent for treatment, data processing and research participation should be distinguished. This does not imply that consent is the only permissible legal basis for every processing operation.

Spain consequently illustrates a model of broad clinical permissibility constrained by administrative, professional and data-governance safeguards. Its principal contribution to the comparison is the need to police transitions between treatment, validation and research. The same dataset and software can move between these contexts, but the legal justification and oversight cannot be presumed to travel automatically with them.

[32] European Union, Regulation (EU) 2016/679, arts 5, 6 and 9; Spain, Ley Orgánica 3/2018, de 5 de diciembre, *de Protección de Datos Personales y garantía de los derechos digitales*, art. 9 and additional provision 17.

[33] Spain, Ley Orgánica 3/2018, additional provision 17(2)(c), (d), (f) and (g).

[34] European Union, Regulation (EU) 2017/745; European Union, Regulation (EU) 2016/679; European Union, Regulation (EU) 2024/1689, arts 6 and 113, original 2024 text.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

AI and Law

5. Brazil: Biosafety, Professional Regulation and Fragmented Oversight

Brazil has no comprehensive federal statute governing all dimensions of assisted reproduction. The legal framework is assembled from constitutional rights, the Biosafety Law, resolutions of the Federal Council of Medicine (CFM), health-surveillance regulation, the Consumer Protection Code, civil-liability rules and the General Data Protection Law (LGPD). This fragmentation provides flexibility but weakens democratic legitimacy and can generate uncertainty about enforcement and institutional competence.[35]

Article 5 of Law no. 11.105/2005 authorises, under specified conditions, research and therapy using embryonic stem cells obtained from IVF embryos not used in the reproductive procedure. Its alternatives concern nonviability or the qualifying cryopreservation circumstances defined by the statute, together with parental consent and ethics review; they are not a general permission to use any surplus embryo for any purpose. The cryopreservation alternative refers to embryos already frozen when the law was published, subject to its three-year conditions. In ADI 3510, the Federal Supreme Court upheld Article 5. Neither that judgment nor the statutory exception creates a complete regime for algorithmic ranking in clinical ART.[36]

CFM Resolution no. 2.320, adopted on 1 September 2022 and published on 20 September 2022, establishes ethical rules for ART, including informed consent, records, transfer, cryopreservation, donation and preimplantation genetic testing. Section I(5) prohibits choosing an embryo's sex or another biological characteristic except to avoid disease in the prospective descendant. Section VI also addresses HLA-compatible embryo selection for treatment of an existing affected child. Algorithmic tools must operate within these substantive limits: a clinic cannot delegate to software a selection criterion that the professional would be prohibited from applying.[37]

Cardin, Cazelatto and Oliveira approach AI-assisted preimplantation diagnosis through dignity and the risk of nontherapeutic selection. Their critique identifies the danger of instrumentalising embryos through selection aims that exceed disease prevention. It requires a careful application here: image-based ranking, genetic diagnosis and genetic alteration are different activities. The relevant lesson is to scrutinise the purpose and consequences of selection, without assuming that every image score reveals genetic characteristics or changes the embryo's genome.[38]

Software used for a medical purpose may also fall within the competence of the National Health Surveillance Agency (ANVISA) as software as a medical device. Classification depends on intended purpose and risk. Registration or notification does not resolve the clinical question of local validation, and a tool presented as administrative or informational may still materially influence care. Functional analysis is therefore essential: marketing language cannot displace actual use.[39]

---

[35] Brazil, Lei n. 11.105/2005; Conselho Federal de Medicina, Resolução CFM n. 2.320/2022; Brazil, Lei n. 13.709, de 14 de agosto de 2018, *Lei Geral de Proteção de Dados Pessoais*.

[36] Brazil, Lei n. 11.105/2005, art. 5; Supremo Tribunal Federal, ADI 3510/DF, judgment of 29 May 2008.

[37] Conselho Federal de Medicina, Resolução CFM n. 2.320/2022, sections I(4-5), V and VI.

[38] V.S.G. CARDIN, C.E.C. CAZELATTO, J.S. DE OLIVEIRA, *Da utilização da inteligência artificial no diagnóstico genético pré-implantacional sob a perspectiva ético-jurídica*, in *Pensar – Revista de Ciências Jurídicas*, 27(3), 2022, 1-13, especially 9-10.

[39] Agência Nacional de Vigilância Sanitária, Resolução RDC n. 657, de 24 de março de 2022, *Regularização de software como dispositivo médico (Software as a Medical Device – SaMD)*.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

The LGPD treats personal health and genetic data as sensitive. Article 20 provides for review of decisions based solely on automated processing affecting the data subject's interests and information about their criteria and procedures, subject to statutory qualifications; its wording does not expressly require review by a natural person. Meaningful clinical human oversight is therefore defended here as part of the proposed governance standard, not attributed verbatim to Article 20. Article 38 allows the authority to require an impact report. ANPD guidance recommends preparing such reports for high-risk processing; that recommendation should not be confused with a universal statutory duty to produce one for every AI application.[40]

Consumer law is particularly significant in private ART. Clinics and technology suppliers may form part of a service chain, although the legal basis and standard of liability can vary with the actor and the nature of the defect. Advertising that presents AI as infallible, promises success rates unsupported by the local population or obscures limitations may violate duties of information and good faith. The medical professional's personal liability is ordinarily assessed through fault, while healthcare establishments may bear broader service-related responsibility. The causal complexity of AI makes documentation decisive.[41]

Brazil's regulatory gap is thus not a total absence of applicable law. The problem is that no single instrument integrates device safety, algorithmic governance, ART ethics, data protection and patient communication. Clinics may comply with each regime superficially while leaving the decision chain ungoverned. A binding statute would provide greater legitimacy, but immediate risk reduction does not need to await legislation. Professional bodies, ANVISA and the data-protection authority can coordinate guidance, and clinics can adopt verifiable governance protocols.

The Brazilian experience also warns against importing European compliance labels without examining local use. A system developed and validated in Europe may encounter different demographics, clinical protocols, data quality and infrastructure. Foreign conformity evidence is relevant but insufficient. The proposed model therefore includes assessment in the intended local setting and monitoring after deployment.

6. Comparative Findings: Convergence, Divergence and Functional Equivalence

The comparison supports three shared governance concerns, without establishing identical national rules. First, the introduction of a score does not dissolve the existing responsibilities of clinics and professionals. Second, the permissible purposes of embryo assessment must be determined under each jurisdiction's substantive ART framework; references to eugenics cannot substitute for identifying the particular prohibited conduct. Third, traceability links information, data use, software performance and the eventual clinical decision. These are reasons for proposing common safeguards, rather than proof of a uniform statutory AI regime.

The principal divergences concern regulatory density and the legal status of the underlying reproductive practices. Italy and Spain share EU device and data rules and the AI Act's phased framework but differ in

[40] Brazil, Lei n. 13.709/2018, arts 5(II), 11, 20, 38 and 46; Autoridade Nacional de Proteção de Dados, *Relatório de impacto à proteção de dados pessoais*.

[41] Brazil, Lei n. 8.078, de 11 de setembro de 1990*, Código de Defesa do Consumidor*, arts 6(III), 12, 14, especially § 4, and 30.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

the historical restrictiveness of ART law. Brazil combines constitutional and statutory norms with professional self-regulation and sectoral authorities, without an integrated ART statute. These differences affect enforcement, but they do not eliminate the proposed common governance standard.

Functional equivalence expresses that proposed standard. Safeguards should correspond to the actual clinical influence of the system. A model that merely organises images presents a different risk from one that ranks embryos and shapes transfer decisions. Conversely, a vendor cannot avoid safeguards by calling a score 'non-binding' when clinic workflow makes it determinative. The relevant evidence includes interface design, default settings, staff practice, time pressure and rates of professional override.

The principle also applies across jurisdictions. Compliance documentation generated for the EU can support Brazilian assessment, but it must be translated into the local clinical, legal and demographic environment. Brazilian data-protection and consumer-law records may serve functions comparable to European accountability documentation, but European and Brazilian regulatory pathways must still be assessed separately. Equivalent protection does not require identical institutions; it requires demonstrably comparable outcomes in validation, transparency, oversight and remedy.

A further comparative finding concerns discrimination. Embryo-ranking systems may perform unevenly across age groups, diagnoses, ethnic backgrounds or laboratory conditions. The legal issue is not limited to intentional discrimination. A model can systematically disadvantage patients if error rates or calibration differ and the clinic does not investigate. To give practical effect to equality, the proposed model calls for subgroup analysis where scientifically and statistically feasible, cautious communication where evidence is limited, and alternative assessment when the tool is unsuitable.[42]

The embryo occupies different doctrinal positions across these systems, and the Italian debate shows why that disagreement cannot be dissolved into a technical measure of quality. Dalla Costa's comparison also shows that protective prohibitions and a broader menu of legally permitted destinations can each leave unresolved problems of custody and implementation. Procedural accountability must address that difficulty without assuming a uniform answer about disposal. The proposed safeguards do not settle the beginning of legal personhood or harmonise rules on research and disposal. They govern the use of information within the activity that is lawfully available, while substantive disagreements remain visible.[43]

7. A Governance Model for Clinical Deployment

The following five components are a normative synthesis of the comparison. They are not presented as a single statutory checklist already binding in all three jurisdictions at the cutoff. Particular duties must be mapped to the applicable device, data, professional and research rules; the proposed protocol also supplies safeguards where those regimes do not expressly prescribe an AI-specific procedure.

A clinic should establish a data dossier before procurement or deployment. The dossier should identify the intended purpose; training, validation and test populations; inclusion and exclusion criteria; out-

[42] M.F. KRAGH, H. KARSTOFT, *Embryo selection with artificial intelligence*, cit.; European Union, Regulation (EU) 2024/1689, arts 9-10, original 2024 text.

[43] S. DALLA COSTA, *Perspectiva legal del manejo de embriones supernumerarios en Italia*, cit., 56-63 and 76-78; M.P. MOLERO MARTÍN-SALAS, *La reproducción asistida en Italia*, cit.; A. HALSBAND, *Embryo selection, AI and reproductive choice*, cit.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

come definitions; missing-data strategy; relevant subgroup performance; calibration; known limitations; cybersecurity measures; retention periods; lawful bases; data recipients; and procedures for access, correction and incident response. Commercial confidentiality may justify controlled access, but it cannot prevent the clinic from obtaining information necessary to discharge its duties.[44]

Second, the clinic should conduct local validation before routine use. The protocol should be prospective where feasible, distinguish technical accuracy from clinical utility, predefine performance thresholds and compare the system with existing practice. The need for revalidation should be assessed after material software updates, changes in imaging equipment or laboratory protocols, or evidence of dataset shift. Monitoring should include override patterns, discordant cases, incidents and subgroup performance.[45]

Third, patient-facing information should be concise but substantive. It should explain: what the tool predicts; whether it is used for exclusion, ranking or supplementary assessment; which categories of data it processes; whether data may be reused for validation or research; the main limitations; the role of the professional; available alternatives; and how to request further information or challenge inaccurate data. The patient need not receive source code, but must understand the decision context.[46]

Fourth, the human decision must be documented. The record should contain the model and version, date, inputs relied upon, output, professional's independent assessment, identified limitations and final decision. Where the professional departs from the score, the system should not impose punitive friction that discourages override. Where the professional follows the score despite conflicting evidence, reasons should be recorded. This structure reduces automation bias and supports later review. In response to the custody problems discussed by Dalla Costa, the proposed protocol should also distinguish non-transfer in the present cycle from any subsequent change in an embryo's destination. The record should identify the applicable consent or other legal authority, the person responsible for custody and the basis for each later decision; none of these entries should be inferred from the score alone.[47]

Fifth, an *ex ante* responsibility matrix should assign tasks among the clinic, medical director, embryology laboratory, data-protection officer where appointed, information-security team, manufacturer and external processor. Roles must reflect the actual legal functions of each actor. The matrix should specify who validates, authorises use, trains staff, monitors performance, communicates updates, handles patient requests, reports incidents, preserves logs and suspends the system. Contracts should include access to necessary documentation, audit rights, update notification, cybersecurity commitments and cooperation in investigations.[48]

As an organisational recommendation, these five components should be overseen by a multidisciplinary committee including reproductive clinicians, embryologists, legal and data-protection specialists, information-security personnel and, where possible, patient representation. Review should occur before de-

[44] European Union, Regulation (EU) 2017/745, arts 10, 61 and 83; European Union, Regulation (EU) 2024/1689, arts 9-15, original 2024 text.

[45] M.F. KRAGH, H. KARSTOFT, *Embryo selection with artificial intelligence*, cit.; P.J. ILLINGWORTH *et al*., *Deep learning versus manual morphology-based embryo selection in IVF*, cit.

[46] European Union, Regulation (EU) 2016/679, arts 13-14; Spain, Ley 14/2006, art. 3; Conselho Federal de Medicina, Resolução CFM n. 2.320/2022, section I(4).

[47] F.J. BLÁZQUEZ RUIZ, *La paradoja de la transparencia en la IA*, cit.; European Union, Regulation (EU) 2024/1689, art. 14, original 2024 text; S. DALLA COSTA, *Perspectiva legal del manejo de embriones supernumerarios en Italia*, cit., 59-63 and 76-78.

[48] Italy, Legge n. 24/2017, art. 7; Brazil, Lei n. 8.078/1990, art. 14; Brazil, Lei n. 13.709/2018, arts 37-39.

Downloaded from https://teseo.unitn.it/biolaw ISSN 2284-4503

ployment and at defined intervals. Governance must remain proportionate: a low-impact image-management tool does not require the same review as a system that can determine non-transfer decisions. Proportionality, however, is assessed by function and consequence, not by vendor description.
The proposed model also clarifies the meaning of explainability. Technical explanation concerns model architecture and feature influence. Clinical explanation concerns why the output is relevant to the patient and how it compares with other evidence. Legal explanation concerns the rules, responsibilities and avenues of review. Ethical explanation concerns the values embodied in outcomes and thresholds. A defensible deployment requires these layers to connect, even if no single actor masters all of them.[49]

8. Concluding Remarks

AI can contribute to consistency and information processing in embryology, but it does not eliminate biological uncertainty or normative judgment. An embryo score is a probabilistic claim produced within a particular dataset, outcome definition and laboratory context. Treating it as neutral or universally applicable would replace professional subjectivity with concealed design choices rather than overcome subjectivity.
The comparison of Italy, Spain and Brazil supports a governance argument, rather than a claim that their substantive ART rules are interchangeable. At the 2025 cutoff, EU product and data regulation, together with the AI Act's staged implementation, offered Italy and Spain a different regulatory architecture from Brazil's combination of statutes, professional resolutions and sectoral oversight. The Italian doctrinal debate also demonstrates that protecting health, preserving clinical discretion and respecting legislative choices are related but distinct concerns. Conformity with product rules cannot alone resolve them.
The principle of functional equivalence translates this conclusion into practice. Safeguards must follow actual influence. A system that materially shapes embryo prioritisation calls for local validation, traceable data governance, intelligible patient information, meaningful human review and allocated responsibility. This proposed standard must operate within national limits on diagnosis, selection, research and embryo disposition; a predictive score cannot supply a missing legal authorisation.
The appropriate legal image is therefore not an autonomous algorithm choosing among embryos, but an auditable decision system in which technology, professional judgment and patient autonomy remain connected. When that connection is documented and contestable, AI may serve reproductive medicine. When it is opaque, unvalidated or effectively unreviewable, its use may conflict with the duties owed in a field where uncertainty and vulnerability are exceptionally high.

[49] F.J. BLÁZQUEZ RUIZ, *La paradoja de la transparencia en la IA*, cit.; M. TOMASI, *Genetica e Costituzione*, cit.

Downloaded from https://teseo.unitn.it/biolaw
ISSN 2284-4503