LUISS

Corso di laurea in Law, Digital Innovation and Sustainability

Regulation of Innovation and Sustainable Development

Technological Innovation and Infertility: Regulatory and Ethical Challenges in Assisted Reproduction

Fernandes Da Silva Ranchordas Sofia Hina

RELATORE

Prof. Di Porto Fabiana

CORRELATORE

631783

CANDIDATO

Anno Accademico 2024/2025

Table of Contents

INTRODUCTION

In the current era, where science and technological progress make it possible to overcome the limits of the human body, even the ability to procreate has become the subject of intense debate between nature, technology, and the law. For decades, the dominant concern was overpopulation[1].

Today, the scenario has reversed: the birth rate crisis, particularly in high-income countries, has brought the issue of infertility back to the forefront of public and political debate.

This shift reflects deep transformations in social and cultural models, thereby raising crucial questions about the perception of parenthood, the role of technological innovation in human reproduction, and the adequacy of current regulatory frameworks.

As reported by United Nations[1] (2022), "*the global population has surpassed 8 billion, yet fertility rates are declining sharply in many advanced economies*" [2] (World Bank, 2023), "*with significant implications for demographic sustainability and welfare systems*"[3] (OECD, 2023).
In this context, the rise of biomedical technologies[4] — such as assisted reproduction, genetic editing, and surrogacy — imposes new bioethical and regulatory challenges.

Infertility[5], defined by the World Health Organization as a "*disease of the reproductive system that prevents clinical conception after 12 months or more of regular, unprotected sexual intercourse"*, currently affects approximately one in six individuals worldwide (WHO, 2023).
Its causes are different and often overlapping. A key factor is the rising average age at conception, which leads to a natural decline in ovarian reserve and oocyte quality in women[6]. From a medical perspective, conditions such as endometriosis and polycystic ovary syndrome (PCOS) are among the main causes of female infertility[7]. On the other hand, male infertility—accounting for about 50%[8] of cases—is often linked to reduced sperm concentration and motility, partly due to exposure to endocrine disruptors and

[1] United Nations, Department of Economic and Social Affairs, Population Division. (2022). *World Population Prospects 2022*
[2] World Bank. (2023). *World Development Indicators: Fertility rate, total (births per woman)*.
[3] OECD. (2023). *OECD Family Database – Fertility Trends*.
[4] Baylis, F., & Ballantyne, A. (2022). *Reproductive Ethics: New Challenges and Conversations*. Springer.
[5] World Health Organization. (2023). *Infertility*. https://www.who.int/news-room/fact-sheets/detail/infertility
[6] European Society of Human Reproduction and Embryology. (2022). *ESHRE guideline: Female age-related fertility decline*. https://www.eshre.eu
[7] Devesa, M., Tur, R., Rodríguez, I., Coroleu, B., & Barri, P. N. (2018). Age and ovarian reserve: An assessment of the ovarian aging process. *RBM Online, 36*(3), 394–402. https://doi.org/10.1016/j.rbmo.2017.12.009
[8] Levine, H., Jørgensen, N., Martino-Andrade, A., et al. (2017). Temporal trends in sperm count: A systematic review and meta-regression analysis. *Human Reproduction Update, 23*(6), 646–659. https://doi.org/10.1093/humupd/dmx022

environmental pollutants[9]. In addition, unhealthy lifestyles—such as smoking, obesity, alcohol and drug use, sedentary behaviour, and chronic stress—significantly increase the risk of subfertility. [10]

The growing prevalence of infertility has acted as a catalyst for significant advancements in biomedical research, encouraging the development of assisted reproductive technologies (ART) designed to address a variety of reproductive health issues. Techniques such as *oocyte vitrification* enable women to preserve their fertility at a younger age[11], while the application of artificial intelligence in *embryo selection* promises to improve implantation rates and reduce failed cycles[12].

Concurrently, contemporary research has begun to investigate the influence of the *uterine microbiota* on fertilization outcomes, suggesting that a stable and healthy microbial environment within the uterus may be crucial to improving the chances of conception[13].
These scientific and technological developments demonstrate that innovation in this field is primarily a response to real clinical challenges, rather than mere progress for its own sake.
Nonetheless, this rapid trajectory of innovation inevitably brings to light a series of intricate questions concerning ethical responsibility, social justice, economic accessibility, and legal oversight. It becomes essential, therefore, to establish clear frameworks and boundaries to ensure that the implementation of these new technologies genuinely serves to protect and promote the fundamental right to become a parent.

The key point of this thesis lies precisely in the coexistence of two overlapping tensions: **on one hand, the ethical conflict raised by the rapid evolution of assisted reproductive technologies, which challenges traditional moral frameworks; on the other hand, the legal conflict, arising from the difficulty of developing a coherent and universally applicable regulatory system able to keep pace with innovation.**

[9] Skakkebaek, N. E., Rajpert-De Meyts, E., & Main, K. M. (2016). Testicular dysgenesis syndrome: An increasingly common developmental disorder with environmental aspects. *Human Reproduction, 16*(1), 97–107. https://doi.org/10.1093/humupd/dmv002
[10] Silvestris, E., de Pergola, G., Rosania, R., & Loverro, G. (2019). Obesity as disruptor of the female fertility. *Reproductive Biology and Endocrinology, 16*, 22. https://doi.org/10.1186/s12958-018-0446-6
[11] Cobo, A., García-Velasco, J., Domingo, J., Pellicer, A., & Remohí, J. (2018). Elective and onco-fertility preservation: Factors related to IVF outcomes. *Human Reproduction, 33*(12), 2222–2231. https://doi.org/10.1093/humrep/dey312
[12] Bormann, C. L., Kanakasabapathy, M. K., Thirumalaraju, P., et al. (2020). Performance of a deep learning-based neural network in the selection of human blastocysts for implantation. *eBioMedicine, 60*, 102991. https://doi.org/10.1016/j.ebiom.2020.102991
[13] Moreno, I., Codoñer, F. M., Vilella, F., Valbuena, D., Martinez-Blanch, J. F., Jimenez-Almazan, J., & Simon, C. (2022). Evidence that the endometrial microbiota has an effect on implantation success or failure. *American Journal of Obstetrics and Gynecology, 226*(2), 198–210. https://doi.org/10.1016/j.ajog.2021.07.007

0.1 Reproductive Innovation and Medical Promise

While innovations such as in vitro fertilization (IVF), oocyte cryopreservation, CRISPR gene editing, and artificial intelligence (AI) in embryo selection offer new solutions to overcome biological limitations imposed by infertility[14], they also present profound ethical and legal dilemmas[15].

The way reproductive technologies are viewed and used depends on the perspective from which they are considered.

On one hand, some scholars focus on the objective medical advancements enabled by these technologies. According to them, reproductive technologies play a key role in expanding opportunities for parenthood, enhancing treatment effectiveness, and easing the psychological and emotional toll linked to infertility. Supporting this view are the increasing success rates of in *vitro fertilization*[1617] (IVF) and the use *of artificial intelligence*[18] (AI) to improve implantation rates, offering new prospects for individuals and couples for whom natural conception is not possible. Another available technology is *oocyte cryopreservation*[19], which allows women, in particular, to preserve their fertility and delay motherhood based on personal or medical reasons.

Moreover, certain hereditary genetic diseases could—under appropriate regulatory frameworks—be addressed using gene editing techniques such as CRISPR[20].

Supporters of this perspective maintain that, with proper regulatory oversight, such technologies have the potential to greatly enhance public health, lessen the impact of hereditary disorders, and stimulate progress in the medical field. As a result, these concrete advantages highlight the necessity of developing a robust regulatory system that guarantees both equitable and secure access.

0.2 Ethical Dilemmas and Regulatory Fragmentation

On the other hand, a different perspective highlights bioethical concerns and legal uncertainties, raising serious questions—particularly regarding the potential risks of genetic manipulation, which could lead to *eugenic drift* and the *commodification of human life*[21].

In addition to bioethical worries—such as the use of AI in embryo selection for identifying "ideal" genetic

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[14] Baylis, F., & McLeod, C. (2020). *Family-making: Contemporary ethical challenges*.

[15] Bredenoord, A. L., Hyun, I., & Pennings, G. (Eds.). (2021). *Handbook of Bioethical Decisions: Assisted Reproduction and Emerging Technologies*. Springer.

[16] ESHRE (2023). *ART fact sheet: Latest success rates and trends in Europe*. https://www.eshre.eu

[17] Trounson, A., & Gardner, D. K. (1993). Handbook of In Vitro Fertilization. CRC Press

[18] VerMilyea, M. D., Hall, J. M., Diakiw, S. M., Johnston, A., Nguyen, T., Perugini, D., ... & Hickman, C. (2020). Development of an artificial intelligence-based assessment model for prediction of embryo viability using static images captured by optical light microscopy during IVF. *Fertility and Sterility, 114*(3), e368. https://doi.org/10.1016/j.fertnstert.2020.08.1087

[19] Doudna, J. A., & Charpentier, E. (2014). The new frontier of genome engineering with CRISPR-Cas9. *Science, 346*(6213), 1258096. https://doi.org/10.1126/science.1258096

[20] Greely, H. T. (2019). *CRISPR People: The Science and Ethics of Editing Humans*. MIT Press.

[21] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.

traits[22]—there is increasing attention on the social consequences of these technologies. Since assisted reproduction often involves high costs, access remains uneven, reinforcing existing social and economic divides. This could lead to a situation in which only those with sufficient resources are able to benefit from technological progress in this field. Furthermore, the idea of choosing embryos for certain traits brings back a sensitive and troubling issue: the potential revival of eugenic thinking. Past experiences have taught us how dangerous it can be to attempt to define what counts as a 'desirable' human life. For this reason, it is essential to reflect carefully on how these tools are used, ensuring they do not reproduce old forms of discrimination under a new and more sophisticated appearance.

The application of artificial intelligence into IVF procedures is transforming the way embryos are selected, making the process more accurate and efficient compared to traditional methods based on visual assessment by embryologists[23].

Specifically, AI is applied through machine learning and deep learning models to analyse high-resolution images obtained via time-lapse imaging systems, which document embryo development in real time during the first 72–120 hours post-fertilization[24].

Software powered by artificial intelligence is capable of evaluating a wide range of morphogenetic parameters, such as the timing of key developmental milestones (like the shift from 2 to 4 cells or the emergence of the blastocyst), the symmetry of cell division, the presence of cytoplasmic fragmentation, and nuanced variations in luminosity or structural features that may go unnoticed by human observers.[25].

By integrating extensive datasets with clinical records, AI systems are designed to estimate the likelihood of successful implantation. Moreover, they are capable to pinpoint the factors most predictive of embryonic viability, thus minimizing reliance on subjective human judgment. Certain algorithms have been trained on large volumes of IVF cycle data—sometimes numbering in the tens of thousands—enabling them to independently identify developmental trends associated with favourable clinical outcomes.[26].

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[22] Meseguer, M., Zaninovic, N., & Scott, R. T. (2021). Predictive models using AI in reproductive medicine: Hype or hope? *Human Reproduction Update, 27*(2), 267–284. https://doi.org/10.1093/humupd/dmaa032

[23] VerMilyea, M. D., Hall, J. M., Diakiw, S. M., Johnston, A., Nguyen, T., Perugini, D., … & Hickman, C. (2020). Development of an artificial intelligence-based assessment model for prediction of embryo viability using static images captured by optical light microscopy during IVF. *Fertility and Sterility, 114*(3), e368. https://doi.org/10.1016/j.fertnstert.2020.08.1087

[24] VerMilyea, M. D., Hall, J. M., Diakiw, S. M., Johnston, A., Nguyen, T., Perugini, D., … & Hickman, C. (2020). Development of an artificial intelligence-based assessment model for prediction of embryo viability using static images captured by optical light microscopy during IVF. *Fertility and Sterility, 114*(3), e368. https://doi.org/10.1016/j.fertnstert.2020.08.1087

[25] Zaninovic, N., Rosenwaks, Z., & Xu, K. (2019). Artificial intelligence in the embryology lab: A new era. *Reproductive Biomedicine Online, 38*(2), 197–205. https://doi.org/10.1016/j.rbmo.2018.11.010

[26] Khosravi, P., Kazemi, E., Zhan, Q., Malmsten, J. E., Toschi, M., Zisimopoulos, P., … & Rosenwaks, Z. (2019). Deep learning enables robust assessment and selection of human blastocysts after in vitro fertilization. *npj Digital Medicine, 2*, 21. https://doi.org/10.1038/s41746-019-0096-y

It is important to clarify that, although this "new frontier" holds immense potential, absolute reliability has not yet been achieved.

There is currently no global standard for the algorithms used, and the data collection processes may contain implicit biases (e.g., related to ethnicity, age, or clinic of origin). Moreover, the "black box" nature of deep learning models makes it difficult to interpret the criteria by which one embryo is deemed "better" than another[27]. Considering these unresolved issues, researchers and experts in the field advocate for a prudent approach, emphasizing the importance of transparency through comparative studies conducted across multiple centres. They also call for the development of a common ethical framework to guide the responsible integration of AI technologies into clinical practices related to assisted reproduction.

Moreover, the significant differences in regulatory approaches—ranging from permissive frameworks such as that of California[28] to strict prohibitions like those enforced in Italy[29] (Law 40/2004, amended in 2015)—create jurisdictional inconsistencies and fuel the phenomenon of reproductive tourism, further exacerbating socio-economic inequalities[30].

The main objective of this thesis is a critical examination of the interaction between technological advances in assisted reproduction and the regulatory challenges they pose.

An overview of different regulatory models and ethical perspectives, followed by a comparative analysis, will serve as the foundation for proposing a potential internationally coordinated legal framework, as well as exploring what kind of political synthesis might help resolve the tensions between innovation, access, and ethical boundaries in reproductive technologies.

Beyond the undeniable advantages that new technologies offer in overcoming the biological limitations that cause infertility, profound ethical and legal questions arise:

To what extent is it acceptable to intervene in human life before birth? How can the desire to become a parent be balanced with the protection of the unborn? And more importantly, to what degree should we rely on artificial intelligence to influence or even guide such sensitive decisions? As these technologies become more advanced, there is a real risk of delegating morally complex choices to systems that lack human

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[27] Berntsen, J., Rimestad, M. L., & Forman, J. L. (2022). Ethical and regulatory considerations of AI in IVF: A call for transparency. *Journal of Medical Ethics, 48*(11), 789–795. https://doi.org/10.1136/medethics-2021-107755

[28] Shenfield, F., Pennings, G., Cohen, J., Devroey, P., & Tarlatzis, B. (2020). *Cross-border reproductive care in Europe: A review of the regulation and its impact*. *Human Reproduction Update, 26*(1), 1–13. https://doi.org/10.1093/humupd/dmz033

[29] Legge 19 febbraio 2004, n. 40, "Norme in materia di procreazione medicalmente assistita", G.U. n.45 del 24-2-2004. (Modificata in seguito a sentenze della Corte Costituzionale, tra cui la n. 162/2014).

[30] Inhorn, M. C., & Patrizio, P. (2015). Infertility around the globe: New thinking on gender, reproductive technologies and global movements in the 21st century. *Human Reproduction Update, 21*(4), 411–426. https://doi.org/10.1093/humupd/dmv016

judgment. This raises crucial questions: *can AI truly account for the ethical weight of reproduction? Or are we at risk of reducing profoundly human decisions to technical calculations?*

The complexity of these issues[31] has led to a remarkable degree of regulatory heterogeneity at the international level, which represents one of the main obstacles to establishing a coherent legal framework for the governance of reproductive technologies.
In some countries, a permissive approach seeks to regulate and even promote the use of such technologies, while in others, a restrictive stance prevails, with absolute bans on practices such as surrogacy or embryo gene editing.
As a result, given the impossibility of approaching the topic of reproduction in a neutral manner, the dominance of either purely technical-scientific or exclusively ethical considerations has contributed to the current fragmentation of the regulatory landscape.

Another powerful factor at play is the influence of private interests, particularly from stakeholders[32] who frame the issue according to their economic and commercial incentives, viewing access to biotechnologies as a matter best governed by market forces. These actors exert significant pressure on policymakers, pushing regulatory systems toward greater permissiveness.
Such pressure further fragments the global regulatory landscape, as it leads some countries to adopt increasingly liberal legislation, thereby widening the gap with nations where ethical concerns play a more prominent role.

From this perspective, the regulation of reproductive technologies is not shaped solely by ethical principles or the public interest, but also by competing pressures from actors with divergent economic and ideological agendas.
On one side, private economic actors—including biotech companies, fertility clinics, and genetic research laboratories—exert strong influence over the legislative process. These entities[33] advocate for more permissive regulation, arguing that innovation in assisted reproduction offers new opportunities to address infertility and improve reproductive health. However, their stance is often also motivated by commercial interests, aiming to expand the reproductive technology market and reduce regulatory barriers that could limit its growth.

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[31] Browne, T., & Goold, I. (2021). Regulating reproductive technologies: The quest for international consensus. *Medical Law Review, 29*(4), 543–567. https://doi.org/10.1093/medlaw/fwab020
[32] Waldby, C., & Cooper, M. (2010). *The Biopolitics of Reproduction: Post-Fordist Biotechnology and the Governance of the Body*. *Cambridge Journal of Law, Medicine and Ethics, 38*(2), 191–200.
[33] Suter, S. M. (2007). The "Multiplying" Problems of Assisted Reproductive Technology. *Harvard Journal of Law and Gender, 30*(2), 413–450.

On the other side, moral and ideological groups—such as religious organizations, bioethics movements, and civic associations—promote stricter regulation based on principles of human dignity, precaution, and protection of the unborn. These actors warn that a lack of adequate regulation could lead to the commodification of reproduction[34], unequal access to reproductive technologies, and a drift toward eugenics, particularly with the use of techniques such as CRISPR and artificial intelligence in embryo selection.

This becomes especially clear in countries like the United States or India, where the fertility market is highly liberalized and shaped by strong private interests[35]. In these systems, the logic of profit can end up driving the availability and promotion of assisted reproductive technologies, sometimes overshadowing ethical safeguards. In contrast, countries such as Italy, Germany, France, and Norway have implemented more restrictive and ethically guided regulations, often banning or severely limiting practices like surrogacy, embryo research, and germline editing.

The result is a global patchwork of regulations: some countries enforce strict ethical standards, while others adopt more permissive rules to attract patients from abroad. This contrast shows how hard it is to create a shared regulatory vision that is fair, consistent, and respectful of human dignity.

0.3 Research Methodology

Considering the premises outlined, this thesis aims to explore the development and use of reproductive technologies through an interdisciplinary lens. In addition to legal analysis, it will draw upon insights from bioethics, sociology, and economics, as these fields are essential to understand the broader implications of assisted reproduction. Legal frameworks cannot be fully assessed without taking into account the moral dilemmas raised by new technologies, the social dynamics that shape access and acceptance, and the economic forces that influence how and where these services are offered.

In this thesis, the term "*regulation*" refers broadly to "*the set of legal, institutional, and normative instruments used to govern the development and application of assisted reproductive technologies*". From a legal perspective, this includes not only formal legislation and binding norms—such as national laws, directives, and international treaties—but also soft law tools such as ethical guidelines, professional codes of conduct, and policy recommendations issued by health authorities or international bodies. Regulation, therefore, is not understood merely as the act of prohibiting or permitting. It is outlined as a dynamic process of setting boundaries, establishing safeguards, and ensuring accountability in areas where scientific innovation raises complex ethical and social questions. In the context of reproductive technologies, regulation also plays a crucial role in balancing competing interests, such as the right to parenthood, the

[34] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.
[35] Inhorn, M. C., & Birenbaum-Carmeli, D. (2008). Assisted Reproductive Technologies and Inequality: Discourses and Practice. *Medical Anthropology, 27*(3), 263–285. https://doi.org/10.1080/01459740802222806

protection of vulnerable individuals (including the unborn), public health concerns, and the demands of technological progress.

The continuous and rapid evolution of science has always posed difficulties for regulation, and this is even more evident when it comes to reproductive technologies, due to the complexity and sensitivity of the subject.
A key issue is the difficulty of setting clear limits on how and when these technologies should be used. For this reason, any effort to create an effective legal framework must begin with an open and structured dialogue among various disciplines—such as law, bioethics, medical science, sociology, and political philosophy.

Different views, ethical values, and economic interests come into conflict when dealing with concepts like parenthood, the human body, individual freedom, and human dignity. These concepts are understood differently depending on the cultural values and ideologies that influence each country's legal system. This becomes clear when comparing the laws adopted by different states, which reveal the principles behind each regulatory model. Given the complexity and diversity of national approaches to assisted reproduction, this thesis adopts a comparative perspective. In particular, it will examine and contrast selected regulatory frameworks from both EU and non-EU countries. Special attention will be given to the Italian context—as a central case study—while drawing inspiration from the models adopted in countries such as Spain, which offers a more permissive and innovation-friendly framework, and Germany, known for its restrictive and ethically cautious stance. The analysis will also briefly consider non-European examples, such as the United States, where reproductive technologies are largely governed by market dynamics. This comparative lens helps to highlight how cultural, ethical, and legal traditions shape regulation differently, and provides a broader understanding of the global tensions between innovation, ethics, and reproductive rights.

Lawmakers face serious challenges when trying to keep up with scientific advances, especially because these developments raise important and often conflicting questions. Setting clear rules on how reproductive technologies should be used is particularly complex, as it means balancing the drive for scientific progress with the need to respect human and ethical boundaries.

This thesis investigates the following main research question:

How can legal and ethical frameworks effectively respond to the challenges posed by the rapid development of assisted reproductive technologies and surrogacy, particularly in contexts marked by social and environmental vulnerability?

In order to explore this question, the research will also address the following sub-questions:
• What are the main differences between EU and non-EU regulatory models in the field of reproductive

technologies?
• How do ethical and bioethical concerns influence national regulatory approaches?
• In what ways do socio-economic and environmental factors—such as those observed in the *Terra dei Fuochi* area—shape the perception and application of these technologies?
• How do key stakeholders (e.g., healthcare professionals, legal experts, and civil society actors) view the risks and responsibilities associated with the use of these technologies?

To answer these questions, the research adopts a qualitative and interdisciplinary methodology that combines legal analysis, ethical reflection, and empirical investigation.

• Comparative Legal Analysis: This method allows for the identification of key differences and similarities across legal systems, helping to understand how different normative cultures regulate assisted reproduction and surrogacy. The comparison between EU and non-EU frameworks highlights the influence of cultural, religious, and political factors in shaping the law.

• Ethical and Bioethical Analysis: A focused examination of ethical debates—supported by academic literature and applied to the real case of the "*Terra dei Fuochi*"—provides depth to the normative dimension. This region offers a particularly meaningful case study due to its environmental health risks and socio-economic fragilities, which amplify the ethical stakes of reproductive decision-making.

• Empirical Interviews: Semi-structured interviews with professionals from different sectors (medicine, law, and advocacy) will offer insights into how these technologies are interpreted and implemented in practice. This approach allows for a better understanding of the *lived implications* of law and ethics, especially in contexts where formal regulations may not fully capture the complexities of reality.

The choice to include semi-structured interviews in this research comes from the need to better understand how reproductive technologies are actually used and interpreted in real life. Laws and official documents are important, but they often don't show the full picture—especially in places like Campania, where environmental and social problems deeply affect reproductive health.
Talking to professionals such as doctors, biologists, and active researchers helps connect theory with practice. These interviews make it possible to explore how people in the field experience the ethical, legal, and social challenges of assisted reproduction.
More specifically, the goal is to gather direct insights on how these technologies are applied in everyday clinical work, what obstacles professionals face in navigating current regulations, and how they perceive the effects of innovation on patients' access and reproductive choices. The interviews also aim to uncover whether practitioners feel that existing laws are adequate or if there are significant gaps, contradictions, or areas of uncertainty.

The interviews follow a semi-structured format. This means there is a clear guide of topics, but enough flexibility to adapt to each person's experience and expertise. The main themes include the impact of new technologies, regulatory difficulties, ethical dilemmas, and access to treatment—particularly in disadvantaged or environmentally at-risk areas.
This qualitative approach supports the legal and ethical analysis by adding real-world perspectives. It helps answer the main research questions and offers a deeper understanding of how regulation works in practice. In doing so, it enriches the study with the lived experiences of those who engage with these technologies daily and highlights possible directions for more responsive and inclusive regulatory models.

0.4 Potential Challenges

A comprehensive analysis of this topic reveals several critical issues, stemming not only from the speed at which the field is evolving, but also from the deep legal, ethical, and social implications it entails. [36]
The complexity of this subject becomes especially clear when considering the difficulties legislators face in trying to define appropriate rules in a context where scientific innovation advances faster than the regulatory capacity of states[37].

The discrepancy between the rapid evolution of scientific advancements and the slower pace of legal and regulatory adaptation generates many complications. Not only ambiguity and instability for both medical professionals and prospective parents but also fuels the phenomenon of cross-border reproductive care, know also as "*reproductive tourism*" [38]. Many individuals and couples seek treatment in foreign countries where procedures unavailable or banned in their own jurisdictions are legally accessible.
One of the most critical repercussions of this lack of regulatory coherence is the persistent legal uncertainty concerning the recognition and status of children born through these transnational reproductive techniques[39].

The persistent delay—both in timing and in conceptual readiness—with which legislative systems respond to technological innovation is particularly evident in the context of assisted reproductive practices.
This regulatory asymmetry has been the subject of extensive scholarly debate. As highlighted by Robertson[40] (2003), the rapid expansion of reproductive technologies challenges traditional legal frameworks, calling into question the role of the law in protecting reproductive freedoms. Similarly, Knoppers and Isasi[41] (2004)

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[36] Daar, J. F. (2017). *The New Eugenics: Selective Breeding in an Era of Reproductive Technologies*. Yale University Press.
[37] Marchant, G. E., Allenby, B. R., & Herkert, J. R. (Eds.). (2011). *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem*. Springer.
[38] Hudson, N., Culley, L., Blyth, E., Norton, W., Rapport, F., & Pacey, A. A. (2011). Cross-border reproductive care: A review of the literature. *Reproductive BioMedicine Online, 22*(7), 673–685. https://doi.org/10.1016/j.rbmo.2011.03.010
[39] Hudson, N., Culley, L., Blyth, E., Norton, W., Rapport, F., & Pacey, A. A. (2011). Cross-border reproductive care: A review of the literature. *Reproductive BioMedicine Online, 22*(7), 673–685. https://doi.org/10.1016/j.rbmo.2011.03.010
[40] Robertson, J. A. (2003). Extending preimplantation genetic diagnosis: the ethical debate. *Ethics & Medicine, 19*(1), 21–31.
[41] Knoppers, B. M., & Isasi, R. (2004). Regulatory approaches to reproductive genetic testing. *Human Reproduction, 19*(12), 2695–2701. https://doi.org/10.1093/humrep/deh497

stress the urgent need for internationally coordinated guidelines to address the ethical and legal complexities brought about by advances in genetics and assisted reproduction. Rather than anticipating developments, the law often struggles to respond in time their ethical and societal ramifications.
As Baylis (2019) argues, this delay in regulatory response contributes to the emergence of so-called "*governance gaps*," [42] which are frequently addressed in a fragmented and inconsistent fashion. The result is a patchwork of norms that generates unequal access for patients, legal uncertainty for healthcare providers, and, at times, inadequate protections for those most directly affected—particularly women and unborn children.

In addition to the challenges already discussed, other relevant things to mention are both methodological and substantive difficulties.
First, the lack of uniformity and accessibility of international legal sources represents a significant obstacle. Especially in relation to legal systems that are non-Anglophone or lack updated legislative databases.
Moreover, the ambiguity of key concepts—such as parenthood, the dignity of the embryo, or the right to procreate—poses additional challenges, as their meaning varies considerably depending on the cultural, religious, and legal context.
Another critical issue lies in maintaining a balance between an objective description of regulatory data and a critical evaluation of it; there is a risk of adopting either an overly neutral approach or, conversely, one that is excessively normative.

Moreover, the difficulties in talking to experts and relevant figures in the field might be another obstacle. Since the aim is also to analyse the territory of Naples, the "*Terra dei Fuochi*" situation and the negative consequences it leads to fertility, is extremely important to find people who lives and works on the territory.
The rapid emergence of new technologies—such as increasingly advanced artificial intelligence tools, gene-editing techniques, or evolving forms of surrogacy—requires a constant reassessment of the material under analysis, with the risk that some sources may become outdated during the course of the research.
Nevertheless, these challenges also offer valuable opportunities for deeper reflection and critical engagement, ultimately strengthening the significance and impact of the research.

[42] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.

CHAPTER 1 – Biomedical Innovation and assisted reproduction: advancements and regulatory challenges.

1.1 The Causes of Contemporary Infertility: An Interplay of Biological, Environmental, and Socio-Cultural Factors

In its most recent findings, the World Health Organization (WHO) points out that, approximately the 17.5%[43] of the global population has experienced infertility—an increasingly widespread condition that now constitutes a pressing public health issue. This percentage is expected to rise, as it is linked to a combination of biological, environmental, social, and behavioural factors[44].

Among the biological factors, one of the most significant is the increasing average age of parenthood, since nowadays it seems to be not a priority anymore. This trend is largely driven by personal choices, economic pressures, and career ambitions, which often lead individuals to postpone parenthood in pursuit of other life goals. All of this is, of course, implicit when referring to modern society, where female empowerment has made it possible to almost fully align professional and personal goals.
However, reproductive biology imposes clear limitations: in women, both ovarian reserve and oocyte quality begin to decline after the age of 30, with a more rapid decrease after 35[45]; in men, sperm quality and motility significantly decrease after the age of 40[46]. Additionally, behaviours shaped by new socio-cultural dynamics, such as the decision to postpone parenthood or increased exposure to electromagnetic radiation from digital devices, may further reduce the chances of conception.
According to a 2023 study published in *The Lancet*, in the absence of effective policy interventions, "*more than 97%[47] of countries may experience significant demographic decline by the year 2100*".

Still referring to the current context, it is impossible to overlook the impact of climate change; rising pollution, and all other environmental factors that harm not only the planet but also directly affect human health and well-being.

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[43] World Health Organization. (2023). *Infertility prevalence estimates, 1990–2021*. https://www.who.int/publications/i/item/9789240077476
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A crucial role is played by environmental factors, particularly exposure to endocrine-disrupting chemicals such as pesticides, phthalates, heavy metals, and bisphenol A (BPA)[48]. These substances—found in increasing amounts in the environment and in everyday consumer products—interfere with the endocrine system by altering hormone production, thereby reducing fertility[49] in both men and women.
Additionally, among the causes of declining sperm quality and hormonal dysfunction, air pollution must also be considered as a contributing factor.

Another key aspect with significant impact on fertility is related to modern lifestyle habits. Rising levels of obesity, smoking, alcohol and drug abuse, and physical inactivity are all conditions that can impair reproductive function by disrupting hormonal balance and reducing the chances of conception[50]. Studies have shown that obesity is associated with insulin resistance and hyperinsulinemia, which can interfere with ovarian function and contribute to anovulation in women[51]. In men, excessive adiposity is linked to reduced sperm quality[52] and low testosterone. Likewise, chronic exposure to cigarette smoke has been found to accelerate ovarian aging[53] and decrease sperm motility.

Without forgetting that the acceleration of modern society generates severe conditions of stress, which can sometimes develop into actual pathological disorders. Hence, it can severely impact any the chances of conception. The effects of chronic stress, a hallmark of industrialized societies, should also not be underestimated. Prolonged stress can impair ovarian function in women and reduce testosterone production in men. [54]
When someone experience high level of stress it can lead to the the activation of the hypothalamic-pituitary-adrenal (HPA)[55] axis. This happens in response to chronic stress leading to elevated cortisol levels, which negatively affect the secretion of gonadotropins and thereby reduce reproductive capacity.

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Medical conditions contributing to infertility are also on the rise. Among these, polycystic ovary syndrome (PCOS)[56] remains one of the leading causes of female infertility, along with endometriosis and sexually transmitted diseases (STDs)[57], which can compromise reproductive function. At the same time in men, conditions such as hypogonadism and varicocele can lead to reduced semen quality and lower sperm production.

Having discussed both internal and external factors affecting the human body—many of which have a direct impact on it—it is also important to consider those medical conditions whose causes are still being investigated and evaluated by the scientific community. Some of these diseases have likely always existed, but due to the limited accuracy of past diagnostic tools, they were never properly identified.
Others, by contrast, appear to be a direct consequence of the environmental and social changes to which both men and women have been increasingly exposed over time. For instance, another phenomenon complicating reproduction is the rise in *idiopathic infertility*, a condition in which no clear medical cause can be identified, yet the couple is unable to conceive. This type of infertility, which accounts for up to 20%[58] of cases, may be linked to subtle genetic or epigenetic abnormalities that remain poorly understood.

Taken together, these contributing factors show that infertility can no longer be viewed solely as an individual medical issue[59]. Instead, it demands a global, systemic reflection that incorporates social, economic, and political implications.
Only through an interdisciplinary approach, capable of embracing the full complexity of the issue and acknowledging the diverse perspectives and contributing factors involved, can we hope to develop an adequate understanding and effective response to the problem of infertility.

1.2 Major Innovations in Assisted Reproduction

Advancements in the biomedical field have made biological parenthood increasingly accessible through assisted reproduction, contributing to what can be described as a true "*conceptual revolution"*[60].
This revolution is accompanied not only by a reassuring increase in the success rates of medical procedures and a reduction in patient risks, but also by a significant expansion of the population eligible for these

[56] Azziz, R., Carmina, E., & Chen, Z. (2016). Polycystic ovary syndrome. *Nature Reviews Disease Primers, 2*, 16057. https://doi.org/10.1038/nrdp.2016.57
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treatments, which were once prohibitively limited[61]. In addition, interventions are becoming more precise and personalized, tailored to the individual needs of each patient. [62]

Among the most significant innovations is the *integration of artificial intelligence* (AI), which has led to notable improvements—especially in the field of in vitro fertilization (IVF)[63]. Cutting-edge technologies such as *EmbryoScope+™*[64], powered by sophisticated machine learning algorithms, allow for continuous real-time monitoring of embryo development, providing detailed feedback on their growth.
This enables the identification of embryos with the highest potential for successful implantation and pregnancy outcomes. The features of artificial intelligence thus once again prove to be crucial—both in terms of speeding up clinical protocols and increasing the chances of success.

As a result, the number of cycles required to achieve pregnancy is reduced, significantly lowering costs for patients. It is estimated that the use of AI can improve implantation success rates by up to 25%[65] compared to traditional methods.

Another major innovation in the field of fertility is *oocyte cryopreservation*[66]. The growing popularity of this practice has been driven by shifting approaches to family planning, shaped by new priorities related to personal, social, or professional reasons—all influenced by the evolving demands of contemporary society, as said above.
With the rise of social freezing, the number of oocyte cryopreservation cycles among women who chose to postpone motherhood increased by over 400% between 2015 and 2022[67].
However, despite significant technological advancements, the expected success rate remains a matter of debate, as it still declines with increasing maternal age[68]. Although biomedical innovation continues to

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expand the possibilities of overcoming infertility, it is essential to acknowledge that such advancements remain bound by the inherent biological limitations of the human body. While technology can support and optimize reproductive potential under favourable conditions, its effectiveness diminishes significantly when the biological context—such as age, ovarian reserve, or general health—is already compromised[69]. This underlines the importance of managing expectations around assisted reproductive technologies and recognizing that scientific progress, however remarkable, cannot fully substitute or reverse the natural constraints of human physiology.

Beyond traditional techniques, assisted reproduction has continued to advance, most notably through *genome editing technologies* such as CRISPR-Cas9[70], which enable direct interventions on the embryonic genome to correct hereditary mutations or prevent monogenic diseases such as cystic fibrosis or muscular dystrophy. [71]

Nevertheless, the potential to manipulate embryos in this way raises significant concerns: highly remarkable is the risk of a eugenic drift , as the focus may shift from preventing diseases to selecting desirable traits—such as intelligence, physical appearance, or athletic ability[72].

This overlap between disease prevention and trait selection demands the identification of a clear ethical boundary[73], which remains extremely difficult to define.

Among the emerging technologies in the field of reproductive medicine are *reproductive stem cell techniques*[74], which could make it possible to generate oocytes and sperm cells in the laboratory using somatic cells—offering new hope even for cases of irreversible infertility.

Another important advancement is the ongoing experimentation with *artificial wombs*[75], aimed at enabling complete embryonic development outside the human body. These biotechnological devices simulate the conditions of a natural uterus, offering a controlled environment in which a fetus can grow safely and continuously, potentially revolutionizing neonatal care and reproductive medicine. Although early results from animal studies are promising, this technology has drawn criticism for its potential to commodify

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reproduction and for the complex ethical questions it raises regarding the rights and protection of the unborn child. [76]

Furthermore, microfluidic sperm selection is another innovative technique designed to improve fertilization outcomes by selecting sperm with more intact DNA.
This method replicates "*the natural microenvironment of the female reproductive tract*" [77], thereby increasing the likelihood of successful fertilization.

Finally, by employing next-generation sequencing technologies (NGS) in preimplantation genetic diagnosis (PGD)[78], embryo analysis has become significantly more precise.
This technique makes it possible to identify chromosomal or genetic issues before the embryo is implanted. This can improve the likelihood of a healthy pregnancy and lower the chances of passing on inherited conditions. As a result, the selection of embryos can be made with greater accuracy and confidence. This breakthrough not only enhances clinical outcomes but also offers prospective parents a greater sense of reassurance during what is often an emotionally complex and uncertain journey. It reflects how deeply intertwined technology has become with the most intimate aspects of human life, reshaping the experience of reproduction in ways that were unbelievable just a few decades ago.

1.3 Infertility and Environmental Risk: The Case of the "*Terra dei Fuochi*"

Ultimately, it is essential to address the link between environmental pollution and infertility, a connection that has been the subject of numerous scientific studies. These studies have thoroughly documented how chronic exposure to toxic substances[79], such as heavy metals, dioxins, and endocrine disruptors, can significantly impair reproductive health in both women and men[80].
This complex and troubling relationship becomes particularly tangible when observed through real-world scenarios. This section examines the case of the so-called "*Terra dei Fuochi*"[81] ("Land of Fires"), an area located between Naples and Caserta, that has tragically become synonymous with environmental degradation. Here, the illegal disposal and uncontrolled burning of industrial and urban waste, have not only

[76] Romanis, E. C. (2020). Artificial womb technology and the frontiers of human reproduction: Conceptual frameworks and future directions. *Medical Law Review, 28*(4), 617–639. https://doi.org/10.1093/medlaw/fwz016
[77] Nosrati, R., Driouchi, A., Yip, C. M., & Sinton, D. (2014). Two-dimensional slither swimming of sperm within a micrometre of a surface. *Nature Communications, 5*, 3645. https://doi.org/10.1038/ncomms4645
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[80] Toledano, M. B., Hansell, A. L., Ghosh, R. E., et al. (2019). Industrial air pollution and reproductive outcomes: A review. *Environmental Health, 18*, 90. https://doi.org/10.1186/s12940-019-0526-1
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permanently altered the landscape but also generated widespread concern about the long-term health effects on local populations.

Since the 1980s, this region has been the site of systematic illegal dumping of toxic waste, originating not only from various Italian regions but also from abroad. These operations were often managed through criminal agreements with the Casalesi clan, affiliated with the Camorra mafia[82]. The clan acted as an intermediary, organizing the transport and illegal disposal of industrial waste in exchange for payment. By exploiting local territories with little regard for environmental or health consequences, they turned toxic waste into a highly profitable business.
According to various parliamentary investigations, tons of industrial waste—including highly hazardous materials, radioactive substances, and special waste—have been illegally buried or incinerated. Among these are the so-called *ecoballe*[83](eco-bales): compacted bundles of mixed urban and industrial waste, which were abandoned or buried illegally rather than being treated safely.

These activities led to the accumulation of high concentrations of persistent pollutants—including dioxins, PCBs[84] (polychlorinated biphenyls), heavy metals (such as lead, cadmium, and mercury), and endocrine-disrupting chemicals (EDCs)[85]—contaminating the air, soil, and groundwater.
Connecting to the topic, exposure to these substances has been associated not only with an increased risk of cancer and congenital malformations, but also with hormonal dysfunctions and reduced fertility, with documented effects on both the local population and wildlife[86].

The case of the *Terra dei Fuochi* represents a striking example of how environmental degradation can severely impact the right to reproduction. It is especially a result of a long-standing pattern of institutional neglect, organized criminal activity, and regulatory failure. In this area, the illegal dumping and burning of toxic waste have not only led to high rates of disease and infertility but have also triggered concerns about the lasting impact on future generations. Numerous scientific studies and medical reports have documented the profound effects of environmental contamination on reproductive health. Exposure to pollutants such as dioxins, heavy metals, and endocrine-disrupting chemicals (EDCs) has been linked to hormonal imbalances,

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[82] Saviano, R. (2006). *Gomorra: Viaggio nell'impero economico e nel sogno di dominio della camorra*. Mondadori.
[83] Commissione Parlamentare d'Inchiesta sulle attività illecite connesse al ciclo dei rifiuti. (2013). *Relazione sullo smaltimento illecito dei rifiuti nella Regione Campania*. Parlamento italiano. https://www.camera.it/_dati/leg17/lavori/documentiparlamentari/indiceetesti/022/022/INTERO.pdf
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[85] Esposito, M., D'Alterio, S., Varriale, L., et al. (2021). Environmental exposure and health risk in Campania Region: Evidence from the Terra dei Fuochi. *Environmental Research, 200*, 111746. https://doi.org/10.1016/j.envres.2021.111746
[86] De Felice, N., Coppola, N., Montano, L., et al. (2018). Biomonitoring of reproductive health in the Land of Fires: A study on hormonal imbalance in young women. *Reproductive Toxicology, 81*, 120–128. https://doi.org/10.1016/j.reprotox.2018.08.002

reduced fertility, miscarriages, and even genetic mutations transmissible to future generations.[87] The World Health Organization (2013) has emphasized the potential for long-term reproductive damage from EDCs[88], while recent studies confirm the specific vulnerability of populations living in high-risk environmental areas.

The *Terra dei Fuochi* case stands as one of the most critical examples of this intersection between environmental devastation and the erosion of fundamental rights. A report by the Istituto Superiore di Sanità (ISS, 2016) identified significantly higher rates of infertility, neonatal complications, and congenital malformations in areas affected by illegal waste disposal. [89] These findings are reinforced in numerous Legambiente reports, which denounce not only the environmental crimes committed by organized criminal networks but also the institutional negligence that has allowed these practices to continue.[90] For instance, the "*Ecomafia*" report series published annually by Legambiente highlights the regulatory inaction and lack of enforcement that characterize environmental governance in regions like Campania.[91]

The seriousness of this systemic failure was officially recognized by the European Court of Human Rights (ECHR) on January 30, 2025, which condemned the Italian state for its inability to safeguard the right to health and life of residents in the Terra dei Fuochi area[92]. The Court pointed to a long-standing pattern of inaction, lack of monitoring, and failure to implement effective preventive measures as violations of Articles 2 and 8 of the European Convention on Human Rights. This judgment reinforces the idea that the denial of reproductive and environmental rights in polluted territories is not merely a socio-political failure, but a direct breach of human rights obligations.

Within this context, several scholars and environmental defenders have adopted the notion of *biocide* to describe the progressive weakening of life conditions, including the genetic integrity of affected communities[93]. The term refers to the destruction—whether active or tolerated—of ecosystems and biological systems necessary for the survival and reproduction of human life. Recognizing this reality demands a regulatory approach that integrates environmental justice into the protection of reproductive rights. This is for ensuring that legal systems are equipped not only to punish wrongdoing, but also to prevent structural harm and promote resilience in vulnerable populations.

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[87] Trasande, L., Zoeller, R. T., Hass, U., et al. (2015). *Estimating burden and disease costs of exposure to endocrine-disrupting chemicals in the European Union*, *Journal of Clinical Endocrinology & Metabolism*, 100(4), 1245–1255. https://doi.org/10.1210/jc.2014-4324

[88] World Health Organization. (2013). *State of the science of endocrine disrupting chemicals*. WHO/UNEP.

[89] Istituto Superiore di Sanità. (2016). *Progetto SENTIERI – aggiornamento sui siti contaminati e salute pubblica*. Roma.

[90] Legambiente. (2023). *Terra dei Fuochi e ambiente: Rapporto annuale sulle criticità ambientali in Campania*. www.legambiente.it

[91] Legambiente. (2023). *Ecomafia 2023: Le storie e i numeri della criminalità ambientale in Italia*. Roma: Edizioni Ambiente.

[92] European Court of Human Rights (ECHR). (2025, January 30). *X and Others v. Italy*, Application no. XXXX/XX.

[93] Giordano, A., & Tarro, G. (2014). *Campania avvelenata. Biocidio e lotta per la salute*. Bari: Edizioni Dedalo; cfr. anche Shiva, V. (2005). *Earth Democracy: Justice, Sustainability and Peace*. South End Press.

Nevertheless, negative effects of environmental contaminants on reproductive health have been widely documented in scientific literature [94] and their impact is anything but distant or teorico. A study published in *Environmental Research* found a significantly higher prevalence of *polycystic ovary syndrome* (PCOS) and *endometriosis* among women living in the most polluted areas of Campania[95]—both of which are major causes of female infertility. These aren't just numbers in a report, but real diagnoses that affect the daily lives of women — often young — who are forced to face complex and sometimes irreversible fertility challenges.

Similarly, an investigation by the Italian National Institute of Health[96] (*Istituto Superiore di Sanità*, ISS) revealed "*an increased incidence of spontaneous miscarriages and preterm births among women residing in the affected regions*". The prolonged exposure to heavy metals and dioxins has been shown to disrupt ovarian function, impair oocyte quality. In addition, It also interfere with hormonal regulation, ultimately reducing the chances of conception[97].

The damage, however, is not limited to women. The effects of pollution are equally visible in male reproductive health. A study by Russo et al. (2018) found that men who had been chronically exposed to environmental pollution in the *Terra dei Fuochi* area showed a decline in sperm quality, concentration, and motility[98]. This is consistent with global evidence linking environmental pollutants to increased oxidative stress in sperm cells, resulting in DNA fragmentation and reduced fertilization capacity. [99]

Even more concerning is the evidence regarding prenatal exposure to endocrine-disrupting chemicals. It has been linked to congenital malformations of the male reproductive system, such as cryptorchidism and hypospadias, both of which can negatively affect future fertility[100].

In essence, what is happening in these polluted territories is not just an environmental crisis, but a silent reproductive emergency, one that leaves visible marks not only in hospital records and medical studies, but in the lived experiences of families, couples, and communities who often struggle in silence.

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[94] Mattioli, A. V., Manenti, A., Farinetti, A., & Montano, L. (2020). Environmental pollution and female reproductive health. *Environmental Research, 183*, 109008. https://doi.org/10.1016/j.envres.2019.109008

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Beyond the threats posed to individual health, infertility in this region also raises serious concerns regarding public health and demographic trends.
Considering that Campania already has one of the lowest birth rates in Italy[101], the simultaneous effects of environmental degradation and declining reproductive health could, in the long term, lead to significant socio-economic problems. [102]
In response to growing public concern, the Italian government launched remediation programs, such as the *Piano di Bonifica della Terra dei Fuochi*[103], aimed at reclaiming contaminated areas and strengthening local healthcare services. However, although necessary, these initiatives are not deemed sufficient by local communities. Residents of the affected areas continue to voice their frustration, calling not only for stricter environmental regulations and transparent, continuous monitoring of pollution levels, but also for concrete, long-term interventions specifically aimed at protecting reproductive health. Their demands reflect a deeper need for justice and recognition — not just of the environmental devastation endured, but of its lasting impact on the most intimate dimensions of human life.

From a legal perspective, the case of the *Terra dei Fuochi* underscores the urgent need to integrate environmental law with public health policy.
Although the European Union's REACH[104] regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) imposes strict guidelines on hazardous substances, its effective implementation at the national and regional levels remains a challenge[105].
Nevertheless, the issue of environmental crime has prompted legislative reform in Italy.
In particular, Law No. 68/2015[106] introduced tougher penalties for the illegal trafficking of waste and more rigorous controls on industrial emissions.
Still, given that exposure to pollutants persists, additional restrictive regulatory measures are needed to adequately control the long-term risks to reproductive health.

The issue of preserving fertility rates in the context of the *Terra dei Fuochi* clearly demonstrates that environmental contamination has a severe impact on reproductive outcomes. It also highlights the need for

[101] Campania recorded a birth rate of 7.7 per 1,000 inhabitants in 2023, slightly down from 7.9 per 1,000 in 2022. While this figure remains above the national average of 6.4 per 1,000, the region has also seen a decline in its fertility rate, which dropped from 1.29 children per woman in 2023 to 1.26 in 2024.
[102] Istat. (2023). *Natalità e fecondità della popolazione residente*. https://www.istat.it/it/archivio/natalita
[103] Ministero dell'Ambiente e della Sicurezza Energetica. (2022). *Piano di Bonifica della Terra dei Fuochi*. https://www.mase.gov.it/bonifiche/terra-dei-fuochi
[104] European Chemicals Agency (ECHA). (2021). *Understanding REACH: What is REACH?* https://echa.europa.eu/regulations/reach/understanding-reach
[105] European Chemicals Agency. (2021). *Understanding REACH: What is REACH?* Retrieved from https://echa.europa.eu/regulations/reach/understanding-reach
[106] Legge 22 maggio 2015, n. 68. "Disposizioni in materia di delitti contro l'ambiente." Gazzetta Ufficiale n. 122 del 28-05-2015.

interdisciplinary approaches that combine biomedical research and environmental remediation, capable of generating regulatory interventions that are both adequate and effective.
Medical care alone is not sufficient to address infertility in high-risk areas; what is also needed are sustainable environmental policies that prioritize public health and eliminate reproduction-related risk factors over the long term.

To enable early detection of reproductive dysfunction among residents of the *Terra dei Fuochi*, fertility screening programs have been launched.
At the clinical level, for infertile couples exposed to environmental pollutants, treatments include oocyte vitrification[107], personalized IVF protocols, and the use of targeted antioxidants to combat oxidative stress in sperm cells[108]. However, economic constraints and regional disparities currently limit access to these treatments. For this reason, public policies are needed to ensure equitable access to reproductive medicine in environmentally high-risk areas.

In conclusion, the case of the *Terra dei Fuochi*, supported by a substantial body of scientific research, offers undeniable evidence of the impact of environmental pollution on reproductive capacity, effectively undermining the possibility of forming a family.
This is not merely a matter of individual health—it is a question of reproductive justice and social inequality[109].
Thus, medical treatments provided to communities affected by environmental contamination are not sufficient unless accompanied by site remediation to repair past damage, preventive policies to avoid similar situations in the future, and guarantees of equitable access to fertility care.

Taking responsibility for addressing infertility in high-risk areas means recognizing that reproductive health is deeply interconnected with the environment[110], and that protecting one requires protecting the other. Therefore, a clear and committed political response is essential to reposition public well-being as a central policy priority.

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[107] Martini, A. C., et al. (2021). *Environmental pollutants and sperm quality: A review of recent literature*. *Andrologia, 53*(6), e14083. https://doi.org/10.1111/and.14083
[108] Di Nisio, A., & Foresta, C. (2019). *Endocrine disruptors and human fertility: Impact on the male and female reproductive system*. *Journal of Endocrinological Investigation, 42*(11), 1365–1371. https://doi.org/10.1007/s40618-019-01061-5
[109] Ross, L. J., & Solinger, R. (2017). *Reproductive Justice: An Introduction*. University of California Press.
(Testo fondamentale per integrare il concetto di giustizia riproduttiva nel contesto ambientale.)
[110] Landrigan, P. J., & Fuller, R. (2015). Environmental pollution: An under-recognized threat to children's health, especially in low- and middle-income countries. *Environmental Health Perspectives, 123*(3), A61–A65. https://doi.org/10.1289/ehp.1409589

CHAPTER 2 – The regulatory challenge: the conflict between innovation and legal limits.

The progress that has been made in the field of reproductive medicine over the last two decades with a mighty acceleration has pushed states to confront the need for regulation. This progress has made it necessary for governments to step in and define clear rules on how these new technologies should be used and where limits should be set. Medically assisted reproduction (MAR) techniques have not only pushed the boundaries of biology but have also transformed the way we think about parenthood and family structures.

However, legal systems have often struggled to keep pace with scientific advancements, mainly because they are still based on traditional legal models that are not always equipped to deal with such complex ethical and social issues.

The gap between scientific progress and regulatory response is not surprising, especially when innovation touches on deeply rooted ethical and social values. Reproductive technologies often raise complex bioethical questions and affect sensitive dimensions of human life. Regulation, therefore, cannot be immediate or superficial; it requires time for reflection, public debate, and adaptation to the specific realities these technologies influence. While such innovations offer concrete solutions to reproductive and health-related challenges, they also bring forward pressing concerns. Questions about the protection of the embryo, the risk of eugenic practices, unequal access, and the commodification of the human body highlight the urgent need for thoughtful and well-calibrated regulatory frameworks.

This regulatory urgency is justified by the fact that, even today, the lack of timely legal updates — whether due to regulatory gaps or overly rigid frameworks — has already led to concrete consequences. One of the most visible effects is *reproductive tourism*[111]: many individuals and couples choose to travel abroad to access procedures that are either limited or banned in their home countries[112]. It is not difficult, in this framework, to mention for instance Italy. In some cases, these practices take place in legal grey areas, with little oversight or protection, and can even result in violations of the fundamental rights of those involved[113].

[111] Inhorn, M. C., & Gürtin, Z. B. (2011). Cross-border reproductive care: A future research agenda. *Reproductive BioMedicine Online, 23*(5), 665–676. https://doi.org/10.1016/j.rbmo.2011.07.009
[112] Pennings, G. (2002). Reproductive tourism as moral pluralism in motion. *Journal of Medical Ethics, 28*(6), 337–341. https://doi.org/10.1136/jme.28.6.337
[113] Shenfield, F., Pennings, G., Cohen, J., Devroey, P., & Tarlatzis, B. (2020). Cross-border reproductive care in Europe: A review of the regulation and its impact. *Human Reproduction Update, 26*(1), 1–13. https://doi.org/10.1093/humupd/dmz033

The *European Parliamentary Research Service* [114](2021), points out that these phenomena are a consequence of the lack of harmonisation of European and international regulations, giving rise to regulatory shopping, i.e. the possibility of circumventing the legal restrictions of states of origin by moving to other states in which the systems are more permissive. This leads to the most obvious ethical and legal implications.

2.1 Fragmentation and Diverging National Approaches

Assisted reproduction, like many other bioethical issues, sits at the intersection of multiple and often conflicting dimensions: individual freedom versus collective interest, scientific innovation versus precaution, and the globalisation of healthcare versus the protection of national sovereignty. Cultural values—frequently divergent across countries—play a crucial role in shaping how each legal system responds to these challenges. As a result, regulation in this field is highly fragmented, with no unified or harmonised international framework. This lack of coherence makes it extremely difficult to develop common standards or coordinated legal responses at the global level.

Some countries adopt a more liberal approach, focused on individual autonomy, which often results in the acceptance and regulation of the fertility market. Others, instead, follow much stricter rules, shaped by ethical or religious principles, and place greater emphasis on protecting human dignity and unborn life. This contrast reflects the deep differences between legal systems, which are shaped not only by law but also by cultural and moral views on what is considered acceptable — or legitimate — when it comes to reproduction.

Among the key principles shaping the European approach is a general attitude of caution toward scientific uncertainty. This stance, while grounded in the desire to protect human dignity and public health, often results in stricter limitations on emerging reproductive technologies—particularly when long-term effects remain unclear.

In some non-European contexts, such as the United States or India (until the recent regulatory clampdown), has been established a more permissive logic has been established. Here, freedom of action is recognised that is essentially regulated by the market, with limited public intervention[115]. In this context access to technologies is not conditioned by ethical criteria but is often determined by purchasing power[116]. This

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[114] European Parliamentary Research Service (EPRS). (2021). *Regulation of cross-border surrogacy arrangements in the EU: State of play and potential options for harmonisation*.
https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2021)698815

[115] Spar, D. L. (2006). *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. Harvard Business Review Press.

[116] Banerjee, S., Basu, P., & Dutta, M. (2018). India's surrogacy regulation dilemma: Critical reflections on the Surrogacy (Regulation) Bill 2016. *Indian Journal of Medical Ethics, 3*(1), 22–27. https://doi.org/10.20529/IJME.2017.087

discrepancy has fuelled the so-called '*global fertility market*', in which access to certain technologies depends on the possibility of circumventing regulatory limits through travel, money or private intermediation rather than the universal right to reproductive health.

2.2 The Global Fertility Market and the Role of International Actors

The globalisation of assisted reproduction has intensified inequalities and created new legal and ethical challenges. In a context where national laws vary dramatically, the global fertility market allows individuals to navigate across jurisdictions in search of more favourable legal and medical conditions. This raises concerns about exploitation, especially in low-regulation or economically vulnerable countries.

Supranational bodies such as the WHO[117] (2021) and the ISSCR[118] (International Society for Stem Cell Research, 2021) have advocated the urgency of adopting a shared regulatory framework, emphasising the need for a common ethical and legal framework. The aim is to avoid public health risks on one hand and to allow substantial equality to benefit from the most advanced reproductive techniques on the other. This need for international consensus remains an arduous objective to achieve because of the difficulties posed by differing moral and political sensitivities.

Having defined the reference context, the aim in this chapter is to make a comparative analysis of the different models for regulating reproductive technologies, with particular attention to the case of genetic editing and the divergences between European and non-European approaches. Understanding how legal systems respond to the challenges posed by scientific innovation, what are the different regulatory instruments adopted, and what are the practical consequences of fragmented regulation. Hence, it could contribute to explore in depth an extreme sensitive topic like this. In this reflection, therefore, the economic, cultural and ideological factors that substantially intervene in the development of formal regulation will also be considered.

2.3 European vs. non-European approaches: comparing models and regulatory implications.

While regulatory divergence has been broadly outlined, it is important to explore how these contrasting models affect the structure, legitimacy, and effectiveness of reproductive governance in practice. European legal systems, shaped by *cautious* and *state-centric principles*, tend to embed reproductive technologies within broader frameworks of public health, ethical oversight, and social equity. As a result, innovation is often integrated slowly, and only after extensive consultation with ethics committees, legal experts, and civil

[117] World Health Organization. (2021). *Infertility prevalence estimates, 1990–2021*. https://www.who.int/publications/i/item/9789240077476

[118] international Society for Stem Cell Research (ISSCR). (2021). *ISSCR Guidelines for Stem Cell Research and Clinical Translation*. https://www.isscr.org/guidelines

society actors. This process, while sometimes delaying access, ensures that technologies are evaluated not only for their efficacy, but for their impact on human dignity, intergenerational justice, and social cohesion.

By contrast, in non-European jurisdictions where market forces are more prominent, the pace of technological adoption is generally faster. However, this speed is often achieved at the expense of regulatory consistency and long-term ethical safeguards. The absence of a strong normative framework can lead to legal ambiguities, unequal access based on financial capacity, and weak protections for vulnerable subjects, including surrogate mothers and children born through cross-border arrangements.

The consequences of these differing regulatory philosophies are not merely theoretical—they shape how technologies are introduced, accessed, and evaluated across countries. In Europe, the precautionary approach may provide more robust safeguards for human rights and ethical scrutiny, but it often results in regulatory inertia, slowing down the implementation of emerging techniques even when these may address urgent medical needs. On the other hand, in more permissive systems, where regulation is minimal and market logic prevails, individual autonomy is foregrounded. They face often this kind of challenges without adequate tools to address broader concerns such as equity, long-term health impacts, or the exploitation of vulnerable groups. This contrast calls for a deeper reflection on the normative foundations of reproductive governance in a globalised and technologically fluid context. Rather than aiming for uniformity, the goal should be to identify shared principles—such as transparency, justice, and human dignity—that can guide national systems in ways that are both ethically sound and socially responsive.

Understanding these differences is crucial for shaping future regulation: not to promote uniformity, but to ensure that innovation respects core human rights, promotes equitable access, and avoids repeating patterns of exploitation masked as medical opportunity.

2.3.1 The European model: bioethical oversight and the precautionary principle

European regulation is guided by a strong normative framework that prioritizes human dignity, social justice, and state responsibility.

Central to this model is the *precautionary principle*[119]—enshrined in Article 191 of the *Treaty on the Functioning of the European Union*[120]—which compels public authorities to prevent potentially harmful practices even without solid or fully established scientific data.

[119] European Commission. (2000). *Communication on the Precautionary Principle*. COM(2000) 1 final. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52000DC0001

[120] European Union. (2012). *Consolidated Version of the Treaty on the Functioning of the European Union*. Official Journal of the European Union, C 326, 47–390. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

The *precautionary principle* is "*a regulatory approach that urges public authorities to act in advance to prevent harm when there is a risk to health or the environment, even if scientific evidence is not yet conclusive*". In reproductive technologies, this principle translates into a careful and restrictive approach toward innovations such as germline gene editing, embryo selection for non-therapeutic purposes, or commercial surrogacy.

This regulatory caution is echoed in the *Oviedo Convention of the Council of Europe*[121] (1997), which prohibits genetic modifications of human beings (Art. 13) and any practice that involves the commodification of the human body (Art. 21). Although there is no single EU law that regulates assisted reproduction, the European Group on Ethics in Science and New Technologies[122] (EGE) has encouraged member states to follow a more inclusive and rights-based approach. Through its recommendations (EGE, 2021), it promotes greater consistency among national laws, aiming to guide countries toward shared ethical standards.

Nevertheless, the significant discretion left to individual countries has resulted in a fragmented regulatory landscape. For instance, countries such as Sweden and Denmark, allow single women and same-sex couples access to assisted reproduction through their national healthcare systems, prioritizing equality and inclusiveness.

In contrast, Germany and Italy maintain highly restrictive policies, often grounded in the protection of the embryo and concerns about medicalizing procreation[123]. France, with its *2021 Loi de bioéthique*[124], represents a hybrid model. Adopted in August 2021, the French *Loi de bioéthique* introduced significant changes to the country's approach to assisted reproduction. It extended access to PMA (procréation médicalement assistée) to single women and lesbian couples through the public healthcare system, reflecting a broader move toward inclusivity. At the same time, the law reaffirmed the ban on surrogacy and maintained strict ethical oversight, particularly in areas such as embryo research, gamete donation anonymity, and genetic intervention.

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[121] Council of Europe. (1997). *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo Convention)*. https://rm.coe.int/168007cf98

[122] European Group on Ethics in Science and New Technologies (EGE). (2021). *Opinion on Ethics of Genome Editing*. Publications Office of the European Union. https://op.europa.eu/en/publication-detail/-/publication/9e927b5d-7fd1-11eb-9ac9-01aa75ed71a1

[123] European Union Agency for Fundamental Rights. (2022). *National regulation of medically assisted reproduction in EU Member States*. https://fra.europa.eu/en/publication/2022/national-regulation-medically-assisted-reproduction

[124] République Française. (2021). *Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique*. https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043915778

Despite differences, the European approach generally aims to strike a balance between scientific innovation and ethical oversight, using public consultation and bioethical boards to mediate ongoing developments[125]. However, the resulting delays in adopting new technologies often place Europe behind in terms of access and availability compared to more liberal systems.

Although the *precautionary principle* was originally developed in the context of environmental protection, it has gradually found important applications in the medical field as well, especially in areas where scientific uncertainty meets sensitive ethical concerns.

In the case of reproductive technologies, the principle offers a useful framework for managing the risks linked to innovations that are still being tested or whose long-term effects are not yet fully understood[126][127]

In Europe, this approach has led to a general attitude of caution when it comes to introducing new and controversial reproductive techniques. Methods like germline gene editing, mitochondrial replacement, or embryo selection for non-medical purposes are seen not just as scientific advances, but as interventions with deep ethical, social, and biological implications. The *precautionary principle*, in this sense, doesn't mean saying "no" to innovation—but rather saying "not yet," or "only under certain conditions." It asks policymakers[128] to reflect before acting, especially when the stakes involve the well-being of future generations or the dignity of human life[129].

What makes this principle particularly relevant in the medical context is its role in encouraging broader forms of participation and oversight. Decisions about which technologies to allow—and how—are rarely left to scientists or markets alone. Ethics committees, legal experts, and even citizens are often called upon to contribute to the debate[130]. This helps ensure that scientific progress is not only safe but also aligned with shared social values.

At the same time, the application of the precautionary principle has raised some concerns. Critics argue that excessive caution can slow down access to potentially beneficial treatments, particularly in areas like infertility, where time matters.

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[125] Andorno, R. (2005). The Oviedo Convention: A European legal framework at the intersection of human rights and health law. *Journal of International Biotechnology Law, 2*(4), 133–143. https://doi.org/10.1515/9783110451075

[126] Weimer, M. (2017). Risk regulation and the precautionary principle. In J. Scott (Ed.), *Environmental Protection: European Law and Governance* (pp. 137–154). Oxford University Press.

[127] De Sadeleer, N. (2020). *Environmental Principles: From Political Slogans to Legal Rules* (2nd ed.). Oxford University Press.

[128] Busschers, M. (2019). *Precaution in the EU: Between innovation and regulation*. *European Journal of Risk Regulation, 10*(3), 551–572. https://doi.org/10.1017/err.2019.55

[129] Busschers, M. (2019). *Precaution in the EU: Between innovation and regulation*. *European Journal of Risk Regulation, 10*(3), 551–572. https://doi.org/10.1017/err.2019.55

[130] Andorno, R. (2005). The Oviedo Convention: A European legal framework at the intersection of human rights and health law. *Journal of International Biotechnology Law, 2*(4), 133–143. https://doi.org/10.1515/9783110451075

In the EU, this cautious stance[131]—combined with the fact that each country retains a high degree of autonomy—has contributed to a fragmented system, where patients may face very different rules and opportunities depending on where they live[132].

Despite these challenges, the *precautionary principle* remains a key reference point for European regulators, helping to navigate the ethical complexity of reproductive technologies without rushing into potentially irreversible choices. While it may slow down innovation it serves as a necessary reminder that not all scientific progress should be embraced unconditionally—especially when it touches the most vulnerable aspects of human life.

2.3.2 The non-European model: individual autonomy, biomedicine and the market

In many non-European countries—such as the United States, Israel, India (until 2021), and Georgia—*individual reproductive autonomy*[133] is recognised as a fundamental right. This approach often reflects a more libertarian view of healthcare, where the role of the state in regulating access to assisted reproduction is minimal or entirely absent.

As a consequence, access to assisted reproduction is often managed within the private sector, where individuals deal directly with clinics, frequently in a commercial framework. In the United States, this approach is evident: oversight relies on professional guidelines and the decisions of local ethics boards, with no central authority coordinating regulation at the national level.

This has led to the development of a highly competitive fertility market, where private clinics offer a wide range of services. This includes procedures such as in vitro fertilisation, genetic testing, egg freezing, and commercial surrogacy— the latter being permitted in several U.S. states, including California, Illinois, and Nevada. These clinics operate much like private companies, without a central licensing system, and often offer customisable "fertility packages."[134] These may include egg donor catalogues, "money-back" guarantees, or even options for selecting specific genetic traits such as eye colour or athletic potential. While legal, these practices raise serious ethical concerns, especially when they begin to resemble eugenic selection.

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[131] Pennings, G. (2002). Reproductive tourism as moral pluralism in motion. *Journal of Medical Ethics, 28*(6), 337–341. https://doi.org/10.1136/jme.28.6.337

[132] European Parliamentary Research Service (EPRS). (2021). *Regulation of cross-border surrogacy arrangements in the EU: State of play and potential options for harmonisation*. https://www.europarl.europa.eu/thinktank/en/document/EPRS_BRI(2021)698815

[133] Robertson, J. A. (1994). *Children of Choice: Freedom and the New Reproductive Technologies*. Princeton University Press.

[134] Sandelowski, M., & de Lacey, S. (2020). The commercialization of reproduction and the commodification of hope. *Journal of Bioethical Inquiry, 17*(2), 165–178. https://doi.org/10.1007/s11673-020-09989-5

Israel, on the other hand, represents a unique case. Although it embraces many of the same advanced technologies, including surrogacy and pre-implantation diagnosis, these are publicly supported and regulated by the state. The health system covers up to two children through assisted reproduction, even for single women[135]. This reflects a broader national policy where reproduction is seen not only as a private matter, but as something tied to collective identity and demographic continuity.

In contrast, countries like pre-conflict Georgia and Ukraine had become well-known for their openness to low-cost commercial surrogacy, attracting intended parents from all over the world[136]. However, in many cases, these legal frameworks lacked sufficient safeguards—both for the women involved, often in vulnerable economic situations, and for the children born through these arrangements[137]. Cases of inadequate legal protections, risk of exploitation, and even concerns over child trafficking have led some governments to impose new restrictions in recent years.

This divergence between European and non-European approaches has contributed to what is often referred to as *regulatory arbitrage*[138]: the practice of crossing borders to access reproductive services that are restricted at home. While this can expand individual choice, it also exposes deeper inconsistencies in global regulation. Only those with the financial means can benefit from this freedom, creating even more clear inequalities within national healthcare systems.

At the same time, the absence of shared legal standards leads to practical and legal complications. For instrance, in the case of international surrogacy, some European countries refuse to recognise foreign birth certificates, making it difficult for children to obtain citizenship or legal recognition of their parent-child relationships. The European Court of Human Rights[139] has intervened several times on this issue, stressing the need to protect the rights of children born through surrogacy abroad140. For instance, in Mennesson v. France (2014), the Court ruled against France for refusing to recognise the legal parentage of a child born via surrogacy in the United States. Similarly, in Foulon and Bouvet v. France (2016), it condemned the non-

[135] Birenbaum-Carmeli, D. (2016). Thirty-five years of assisted reproductive technologies in Israel. *Reproductive Biomedicine & Society Online, 2*, 16–23. https://doi.org/10.1016/j.rbms.2016.05.001
[136] Wikler, D. (2019). Exploitation in international surrogacy: Clinical and ethical perspectives. *Cambridge Quarterly of Healthcare Ethics, 28*(2), 239–247. https://doi.org/10.1017/S0963180118000469
[137] Hammarberg, K., Rapp, P., & Jones, C. (2021). Surrogacy, ethics and law: Contemporary international perspectives. *Human Fertility, 24*(3), 244–250. https://doi.org/10.1080/14647273.2021.1878507
[138] Pennings, G. (2004). Legal harmonization and reproductive tourism in Europe. *Human Reproduction, 19*(12), 2689–2694. https://doi.org/10.1093/humrep/deh506
[139] European Court of Human Rights. (2014). *Mennesson v. France*, Application no. 65192/11. https://hudoc.echr.coe.int/eng?i=001-145179
[140] European Court of Human Rights. (2016). *Foulon and Bouvet v. France*, Applications nos. 9063/14 and 10410/14. https://hudoc.echr.coe.int/eng?i=001-160778

recognition of the legal bond between intended parents and children born through surrogacy arrangements carried out abroad.[141]

What emerges, therefore, is a kind of global geography of reproduction. Access to parenthood no longer depends only on medical need, but also on factors like citizenship, economic resources, and the ability to "choose" the legal system most favourable to one's desires. This landscape highlights not only cultural and legal diversity, but also the growing need for international dialogue on how to ensure fairness, protection, and dignity in the context of assisted reproduction.

The regulatory divide between the European and non-European models of reproductive technologies does not lie merely in the presence or absence of specific laws, but in the deeper principles, values, and visions of society that guide those laws[142].

At the heart of this divide is a fundamental contrast between two regulatory philosophies: one centred on collective ethics and public oversight, and the other on individual autonomy and market freedom.

Although there is no fully unified legal framework, the European approach is generally guided by a common set of principles, including caution in the face of scientific uncertainty, respect for human dignity, and strong public involvement in setting ethical limits. These values have shaped a model where reproductive technologies are not treated as purely technical or commercial tools, but as practices that raise important social and ethical questions. For this reason, innovations such as gene editing, surrogacy, or embryo selection are introduced gradually and often under close public and institutional oversight. Instruments like the Oviedo Convention (1997) and the opinions of the European Group on Ethics reflect this broader vision, where human rights and collective responsibility play a central role.

In many non-European countries, on the other hand, the focus tends to be on individual freedom and market access. Assisted reproduction is often seen as a private matter, regulated more by personal choice, clinical practice, and contractual arrangements than by national ethical guidelines or public institutions.

The United States, for instance, places few federal restrictions on reproductive technologies, allowing for a vast and competitive fertility industry, where the patient-consumer chooses services much like any other product—ranging from IVF to commercial surrogacy, sometimes including genetic trait selection.

This libertarian approach is driven by cultural values that prioritise freedom of choice, minimal state interference, and the right to privacy[143]. In countries like Israel, these liberal principles coexist with national

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[141] *Mennesson v. France*, no. 65192/11, European Court of Human Rights, Judgment of 26 June 2014; *Foulon and Bouvet v. France*, nos. 9063/14 and 10410/14, European Court of Human Rights, Judgment of 21 July 2016.
[142] Brownsword, R. (2008). *Rights, Regulation and the Technological Revolution*. Oxford University Press.
[143] Sandelowski, M., & de Lacey, S. (2020). The commercialization of reproduction and the commodification of hope. *Journal of Bioethical Inquiry, 17*(2), 165–178. https://doi.org/10.1007/s11673-020-09989-5

identity goals, leading to state-supported access to advanced reproductive technologies, even for single women, while maintaining tight domestic control over practices like surrogacy. [144]

What's truly behind these two models, then, are different conceptions of what reproduction means in society. The European approach treats it as a matter of public interest and collective ethics, where state intervention is necessary to prevent inequalities, exploitation, or irreversible harm. The non-European model, on the other hand, sees reproduction primarily as a matter of personal freedom, where the market is viewed as a tool for expanding choice and satisfying demand.

These divergent visions also reflect broader socio-political traditions. In Europe, regulation tends to be top-down, cautious, and grounded in human rights jurisprudence. In the U.S. and other liberal-market contexts, it is more bottom-up, with market logic and contractual autonomy playing a greater role.

Ultimately, the contrast between these models is not just legal or technical: it is deeply cultural. It reveals different ways of balancing science, ethics, and power in shaping the boundaries of human reproduction. And it explains why harmonising[145] international regulations in this field remains such a complex and contested task.

2.4 Regulatory models of medically assisted procreation around the world

The considerable regulatory asymmetry observed at the global level in the field of medically assisted procreation[146] (MAP) stems from a complex interplay of scientific, cultural, economic, and ethical factors. As previously discussed, these differences are not merely technical but reflect diverse national interpretations of the balance between individual freedom, state intervention, and the value attributed to human life and dignity[147].

A comparative analysis of these models allows us to understand how states interpret and mediate the tensions between autonomy and protection in the regulation of reproductive technologies.

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[144] Birenbaum-Carmeli, D. (2016). Thirty-five years of assisted reproductive technologies in Israel. *Reproductive Biomedicine & Society Online, 2*, 16–23. https://doi.org/10.1016/j.rbms.2016.05.001

[145] Pennings, G. (2004). Legal harmonization and reproductive tourism in Europe. *Human Reproduction, 19*(12), 2689–2694. https://doi.org/10.1093/humrep/deh506

[146] Pennings, G. (2004). Legal harmonization and reproductive tourism in Europe. *Human Reproduction, 19*(12), 2689–2694. https://doi.org/10.1093/humrep/deh506

[147] Scott, R. (2000). Reproductive autonomy and the ethics of human reproduction. *Ethics, 110*(4), 714–738

2.4.1 The permissive model: the primacy of the market and individual autonomy

The *permissive model*[148] is rooted in a liberal and secular vision of procreation. This means that reproduction is framed primarily as a private matter and reproductive technologies are treated as instruments to realise individual desires.

In this model, "*technology is considered neutral, detached from moral or collective implications, and fully available to individual choice, if it does not pose a direct threat to public health or safety"*[149]. This approach is most clearly visible in countries like the United States, India (before the 2021 reform), and Ukraine (prior to the war), though it manifests with local variations.

In the United States, there is no overarching federal legislation on MAP. Regulation is decentralized and left to the individual states, resulting in a patchwork of norms and a high degree of legal uncertainty. In California, for instance, commercial surrogacy is not only legal but institutionalised: pre-birth[150] orders are issued by courts to establish parental rights even before the child is born, and the contracts between intended parents and surrogates are enforceable[151].

At the heart of this model lies the idea that *"reproductive freedom is an extension of individual autonomy, and that the state should play a minimal, if any, role in shaping or restricting reproductive choices"*[152]. Fertility clinics operate as private economic actors in a competitive market. These systems offer a broad range of services—such as IVF, genetic screening before implantation, egg and embryo freezing, and surrogacy—without setting restrictions related to a person's marital status, age, or sexual orientation.[153].

Among the main advantages of this model are the rapid development of biomedical innovation, the promotion of reproductive pluralism, and access to advanced procedures that may not yet be permitted elsewhere. This liberal setting also supports the growth of a dynamic biotech sector and encourages patient-centred care that responds directly to demand.

However, the risks associated with the permissive model are substantial. First and foremost is the commercialisation of parenthood, in which reproductive relationships are redefined through market logic, potentially reducing gestation and birth to contractual services. This opens the door to economic exclusion,

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[148] Robertson, J. A. (1994). *Children of Choice: Freedom and the New Reproductive Technologies*. Princeton University Press.
[149] Thompson, C. (2005). *Making Parents: The Ontological Choreography of Reproductive Technologies*. MIT Press.
[150] Markens, S. (2007). *Surrogate Motherhood and the Politics of Reproduction*. University of California Press.
[151] Appleton, S. F. (2018). Surrogacy and limitations to freedom of contract: Toward being more fully human and less commodified. *Washington University Journal of Law & Policy, 57*, 27–52.
[152] Robertson, J. A. (1994). *Children of Choice: Freedom and the New Reproductive Technologies*. Princeton University Press.
[153] Spar, D. L. (2006). *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. Harvard Business School Press.

as access to MAP becomes heavily dependent on one's financial resources. Treatments can easily exceed $100,000 per cycle in the U.S., making them inaccessible for a large portion of the population[154] .

Moreover, the lack of ethical oversight and shared public standards contributes to an environment in which the pursuit of reproductive goals may slide into eugenic temptations—such as selecting for cosmetic or cognitive traits.

These dynamics became particularly evident in the case of India, which until 2021 had become a global hub for low-cost surrogacy. The absence of comprehensive legislation allowed the growth of a transnational reproductive market in which economically vulnerable women were recruited—often by intermediaries—to carry pregnancies for foreign clients[155]. While this offered short-term financial relief to many, it also raised concerns about systemic exploitation, lack of informed consent, and limited postnatal protections for both children and surrogates. This situation, combined with increasing international pressure, eventually led the Indian government to pass the *Surrogacy (Regulation) Act, 2021*[156]. This act is a national law that aims to protect the rights and well-being of surrogates and children by prohibiting commercial surrogacy and allowing only altruistic surrogacy among close relatives, under strict conditions.

Ultimately, the permissive model embodies a vision of reproductive liberty that aligns with globalised capitalism and a neoliberal interpretation of healthcare. While it expands access to technology and personal choice, it does so at the cost of equity, ethical consistency, and social responsibility, particularly in the absence of safeguards for the most vulnerable actors involved in the reproductive process.

2.4.2 The intermediate model: regulated openness and centrality of the public interest

Some European countries—such as the United Kingdom, Spain, the Netherlands, and Belgium—have adopted an *intermediate regulatory model*[157] that seeks to reconcile technological openness and respect for individual reproductive autonomy with strong public oversight and a commitment to shared ethical principles. This model is characterised by "*a proactive role of the state, which assumes the task of defining the limits and conditions under which reproductive technologies may be accessed, monitored, and developed, always in the light of broader public interests"*[158].

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[154] Sandelowski, M., & de Lacey, S. (2020). The commercialization of reproduction and the commodification of hope. *Journal of Bioethical Inquiry, 17*(2), 165–178. https://doi.org/10.1007/s11673-020-09989-5

[155] Pande, A. (2014). *Wombs in Labor: Transnational Commercial Surrogacy in India*. Columbia University Press.

[156] Government of India. (2021). *The Surrogacy (Regulation) Act, 2021*. Ministry of Law and Justice. https://egazette.nic.in/WriteReadData/2021/232118.pdf

[157] Pennings, G. (2005). How to respond to the demand for cross-border reproductive care? Ethical guidance for European policy. *Human Reproduction, 20*(12), 3235–3239. https://doi.org/10.1093/humrep/dei200

[158] Knoppers, B. M., & Isasi, R. M. (2004). Regulatory approaches to reproductive genetic testing. *Human Reproduction, 19*(12), 2695–2701. https://doi.org/10.1093/humrep/deh510

A clear example is the United Kingdom, where since the *Human Fertilisation and Embryology Act of 1990*[159] was issued, the legal framework has allowed a wide range of MAP techniques, including pre-implantation genetic diagnosis, IVF with donor gametes, and embryo cryopreservation. At the same time are imposed a clear set of limitation—for example, on the number of embryos that can be implanted—and commercial surrogacy is prohibited, being allowed only in altruistic forms.

What distinguishes the British system is the presence of the *Human Fertilisation and Embryology Authority* (HFEA)[160]. It is an independent public body that authorises, licenses, monitors, and evaluates all fertility clinics and research centres involved in MAP. It is a clear example of how regulatory institutions can actively shape technological development rather than merely reacting to it. The HFEA guarantees transparency, safety standards, and the ethical consistency of procedures, playing a central role in ensuring accountability and public trust.

Spain represents another significant case within this model. With *Law 14/2006*[161], the Spanish system guarantees access to assisted reproduction for single women and same-sex couples, recognising a wide array of family configurations. Law 14/2006 on Assisted Human Reproduction Techniques establishes the legal framework for access to fertility treatments in Spain. It affirms the right to assisted reproduction regardless of marital status or sexual orientation and allows the use of donor gametes under conditions of anonymity. The law also regulates embryo cryopreservation, preimplantation genetic diagnosis, and ensures that treatments are carried out in accredited centres, with informed consent and medical oversight as fundamental principles. It also permits anonymous gamete donation, promoting privacy and voluntariness.

However, surrogacy remains explicitly banned, and Spanish courts do not recognise parental rights derived from international surrogacy arrangements. The Spanish health system also offers public or subsidised access to MAP treatments, ensuring a substantial degree of equity in access and reducing socio-economic barriers. Thanks to this combination of openness and regulation, Spain has become one of the leading European countries in the number of MAP cycles performed, according to data from the European Society of Human Reproduction and Embryology[162] (ESHRE, 2023). Its model is praised for the quality of care, efficiency, and inclusiveness.

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[159] Human Fertilisation and Embryology Act 1990. (UK Public General Acts). https://www.legislation.gov.uk/ukpga/1990/37/contents

[160] Human Fertilisation and Embryology Authority (HFEA). (n.d.). *Who we are and what we do*. https://www.hfea.gov.uk/about-us/

[161] Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida. *Boletín Oficial del Estado (BOE)*, núm. 126, 27 de mayo de 2006. https://www.boe.es/buscar/act.php?id=BOE-A-2006-9292

[162] European Society of Human Reproduction and Embryology (ESHRE). (2023). *ART Fact Sheet – European data 2020–2021*. https://www.eshre.eu/Data-collection-and-research/Consortia/EIM/Data-collection

A shared feature of this intermediate approach is the recognition that reproduction is not solely a private matter, like many thoughts. Instead, it is one with significant social, ethical, and intergenerational consequences. In this sense, reproduction is not only a matter of private desire, or something related exclusively on the status, but a collective concern that requires thoughtful and forward-looking regulation.

As such, it is regulated through institutional mechanisms that ensure a responsible use of innovation[163]. These mechanisms typically include:

- Independent public bodies tasked with ethical and scientific evaluation of reproductive procedures.
- Legislative frameworks updated regularly to reflect scientific progress and social change.
- Public debate and ethical consultation as part of the policymaking process.
- Access policies aimed at minimising inequalities related to gender, sexual orientation, and economic status.

Important not to forget that while this model does not eliminate all inequalities—since regional disparities, waiting times, and bureaucratic barriers may still limit effective access—it represents a balanced and sustainable approach to regulating MAP. It preserves reproductive freedom within a framework of ethical responsibility and aims to democratise access to reproductive technologies without succumbing to market-driven logics or ethical indifference.

In this sense, the intermediate model can be viewed as "*a form of responsible governance of innovation, where technological progress is actively shaped and guided by public institutions, in dialogue with society, rather than being passively accepted or aggressively pursued without constraint"*[164].

2.4.3 The restrictive model: embryo protection and strong bioethical limits

In countries such as Italy, Germany, and— even though some recent changes show a move toward greater openness —France, a *restrictive regulatory model prevails*. This approach is largely shaped by conservative bioethical visions and, in some cases, religious or cultural traditions[165]. This kind of influences, assign intrinsic moral value to the embryo and frame reproductive interventions as ethically sensitive acts requiring strict control. At the core of this model lies a fundamental assumption: "*human life—and, by extension,*

[163] Knoppers, B. M., & Isasi, R. M. (2004). Regulatory approaches to reproductive genetic testing. *Human Reproduction, 19*(12), 2695–2701. https://doi.org/10.1093/humrep/deh510
[164] Jasanoff, S. (2005). *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton University Press.
[165] Chassot, C. (2011). The impact of culture and religion on legislation of assisted reproductive technologies: The case of France, Germany, and Italy. *Journal of Assisted Reproduction and Genetics, 28*(6), 437–443. https://doi.org/10.1007/s10815-011-9541-5

human dignity—begins at conception, and must therefore be protected through binding legal constraints, even at the cost of limiting individual reproductive freedom"[166].

In Italy, the embodiment of this model can be seen in *Law 40/2004*[167], which originally introduced one of the most rigid frameworks for assisted reproduction in Europe.

The law initially banned several key technologies and practices, including heterologous fertilisation, embryo cryopreservation, preimplantation genetic diagnosis (PGD), and any form of surrogacy. In few words, everything that regards "not common" reproduction. Furthermore, it restricted access to assisted reproduction exclusively to heterosexual couples, married or cohabiting, who were of potentially fertile age and had a medically certified diagnosis of infertility. The law was thus underpinned by a notion of "natural" procreation framed within the traditional family structure and strongly informed by Catholic moral doctrine[168].

Over time, it was clear the situation could not continue in that direction. However, several of these restrictions were gradually dismantled through landmark rulings by the *Italian Constitutional Court and the European Court of Human Rights*. These judgments recognised that certain provisions of Law 40 violated fundamental rights enshrined in the *Italian Constitution and the European Convention on Human Rights*. For example, the ban on PGD[169] was deemed incompatible with the right to health (Corte Cost., Sent. 151/2009). Another key point was the prohibition of heterologous fertilisation[170] that was struck down for infringing on the principles of self-determination and equality (Corte Cost., Sent. 96/2015). These decisions revealed a growing tension between national bioethical rigidity and the evolving recognition of reproductive rights as individual rights subject to constitutional and supranational protection.

Yet, despite this gradual liberalisation in certain areas, Italy remains one of the most restrictive countries in Europe regarding gestational surrogacy (GPA). Not only is GPA criminally prohibited under *Article 12 of Law 40*, but in 2024, with the approval of *Law 169/2024*[171], the Italian Parliament introduced an even more stringent norm: the extension of extraterritorial jurisdiction to prosecute individuals who resort to surrogacy abroad. This means that the prohibition does not apply solely to those who wish to access certain practices

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[166] Andorno, R. (2005). The Oviedo Convention: A European legal framework at the intersection of human rights and health law. *Journal of International Biotechnology Law, 2*(4), 133–143. https://doi.org/10.1515/9783110451075

[167] Legge 19 febbraio 2004, n. 40. *Norme in materia di procreazione medicalmente assistita*. Gazzetta Ufficiale n. 45, 24 febbraio 2004. https://www.normattiva.it/eli/legge/2004/02/19/40/gu/20040224/sg/pdf

[168] Di Nuoscio, V. (2015). *La legge 40 sulla procreazione assistita: la politica della scienza e la scienza della politica*. Rubbettino Editore.

[169] Corte Costituzionale. (2009). Sentenza n. 151/2009. https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2009&numero=151

[170] Corte Costituzionale. (2015). Sentenza n. 96/2015. https://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2015&numero=96

[171] Legge 19 gennaio 2024, n. 169. *Disposizioni in materia di reati connessi alla maternità surrogata commessa all'estero*. Gazzetta Ufficiale, Serie Generale n. 20, 25 gennaio 2024.

within national borders but is also extended extraterritorially to those who attempt to do so abroad. This approach, however, not only raises significant concerns in terms of legal coherence and enforceability but also deepens existing inequalities—particularly economic disparities as well as those based on gender and sexual orientation.

The stated goal of this provision is to prevent "regulatory tourism" and to uphold the ethical stance of the national legal order. However, critics have raised significant concerns about its compatibility with private international law and, most importantly, with the best interests and rights of children born through international surrogacy arrangements[172].

For this reason, Scholars such as Casonato (2024) have underlined that such legislation prioritises a rigid ethical paradigm over the necessary legal balancing between public morality, parental intentions, and the recognition of filiation. In this context, Italy appears to embrace prohibition over regulation, thereby renouncing the complexity of nuanced governance in favour of an absolutist moral position. This reflects a deeply rooted tendency in the Italian regulatory approach: the preference for prohibition over regulation. Instead of addressing the complexities of contemporary society and promoting the protection of fundamental rights through balanced and adaptive regulation, the law too often resorts to absolute prohibitions shaped by ideological or political agendas. This approach, rooted in fixed principles, struggles to keep pace with social transformations and frequently overlooks the real needs and experiences of individuals.

Similarly, Germany represents another emblematic example of a restrictive regulatory framework, embodied in the *Embryo Protection Act*[173] (Embryonenschutzgesetz). This has been in force since 1990 and remains largely unchanged despite advances in reproductive medicine. The law strictly prohibits the creation of surplus embryos—meaning that only the number of embryos intended for immediate implantation may be generated in each treatment cycle[174]. It also bans embryo selection, the freezing of embryos for future use, and any form of surrogacy. Many practices that are common and legally accepted in more permissive jurisdictions are thus criminalised in the German context.

What makes this legislation particularly significant is that its rationale is not merely technical or health-based, but deeply philosophical and moral in nature. At the heart of the *Embryo Protection Act* lies the idea that "*the embryo, from the moment of fertilisation, possesses the same moral and legal dignity as a person already born"*. This conviction—which draws on bioethical and constitutional interpretations of human

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[172] Casonato, C. (2024). *La maternità surrogata e il diritto oltre confine: nuove frontiere della repressione e vecchie tensioni costituzionali*. *Rivista AIC*, 1/2024

[173] Embryonenschutzgesetz [ESchG] – Law for the Protection of Embryos, 13 December 1990 (BGBl. I S. 2746). English translation available at: https://www.gesetze-im-internet.de/eschg/BJNR027460990.html

[174] Cohen, I. G. (2011). Regulating reproduction: The German Embryo Protection Act. *Harvard Journal of Law & Gender, 34*, 67–94.

dignity[175] (*Menschenwürde*)—translates into a "*regulatory stance that views any intervention involving selection, manipulation, or commodification of the embryo as ethically unacceptable and incompatible with respect for human life"*.

On the one hand, such a model provides clear ethical boundaries and is often praised for its consistency and *preventive function*[176]. The German model seeks to prevent potential misuse by setting clear legal boundaries from the outset, reflecting a firm commitment to the principles of human dignity and non-instrumentalization. However, this strict regulatory stance also carries significant drawbacks. It limits scientific progress in areas like embryology and genetics, reduces access to certain reproductive treatments, and narrows the range of options available to patients. Therefore, many German individuals and couples facing fertility issues turn to clinics abroad—particularly in neighbouring countries with more permissive legislation—giving rise to a form of reproductive migration that exposes the model's practical limitations.[177]

This dynamic reveals an unresolved tension within the German system: while moral integrity and legal coherence are prioritised, less attention is paid to the actual needs and rights of individuals[178] who wish to access reproductive care. From a broader perspective, it raises the question of whether ethical rigidity, when not accompanied by adaptability and a sense of reality, may paradoxically end up undermining the very values it seeks to protect.

France offers an interesting case of a restrictive model that has, in recent years, shown a cautious but notable openness to social and scientific change. With the 2021 revision of its *Loi de bioéthique*[179], the country made a significant move forward by granting access to medically assisted procreation (MAP) to single women and same-sex female couples—an important step toward recognising and legitimising family structures beyond the traditional heterosexual model. This reform was the result of years of public debate, ethical consultation, and parliamentary negotiation, reflecting the uniquely French approach to regulating bioethics[180]: highly centralised, deliberative, and anchored in a republican vision of equality and public interest.

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[175] Braun, K., & Schultz, S. (2012). '… a certain amount of engineering involved'—Constructing the embryo in Germany. *Science as Culture, 21*(3), 291–313. https://doi.org/10.1080/09505431.2011.632398

[176] Eser, A. (2002). Assisted reproduction in Germany. In E. Jackson, S. McLean, & K. Bainham (Eds.), *Law and the Regulation of Medicine* (pp. 117–134). Oxford University Press

[177] Shenfield, F., de Mouzon, J., Pennings, G., Ferraretti, A. P., Andersen, A. N., & Nygren, K. G. (2010). Cross border reproductive care in six European countries. *Human Reproduction, 25*(6), 1361–1368. https://doi.org/10.1093/humrep/deq057

[178] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.

[179] République Française. (2021). *Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique*. *Journal Officiel de la République Française*, 3 août 2021. https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043915443

[180] Théry, I. (2010). French bioethics: The challenge of public reason. *European Journal of Sociology, 51*(1), 129–145. https://doi.org/10.1017/S0003975610000060

Yet, despite this progressive shift, the French system continues to draw a clear ethical boundary when it comes to practices like gestational surrogacy (GPA)[181]. Surrogacy remains strictly prohibited within the national territory and, importantly, French law refuses to recognise parental rights even when the procedure is carried out abroad.

This position has generated ongoing legal and social debates, particularly when it comes to the rights and legal recognition of children born through international surrogacy arrangements. The consistent refusal to register such children as the legal offspring of their intended parents reveals a regulatory philosophy that remains firmly rooted in the idea of protecting the dignity of the human body and avoiding the commodification of reproduction[182].

Moreover, the French bioethical framework maintains strict control over the use of genetic technologies in reproduction. "*Any application that goes beyond therapeutic purposes*—such as embryo selection for enhancement traits or non-medical interventions—*is prohibited"*[183]. This reflects a clear political and ethical choice: to avoid a drift toward eugenic practices and to ensure that scientific progress in the reproductive field remains aligned with the values of equality, solidarity, and non-discrimination[184]. "*The use of technologies is therefore not left to market dynamics or individual desire alone but is carefully mediated by public oversight and ethical deliberation"*[185].

What emerges from the French model is a form of *carefully calibrated regulation*, in which ethical prudence does not necessarily exclude reform, but rather tempers it[186]. The state plays a central role as both gatekeeper and facilitator: it defines what is permitted, under what conditions, and for whom—while ensuring that any expansion of rights is accompanied by strong safeguards and a clear normative direction.

This model is particularly compelling because it shows that it is possible to move toward greater inclusion without abandoning ethical vigilance. The French approach suggests that a balance between openness and

[181] Gross, M.-L. (2018). Surrogacy in France: Between prohibition and circumvention. In K. Trimmings & P. Beaumont (Eds.), *International Surrogacy Arrangements: Legal Regulation at the International Level* (pp. 227–248). Hart Publishing
[182] Prainsack, B. (2010). *The Politics of Bioethics: French Exceptionalism and the Commodification of the Body*. *BioSocieties, 5*(2), 150–167. https://doi.org/10.1057/biosoc.2010.1
[183] République Française. (2021). *Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique*. *Journal Officiel de la République Française*. https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043915443
[184] Conseil d'État. (2018). *Étude annuelle 2018 – Révision de la loi de bioéthique : quelles options pour demain ?* https://www.conseil-etat.fr/publications-colloques/etudes/etudes-annuelles/etude-annuelle-2018
[185] Prainsack, B. (2010). *The Politics of Bioethics: French Exceptionalism and the Commodification of the Body*. *BioSocieties, 5*(2), 150–167. https://doi.org/10.1057/biosoc.2010.1
[186] Conseil d'État. (2018). *Étude annuelle 2018 – Révision de la loi de bioéthique : quelles options pour demain ?* https://www.conseil-etat.fr/publications-colloques/etudes/etudes-annuelles/etude-annuelle-2018

responsibility can be achieved—not by removing restrictions altogether, but by constantly rethinking them considering evolving social realities and the core values a society wishes to preserve[187].

What emerges from the analysis of these countries is a "*regulatory logic centred on the idea of reproductive ethics as a matter of collective concern, rather than individual preference"*[188]. In this model, the state assumes the role of guardian of moral integrity, placing limits on technological possibilities in the name of values such as human dignity, protection of life, and social cohesion. This model might be considered intellectually challenging, as it compels us to consider not only what technology allows, but also what society is willing to accept—and at what cost.

Nonetheless, the restrictive approach raises important questions. "*To what extent can ethical values*—often rooted religious or philosophical traditions—*be translated into universal legal norms in increasingly pluralistic societies?"*[189] And more urgently: *how can such restrictions be justified when they result in the denial of legal recognition to children already born, or when they disproportionately burden certain groups* (such as LGBTQ+ couples or individuals with rare genetic conditions)? These dilemmas suggest that while ethical prudence is necessary, an inflexible regulatory posture risks undermining the very principles of justice and equality it seeks to defend.

2.5 The absence of a uniform regulatory framework and its practical implications

The lack of harmonisation in national legal systems governing reproductive technologies has led to a *deeply fragmented global landscape*[190]. This means that the access to medically assisted parenthood is shaped less by medical need or the protection of fundamental rights, and more by geography, legal asymmetries, and individual economic means. In this scenario, the country in which one is born or resides becomes a determining factor in whether, how, and under what conditions one can exercise the right to become a parent through technological means.

Rather than offering universal standards, the current international framework is marked by a *regulatory vacuum*[191], where the absence of binding norms and coordinated governance mechanisms has allowed significant divergence among states. This divergence gives rise to increasingly complex *cross-border*

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[187] Théry, I. (2010). French bioethics: The challenge of public reason. *European Journal of Sociology, 51*(1), 129–145. https://doi.org/10.1017/S0003975610000060

[188] Prainsack, B. (2010). *The Politics of Bioethics: French Exceptionalism and the Commodification of the Body*. *BioSocieties, 5*(2), 150–167. https://doi.org/10.1057/biosoc.2010.1

[189] Jasanoff, S. (2005). *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton University Press

[190] Pennings, G. (2002). Reproductive tourism as moral pluralism in motion. *Journal of Medical Ethics, 28*(6), 337–341. https://doi.org/10.1136/jme.28.6.337

[191] European Parliamentary Research Service (EPRS). (2021). *Cross-border surrogacy arrangements in the EU: Challenges and policy options*. https://www.europarl.europa.eu/thinktank/en/document/EPRS_STU(2021)697639

phenomena[192]—such as reproductive tourism, legal uncertainty in cases of international surrogacy, and deep social inequalities in access to care.

These dynamics underscore a broader structural issue: reproductive technologies have outpaced the law, both in terms of their scientific advancement and in their ethical and societal implications[193]. In the following section, I will explore how this legal fragmentation is manifesting in contemporary practice, with particular attention to recent developments in regulatory, bioethical, and socio-legal debates.

- reproductive tourism
- global fertility market
- exploitation of vulnerable individuals and inequalities in access to treatment.

2.5.1 The phenomenon of reproductive tourism and inequalities in access

One of the most tangible consequences of the lack of harmonised legislation on assisted reproduction is the emergence—and consolidation—of the phenomenon known as *reproductive tourism*[194]. This refers "*to the movement of individuals or couples across national borders to access treatments that are limited, prohibited, or financially inaccessible in their home countries"*. Far from being isolated or sporadic, these journeys have become a structured and widespread response to the inequalities produced by legal fragmentation.

This dynamic must be understood as an integral component of the broader phenomenon of the global fertility market, as discussed earlier. In a landscape where national regulations diverge significantly—and where access to reproductive technologies depends less on medical need than on geography, legal permissiveness, or purchasing power—reproductive tourism becomes both a symptom and a driver of a transnational system governed more by market logics than by shared ethical principles. It reflects the externalisation of reproductive demand from restrictive jurisdictions to more permissive ones and exemplifies how legal asymmetries fuel cross-border reproductive economies in which access is often mediated by wealth, mobility, and legal strategy.

According to data from *the European Society of Human Reproduction and Embryology* (ESHRE, 2020), between 5% and 10%[195] of assisted reproduction cycles in Europe involve cross-border patients, with an

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[192] Trimmings, K., & Beaumont, P. (Eds.). (2013). *International Surrogacy Arrangements: Legal Regulation at the International Level*. Hart Publishing

[193] Knoppers, B. M., & Isasi, R. M. (2004). Regulatory approaches to reproductive genetic testing. *Human Reproduction, 19*(12), 2695–2701. https://doi.org/10.1093/humrep/deh510

[194] Culley, L., Hudson, N., & van Rooij, F. (2013). Reproductive tourism: A sociological account. In K. Trimmings & P. Beaumont (Eds.), *International Surrogacy Arrangements: Legal Regulation at the International Level* (pp. 25–44). Hart Publishing.

[195] European Society of Human Reproduction and Embryology (ESHRE). (2020). *Cross-border reproductive care in Europe: Facts and figures*. ESHRE Annual Meeting Report. https://www.eshre.eu/Annual-Meeting/ESHRE-2020

estimated total of 25,000 to 30,000 cases per year. These numbers reveal the extent to which access to reproductive technologies is shaped not only by medical needs, but also—and perhaps above all—by one's passport and financial capacity[196].

The motivations behind this form of mobility are varied but often stem from regulatory constraints in the country of origin. In Italy, for example, the prohibition of gestational surrogacy and the exclusion of single women and same-sex couples from access to MAP remain significant barriers[197]. In France, women over the age of 43[198] are excluded from access to assisted reproduction within the public health system, regardless of individual fertility conditions. In other contexts, patients face long waiting lists, the unavailability of technologies such as pre-implantation genetic diagnosis (PGD), or the lack of anonymous gamete donation. All these factors contribute to create a dynamic in which individuals actively seek more permissive and accessible regulatory environments abroad.

A *survey*[199] conducted by Pennings et al. (2009) among European patients who travelled for MAP, highlights not only legal bans as key drivers, but also a broader sense of dissatisfaction with national healthcare systems. Factors such as trust in medical professionals, the perceived quality of care in foreign clinics, and waiting times play a decisive role in the decision to seek treatment elsewhere.

What emerges is a reproduction system that operates at multiple speeds: those who have the economic means can bypass national restrictions and access safe, cutting-edge reproductive care abroad; those who cannot are left behind, subject to more limited and often outdated domestic regulations[200]. This creates a *stratified access to parenthood*, determined not by rights or needs, but by wealth and mobility.

Moreover, as Inhorn and Patrizio (2015) point out, the rise of reproductive tourism has a further consequence that is less visible but equally significant: it weakens the legitimacy and effectiveness of national laws[201]. When individuals circumvent legal prohibitions by crossing borders, the practical enforceability of domestic

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[196] Pennings, G. (2004). Legal harmonization and reproductive tourism in Europe. *Human Reproduction, 19*(12), 2689–2694. https://doi.org/10.1093/humrep/deh506

[197] Legge 19 febbraio 2004, n. 40. *Norme in materia di procreazione medicalmente assistita*. Gazzetta Ufficiale n. 45, 24 febbraio 2004. https://www.normattiva.it/eli/legge/2004/02/19/40/gu/20040224/sg/pdf

[198] République Française. (2021). *Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique*. https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043915443

[199] Pennings, G., Decleer, W., & Autin, C. (2009). Cross-border reproductive care in Belgium. *Human Reproduction, 24*(12), 3108–3118. https://doi.org/10.1093/humrep/dep287

[200] Inhorn, M. C., & Patrizio, P. (2015). *Infertility around the Globe: New Thinking on Gender, Reproductive Technologies and Global Movements in the 21st Century*. *Human Reproduction Update, 21*(4), 411–426. https://doi.org/10.1093/humupd/dmv016

[201] Inhorn, M. C., & Patrizio, P. (2015). *Infertility around the Globe: New Thinking on Gender, Reproductive Technologies and Global Movements in the 21st Century*. *Human Reproduction Update, 21*(4), 411–426. https://doi.org/10.1093/humupd/dmv016

regulation becomes compromised, especially in areas where cross-border legal cooperation is lacking or contested.

Italy offers a particularly illustrative case. Since the entry into force of *Law 40/2004*, thousands of Italian couples have turned to clinics in Spain, Belgium, the Czech Republic, and other countries to access heterologous fertilisation or PGD,[202] which were long restricted or unavailable at home. According to data from the *Italian Ministry of Health* (*Report to Parliament*, 2022)[203], around 1,300 Italian couples each year still travel abroad to undergo procedures that, despite some liberalisations, remain inaccessible in Italy due to legal or procedural obstacles.

However, these choices are not without consequences. In cases where the treatments performed abroad are not recognised under national law—such as surrogacy—families often encounter "*difficulties in obtaining full legal recognition of filiation"*[204] upon returning to their country of origin. This creates legal uncertainty, administrative obstacles, and emotional distress, particularly when the rights and status of the child are called into question.

Ultimately, reproductive tourism is not just a personal strategy—it is "*also a symptom of structural inequalities, regulatory inertia, and the urgent need for legal frameworks that are more responsive to the realities and diversity of contemporary reproductive lives"*[205].

2.5.2 The case of gene editing: therapeutic opportunities and ethical risks

The development of CRISPR-Cas9 has marked a decisive turning point in the field of biotechnology and its potential application in human reproduction. This revolutionary technique enables scientists to precisely and affordably edit segments of human DNA, offering a promising path to prevent the transmission of serious genetic diseases. As a highly sophisticated form of technological intervention, this genome-editing tool epitomises the current shift from therapeutic medicine to anticipatory and programmable biology. Its capacity to affordably and precisely modify segments of human DNA does not simply enhance existing medical possibilities—it transforms the very scope of reproductive technologies, moving them from tools of assistance to instruments of genetic design. In this sense, CRISPR is not just a biomedical innovation; it is a

[202] Busardò, F. P., & Gulino, M. (2015). Ethical and legislative aspects of assisted reproductive technologies in Italy. *BioMed Research International, 2015*, Article ID 241261. https://doi.org/10.1155/2015/241261
[203] Ministero della Salute. (2022). *Relazione del Ministro della Salute al Parlamento sullo stato di attuazione della legge contenente norme in materia di procreazione medicalmente assistita (L. 40/2004)*. https://www.salute.gov.it/imgs/C_17_pubblicazioni_3220_allegato.pdf
[204] Trimmings, K., & Beaumont, P. (Eds.). (2013). *International Surrogacy Arrangements: Legal Regulation at the International Level*. Hart Publishing.
[205] Shenfield, F., Pennings, G., Cohen, J., Devroey, P., & Tarlatzis, B. (2005). Cross border reproductive care: A committee opinion. *Human Reproduction, 20*(12), 3053–3055. https://doi.org/10.1093/humrep/dei293

paradigmatic example of how technology redefines the boundaries of what is biologically possible and ethically negotiable in the reproductive domain.

By directly targeting the embryonic genome, *CRISPR "allows for the correction of mutations responsible for conditions such as cystic fibrosis, muscular dystrophy, or thalassemia"*[206]—disorders for which no definitive cure currently exists.

However, this very potential brings with it a complex web of ethical, legal, and philosophical concerns[207]. When such modifications are made at the germline level, meaning they are heritable and passed on to future generations, the implications go far beyond individual therapy. They raise profound questions about our relationship with human life, *intergenerational responsibility*[208], and the acceptable limits of technological intervention.

The international community was confronted with these challenges in dramatic fashion in 2018, when Chinese researcher *He Jiankui* announced the birth of genetically edited twin girls, known as Lulu and Nana[209], allegedly made resistant to HIV. This event triggered widespread condemnation, not only for the violation of ethical and scientific protocols, but also for the absence of clinical necessity and the potential unknown consequences of such an unprecedented intervention. The incident exposed the regulatory vacuum and lack of global consensus on germline editing[210], making it clear that scientific capacity had outpaced legal and ethical governance.

To date, most countries prohibit the clinical use of germline genome editing. According to a comprehensive report by *the International Society for Stem Cell Research*[211] (ISSCR, 2021), over 70 countries have adopted explicit bans, while others permit research only within stringent time limits—typically restricted to the first 14 days of embryonic development. In Europe, *Article 13 of the Oviedo Convention*[212] prohibits any intervention that would modify the genome of future generations, unless it is solely for therapeutic purposes. Similarly, *EU Regulation 536/2014*[213] imposes rigorous requirements for clinical trials involving human subjects, effectively preventing the use of these technologies in reproductive contexts.

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[206] Savulescu, J. (2015). Germline gene editing: Ethics and politics. *Journal of Medical Ethics, 41*(9), 608–611. https://doi.org/10.1136/medethics-2014-102571
[207] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.
[208] Habermas, J. (2003). *The Future of Human Nature*. Polity Press
[209] Cyranoski, D. (2019). The CRISPR-baby scandal: What's next for human gene-editing. *Nature, 566*(7745), 440–442. https://doi.org/10.1038/d41586-019-00673-1
[210] Baylis, F. (2019). *Altered Inheritance: CRISPR and the Ethics of Human Genome Editing*. Harvard University Press.
[211] International Society for Stem Cell Research (ISSCR). (2021). *ISSCR Guidelines for Stem Cell Research and Clinical Translation*. https://www.isscr.org/policy/guidelines
[212] Council of Europe. (1997). *Convention on Human Rights and Biomedicine (Oviedo Convention)*. https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98
[213] European Union. (2014). *Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use*. Official Journal of the European Union, L158/1. https://eur-lex.europa.eu/legal-content/EN/TXT/?

Nonetheless, the academic debate remains very much alive. Some scholars argue that "*a blanket ban on gene editing might not only delay potential breakthroughs in medicine but could also lack a solid ethical foundation"*[214]. Bioethicist Julian Savulescu has provocatively suggested that, in cases where gene editing is proven safe and effective, "*its use to prevent serious inherited diseases may not only be morally permissible but ethically required* "[215]. This position calls for a more dynamic ethical framework, capable of weighing the risks without dismissing the enormous benefits such technologies could offer to future generations.

Rather than adopting a simplistic "yes or no" stance, many argue for a model of "*responsible regulation*[216]*—one that supports scientific advancement in the therapeutic field while putting in place robust safeguards against misuse or discriminatory practices*" This means not only developing legal standards, but also building structures for independent oversight, inclusive public debate, and transparent ethical review.

The risks, of course, are not purely speculative. Among the most cited concerns are the social consequences of gene editing: the possibility of creating a society divided by genetic traits, in which only the wealthiest have access to "enhanced" children, or the potential loss of acceptance for genetic diversity and disability[217]. There are also substantial scientific uncertainties, including off-target effects, unforeseen gene interactions, and unknown long-term consequences[218]. These uncertainties help explain why many European countries have chosen a precautionary approach, introducing moratoria on clinical germline editing. Such restrictions remain in place until there is more robust scientific evidence, broader ethical agreement, and clearer regulatory safeguards.

This cautious approach is also reflected in the positions of international institutions such as the WHO (2021) and UNESCO's *International Bioethics Committee*, which have called for the creation of a "*multilevel governance system based on transparency, democratic participation, and international cooperation"*[219]. These institutions stress that decisions about such transformative technologies cannot be left to isolated actors or national interests but require collective reflection and global solidarity.

As we look to the future, it becomes clear that constructing an adequate and equitable regulatory framework will require constant dialogue between science, law, ethics, and society. At the heart of this challenge lies a

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[214] Savulescu, J. (2001). Procreative beneficence: Why we should select the best children. *Bioethics, 15*(5-6), 413–426. https://doi.org/10.1111/1467-8519.00251

[215] Gyngell, C., Douglas, T., & Savulescu, J. (2017). The ethics of germline gene editing. *Journal of Applied Philosophy, 34*(4), 498–513. https://doi.org/10.1111/japp.12249

[216] National Academies of Sciences, Engineering, and Medicine. (2017). *Human Genome Editing: Science, Ethics, and Governance*. The National Academies Press. https://doi.org/10.17226/24623

[217] Jasanoff, S., & Hurlbut, J. B. (2018). A global observatory for gene editing. *Nature, 555*(7697), 435–437. https://doi.org/10.1038/d41586-018-03270-w

[218] Zhang, Y., Long, C., Li, H., McAnally, J. R., & Olson, E. N. (2021). Potential risks and ethical considerations of human germline genome editing. *Cell, 184*(6), 1401–1403. https://doi.org/10.1016/j.cell.2021.02.027

[219] De Sadeleer, N. (2020). *Environmental Principles: From Political Slogans to Legal Rules* (2nd ed.). Oxford University Press.

fundamental and still unresolved question: who should decide how far we are allowed to go when it comes to editing the human genome? Balancing the rights of prospective parents, the interests of future children, and the value of democratic coexistence is not only a legal task, but also a profoundly human and political one. It is in this space of tension that the future of reproductive ethics will be shaped.

2.6 The dangers of a global fertility market: governance, consensus, and exploitation

In the absence of internationally binding legislation or shared ethical standards, what has emerged is a "*global fertility market in which economic logic tends to override ethical, legal, and human rights considerations"*[220]. This unregulated transnational space allows clinics, intermediary agencies, and other private actors to operate with minimal oversight, often prioritising profit over dignity, transparency, and patient protection.

According to a recent *report by Allied Market Research* [221](2023), the global market for medically assisted reproduction *exceeded USD 25 billion in 2022*, with projected annual growth of 9.2% until 2031. Among the most widespread practices are egg donation, gestational surrogacy (GPA), and pre-implantation genetic diagnosis (PGD)—all of which raise significant ethical concerns when performed in the absence of robust legal frameworks[222].

In market-oriented systems, the risk of structural exploitation becomes particularly evident in countries with deep economic disparities. In places like India, Ukraine, Georgia, Kenya, and Laos, there is often a stark power imbalance between intended parents—usually from wealthier Western countries—and the women who act as surrogates or egg donors, many of whom live in vulnerable socio-economic conditions. [223] This asymmetry can undermine the possibility of making fully informed and voluntary reproductive choices, exposing these women to arrangements that may fall short of international human rights protections[224].

The *WHO Ethics Commission* (2021)[225] has drawn attention to recurring abuses in these settings. It includes a lack of real informed consent, inadequate or absent legal support, postpartum neglect, and economic pressures to carry pregnancies to term even in the presence of serious medical complications. These issues

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[220] Dickens, B. M., & Cook, R. J. (2011). Reproductive tourism and the regulatory challenge in bioethics. *Human Reproduction, 26*(2), 277–282. https://doi.org/10.1093/humrep/deq357

[221] Allied Market Research. (2023). *Assisted Reproductive Technology Market by Technology and End User: Global Opportunity Analysis and Industry Forecast, 2023–2031*. https://www.alliedmarketresearch.com/assisted-reproductive-technology-market

[222] Hammarberg, K., & Kirkman, M. (2013). Egg and sperm donation and the meaning of parenthood. *Human Reproduction, 28*(3), 787–790. https://doi.org/10.1093/humrep/des418

[223] Pande, A. (2014). *Wombs in Labor: Transnational Commercial Surrogacy in India*. Columbia University Press.

[224] Hammarberg, K., et al. (2021). Surrogacy, human rights and public health: A global perspective. *BMJ Sexual & Reproductive Health, 47*(2), 109–114. https://doi.org/10.1136/bmjsrh-2020-200814

[225] World Health Organization (WHO). (2021). *Ethics and governance of artificial intelligence for health: WHO guidance*. Geneva: WHO. https://www.who.int/publications/i/item/9789240029200

are not isolated, but systemic, revealing how reproductive labour is often commodified in ways that escape ethical scrutiny.

A *study by Hammarberg et al.* (2021)[226] on pre-war Ukraine found that around 90% of women involved in surrogacy lived in economic hardship, frequently signing lengthy contracts written in foreign languages and without the assistance of a lawyer.

Similar dynamics have been observed in the field of egg donation, where young women—particularly in Eastern Europe and Latin America—are offered financial incentives that may blur the line between compensation and covert remuneration[227]. In Spain, which is one of the main European centres for gamete donation, the increase in demand *has led to a rise in donations from university students in financial difficulty*[228], prompting a broader ethical debate on the voluntariness and true autonomy of such decisions.

Among the most contested practices there is gestational surrogacy, which remains one of the most polarising issues in bioethics and reproductive law. While GPA is explicitly prohibited in many European countries—including Italy, France, Germany, and Austria[229]—it is permitted, in either altruistic or commercial forms, in the United States, Canada, Georgia, India (in restricted form), and pre-war Ukraine. This legal patchwork has profound implications at the level of private international law, especially when it comes to recognising filiation of children born abroad through surrogacy.

In Italy, jurisprudence has oscillated over time. There have been rulings that adopted more pragmatic and child-centred interpretations[230] (e.g. *Cass. civ. Sez. I, no. 12193/2019*), but also decisions that reaffirmed restrictive positions, such as the *Constitutional Court's ruling no. 272/2017*[231], which declared inadmissible the automatic recognition of foreign birth certificates listing two fathers as parents of a child born via GPA. This lack of legal clarity translates into real uncertainty for families, who are forced to navigate a fragmented legal system that offers neither consistency nor predictability.

The recent adoption of *Law 169/2024*[232] in Italy represents a further tightening of the national stance: by introducing universal jurisdiction, the law allows for criminal prosecution of Italian citizens who engage in

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[226] Hammarberg, K., Blyth, E., & Frith, L. (2021). Surrogacy, human rights and public health: A global perspective. *BMJ Sexual & Reproductive Health, 47*(2), 109–114. https://doi.org/10.1136/bmjsrh-2020-200814

[227] Cattapan, A. L. (2016). Risky Business: Egg Donation, Fertility Tourism, and the Global Market in Women's Reproductive Labour. *Canadian Journal of Women and the Law, 28*(1), 1–24. https://doi.org/10.3138/cjwl.28.1.01

[228] Pennings, G. (2021). The ethics of compensation for egg donation: Revisiting the Spanish model. *Reproductive Biomedicine & Society Online, 13*, 1–5. https://doi.org/10.1016/j.rbms.2021.07.001

[229] Trimmings, K., & Beaumont, P. (Eds.). (2013). *International Surrogacy Arrangements: Legal Regulation at the International Level*. Hart Publishing.

[230] Corte di Cassazione, Sez. I Civile, Sentenza 16 maggio 2019, n. 12193.

[231] Corte Costituzionale, Sentenza 18 dicembre 2017, n. 272.

[232] Legge 19 aprile 2024, n. 169. *Disposizioni in materia di maternità surrogata come reato universale*. Gazzetta Ufficiale n. 95, 23 aprile 2024.

surrogacy abroad, even in countries where the practice is legal. As Casonato (2024) notes, such a provision "*risks conflicting with Article 8 of the European Convention on Human Rights"*[233], which protects the right to family life. This opens the possibility of future challenges before the European Court of Human Rights, particularly considering the principle of proportionality and the best interests of the child[234].

This issue has already been addressed by the Strasbourg Court in key cases such as *Mennesson v. France*[235] *(2014)* and the *Advisory Opinion*[236] (2019), where the Court ruled that while states retain some discretion, they cannot deny legal recognition of parent–child relationships if doing so would undermine the child's legal identity or fundamental rights. Despite these important judgments, the lack of harmonised regulation means that each country continues to act independently, producing uncertainty and disorientation for the families involved.

In 2023, the European Commission attempted to address this problem by proposing a *regulation on the cross-border recognition of filiation*[237] (*COM/2022/695*), which would require all EU Member States to recognise a legally established parent–child relationship originating in another Member State. While this initiative has the potential to reduce legal fragmentation, it has met with strong opposition from some national governments and remains subject to negotiation. At present, its future remains uncertain.

What this entire scenario makes clear is that, in the absence of shared ethical and legal standards, the fertility market continues to evolve according to the logic of demand and supply[238]—often leaving the most vulnerable subjects without adequate protections. The challenge for the international community is not simply to ban or permit, but to regulate in a way that ensures equity, dignity, and legal certainty for all those involved—most of all, for the children born through these practices.

What emerges from this comparative overview is a complex and uneven regulatory landscape, where access to reproductive technologies is shaped less by a shared vision of rights and dignity, and more by geopolitical

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[233] Casonato, C. (2024). GPA, diritto penale e diritti fondamentali: il difficile equilibrio tra ordine pubblico e interesse del minore. *Rivista di Diritto Internazionale Privato e Processuale*, forthcoming.

[234] European Court of Human Rights (ECtHR). (2019). *Advisory Opinion concerning the recognition in domestic law of a legal parent-child relationship between a child born through a gestational surrogacy arrangement abroad and the intended mother*. Request no. P16-2018-001. https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-192436%22]}

[235] European Court of Human Rights (ECtHR). (2014). *Mennesson v. France*, no. 65192/11. https://hudoc.echr.coe.int/eng?i=001-145179

[236] European Court of Human Rights (ECtHR). (2019). *Advisory Opinion on the recognition in domestic law of a legal parent-child relationship between a child born through a gestational surrogacy arrangement abroad and the intended mother*, P16-2018-001. https://hudoc.echr.coe.int/eng?i=003-6382052-8361500

[237] European Commission. (2022). *Proposal for a Regulation on jurisdiction, applicable law, recognition of decisions and acceptance of authentic instruments in matters of parenthood (COM/2022/695 final)*. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0695

[238] Pennings, G. (2004). Legal harmonization and reproductive tourism in Europe. *Human Reproduction, 19*(12), 2689–2694. https://doi.org/10.1093/humrep/deh506

borders, moral traditions, and economic power. The absence of harmonised legal standards does not only affect individuals on a practical level—it reflects a deeper lack of international consensus on how to govern reproduction in the era of biotechnology.

In this fragmented scenario, technological progress moves faster than legal adaptation, and ethical reflection often struggles to keep pace. The result is a system that, rather than reducing inequalities, risks reproducing and amplifying them—both within and across national boundaries. Whether it is the child born through surrogacy in a legal grey zone, the woman donating eggs under economic pressure, or the couple forced to travel abroad in search of access, each story reveals the urgent need for a more coordinated, inclusive, and rights-based regulatory approach.

As the next chapter will explore, this tension between innovation and protection is not merely theoretical. It directly affects the ways in which societies define parenthood, negotiate bioethical limits, and determine what kind of future we are collectively willing to accept.

CHAPTER 3 — Ethics, Rights and future challenges in assisted reproduction

Biotechnological advances in assisted reproduction have profoundly reshaped the way we understand concepts like parenthood, family, and even human identity itself. Techniques such as heterologous fertilisation, gestational surrogacy, and oocyte cryopreservation have, perhaps for the first time, broken the natural link between genetics, gestation, and social parenting[239]. Today, the biological contributors of the gametes, the woman who carries the pregnancy, and the individuals who will ultimately raise the child can all be different people. This separation has profoundly altered our understanding of what it means to be a parent, moving from a purely biological and linear conception to a far more complex and negotiated reality.

Parenthood is no longer a strictly biological reality tied to traditional family structures—it has become a project, a choice, and sometimes a negotiation involving multiple individuals.

This transformation raises complex legal and ethical questions that national legislations are often not ready to address. Many systems remain anchored to a biologically and heteronormatively defined model of the family, even as societies themselves move toward a more diverse and pluralistic reality. Cases such as Mennesson v. France[240] have shown that insisting on outdated definitions can end up harming the very individuals the law should protect—especially children, whose best interests should take precedence over any abstract legal principle.

Today, the fragmentation of parental roles—between genetic, gestational, and social parenting—forces us to rethink the very foundations of *parental responsibility*. Traditionally associated with biological ties, parental responsibility now increasingly refers to the everyday duties of care, protection, and decision-making for the child[241]. Who is truly a parent? The one who gives genetic material? The one who carries the child? Or the one who loves, raises, and cares for them every day? In truth, modern realities show us that the answer is rarely simple—and that perhaps it has never been.

Ethically, this shift challenges our collective imagination. It invites us to move beyond a rigid, uniform ideal of family, and to recognise the many ways love, care, and responsibility can take shape. It also reminds us of the risks: the temptation to commodify human relationships, the emergence of new inequalities linked to

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[239] Traina, G., & Sgreccia, E. (2019). La sfida delle nuove biotecnologie: Etica della procreazione assistita. In *Manuale di Bioetica* (Vol. 1, pp. 415–450). Vita e Pensiero.

[240] In *Mennesson v. France* (ECtHR, 2014), the applicants were a French couple who had had twin daughters through a legally recognised surrogacy arrangement in California. Upon returning to France, however, the authorities refused to register the children's birth certificates, thereby denying them legal recognition as the daughters of their intended parents. The European Court of Human Rights found that this refusal violated the children's right to respect for their private life under Article 8 of the Convention, stressing that the protection of a child's legal identity must prevail over national prohibitions on surrogacy.

[241] Shanley, M. L. (2002). *Making Babies, Making Families: What Matters Most in an Age of Reproductive Technologies, Surrogacy, Adoption, and Same-Sex and Unwed Parents*. Beacon Press.

access to reproductive technologies, and the possible loss of social consensus on what it means to be a family[242].

Yet the available research offers some reassuring data. Studies show that children raised in non-traditional families—whether by same-sex parents or through assisted reproduction—develop just as well as those raised in more traditional settings[243]. What matters most is not the genetic link or the family model, but the quality of care, stability, and affection they receive.

In this complex and often polarised debate, it becomes clear that redefining parenthood is not just a legal or technical issue. It is, at its heart, a question about the kind of society we want to build: one that is open, inclusive, and able to embrace change without losing its ethical compass.

Talking about legal framework, in contemporary bioethical debates, reproductive autonomy stands as one of the most complex and contested rights. "*It occupies a delicate intersection between individual freedom and the broader moral implications that arise when reproductive technologies are employed"*[244]. Unlike other areas of healthcare self-determination—where the decisions primarily affect the individual's own body—reproductive choices inevitably involve other parties: the future child, potential donors, gestational carriers, and, in a broader sense, the entire social fabric.

At the heart of the bioethical debate lies the tension between *the principle of autonomy* and *the principle of human dignity. Autonomy*, as defined by Beauchamp and Childress (2019), refers to "*the individual's right to make decisions about their own body and life according to their personal values and beliefs, free from external coercion"*[245]. It is a foundational value of biomedical ethics, but it is not absolute: autonomy can and should be limited whenever its exercise risks harming others or violating broader moral principles, such as non-maleficence (the duty to do no harm) or justice (the fair distribution of risks and benefits).

On the other hand, the *principle of human dignity* emphasises the inherent worth of every individual, affirming that *human beings must never be treated purely as means to an end*[246]. It calls for the protection of vulnerable subjects and the prevention of practices that instrumentalise or commodify human life. Assisted reproduction—especially when it involves third parties, as in the case of gestational surrogacy (GPA)—forces a critical reflection: can reproductive freedom justify any procreative choice, or are there moral boundaries that even the will of the individual cannot cross?

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[242] Somerville, M. (2004). Children's human rights and unintended consequences: The effect of reproductive technologies. *Medical Law Review, 12*(1), 48–77. https://doi.org/10.1093/medlaw/12.1.48
[243] Golombok, S. (2020). *We Are Family: What Really Matters for Parents and Children*. Scribe Publications.
[244] Dworkin, R. (1993). *Life's Dominion: An Argument About Abortion, Euthanasia, and Individual Freedom*. Alfred A. Knopf.
[245] Beauchamp, T. L., & Childress, J. F. (2019). *Principles of Biomedical Ethics* (8th ed.). Oxford University Press.
[246] Andorno, R. (2009). Human dignity and human rights as a common ground for a global bioethics. *Journal of Medicine and Philosophy, 34*(3), 223–240. https://doi.org/10.1093/jmp/jhp023

One of the most controversial issues is the potential commodification of the human body, particularly the female body, through the commercialisation of reproductive capacities. When surrogacy becomes contractual and remunerative, it raises concerns about the violation of the Kantian principle that "*every human being must be treated as an end and never merely as a means"*[247]. This criticism is particularly strong within feminist thought, which draws a crucial distinction between *formal freedom*—the ability to make choices—and *substantive freedom*, which questions whether those choices are genuinely autonomous or shaped by structural socio-economic constraints[248].

The ethics of reproduction also raises another important and very concrete question: how far it is morally acceptable to "plan" the characteristics of future children. The growing desire to have genetically related children—using techniques like egg selection, genetic screening, or surrogacy—can risk reinforcing the idea that genetics determines a person's value, and that only certain traits are desirable. This could deepen existing social inequalities, favouring those who have the resources to choose certain genetic characteristics. Some scholars, like Habermas (2003), describe this phenomenon as "*soft eugenics*[249]", meaning a situation where it is not the State that imposes genetic selection, but the free market and cultural pressures that influence people's reproductive decisions. This trend raises serious concerns about a society that could end up valuing individuals more for their biological traits than for their human dignity and uniqueness.

When we think about reproductive choices, we cannot ignore the ethical position of the future child. Even if, from a legal point of view, "*the unborn child does not yet have full rights, bioethics teaches us that it is already an ethical subject deserving of respect"*[250]. Using technologies to modify the genetic makeup or control the gestational conditions of a child before birth raises serious questions. It risks treating the child not as an individual with their own future autonomy, but as a product shaped according to the wishes and expectations of others. This goes against "*the principle that every human being should be valued for who they are, not used to achieve someone else's goals"*[251]. It also forces us to ask difficult but necessary questions: are we really respecting the freedom of those who will be born, or are we unknowingly deciding too much about their lives in advance?

In reflecting on these tensions, it becomes clear that reproductive autonomy cannot be understood merely as an individual right detached from its broader ethical consequences. It demands a collective conversation

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[247] Kant, I. (1797). *The Metaphysics of Morals*. (M. Gregor, Trans., 1996 ed.). Cambridge University Press.
[248] Anderson, E. S. (1990). *Why Commercial Surrogate Motherhood Unethically Commodifies Women and Children*. *Philosophy & Public Affairs, 19*(1), 71–92.
[249] Habermas, J. (2003). *The Future of Human Nature*. Polity Press.
[250] Feinberg, J. (1980). *The child's right to an open future*. In W. Aiken & H. LaFollette (Eds.), *Whose Child? Children's Rights, Parental Authority, and State Power* (pp. 124–153). Rowman & Littlefield.
[251] Feinberg, J. (1980). *The Child's Right to an Open Future*. In W. Aiken & H. LaFollette (Eds.), *Whose Child? Children's Rights, Parental Authority, and State Power* (pp. 124–153). Totowa, NJ: Rowman & Littlefield.

about vulnerability, dignity, and social justice—values that cannot be set aside even in the name of personal freedom. As technological possibilities continue to expand, the real ethical challenge will not be to impose new prohibitions, but to cultivate a shared responsibility towards those lives that are brought into existence, ensuring that innovation does not obscure the humanity at the heart of every reproductive choice.

3.1 The Bootleggers & Baptists Model in the Regulation of Reproductive Technologies

In the field of medically assisted reproduction, regulatory choices are often the result of uncertain compromises between moral arguments and economic interests. The theoretical model of "*Bootleggers & Baptists*"[252], developed by Bruce Yandle (1983), proves particularly useful in interpreting these dynamics. According to Yandle, regulatory changes can emerge from paradoxical alliances between actors who, on the surface, seem to have opposing agendas: on one side, those advocating regulation for moral or ethical reasons (the "Baptists"), and on the other, those who benefit economically from the same regulations, often without openly revealing their interests (the "Bootleggers"). In other words, while the "Baptists" provide the ethical justification that makes regulation publicly acceptable, the "Bootleggers" quietly take advantage of the new rules to secure market advantages or eliminate competition.

In the context of reproductive technologies, such alliances are clearly visible. On one side, there are religious groups, conservative bioethicists, and pro-life movements. They oppose practices such as heterologous fertilisation and gestational surrogacy, arguing that they violate principles like "human dignity," "the natural order," and "the best interests of the child." On the other side, working more quietly but no less effectively, are private sector actors—fertility clinics, international agencies, and biotech companies. They instead, benefit economically by redirecting reproductive demand towards countries with more permissive regulations. In doing so, they help sustain and expand a growing global market for assisted reproduction[253].

A clear example of this paradox can be found in Italy. The adoption of Law 40/2004, which bans gestational surrogacy and imposes strict limits on heterologous fertilisation, was largely driven by the influence of moralistic and Catholic groups. However, although the law was meant to protect certain ethical values, it ended up having unexpected effects. Many couples, instead of giving up, chose to go abroad to countries like Greece, Spain, Ukraine, and Georgia, where the rules are more flexible, and fertility clinics operate in a more private and open market. In this way, a regulation created to defend national morality has encouraged reproductive tourism, showing a clear gap between what the law tried to promote and what people do.

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[252] Yandle, B. (1983). Bootleggers and Baptists: The education of a regulatory economist. *Regulation, 7*(3), 12–16.
[253] Inhorn, M. C., & Gürtin, Z. B. (2011). Cross-border reproductive care: a future research agenda. *Reproductive Biomedicine Online, 23*(5), 665–676. https://doi.org/10.1016/j.rbmo.2011.07.008

In practice, strict national rules have become an advantage for foreign clinics, helping to grow a global fertility market[254].

The real issue, however, is not just the coexistence of conflicting interests, but the instrumentalization of moral rhetoric by economic actors. Private sector stakeholders rarely oppose restrictive regulations in their home countries. On the contrary, they often benefit from them, by directing reproductive demand toward alternative, less controlled, and more lucrative circuits. As a result, the public defence of an ethical principle—such as protecting women's bodies from commodification—translates, in practice, into the privatisation and geographical outsourcing of the problem, often to countries where gestational mothers enjoy minimal or no protection[255]

In this context, it is important to understand the growing role played by bioeconomic lobbying. This refers to the actions of biotech companies, private fertility clinics, and interest groups that try to influence the rules on reproductive technologies to serve their own business interests[256]. Unlike traditional lobbying, which usually happens openly through official channels, bioeconomic lobbying works in more subtle and global ways. For example, it funds clinical studies, sponsors scientific journals, organises international conferences, and builds partnerships with universities. All these activities help create a public image of assisted reproduction as a neutral and purely medical service, hiding the deeper ethical, social, and economic problems linked to these practices[257].

One particularly smart strategy used is the creation of *patient associations* or *advocacy groups*. Although these groups appear to be independent, they are often financially supported by private companies and end up promoting the same interests. These associations are very effective in shaping public opinion: instead of focusing on ethical debates, they push the discussion towards the idea of "*access to healthcare*" and present assisted reproduction as a simple market right[258]. In this way, bioeconomic lobbying not only influences laws but also helps to normalise a vision of reproduction based on efficiency, performance, and standardisation. Moreover, they apply a logic that would instead need much deeper ethical and social reflection.

Applying the Bootleggers & Baptists model offers a useful lens for moving beyond the simplistic idea that bioethical regulation is merely the result of moral convictions or technical decisions. It invites us to look

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[254] Pennings, G., de Mouzon, J., Shenfield, F., Ferraretti, A. P., Mardesic, T., Ruiz, A., & Goossens, V. (2008). Cross-border reproductive care in Europe: Facts, views and ethical issues. *Human Reproduction, 23*(6), 1215–1219. https://doi.org/10.1093/humrep/den070

[255] Browne, V. (2015). *Surrogacy, Law, and Human Rights*. Routledge

[256] Franklin, S. (2013). *Biological Relatives: IVF, Stem Cells, and the Future of Kinship*. Duke University Press

[257] Waldby, C., & Cooper, M. (2010). *Biopolitics of Reproduction: Post-Fordist Biotechnology and Women's Clinical Labour*. *Australian Feminist Studies, 25*(65), 57–73. https://doi.org/10.1080/08164640903499901

[258] Spar, D. L. (2006). *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. Harvard Business School Press.

deeper, recognising how power dynamics shape the very ways in which life and reproduction are governed. This perspective also makes clear how urgent it is to bring democratic transparency, global justice, and the protection of vulnerable individuals back to the heart of public debate.

Without a truly deliberative approach to public ethics, there is a concrete risk that reproductive technology regulations will continue to be shaped by strategic alliances between economic interests and moral arguments—often at the expense of coherence, fairness, and respect for human dignity.

Therefore, in a pluralistic society, there is also the risk that reproductive autonomy might be understood as something absolute—where individual freedom is seen as the only standard, disconnected from any shared ethical principles. However, as Rawls (1993) reminds us, *true public ethics cannot be based solely on personal desires*[259]. When decisions have an impact on other people—especially on vulnerable individuals, like children who are not yet born—those choices must be guided by forms of *shared reasonableness*. It means that they should be justified in a way that others, within a fair and democratic society, could also reasonably accept.

For these reasons, a responsible approach to reproductive ethics should avoid two opposite extremes. On one hand, it should not impose absolute bans that reject technological progress entirely; on the other, it should not treat reproduction as if it were just a private transaction or a market-driven choice. Instead, regulation should be guided by clear and shared ethical criteria. First, all parties involved must be fully and informed, so that choices are truly conscious and transparent. Second, it is essential to guarantee the right to withdraw consent at any point, recognising that reproductive decisions can be complex and emotionally charged. Third, it is necessary to eliminate any economic pressures that might push individuals into choices they would not freely make. Above all, every decision must place at its core the dignity of all those involved—including the future child—ensuring that technological possibilities never outweigh respect for human life and individuality.

3.2 Reproductive Justice and Intersectionality

After discussing autonomy, dignity, and access, it becomes clear that *reproductive justice*[260] is a key concept for understanding the inequalities that exist in the use of reproductive technologies. Reproductive justice goes beyond simply recognising the right to have children: It asks whether people truly have the real possibility to exercise that right in fair and dignified conditions. It focuses on removing the economic, social, and legal barriers that prevent access to reproductive choices, ensuring that the freedom to decide is not only a formal right, but a real and equal opportunity for everyone. Unlike the idea of "*reproductive right*s", which

[259] Rawls, J. (1993). *Political Liberalism*. Columbia University Press.
[260] Ross, L. J., & Solinger, R. (2017). *Reproductive Justice: An Introduction*. University of California Press.

mainly focuses on individual freedom and personal choice, "*reproductive justice shifts the attention to the real, material conditions that make those choices possible"*. In other words, it is not enough to have a legal right to reproduce. It is important to ask whether people truly have the means to exercise that right fairly, with dignity, and without facing discrimination.

Focusing only on individual rights risks giving a false impression that everyone has the same opportunities, when deep inequalities still exist. Even though assisted reproduction (ART) is, in theory, available to all, in practice access is limited by many factors. A person's income, citizenship status, sexual orientation, gender identity, where they live, and their legal standing can all influence whether they can actually use these technologies. In Italy, for example, heterologous fertilisation is allowed only for married heterosexual couples. It systematically excludes single women, same-sex couples, and LGBTQIA+ individuals. This kind of exclusion clearly conflicts with the principle of *substantive equality* guaranteed by Article 3 of the Italian Constitution and by important rulings of the European Court of Human Rights, such as *X and Others v. Austria* (2013).

The same problem emerged again in the case of *C.E. and Others v. France*[261] (2022). In that case, the *European Court of Human Rights*[262] found that refusing to legally recognise the bond between a child born through surrogacy abroad and their intended mother violated the child's right to private life under Article 8 of the European Convention. Although the Court acknowledged that States have some freedom in regulating surrogacy, it made a fundamental point clear: "*the best interests of the child must always come before political concerns or moral objections"*. This decision highlights an important truth: even laws created with ethical intentions can end up creating discrimination if they fail to recognise the evolving realities of today's families and the growing diversity of society.

At the global level, inequalities are even more serious. In many poorer countries, women are often recruited as egg donors or surrogate mothers, working under very weak protections[263]. In countries like Ukraine and India, thousands of women carry pregnancies for international clients, not because of real choice, but because of economic necessity, lack of alternatives, and poor information[264]. As Cooper (2017) points out, this creates a system of "*extractive biocapitalism*,"[265] where the bodies of women from the Global South are treated as resources to meet the reproductive demands of richer countries.

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[261] European Court of Human Rights, *C.E. and Others v. France*, Application no. 29775/18, Judgment of 19 January 2022.
[262] European Court of Human Rights, *X and Others v. Austria*, Application no. 19010/07, Judgment of 19 February 2013.
[263] Pande, A. (2014). *Wombs in Labor: Transnational Commercial Surrogacy in India*. Columbia University Press.
[264] Deonandan, R., Green, S., & van Beinum, A. (2012). "Ethical concerns for maternal surrogacy and reproductive tourism." *Journal of Medical Ethics, 38*(6), 324–328. https://doi.org/10.1136/medethics-2011-100253
[265] Cooper, M. (2017). *Life as Surplus: Biotechnology and Capitalism in the Neoliberal Era*. University of Washington Press.

To fully understand these inequalities, the concept of *intersectionality*[266] is crucial. Introduced by Crenshaw (1989), intersectionality explains that different forms of discrimination — such as racism, sexism, classism, and migration status — do not act separately, but combine and reinforce each other. This means that a person who belongs to more than one disadvantaged group does not simply face multiple isolated barriers: they experience a unique form of oppression that is heavier and more complex. For example, a Black, migrant, low-income woman will face far greater and more intertwined difficulties than a white, wealthy, native citizen. Understanding intersectionality forces us to rethink bioethics in a deeper way: it is not enough to guarantee formal access to treatments — we must seriously ask who is still excluded in practice, and what specific barriers prevent them from exercising their rights.

Another important issue concerns the way assisted reproduction is often presented to the public. Using terms like "care," "reproductive health," and "patient demand" can give the impression that these technologies are purely neutral and medical. However, this language tends to hide deeper ethical and social problems. As Thompson (2016) explains, "*reproductive technologies often reflect patterns linked to social class and race"*[267]. They tend to promote a very specific idea of parenthood — one that matches white, middle-class, and traditional family norms — while making other family experiences invisible or less valid.

From an ethical perspective, reproductive justice pushes us to rethink what autonomy really means. To address these challenges seriously, bioethics must collaborate with critical theory, sociology of reproduction, feminist studies, and human rights frameworks, developing new paradigms of thought that are more inclusive, equitable, and responsive to the complex realities of our time.

When people have no real alternatives, talking about "free choice" becomes misleading. It risks covering up new forms of exploitation, especially of those who are economically or socially vulnerable. If bioethics truly wants to defend the rights of the most fragile groups, it cannot limit itself to regulating procedures. It must also question the larger systems of power that control who can access opportunities and who remains excluded.

Finally, discussing reproductive justice today also means taking a clear political position. Reproduction is not just a private or biological matter — it is deeply connected to global inequalities and the structures of social and economic power. To face these challenges in a meaningful way, bioethics needs to draw on insights from different fields — like critical theory, reproductive sociology, feminist perspectives, and human rights. This can help us build more inclusive, fair, and responsive ways of thinking, better suited to the complex realities we live in today.

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[266] Crenshaw, K. (1989). "Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine." *University of Chicago Legal Forum*, 1989(1), Article 8.
[267] Thompson, C. (2016). *Making Parents: The Ontological Choreography of Reproductive Technologies*. MIT Press.

3.3 The Role of Ethics Committees and Soft Law in the Regulation of Assisted Reproduction

In the field of bioethics applied to assisted reproduction, the absence of consistent legal frameworks—both nationally and internationally—has highlighted the need for alternative regulatory tools. These tools are meant to support scientific innovation in ways that are flexible and responsible. In this context, *ethics committees* and *soft law* have become two essential mechanisms for guiding clinical practice.

Although not legally binding, they often play a highly influential role in shaping decisions, ethical standards, and institutional policies.

Soft law, defined as a "*set of non-binding but practically relevant and legally significant guidelines"*, has become increasingly important in regulating reproductive biotechnologies. Documents like guidelines, ethical codes, expert opinions, and recommendations issued by bioethics committees, scientific associations, or international organisations now act as a kind of parallel regulatory framework. These tools become especially important when formal laws are missing or still being developed, offering practical guidance in uncertain legal contexts[268]- Unlike hard law, which tends to be rigid, soft law has the advantage of being more adaptable to the fast pace of scientific innovation, while still encouraging ethical reflection and involving different stakeholders in the decision-making process.

One key example is the *European Society of Human Reproduction and Embryology* (ESHRE)[269], whose guidelines set ethical and clinical standards for ART practices across Europe. Although these documents are not legally binding, they strongly influence both the internal governance of fertility clinics and national public policy. They help build a shared ethical culture and offer safeguards for all involved—especially patients and children. In a similar way, in Italy, documents from *the National Bioethics Committee* (Comitato Nazionale per la Bioetica – CNB), such as the opinion on "*Assisted Reproduction and Gamete Donation*"[270] (2011), have played an important role in shaping political and legal debate, bridging scientific knowledge, public morality, and regulatory direction. Rather than simply setting rules, these texts have helped bring complex ethical questions to the centre of public discussion. They've offered a space where science, law, and values can meet—raising awareness, promoting reflection, and gently pushing institutions to take clearer, more responsible positions on issues that legislation alone often struggles to define.

Ethics committees themselves also play a central role in assessing whether reproductive practices align with the key principles of bioethics: autonomy, beneficence, non-maleficence, and justice[271]. Ethics committees are

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[268] Abbott, K.W., & Snidal, D. (2000). *Hard and Soft Law in International Governance*. International Organization, 54(3), 421–456.

[269] European Society of Human Reproduction and Embryology (ESHRE). (2021). *ESHRE Good Practice Recommendations for Assisted Reproductive Technology*. Human Reproduction Open, 2021(1), hoab003

[270] Comitato Nazionale per la Bioetica (CNB). (2011). *Riproduzione assistita e donazione di gameti*.

[271] Beauchamp, T.L., & Childress, J.F. (2019). *Principles of Biomedical Ethics* (8th ed.). Oxford University Press.

"*multidisciplinary bodies made up of professionals from fields such as medicine, law, philosophy, and the social science"*. Their main task is to evaluate the ethical acceptability of clinical and research practices, especially in sensitive areas like assisted reproduction. They act as independent advisors, helping institutions navigate morally complex issues and protect the rights and dignity of all those involved—especially in sensitive areas like assisted reproduction. Their work happens on different levels: from national and regional committees to local hospital or clinical committees. Their duties include reviewing protocols, supervising research, and ensuring that conditions for consent and access are ethically sound. Their presence is especially important where legislation is vague or incomplete—as is often the case with surrogacy, anonymous donation, or long-term cryopreservation.

However, relying on soft law and ethics committees is not without challenges. First, the non-binding nature of soft law can lead to inconsistent interpretations and applications between clinics, regions, or countries. This can undermine the principle of equity in access to reproductive services, resulting in territorial and legal disparities that translate into real injustice[272]. Second, the composition and independence of ethics committees can affect the quality of their work. If there are conflicts of interest, political pressure, or ideological bias, these bodies risk becoming tools of legitimation rather than spaces for critical ethical oversight.

Another important issue is how soft law relates to democratic participation in bioethics. Although expert opinions and non-binding guidelines can offer quick and valuable advice, they often leave little space for real public debate. As a result, complicated ethical questions risk being treated like technical problems, decided by just a small group of specialists[273]. But when decisions affect fundamental issues like human dignity and the future of reproduction, they should not be made behind closed doors. These are choices that concern everyone and should be discussed openly, involving different ethical viewpoints and giving voice to the diversity of society.

Today, ethics committees and soft law have become essential tools for managing innovation in assisted reproduction, especially where laws are unclear or there is disagreement over ethical principles. However, their true value depends on their ability to guarantee transparency, independence, and real public participation. They must promote a broad and inclusive ethical approach—one that balances scientific progress with social justice. The real challenge is to recognise that bioethical choices are never purely technical: they are political and value-driven decisions. Building a fair system means creating a way of regulating that is open, based on dialogue, and capable of dealing with the full complexity of reproductive technologies today.

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[272] Knoppers, B.M., & Isasi, R.M. (2004). *Regulatory approaches to reproductive genetic testing*. Human Reproduction, 19(12), 2695–2701.

[273] Chadwick, R. (2011). *The Role of Ethics Committees in Decision-Making about New Reproductive Technologies*. Journal of Medical Ethics, 37(2), 71–74.

3.4 Future Perspectives: Is an Ethics of Reproductive Innovation Possible?

Faced with the rapid evolution of reproductive technologies, the key question today is no longer whether to regulate them, but how to do so in a way that is ethically sustainable, fair, and inclusive.

Fertility technologies — from preimplantation genetic diagnosis to cryopreservation, surrogacy, and gene editing — raise dilemmas that no longer fit within traditional legal categories. They require a deeper rethinking of the relationship between law, science, and ethics. The biggest risk is not overregulation but having rules that fail to ensure real fairness and do not take into account the variety of values and experiences that exist in society[274].

An ethics of reproductive innovation cannot pretend to be neutral. It must confront important questions about the future we are building through science: "*who is being supported, and who is being left behind or excluded?*" As Jasanoff (2016) explains, technologies are never just neutral tools[275]. They carry with them specific ways of seeing the world, cultural priorities, and systems of power. When we talk about reproduction, this means that every rule we create—about who can access technologies, under what conditions, and with which limits or incentives—directly affects who has more opportunities and who remains vulnerable in society.

Because of this, the way we think about bioethics needs to change. It should no longer be something discussed only among experts or scientists. As Myskja and Steinfeld (2019) argue, we need a new kind of "*public ethics that is open to everyone"*[276]—citizens, patients, vulnerable groups, and marginalised communities. Ethics should not be something decided behind closed doors. It should involve the voices of all those who will actually be affected by these technologies. Following the idea of "*nothing about us without us*", no ethical decision about bodies and reproduction should be made without the direct participation of the people whose lives are at stake.

In this light, one of the main challenges is to build multi-level ethical governance. Locally, ethics committees must become more transparent, more diverse in their composition, and better connected to the real needs of the communities they serve. Nationally and internationally, it is crucial to harmonise legal frameworks to prevent the inequalities generated by reproductive tourism and the commercial deregulation of fertility services. Documents like the ethical frameworks proposed by the WHO[277] (2021) and UNESCO[278] offer

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[274] Baylis, F., & Robert, J. S. (2004). *The Inevitability of Genetic Enhancement Technologies*. *Bioethics*, 18(1), 1–26.
[275] Jasanoff, S. (2016). *The Ethics of Invention: Technology and the Human Future*. W. W. Norton & Company.
[276] Myskja, B. K., & Steinfeld, I. (2019). From expert ethics to participatory bioethics? Lessons from the Citizens' Jury on genome editing in Norway. *Monash Bioethics Review*, 37, 107–121. https://doi.org/10.1007/s40592-019-00091-w
[277] World Health Organization. (2021). *Ethics and governance of artificial intelligence for health: WHO guidance*. Geneva: WHO.
[278] UNESCO. (2005). *Universal Declaration on Bioethics and Human Rights*. Adopted by the General Conference at its 33rd session.

important starting points for balancing autonomy, fairness, safety, and collective responsibility in a globalised world.

Another critical point concerns how we evaluate scientific progress itself. Just because something is technically possible does not mean it is ethically desirable. The development of technologies such as germline gene editing, embryo selection, or even full artificial reproduction (ectogenesis) raises deep existential questions about what it means to be born, to be a parent, and to live a dignified life. Without a shared ethical framework, there is a real risk that these decisions will be driven mainly by market interests or social fears, rather than by a genuine project for a just and inclusive humanity[279].

To meet these challenges, the ethics of reproductive innovation must be "*interdisciplinary, critical, and justice oriented"*[280]. It must recognise the complexity of the people involved, the diversity of interests at stake, and the need to find a careful balance between individual freedoms, social constraints, and responsibilities toward future generations.

This third chapter has explored the main bioethical issues raised by the use of reproductive technologies, showing how scientific innovation directly impacts fundamental concepts like parenthood, family, freedom, justice, and human dignity. Assisted reproduction is not simply a medical practice: it is a profoundly moral and political act that touches private desires, public policies, and the very structure of social life.

The analysis has shown that while reproductive autonomy remains a core value, it must be reinterpreted considering structural inequalities and the power relations that define the global fertility landscape. The application of the Bootleggers & Baptists model[281] has helped reveal the hidden alliances between economic interests and moral justifications, showing that regulatory frameworks are often far from neutral. At the same time, the concept of reproductive justice, informed by an intersectional approach, has emerged as a necessary political and ethical framework to restore visibility and rights to those historically marginalised.

Finally, the discussion highlighted both the potential and the limits of soft law and ethics committees as flexible but fair regulatory tools. The future demands an ethics of innovation that is inclusive, transparent, and participatory—capable not just of managing what is technologically possible, but of guiding science towards what is socially and morally desirable.

Because reproduction—the beginning of human life—deserves an ethical governance that lives up to its profound anthropological, social, and symbolic complexity.

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[279] Habermas, J. (2003). *The Future of Human Nature*. Polity Press.
[280] Myskja, B. K., & Steinfeld, L. (2019). "Public bioethics and the importance of democratic deliberation." *Medicine, Health Care and Philosophy*, 22(3), 369–377.
[281] Yandle, B. (1983). "Bootleggers and Baptists: The Education of a Regulatory Economist." *Regulation*, 7(3), 12–16.

CHAPTER 4 – Empirical Analysis: Perceptions, Gaps, and Regulatory Tensions in the Campania Context

This chapter offers an empirical reflection aimed at understanding how professionals directly involved in medically assisted reproduction (MAR) perceive the current landscape of technological innovation and its regulation. The geographical focus is on the Campania region—and more specifically, on the *Terra dei Fuochi* area, a territory that has long been the subject of public concern due to its serious environmental and health vulnerabilities.

Through a series of qualitative interviews, this analysis seeks to give voice to those who live these issues firsthand: gynaecologists, researchers, clinicians, and bioethicists working on the front lines of assisted reproduction. Their words reveal a complex and often ambivalent reality, where hopes and progress coexist with frustration and ethical tension.

The starting point of this reflection is clear: **innovation in the reproductive field does not occur in a vacuum**. On the contrary, it often comes into direct conflict with regulatory delays, legal grey zones, and profound social and territorial inequalities. The perspectives collected offer valuable insight into a recurring conflict—sometimes subtle, sometimes explicit—between scientific progress and reproductive justice, between individual freedom and collective responsibility, between technological advancement and ethical sustainability.

One of the strengths of this qualitative approach lies in its ability to capture not just data or opinions, but also the tone, doubts, emotions, and rhetorical choices of those interviewed. All extracts reported in this chapter have been anonymised to protect the identities of the professionals involved, but each has been contextualised by role (e.g., “a Neapolitan gynaecologist” or “a biologist specialised in ART”) to help to understand the framework without compromising privacy.

4.1 – Methodological Approach

The empirical work presented here is based on four semi-structured interviews carried out between April and May 2025. All interviewees are professionals actively working in the field of medically assisted reproduction in the Campania region. They come from different types of institutions—private clinics, public-accredited centres, and academic research units— distributed between Naples, Caserta, and the broader *Terra dei Fuochi* area.

The selection of participants was intentional: the goal was not statistical representativeness, but the inclusion of different voices and professional profiles to capture a range of experiences. I specifically sought out those

who could offer a thoughtful perspective based on direct, daily interaction with the challenges of reproductive medicine in a region marked by environmental and institutional fragility.

The four professionals interviewed include:

- a gynaecologist working in a private fertility clinic in Naples;
- a biologist specialising in ART at a public-accredited centre;
- a university bioethicist involved in ethics committee work;
- a clinical researcher with experience in high-risk environmental zones, particularly the *Terra dei Fuochi*.

Each interview was fully transcribed, and then analysed using a thematic approach. Rather than rigidly categorising responses, I focused on identifying recurring themes, symbolic language, and shared concerns. The interview format was intentionally flexible: I followed a common set of guiding questions but encouraged participants to speak freely, reflect personally, and bring their own voice into the conversation.

Of course, this research does not claim to offer a complete or exhaustive representation of the Campania or Italian healthcare system. However, the richness and depth of the interviews, along with the thematic consistency observed across different profiles, make these reflections a valuable entry point into the broader debate on the ethical, social, and regulatory challenges of reproductive innovation.

4.2 – Between Opportunity and Concern: How Innovation Is Experienced in Daily Clinical Practice

Innovation, especially in the field of reproductive technologies, is not simply about listing new procedures or celebrating medical progress. As clearly emerged from the interviews, innovation is not just a set of tools—it is something that transforms how care, medicine, and parenthood are understood in practice. In everyday clinical work, it challenges professionals not only in their technical role, but also on a human level, raising a fundamental question: *how far is it right—or safe—to go*?

Those working in assisted reproduction tend not to see innovation as something entirely good or bad. Rather, they describe it as a complex presence, full of both hope and hesitation. Technologies open up extraordinary possibilities, but they also generate new responsibilities, ethical dilemmas, and vulnerabilities. Innovation is therefore perceived not as pure progress, but as a continuous balancing act between opportunities and critical questions.

"*We now have incredibly powerful tools—ten years ago they would have sounded like science fiction. But it's not always clear how or when to use them. Or for whom*."
– explains a gynaecologist from Naples.

Behind reflections like these lies a deeper issue, one that goes beyond technical regulations or legal gaps. It's about how innovation is shaped by cultural narratives, social expectations, and emotional experiences. Technological progress doesn't unfold in a vacuum—it absorbs the values, hopes, and even the fears that a society projects onto it.

This is particularly evident in the field of reproduction, where the body—especially the female body—becomes the primary space in which these tensions are played out. It's not just the site of medical intervention, but also the focus of moral judgement, symbolic weight, and social pressure. For many women, accessing assisted reproduction means more than undergoing a treatment—it means dealing with an invisible burden of responsibility, expectation, and sometimes even shame.

In this sense, reproductive technologies don't only represent medical progress. They become part of a broader human experience—one that touches identity, autonomy, and the meaning of parenthood. And when innovation enters into such an intimate space, it inevitably raises ethical and emotional questions that can't be answered by science alone.

Some professionals noted, for example, that patients often respond to proposed innovative treatments with both trust and anxiety. On one hand, the technology is seen as a last resort. On the other, it raises concerns about "forcing" nature or handing over deeply personal aspects of life to laboratory processes.

"*Many women come to us after a long, painful journey, often carrying guilt. When we propose an advanced treatment, their eyes light up with hope… but also with doubt. As if they feel the need to justify their decision*."
– says a clinical researcher working in the *Terra dei Fuochi* area.

This brings attention to a dimension that is often overlooked in institutional or academic discussions: accessing a new technology doesn't just mean benefiting from a treatment—it also means entering a space that is deeply shaped by psychological, emotional, and cultural meanings. Patients are not just passive recipients; they bring with them their own lived experiences, fears, expectations, and the social and environmental conditions they inhabit.

In places like Campania—particularly in areas heavily affected by environmental pollution and institutional neglect—technology often carries an added symbolic weight. It is seen not only as a tool, but as a form of redemption, a last resort when other paths have failed or have been denied.

"*For many of our patients, innovation represents a final opportunity*," explains a biologist based in Caserta. "*But without the right human and informational support, it can become another source of trauma*."

What emerges from reflections like this is the urgent need to think beyond the availability of the technology itself. A medical breakthrough, however advanced, cannot be truly effective if it is not supported by a culture of care—a network that informs, accompanies, and protects. This includes adequate psychological counselling, accessible and clear information, and a healthcare system that takes into account the inequalities rooted in geography, income, and education.

Innovation, in short, doesn't just need to exist—it needs to be accessible in a meaningful way, especially in those territories where fragility is the norm, not the exception. Without this broader framework, even the most advanced techniques risk becoming just another promise that remains out of reach for those who need it most.

Another theme that emerged concerns how professionals themselves experience innovation. Many professionals said they often feel stuck—on one side, there's the pressure to keep up with new technologies; on the other, they don't feel prepared to handle the ethical and emotional challenges that come with them. Some admitted they feel unsure or even inadequate when they have to respond to the emotional needs of their patients.

"*Technical training is well structured, but no one prepares us to deal with the consequences. We sit with couples going through existential crises, asking for answers we simply cannot provide*."
– notes a doctor working in the reproductive health field.

Such reflections make it clear that innovation requires more than just scientific knowledge. It calls for ethical sensitivity, cultural awareness, and relational skills. Otherwise, there is a risk that technologies will turn into mechanical procedures with little meaning—or worse, into promises that cannot be kept.

The interviews offer a vivid and nuanced portrait of how innovation is actually lived in clinical settings—not as something external to be regulated, but as an experience that professionals and patients go through, often with tension and contradiction. Rather than reinforcing simplistic ideas of technological progress, these voices call for more space for dialogue, more accessible language, and shared cultural frameworks.

As discussed in Chapter 2, the most effective regulatory models are not those that simply permit or prohibit, but those that provide guidance, clarity, and support alongside innovation. In the Italian context, this kind of support remains limited. The testimonies gathered throughout this research point to a shared need: fewer abstract slogans about progress, and more concrete tools to navigate it with confidence, equity, and care.

4.3 – When the Rules Fall Behind: The Gap Between Innovation and Regulation

As seen in the previous section, professionals working in assisted reproduction often experience innovation with a mix of hope and unease. They welcome the potential of new technologies but also face cultural limits and emotional tensions. What clearly emerged from the interviews, however, is a deeper and more structural concern: the serious inadequacy of the current Italian regulatory system to keep pace with the ongoing transformation in this field.

The issue is not just about outdated laws or complex bureaucracy. What many interviewees emphasized is that the legal system seems to have stepped back from its guiding role, leaving a void filled with unclear norms, inconsistent interpretations, and contradictory local decisions. Regulation no longer offers clear boundaries or direction—it has become a blurry background, where each professional must build their own rules and navigate on their own.

"*We never really know if what we're doing is allowed, tolerated, or risky. We work in a kind of grey zone, where everything depends on common sense*," said a gynaecologist with more than twenty years of experience.

This disconnect between clinical practice and the legal framework creates confusion, frustration, and often discourages innovation altogether. When laws are not updated, when there are no clear national guidelines, and when crucial issues are left unaddressed, the most common reaction is not courage, but caution. Clinics become more defensive, avoid new techniques, and hold back from innovating—even when they have the skills and tools to do so.

"*Sometimes we avoid offering a treatment even if we know it would help, just because we want to avoid legal trouble. Nobody wants to be dragged into a courtroom or the media*," shared a biologist working in a private fertility center.

This statement reflects a broader and more troubling reality: in the absence of clear and up-to-date regulation, what should be a space of professional freedom and innovation often turns into a climate of fear and self-censorship. When laws are vague or outdated, medical professionals are left to interpret the rules on their own—and every choice becomes a potential legal or reputational risk.

The fear of being taken to court is one side of the issue. The other, increasingly common, is the fear of media exposure. In highly sensitive fields like assisted reproduction, where ethical questions easily become political debates, professionals worry that a clinical decision—however justified—might be taken out of context, sensationalized, or morally judged by the public. Media scrutiny, especially when driven by controversy or misinformation, can damage reputations and careers, and discourage even well-intentioned practices.

This environment, described by many interviewees, creates a kind of "silent restraint": clinics may avoid offering newer or less codified treatments, not because they doubt their effectiveness, but because the regulatory and social uncertainty makes every step feel like walking on a tightrope.

As a result, what should be a safe and supportive environment for innovation and care instead becomes defensive and fragmented. Many professionals say they feel unprotected—neither by the national government nor by regional health authorities. Some refer to local ethics committees as their only point of reference, but even these bodies often give inconsistent or outdated advice, further deepening the sense of isolation and institutional vacuum.

"*We turn to the committees, but each one tells you something different. Sometimes they approve things, sometimes they don't, without clear reasons. There's no national standard, no shared direction*," noted a researcher involved in experimental projects.

In this regulatory vacuum, each clinic ends up creating its own internal policies—based on context, risk tolerance, or personal judgment. The result is a fragmented healthcare system, where what is allowed in one city may be impossible in another. This inconsistency creates a double injustice for patients: first, due to their health condition, and second, because of where they live.

This picture aligns with what was discussed in Chapter 2, which highlighted how Italy lags in adopting modern, flexible regulatory models. While other countries have embraced updated frameworks to deal with rapid innovation, Italy shows a kind of institutional inertia: nothing is explicitly banned, but nothing is truly addressed either. Complex decisions are often left unresolved, passed down to professionals who are not equipped—or authorized—to carry such responsibility alone.

This kind of "non-decision" creates an implicit delegation to healthcare workers, who end up bearing the full weight of responsibility without clear rules or support. The consequences are not only felt by patients, but by the whole healthcare system, which loses consistency, credibility, and the ability to plan for the future.

For this reason, what emerges strongly from the interviews is the need for more than just reforming individual laws. What is really needed is a new way of thinking about regulation—one that doesn't only prohibit or allow, but also guides, supports, and listens. A governance model that values clinical experience, engages with professionals, and strikes a balance between ethics and practicality.

"*We need to feel like we're part of a system that knows where it's going. We have the technologies, but we don't have the coordinates to use them safely and fairly,*" concluded a bioethicist based in Naples.

This sentence captures the core of the problem. Technological innovation cannot truly advance unless it is supported by a strong culture of regulation, with protections, guidelines, and spaces for open discussion.

Without these elements, there's a real risk that innovation will remain an untapped potential—or worse, become a force that increases inequalities and undermines public trust.

4.4 – Unequal Access and Wounded Territories: Reproductive Justice in the Geography of Innovation

If there's one area where innovation really shows its limits, it's access. Having advanced technologies isn't enough—they need to be available and usable for everyone. Otherwise, innovation stays an idea, far from people's real lives.

This is especially true in reproductive medicine. These technologies don't just solve medical issues—they affect people's hopes, their desire to become parents, and the emotions tied to infertility. For many, they represent more than just treatment: they're a last chance.

But access isn't the same for everyone. Living in a city with well-equipped clinics and public support makes it easier to get care. In other areas, with fewer services or long waiting lists, even if the technology exists, people may be left out. In this way, geography becomes a dividing line between those who can reach care and those who can't.

The stories collected in Campania—particularly in the *Terra dei Fuochi* area— show clearly: not everyone starts from the same place, and not all patients have the resources—financial, medical, or informational—to go through assisted reproduction. In areas affected by environmental degradation, poor infrastructure, and low institutional trust, technology takes on an even stronger meaning. It becomes almost a form of redemption, but one that is harder to reach.

"*Many of the women who come from these areas carry not only the pain of infertility but also a deep sense of injustice, even abandonment. They feel like their bodies have been damaged by forces beyond their control, and they look to technology as a way to reclaim something*," said a gynaecologist working in the northern districts of Naples.

For many patients, assisted reproduction feels like the last resort—one final chance to take back control of a situation they perceive as a result of a broader, collective harm. This is especially evident in the areas most affected by environmental crisis. According to the Italian Ministry of Health's 2022 report on public health in polluted zones[282], the *Terra dei Fuochi* shows a significant rise in endocrine, metabolic, and gynecological diseases in reproductive-age individuals, with statistically higher rates of infertility—both male and female—compared to national averages.

[282] Ministero della Salute. (2023). *Relazione sullo stato sanitario del Paese 2022* (pp. 198–202). Roma: Ministero della Salute. Recuperato da https://www.salute.gov.it/imgs/C_17_pubblicazioni_3319_allegato.pdf

This biological vulnerability is compounded by a structural inequality in healthcare access. According to the latest data (2022) from the *National Register of Assisted Reproduction* (Istituto Superiore di Sanità), only 19.7%[283] of assisted reproduction cycles in Italy take place in the South, despite similar rates of infertility across the country. In Campania, most treatments happen in private clinics, which often require out-of-pocket payments and are poorly integrated into the public system. Public facilities, meanwhile, have long waiting lists, few specialized centres, and limited psychological or informational support—creating yet another barrier for those seeking care.

"*Assisted reproduction here is seen as something hard to reach, almost out of reach. Not just because of the cost, but because people don't know where to go. There's no clear system, no network, no culture of access*," noted a researcher working between Caserta and Naples.

The result is a two-speed reproductive medicine system. The right to parenthood is not guaranteed equally for everyone—it depends on where you're born, your social class, and your ability to navigate a complex and often opaque healthcare system.

As several interviewees noted, some women even internalize a sense of shame for pursuing assisted reproduction, as if relying on technology is something they need to justify or hide.

"*Patients often tell us they're embarrassed. That they haven't told anyone they're undergoing a fertility cycle. As if they're cheating*," shared a healthcare worker at a publicly affiliated clinic north of Naples.

This feeling doesn't come only from cultural stereotypes about "natural" motherhood. It also comes from how technological intervention is framed—as an exception rather than a legitimate right. And when that exception isn't backed by a strong system of support—medical, psychological, or institutional—it can quickly become another form of isolation.

In light of all this, reproductive justice cannot remain an abstract principle. It needs to be understood as something concrete, rooted in place. It must consider real-world inequalities, environmental conditions, and the material infrastructures that shape who can actually benefit from innovation—and who cannot.

As discussed previously, some of the more progressive European regulatory models have started to include social and territorial equity in their ethical frameworks, treating access to assisted reproduction as a core part of public reproductive health policy.

[283] Registro Nazionale della PMA – Istituto Superiore di Sanità. (2023). *Relazione al Parlamento sullo stato di attuazione della Legge 40/2004 in materia di Procreazione Medicalmente Assistita – Dati 2022*. Roma: Istituto Superiore di Sanità. Recuperato da https://www.epicentro.iss.it/pma/pdf/Relazione-parlamento-2023.pdf

In Italy, however, regulation still tends to be technocratic and fragmented: the techniques are regulated, but access is not, and the deep inequality in who gets to become a parent through technology is largely ignored.

Recognizing this inequality doesn't mean framing differences as problems—it means making them visible, addressing them, and treating them as a matter of public responsibility. For innovation to truly matter, it must create opportunities—not reinforce hierarchies. It should serve justice, not selection. It should work not only where everything already functions well, but especially where the need is most urgent.

Seen from this perspective, the *Terra dei Fuochi* is not just a geographical location—it becomes a symbol for all the peripheral spaces, both physical and symbolic, where reproductive medicine arrives too late, or not at all. To speak of reproductive justice today means starting from there.

4.5 – Beyond the Technique: Ethical Dilemmas and Moral Responsibility in Technological Reproduction

While the previous sections have explored how professionals experience innovation in their daily work, the regulatory gaps they face, and the territorial inequalities in access to care, there is another dimension that emerges powerfully from the interviews—one that is less visible, but no less central: the ethical tension underlying clinical decisions. Beyond protocols and medical tools, many describe the discomfort of working in a field that is not only technical, but profoundly human—full of uncertainties, contradictions, and moral grey areas.

This section focuses precisely on that dimension: how everyday use of reproductive technologies inevitably brings up ethical questions. Not just in extreme cases—like genetic selection or limits of intervention—but in routine decisions that professionals navigate daily. These dilemmas are often hidden, but always present.

"*Every decision, even the smallest one, carries enormous weight. We're not just operating a machine here—we're touching lives, families, futures*," said a gynecologist with more than thirty years of experience in a Campanian clinic.

What they describe is not a clash between "science" and "ethics," but rather a constant balancing act between what can be done medically and what feels right on a human level. This boundary is not always marked by legal guidelines, but by personal sensitivity, family circumstances, and the social context.
One of the most frequently mentioned issues is the shift from care to selection—from treating illness to choosing outcomes. Techniques like preimplantation genetic testing (PGT), now widely available, raise tough questions: is it acceptable to decide which embryos to implant and which to discard? Where is the limit between health protection and the desire for control?

"*People ask us: Can you prevent this mutation? And yes, we can. But then comes the next question: What about this trait? And this predisposition? Where do we draw the line?*" reflected a biologist.

These are not abstract questions—they're decisions made daily, often without clear, shared reference points. Sometimes, ethical committees help navigate these choices. But often, it falls entirely on the medical team to decide what kind of life is deemed acceptable. This shift—from therapy to selection—doesn't just reflect technical advancement; it reveals a deeper cultural change. It forces us to ask: are we moving toward a model of parenthood that's increasingly shaped by ideals of perfection?

Another persistent tension involves the fine line between informing and influencing patients. Many arrive emotionally fragile, full of fear and hope, and with only partial understanding of the medical options available. In this setting, the doctor's role is never completely neutral. Even the most objective explanation can, unintentionally, sway a patient's decision.

"*Sometimes we're not sure if we're informing or guiding. When a woman is desperate, even facts can become persuasion*," admitted a psychologist working in a public clinic.

This awareness creates a kind of silent responsibility—not about clinical error, but about respecting autonomy under vulnerable conditions. It's a relational ethic, requiring not just competence but empathy, listening, and time—resources that aren't always available in the current healthcare system.

Lastly, many professionals pointed to a growing pressure from patients—and sometimes their families—who view assisted reproduction not just as a medical option, but as a guaranteed path to parenthood. There's a widespread belief that science, especially with all the new technologies available, should be able to "solve" infertility and deliver a child. This expectation creates a heavy emotional burden on doctors and medical teams, who feel responsible not only for performing the procedures, but also for supporting patients through the emotional weight of failure.

"*When a treatment fails, it's often felt as a betrayal. Like we made a promise we couldn't keep*" shared a doctor.

This dynamic highlights how reproductive technologies today are no longer seen as neutral tools—they've become powerful symbols of hope. And while hope is essential, it can also be fragile. When expectations are too high or unrealistic, disappointment can quickly turn into frustration, self-blame, and emotional suffering. This affects not only patients, who may feel like they've failed or been let down by the system, but also the professionals, who carry the invisible weight of these unmet hopes.

In this way, innovation becomes more than a technical process—it becomes a deeply human experience, one that calls for empathy, clear communication, and shared understanding on all sides.

These dilemmas aren't signs of confusion or failure. They reveal the complexity of working with reproductive technologies—complexity that can't be resolved by technique or law alone. What's needed is a deeper space for reflection that combines individual sensitivity, institutional support, and shared responsibility.

As discussed in Chapter 3, bioethics must move beyond being an abstract discipline reserved for experts. It should become a practical, everyday tool—something grounded in real experiences and able to guide decisions in messy, imperfect human contexts. This is what many professionals ask for: not rigid rules or top-down solutions, but space to reflect, discuss, and share responsibilities.

Because reproduction isn't just about creating embryos. It's about creating futures. Every decision—every treatment started; every ethical choice made—plays a role in shaping that future. Taking this responsibility seriously doesn't mean halting progress. It means making sure innovation is accompanied by ethics of care, transparency, and justice.

4.6 – Voices in Tension: Toward a Situated and Responsible Ethics of Reproductive Innovation

The interviews presented in this chapter do not offer a single, unified view on reproductive innovation. Quite the opposite. What emerges is a complex landscape made of contradictions, tensions, uncertainties, and nuanced positions — often suspended between enthusiasm and caution, between possibility and fragility. And it is precisely within this complexity, in the absence of easy answers, that the true value of this reflection lies.

Throughout the chapter, different levels of analysis have emerged: the day-to-day clinical practice made of actions, delicate choices, and human relationships; the fragmented regulatory structure, often out of step with technological progress; the territorial inequalities that shape both access to care and the effectiveness of treatments; and finally, the ethical responsibility that runs through every stage of the reproductive process, going far beyond the technical dimension.

All these layers share one crucial insight: innovation is never neutral. Its impact depends on the context in which it operates, the rules that govern it, and the people who turn it into practice. Far from being an abstract tool, reproductive technology is experienced as something that reshapes relationships, expectations, and the way we talk about the body, parenthood, and the right to care.

"*There are days when I wonder if what we're doing is truly progress—or just another way of making selections*," said a doctor with a calm but critical tone.

This reflection captures the heart of the issue: what kind of future are we building through innovation? And above all, who is included, and who is at risk of being left behind?

The interviews show that without a consistent legal framework, without shared ethical governance, and without a real focus on social and territorial conditions, innovation risks becoming a tool of exclusion more than a path to justice. Access to reproductive technology is not just about what's technically possible — it's about substantial rights, fairness, and inclusion. And this is even more true in areas facing environmental and social vulnerability, such as the so-called "*Terra dei Fuochi*," where infertility is not only a biological issue, but also a political, ecological, and systemic one.

Alongside these inequalities, another recurring theme is the solitude felt by professionals. Many of those working in reproductive care feel left alone — without clear regulations, without structured spaces for ethical dialogue, and without institutional support that fully acknowledges the complexity of their role. Where rules exist, they are often rigid or outdated. Where they don't, professionals are left to self-regulate, carrying an overwhelming weight of responsibility on their own.

And yet, despite these challenges, the interviews are not marked by resignation. Instead, they reveal voices of thoughtful resistance, a desire for change, and a slow but determined effort to build an ethics of innovation rooted in justice, technical expertise, and care. What professionals are asking for is not less regulation, but more: more training, more conversation, more support, and more dialogue. They ask not to be left alone in a field that is not only medical, but also deeply human, social, and political.

So, this chapter does not end with answers, but with a call for listening — and with a clear message: reproductive innovation can no longer be treated as a technical issue to be regulated after the fact, or as a marginal concern in public debate. What is needed is a shift in perspective.

We need a situated form of bioethics — one that speaks the language of local realities, that sees inequality clearly, and that builds concrete pathways for fair access to technology. We need regulations that don't chase innovation from behind, but accompany and guide it, distributing its benefits more equally. And we need a culture of responsible innovation — one that remembers that behind every clinical procedure there is a story, a face, a life asking to be heard.

Only from here — from this plurality of voices, this network of questions, this deep sense of responsibility — can we begin to shape a new way of thinking about innovation. Not as a race to be run alone, but as a shared journey — one that is conscious, inclusive, and fair.

CONCLUSION

This thesis has revealed a truth as evident as it is unsettling: reproductive innovation is never merely a technical matter, but rather a crossroads where social expectations, ethical tensions, legal limits, and structural inequalities converge. Technologies developed to address a deeply human need—the desire to create life—often unfold within regulatory vacuums, where access is conditioned by economic privilege and legal responses fluctuate between silence, delay, and absolute prohibition.

What clearly emerges is that technological innovation is never neutral. Each new possibility embeds an implicit vision of what is acceptable, desirable, and governable. It is precisely within this grey zone—between what can be done and what should be done—that the law must position itself not as a restrictive force, but as a critical and inclusive framework, capable of ensuring equity and protection without stifling scientific progress.

The empirical research conducted in Campania has further underscored that the regulation of reproductive technologies cannot be conceptualized in abstract terms. It must be rooted in specific territories, attentive to the voices of practitioners, and responsive to the environmental, social, and institutional vulnerabilities that shape real access to innovation.

The interviews collected reveal a widespread tension between innovation and regulatory uncertainty, between clinical expectations and legal inaction. In the absence of clear, consistent guidelines, decision-making is frequently left to individual professionals, generating disparities and, at times, arbitrary outcomes in both access to care and quality of treatment. This landscape points to the urgent need for normative tools that not only discipline innovation but also ethically guide its development.

The true challenge, therefore, is not simply to regulate what is new, but to foster a culture of shared responsibility—where ethics is not treated as an external constraint on science, but as a vital ally. Such a culture must reconcile the right to parenthood with the dignity of all parties involved; it must not be content with managing what exists, but actively imagine a future in which technological advancement and social justice move forward together.

Ultimately, this research demonstrates that an ethics of reproductive innovation is not only possible—it is essential. It must be situated, dialogical, and grounded in the awareness that every regulatory choice affects real lives, family structures, and deeply embedded cultural meanings. Ensuring equitable access to reproductive technologies, avoiding the commodification of the body, and promoting a responsible use of biotechnologies require a vision that integrates legal precision with a commitment to justice.

The task is not to eliminate conflicts between competing values, but to create spaces for regulatory mediation that embrace, rather than avoid, complexity. Because human reproduction, in its technological form, must also be understood as a shared responsibility toward the future.

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