

## Global legal trends in fertility interventions: A criminal justice perspective

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**Abstract:** The global decline in birth rates has heightened the urgency of addressing infertility, a condition that affects approximately one in six individuals worldwide. This paper explores the complex causes of infertility, including genetic predispositions, lifestyle choices, and environmental exposures, which collectively contribute to reproductive challenges in both men and women. The advent of Assisted Reproductive Technologies (ART), particularly In Vitro Fertilization (IVF), has revolutionized infertility treatment since 1978, providing hope to millions. Despite the remarkable advancements in ART, these technologies raise significant legal and ethical concerns, necessitating robust regulatory frameworks. This paper examines the historical development of ART, with a focus on global trends and data from ART registries, highlighting the steady increase in ART cycles worldwide. Furthermore, it delves into the legal and ethical challenges associated with ART, including issues related to donor rights, parental responsibilities, and the potential health risks for children born through these technologies. The paper advocates for continued refinement of ART practices and regulations to ensure safety, efficacy, and ethical integrity. It also underscores the importance of ongoing research into the long-term health implications for children conceived via ART and the broader societal impacts. By addressing these concerns, ART can continue to offer a viable solution to infertility while upholding human dignity and societal well-being.

**Keywords:** *Assisted reproductive technologies, Environmental factors, In Vitro fertilization, Infertility, Legal and ethical considerations,*

### 1. Introduction

The regulation of Assisted Reproductive Technologies (ART) constitutes one of the most intricate and dynamic challenges confronting contemporary legal systems globally. With the ascendancy of infertility rates, ART has emerged as an indispensable medical intervention, offering hope to millions of individuals and couples desiring to conceive. Nonetheless, the escalating reliance on these technologies has elicited profound legal, ethical, and social considerations, especially regarding their governance under criminal statutes. The criminal-legal framework governing ART is far from homogeneous worldwide; it mirrors different nations' varied cultural, ethical, and legal contours. In certain jurisdictions, rigorous legislations regulate ART deployment, frequently anchored in religious or moral convictions, whereas other regimes adopt a more liberal stance, underscoring reproductive rights and individual autonomy. Such disparities engender a complex international schema in which the legality and accessibility of ART differ markedly across geographic locales.

This paper endeavors to scrutinize the comparative criminal-legal regulation of ART from an international standpoint, analyzing the diverse approaches nations adopt in addressing the ethical and legal challenges these technologies pose. Through a detailed examination of varied legal frameworks, this study aims to elucidate the fundamental principles that underpin ART regulation and to delineate best practices that could guide future legal evolutions in this arena. Furthermore, the paper will illuminate the repercussions of these regulations for individuals seeking ART, healthcare providers, and

the broader society, emphasizing the necessity for a harmonized approach that safeguards both individual rights and public welfare.

## 2. Causes of Infertility: Male and Female Reproductive Issues

In contemporary society, depopulation emerges as a significant concern, thereby elevating the importance of utilizing all available resources to enhance birth rates. There is a particular focus on reducing infertility rates, which in any nation are considered minimal at 10% and reach a critical level with nationwide implications at 15%. The escalation in infertility rates is attributed to a variety of factors, most commonly related to the adverse impacts of the external environment—including exposure to chemicals, radiation, lifestyle choices, and the nature of work—on human reproductive function. A recent report by the World Health Organization (WHO) highlights the widespread nature of this issue, indicating that approximately 17.5% of the adult population suffers from infertility. This statistic suggests that about every sixth person globally faces challenges with infertility [1].

Infertility within a couple can stem from disorders in either female or male reproductive function, affecting up to 80% of couples for female-related issues and up to 45% for male-related issues. Approximately one-third of couples experience combined infertility, where the causes are simultaneously attributed to both male and female factors [2]. For many years, infertility was a condition that could be diagnosed but remained largely untreatable. Historically, the absence of effective treatments meant that only about three out of ten couples with reproductive disorders could realistically hope to have their child. This landscape transformed fundamentally after 1978 with the birth of Louise Brown in the United Kingdom, the first baby successfully conceived through in vitro fertilization (IVF), a key assisted reproductive technology (ART) that facilitates conception outside the body. The advent of IVF and subsequent advancements in ART have provided foundational solutions to the pervasive issue of infertility in society [3].

## 3. Assisted Reproductive Technologies (ART) and its Historical Development

In the 21st century, a significant advancement in addressing infertility is the utilization of Assisted Reproductive Technologies (ART). These technologies comprise various treatment methods and procedures aimed at facilitating pregnancy, with one or all stages of conception taking place outside the future mother's body. ART enhances the chances of achieving pregnancy and birthing a healthy child.

Key reasons why individuals and couples may turn to assisted reproductive technologies include:

1. *Infertility*: Often the principal reason for considering ART is infertility, defined as the inability to conceive after one year of regular, unprotected intercourse. This issue can stem from various factors affecting either partner, including problems with the ovaries, uterus, or sperm.
2. *Sperm quality issues*: Men with low sperm count or poor sperm quality may find natural conception challenging. ART offers solutions such as artificial insemination and in vitro fertilization (IVF) to address these reproductive hurdles.
3. *Egg issues*: Women experiencing issues such as a low quantity or poor quality of eggs may utilize ART methods like in vitro fertilization with donor eggs.
4. *Aging processes*: As fertility declines with age for both men and women, ART can facilitate pregnancy and childbirth for couples dealing with age-related fertility issues.
5. *Genetic issues*: To avoid the risk of transmitting genetic diseases, techniques such as preimplantation genetic diagnosis within ART can help select embryos free from genetic abnormalities.
6. *Preservation of eggs and sperm*: Individuals anticipating cancer treatments or other interventions that might impair fertility may use ART for cryopreservation of eggs or sperm for future use.
7. *Surrogacy*: For women who are unable to carry a pregnancy due to the absence of a uterus or other reasons, surrogacy offers a potential solution through ART.

8. ART also enables the prevention of inherited diseases by allowing for genetic screening and interventions before pregnancy.

These reasons underscore the multifaceted applications and profound impact of ART in contemporary reproductive medicine.

The World Health Organization recognizes in vitro fertilization (IVF) as the most effective method for treating infertility. For nearly three decades, a variety of ART registries—international (such as ESHRE and ICMART), regional, and national (including RARCH, ASRM, REDLARA, FSA, and JSRM)—have been actively engaged in collecting, analyzing, and disseminating data about ART cycles. At a notable 2018 conference in Lisbon, Jacques de Mouzon presented a report entitled "ART in the World: Present Data and Future Perspective." This report highlighted that ICMART had documented over 12.6 million ART cycles from 1991 to 2014, reflecting a consistent annual increase in the number of ART cycles globally over the preceding five years. This data underscores the growing reliance on and effectiveness of ART technologies in addressing infertility issues worldwide. Jacques de Mouzon emphasized that the records maintained by ICMART account for only 63% to 70% of the ART cycles conducted worldwide, suggesting that between 30% and 40% of data might go unreported. Based on these figures, it is estimated that the actual total number of ART cycles performed globally could range from 32.5 to 35 million to date. Since the advent of IVF in 1978, which heralded the birth of the first IVF child, approximately 8 million children had been born using this technology by 2014. In the year 2014 alone, the number of children born through ART ranged between 510,000 and 567,000. From these data, it is reasonable to conclude that the total number of children born via ART has now exceeded 10.5 million worldwide [4].

The introduction of innovative reproductive methods like ART demands extensive legal regulations due to their significant implications. These technological advancements pose challenges to the preservation of human self-identity amid rapid scientific and technological progress (STP), emphasizing the essential roles of law, bioethics, medical ethics, and religion in safeguarding human rights and individual dignity.

Legal frameworks governing ART are crafted to set forth clear restrictions and requirements that protect the rights and interests of donors, and carrier parents, and ensure accountability among medical professionals. These regulations tackle ethical considerations, such as prohibiting certain interventions or setting limitations based on the age or health of prospective ART users.

Thus, the regulation of ART covers a wide spectrum of issues, requiring oversight through various branches of law including civil, family, or administrative, to remain aligned with the evolving societal and technological landscapes.

In the realm of assisted reproductive technologies (ART), several key regulatory aspects ensure ethical practices and protect the rights of all parties involved:

1. *Medical Standards and Licensing*: Many countries implement rigorous standards and licensing requirements for medical institutions that provide ART services. These include periodic reviews and monitoring to maintain high medical standards.
2. *Rights of Donors and Parents*: Legislation often defines the rights and responsibilities of gamete (eggs or sperm) and embryo donors, as well as the legal status of parents who use ART to have children. These laws ensure that all parties are aware of their legal positions and obligations.
3. *Confidentiality and Anonymity*: Legal frameworks may grant the right to donor anonymity, while others may require the retention of donor information to allow future inquiries by offspring. This balances donor privacy with the rights of children to know their biological origins.
4. *Ethical Standards and Restrictions*: Laws are designed to prevent unethical practices in ART, such as surrogacy under coercive conditions or the selective breeding for desired traits. These provisions aim to uphold ethical standards within the practice of ART.
5. *Protection of Children's Rights*: Regulations also focus on safeguarding the rights of children born through ART. These laws address the child's legal status and the rights and responsibilities of parents, ensuring the child's well-being is a priority.

Each of these regulatory aspects is crucial for maintaining the integrity and ethical practice of ART, ensuring it serves the best interests of individuals and society alike.

#### 4. Ethical Issues and Legal Challenges in Different Countries

In numerous advanced democratic societies, the regulation of biotechnological endeavors, especially those involving genetically modified organisms (GMOs), is guided by the 'precautionary principle.' This principle advocates a prudent approach to the management of GMOs and imposes rigorous controls on the dissemination of products containing GMOs and their derivatives. Such regulatory measures are founded on the imperative of prioritizing human health and environmental safety.

In contrast, an alternative regulatory perspective allows for the unrestricted distribution of GMOs unless definitive evidence demonstrates their potential harm. This approach is frequently critiqued for its potential shortsightedness, as it may compromise the paramount importance of safety in human health and life. The adoption of this less cautious strategy in some regions is often ascribed to the influential lobbying activities of industries engaged in GMO production, which may sway regulatory frameworks towards more lenient controls [5].

Criminal policies concerning ART exhibit substantial variation across different nations, mirroring the diversity in legal obligations and definitions of criminal conduct within the realm of artificial human reproduction. For example, the Criminal Code of the Netherlands delineates specific penalties for activities associated with surrogacy. As stipulated in Article 151b, organizing or promoting negotiations between a surrogate mother and a prospective party, or facilitating meetings to arrange surrogacy, may lead to a penalty of imprisonment for up to one year. This legal provision is designed to govern the surrogate arrangement process meticulously, aiming to safeguard all parties involved, particularly the surrogate mother and the intended parents [6].

In Germany, the legal framework explicitly criminalizes the attempt to perform artificial insemination or embryo implantation in a woman who intends to relinquish her child after birth. These actions are categorized within the context of surrogacy as a criminal offense, with legal repercussions aimed specifically at the medical professionals involved, rather than at the intended parents or the surrogate mother.

This stringent regulation of surrogacy forms part of wider efforts to prevent practices perceived as analogous to human trafficking, including the trafficking of embryos. A notable example of the complex ethical and legal challenges associated with surrogacy and human rights is seen in the case of *Paradiso and Campanelli v. Italy*. This case reached the European Court of Human Rights, where Donatina Paradiso and Giovanni Campanelli, two Italian nationals, lodged a complaint against the Italian Republic (No. 25358/12) under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms on April 27, 2012. The proceedings illuminate profound dilemmas related to ART and parental rights under the scope of European human rights law [7].

In a notable case, a child born via a surrogacy agreement in the Russian Federation was brought to Italy, where surrogacy is prohibited. The child's parents, previously identified in legal discussions as Paradiso and Campanelli, encountered legal challenges when they could not establish a genetic link to the child. They faced accusations from Italian authorities of falsifying civil documents, violating adoption laws, and illegally importing a minor. As a result, an Italian court ordered the removal of the child from their custody, viewing the surrogacy agreement as tantamount to child selling.

The couple subsequently appealed to the European Court of Human Rights, alleging that the actions of the Italian government violated their rights to personal and family life as enshrined in Article 8 of the Human Rights Convention. However, the court rejected their complaint, citing the absence of a genetic link and concluding that the child would not suffer from the separation.

This case highlights broader legal controversies and has spurred some foreign legal experts to advocate for criminal penalties in cases involving embryo substitution or the transfer of genetically unrelated embryos. They argue that such incidents represent irremediable errors within ART programs.

This perspective is supported by similar cases and underscores the necessity for stringent oversight in ART practices to avert such significant mistakes.

In the *Herbert v. Ochsner* case, an incident involving the misuse of biological material during an IVF procedure prompted a significant legal dispute. A married couple initiated legal action against an IVF clinic after discovering that the sperm used to fertilize the wife's eggs was not from the husband but from another patient. This error became evident after the couple had a daughter who genetically did not match the husband.

The court ultimately dismissed the claims against the gynecologist involved, citing no evidence that the doctor was aware of the mix-up during the embryo transfer. However, the court found that the embryologist, who had direct handling of the biological materials, had acted negligently. It ruled that the embryologist's actions violated the informed consent terms that had been explicitly agreed upon for the IVF procedure, which included stipulations about the handling of biological material.

Consequently, the court held that the medical institution was liable for the embryologist's negligence, reinforcing the principle of vicarious liability where employers are responsible for their employees' actions within the scope of their employment. This case highlights the imperative need for rigorous procedural adherence and accountability in the field of reproductive technologies, emphasizing the severe consequences of procedural lapses [8].

In May 2018, a notable incident unfolded at the Regional Perinatal Center in Chelyabinsk, Russia, involving a couple who underwent IVF treatment in the ART department. While the procedure initially appeared successful and led to a birth, a DNA test initiated by the couple later revealed that the newborn was not genetically related to them. This startling discovery prompted the couple to seek legal redress for moral damages.

The couple proceeded to file a civil lawsuit against the clinic, which ultimately resulted in a settlement agreement. Under the terms of this agreement, the clinic compensated the wife with 2.4 million rubles and the husband with 1.6 million rubles. Despite the settlement, the couple's lawyer argued that there were sufficient grounds for a criminal case based on the provision of services of improper quality and the negligence of the medical staff. However, no criminal case was initiated.

This case garnered significant media attention and highlighted the urgent need for strict procedural compliance and accountability within the sphere of reproductive technologies in Russia. It serves as a critical reminder of the potential consequences of procedural failings and the importance of maintaining rigorous standards in the administration of such sensitive medical treatments [9].

Restrictions on the use of ART are notably stringent in many Muslim-majority countries, where specific conditions dictate their utilization. For example, in nations such as the Republic of Algeria, Bahrain, Jordan, Morocco, Pakistan, Saudi Arabia, Oman, and the UAE, ART is permitted only after a couple has unsuccessfully attempted natural conception for 12 months within the confines of marriage, without the use of contraceptives or encountering other pregnancy-related difficulties. Furthermore, the implementation of these technologies requires the written consent of both married partners.

Crucially, any embryo transferred must originate from sperm provided by the husband, reflecting cultural and religious norms that prioritize lineage and marital fidelity. The use of stem cells from one individual to treat infertility in another is expressly prohibited, and violations of this rule can lead to legal repercussions. Moreover, individuals who are determined to be completely infertile are not eligible for ART services under these regulatory frameworks, underscoring a cautious approach in line with specific ethical and religious considerations [10].

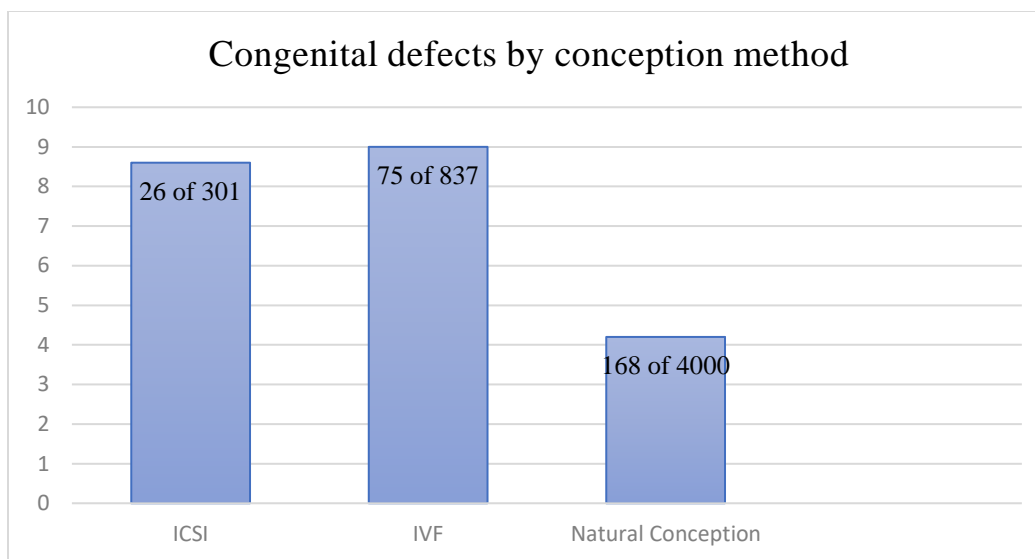
## 5. Potential Health Implications for Children Born Via ART

Pregnancies achieved through Assisted Reproductive Technologies (ART) are often classified as high-risk, and these methods are sometimes described as 'methods of desperation.' In response to such challenges, the World Health Organization consistently offers recommendations aimed at improving the reproductive health of adolescents and adults.

It is essential to recognize that the issues leading to the use of ART frequently persist and can influence the progression of pregnancy. For instance, an analysis involving 52 married couples who experienced unsuccessful IVF attempts uncovered significant diagnostic lapses. Infectious pathologies were underdiagnosed in 70% of these cases, with endocrine disorders not adequately recognized in 23% of cases. Among the most commonly overlooked infections were urogenital chlamydial infections, noted in 42% of cases, followed by mycoplasmal infections in 33%, and trichomonal infections in 25% of cases. This data underscores the need for comprehensive pre-ART assessments and interventions to address underlying health issues, enhancing both the effectiveness of ART and the overall health outcomes for prospective parents.

The least problematic outcome in ART is a non-developing pregnancy, rather than a pregnancy that progresses amidst untreated infectious and endocrine issues, which can harm the fetus and affect the child's genetic makeup. Such unresolved health conditions during pregnancy may lead to various somatic and mental disorders in children post-birth, with the potential to worsen over time. These observations highlight that while ART offers hope to many aspiring parents, it also carries significant risks and does not always ensure the birth of a healthy generation. This underscores the necessity for thorough medical assessments and interventions prior to and during ART procedures to mitigate potential adverse effects on both maternal and child health [11, 12]. The chief pediatrician of the Russian Federation and Academician of the Russian Academy of Medical Sciences (RAMS), A.A. Baranov, revealed alarming statistics in his addresses to the State Duma and during hearings in the Public Chamber. He reported that 75% of children born via ART exhibit health deviations, a rate significantly higher than that observed in children conceived naturally. This stark contrast highlights the potential risks associated with ART and underscores the critical need for ongoing research and rigorous evaluation of these reproductive technologies to better understand and mitigate the associated health risks for children born through these methods [13]. M. Hansen and colleagues conducted an analysis based on data from three Australian registries covering the period from 1993 to 1997 [14]. This study focused on births following the use of ART and examined the prevalence of major congenital defects in these children. Such research is essential for understanding the potential risks and long-term health implications associated with ART, providing critical insights into the safety and efficacy of these reproductive technologies.

The assessment of congenital defects in children up to one year after conception demonstrated significant differences based on the method of conception, as outlined in the study. Specifically, 8.6% of the infants born through intracytoplasmic sperm injection (ICSI), equating to 26 out of 301, were found to have significant congenital anomalies. Similarly, 9.0% of infants born IVF, or 75 out of 837, also exhibited significant anomalies. In stark contrast, only 4.2% of naturally conceived children, or 168 out of 4000, displayed such defects. This data underscores the increased risk of congenital anomalies associated with ART methods like ICSI and IVF compared to natural conception, highlighting the need for thorough monitoring and further research into the factors contributing to these outcomes [15].



**Figure 1.**  
Comparison of congenital defect rates by conception method.

Consequently, children conceived through ICSI or IVF are approximately twice as likely to develop significant congenital anomalies, including chromosomal and musculoskeletal defects, compared to those conceived naturally [16]. This increased risk highlights the need for prospective parents to be well-informed about the potential outcomes and for medical professionals to offer comprehensive prenatal and postnatal care to monitor and manage any health issues that may arise from these assisted reproductive technologies.

International research suggests that children born via IVF often display congenital developmental anomalies, with an attributable risk factor of 2.2. Predominantly, these defects affect the cardiovascular and musculoskeletal systems. This elevated risk underscores the necessity for careful prenatal screening and postnatal care to identify and address any potential health issues early. The data also points to the importance of ongoing research and potential adjustments in IVF protocols to mitigate these risks and improve health outcomes for children conceived through this technology [17]. Moreover, a range of inherited syndromes has been noted in children born through IVF, including Angelman syndrome, Beckwith-Wiedemann syndrome, lissencephaly, and hyperinsulinemic hypoglycemia. Additionally, a significant body of research reports a higher prevalence of mental disorders such as autism, intellectual disabilities, and behavioral disorders in these children [18]. Neurological conditions like cerebral palsy are also more frequently observed. These findings highlight the complex interplay between assisted reproductive technologies and genetic and developmental health, necessitating comprehensive genetic counseling and ongoing medical support for families undergoing IVF. This also calls for further research to better understand the mechanisms behind these associations and to develop strategies to reduce potential risks.

The study conducted by C. Patrat and colleagues concentrated on identifying pathologies during pregnancy and closely monitoring the growth and development of children born following subzonal sperm injection (SZI). This particular form of assisted reproductive technology involves the injection of sperm into the perivitelline space of an oocyte, which is slightly less invasive than intracytoplasmic sperm injection (ICSI) where sperm is injected directly into the cytoplasm of the egg. The research aimed to understand the short and long-term health outcomes of children conceived through this specific method, providing valuable insights into potential developmental and health challenges they may face [19]. SZI is an early micromanipulation technique designed to address male infertility when conventional IVF is unsuccessful. In their retrospective study, C. Patrat and colleagues focused on the

development of embryos conceived via SZI, scrutinizing aspects such as the progression of pregnancies, childbirth outcomes, and the incidence of congenital anomalies.

Their findings indicated a higher rate of miscarriages in SZI-assisted pregnancies compared to those conceived naturally. Notably, the incidence of congenital defects in newborns from SZI was found to be 4.2%, which is higher than both the general population and the rates observed in traditional IVF and ICSI, which typically range from 1.2% to 3.7%. This data suggests that congenital defects, including those affecting the central nervous system (CNS), are more prevalent in children conceived through SZI compared to those from natural conception or other ART methods. This underscores the need for careful monitoring and further research to better understand the risks associated with SZI and to improve outcomes for children conceived through this technique.

**Table 1.**

Comparison of the incidence of congenital defects in newborns by different conception methods, including SZI.

<b>Method of conception</b>	<b>Incidence of congenital defects</b>
Subzonal sperm injection (SZI)	4.2%
Traditional IVF	1.2% to 3.7%
Intracytoplasmic sperm injection (ICSI)	1.2% to 3.7%
Natural conception	Lower than ART methods

In numerous jurisdictions, medical negligence transitions to a criminal matter when it encompasses reckless or grossly negligent behavior that compromises patient safety. Particularly with high-risk procedures like SZI, it is imperative for medical professionals to provide thorough risk disclosures to prospective parents. Neglecting to do so not only breaches medical ethics but could also lead to legal repercussions under criminal statutes, especially if harm results from a lack of informed consent.

The intersection of criminal law with reproductive technologies underscores the legal obligations of medical providers to maintain a high standard of care. This ensures that both ethical practices and patient safety are prioritized, aligning with broader healthcare regulations and safeguarding the rights and well-being of patients engaging with advanced medical procedures such as ART.

## 5. Conclusion

The exploration of infertility and its treatment through Assisted Reproductive Technologies (ART) reveals a complex landscape filled with both hope and intricate challenges. As infertility rates pose significant concerns for population stability globally, ART has emerged as a pivotal advancement, providing many individuals and couples with the potential for parenthood. However, the deployment of these technologies brings forth substantial ethical and legal dilemmas, particularly concerning the rights of donors, parents, children, and the potential health implications for offspring.

To effectively navigate the advancements in biomedical technologies, especially through Assisted Reproductive Technologies, the following recommendations are proposed:

1. *Development of Robust Regulatory Frameworks:* It is crucial to establish comprehensive regulatory systems that ensure the safe, ethical, and equitable use of ART. These frameworks should be flexible enough to adapt to technological advancements while being sensitive to diverse cultural and moral perspectives.
2. *Enhanced Data Collection and Accessibility:* Continuous and expanded data collection by international ART registries is vital. Making this data accessible for global research and policy-making will support the assessment of ART outcomes and its long-term effects on children and families.
3. *Public Awareness and Education:* Increasing public knowledge about the causes of infertility and the potential and limitations of ART can help manage public expectations and ethical considerations. Educational initiatives should also focus on lifestyle and environmental factors that contribute to infertility.



4. *Improving Accessibility and Affordability*: There should be concerted efforts to make ART more accessible and affordable across various socio-economic groups and countries. This includes tackling disparities in the availability of ART and advocating for insurance policies that cover infertility treatments.
  5. *Ongoing Research into Long-term Effects*: Continued research into the long-term health effects of ART on children and subsequent generations is essential. This research should also examine the psychological and social impacts of using ART.
- By implementing these recommendations, stakeholders can better manage the complexities associated with ART, ensuring that it not only provides a solution to infertility but does so in a way that upholds human dignity and enhances societal well-being.

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