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Assisted Reproductive Technology procedures and related Malpractices: A Holistic Overview of the Indian Legal system

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Abstract
Despite the hyped success rate claimed by Assisted Reproductive Technology (ART) clinics, commissioning couples blame repeated failures on the negligence and malpractice of these clinics. Although a mechanism has been put in place, to regulate these malpractices, how far these legislations have succeeded in addressing the grievances of the parties to the ART remains to be seen. Against this backdrop, the paper covers the nature, scope, and stakeholders involved in ART. Moving forward, it highlights the medical malpractices in the ART industry and the provisions in the legal system to deal with them. Finally, it highlights the gaps in the legal system. The method for the study was a doctrinal one, wherein references were made to scholarly articles, newspapers, reports of national and international agencies, and case laws while conducting the research.

Keywords: Medical malpractice, Assisted Reproductive Technology, Surrogacy

1. Introduction
In the traditional Indian social milieu, infertility can lead to social intrigue and stigmatisation. (Patel et al., 2018, p. 174). Wherein infertility has resulted due to reasons like delayed marriage, unhealthy lifestyles, excessive alcohol consumption, sexually transmitted diseases, and obesity or malnourishment, among others (World Health Organization, 2024). Reportedly, 17.5% of adults experience infertility globally (World Health Organization, 2023), while 27.5 million people in India face the challenge (Kapasi, 2025). Compared to the approximately 2.5 million cycles performed annually globally, 2–2.5 lakh IVF cycles are performed in India. The Indian fertility industry is growing exponentially, as evidenced by the projection of its growth from $746 million in 2021 to $1,453 million by 2027 (Nayana & Sandeep, 2024 p. 82). According to the 2022 revision of The Prospects of World Population, India's total fertility rate, which is the average number of children a woman has given birth to, has declined to 2.159 children per woman in 2021 (United Nations, Department of Economic and Social Affairs, Population Division, 2022), and this is expected to reduce to 1.29 by 2050 as per the study done by the Lancet (Institute for Health Metrics and Evaluation, 2024). Recently, a study found that 55% of women under 35 gave birth to a live child after one egg retrieval cycle. (Devesa et al., 2018, p. 1834). Seemingly, the mushrooming of infertility clinics all over the country, with over 2500 fertility clinics, (Fatehi, 2022) has been caused by the patriarchal mentality prevalent in society and a failing public health system (Nadimpally & Venkatachalam, 2016, p. 88)

The paper discusses the nature, scope, and data relating to ART in this background. It also briefly lists all the stakeholders involved in ART. Moving forward, it highlights medical malpractices in the ART industry, simultaneously analysing and highlighting the loopholes in

the legal framework regarding the same. Finally, the concluding part summarises the gaps in the framework, seeking the attention of the concerned.

2. Nature And Scope Of Art

Assisted Reproductive Technology (hereinafter referred to as ART) involve retrieving eggs from a woman's reproductive system and fertilising them with sperm in a lab, further placed back into the commissioning woman or the surrogate, (Assisted Reproductive Technology (Regulation) Act, 2021, § 2(1)(a)) including procedures like intrauterine insemination (IUI), in-vitro fertilisation and embryo transfer (IVF-ET), (Jain & Singh, 2023), excluding medicinal treatment. It could be a boon for various infertile couples. (Patrizio et al., 2022, p. 312) Additionally, Preimplantation Genetic Diagnosis (PGD) has helped couples with genetic issues (Xu et al., 2022, p. 4). Moving forward, we must understand the sector's stakeholders to gauge the industry's challenges and identify the malpractices.

3. Stakeholders In Art

The prime stakeholders in ART are the commissioning couples, i.e., infertile and married couples (ART Act, 2021, § 2(1)(e)) facing problem convincing after one year of unprotected sexual intercourse (ART Act, 2021§ 2(1)(j)). Secondly, fertility clinics and healthcare providers, including nurses and support staff, play a central role. Thirdly, sperm and egg donors. Fourthly, surrogate mothers. Fifthly, regulatory authorities, including government agencies and lastly, the children born through ART (ART Act, 2021, § 2(1)(d)). The stakeholders on the receiving end of the procedures, like commissioning couples, frequently face medical malpractice without proper redress.

4. Regulatory Malpractices In The Art Industry

Medical malpractice is a course of action that manifests when a health care professional, through reckless behaviour or omission, departs from benchmarks in their discipline, causing injury or demise of the patient (De et al., 2020, p. 153).These malpractices range from pre-conception (Nahvi, 2021, p. 5) to financial (Nadimpally et al., 2011), clinical (Balasch, 2000, p. 2252) and regulatory aspects (Kotiswaran & Banerjee, 2021, p. 378) concerning issues like surrogate abuse (Suryanarayanan, 2022commercialisation Ghosal, 2018, p. 95).Thus, there are a variety of malpractices, and for brevity, we will only focus on regulatory malpractice in the ART industry, the related gaps, and remedies.

The regulatory malpractices constitute an infringement of legal accountability and benchmarks set by healthcare regulatory bodies (Ifenatuoha et.al, 2023, p. 6). These malpractices include practising without a proper licence, fake advertisement, challenges in compliance with informed consent, and improper grievance redressal mechanisms, which are dealt with in detail below.

4.1. Operating without a proper licence:

The Indian Council of Medical Research (ICMR) guidelines required registration of the ART clinics with the State Accreditation Authority, (ICMR, 2005, Guideline 3.1) but only 20% of the IVF clinics were registered with the ICMR as reported (Dey, 2017). Later, the Assisted Reproductive Technology Act, 2021 (ART Act) also made it mandatory that clinics should be enrolled with the National ART and Surrogacy Registry; otherwise, they were not allowed to carry out their services (ART Act, 2021, §15(1))

As of March 2024, 263 surrogacy clinics, 973 ART clinics, and 252 ART banks were registered with the Registry. However, the number of clinics might exceed 40,000 (Tank et al., 2023, p. 305). These data indicate the gap in the registration process, excluding various clinics and labs from the regulatory framework around ART (Department of Health Research, n.d.).

A clinic could only be registered if it had the required facilities and sufficient workforce (ART Act, 2021, §15(4)), the premises had also undergone inspection (ART Act, 2021, §16(5)) and the registration would be renewed every five years (ART Act, 2021, §16(6)). Further, in case of denial, the applicants had an opportunity to be heard (ART Act, 2021, §16(ii)).

Furthermore, if anyone were found operating a fertility clinic without registration, they would face a fine ranging from five lakh to ten lakh rupees for the first offence. They may be imprisoned for three to eight years for subsequent violations, with a fine ranging from ten to twenty lakh rupees (ART Act, 2021 at §33(2)). Still, such non-registered clinics are functioning. In one such case, where a swindler was performing the procedure, a woman died (Bahl and Singh, 2022).

Even the Surrogacy Regulation Act, 2021 (SRA)) required registration with the National ART and Surrogacy Registry (SRA, 2021, §11(1)), whereby no surrogacy clinic should be registered unless it had requisite manpower and physical infrastructure (ART Act, 2021,§12(3)) and the registration had to be renewed every three years (SRA, 2021,§12).
If a surrogacy clinic fails to obtain registration, the responsible individual will face imprisonment for up to five years and a fine of up to ten lakh rupees. In the event of repeated violations, the appropriate authority might refer the medical practitioner's name to the medical council for suspension of their registration for up to five years (SRA, 2021, §39).
Thus, operating without proper registration undermines the quality of care and exposes patients to potential risks, including unethical of practices, financial exploitation, and compromised medical standards (Sadeghi, 2023, p.68). To address the challenges, specific measures can be implemented, such as the registration process can be streamlined (Letterie, , 2017, p. 46), surprise inspections and audits should be conducted (Bajpai, 2024) , the registration costs may be kept low for smaller clinics (Bhargava, 2003, p. 278) , awareness about the risks of seeking treatment from unregulated clinics may be raised (Gouda & Hiremath, 2009, p. 406) and a registry should be established to verify the credentials of the clinics and the regulatory bodies can collaborate (Menon, 2007, p. 8).

4.2. Fake Advertisement:

Another concern is fake advertisements. Reportedly, advertisements attracted about 54% of patients who underwent IVF procedures (Unnithan, 2015). In the pre-ART legislation era, the ICMR guidelines covered counterfeit advertisements. However, in the post-ART legislation era, there were barely any provisions directly dealing with the issue, either under the ART Act or the SRA.

However, a complication of guidelines issued by the Ministry of Consumer Affairs had set a roadmap for fair advertisements. Accordingly, an advertisement shall be considered to be legitimate as per the Consumer Protection Act, 2019 (CPA) if it includes trustworthy and genuine information (Guidelines for Prevention of Misleading Advertisement and

Endorsements for Misleading Advertisement, 2022, Rule 4(1)(a)), it must not overstate its validity or correctness (Guidelines for Prevention of Misleading Advertisement and Endorsements for Misleading Advertisement, 2022, Rule 4(1)(b)) and it must guarantee that consumers were not misled by statements that have not been independently verified (Guidelines for Prevention of Misleading Advertisement and Endorsements for Misleading Advertisement, 2022, Rule 4(1)(f)). Additionally, advertisements employing phrases like "Prices from as low as Rs. Y" or "up to five years guarantee" should not be used by fertility clinics (Guidelines for Prevention of Misleading Advertisement and Endorsements for Misleading Advertisement, 2022, Rule 12). Further, it must not deceive customers by leaving out limitations like age and past medical history. Also, other laws were required to be followed regarding forbidden advertisements (Guidelines for Prevention of Misleading Advertisement and Endorsements for Misleading Advertisement, 2022, Rule 9). Also, the CPA penalised anyone who displayed a misleading ad with a maximum punishment of two years in prison and a penalty extending to ten lakh rupees. The punishment extended to five years of incarceration and a sanction of up to fifty lakh rupees for each extra infraction (CPA, 2019, § 89)

Still, various challenges persisted, leading to multiple concerns relating to fake advertisements, ranging from counterfeit success rates, deceptive disclaimers, misleading endorsements, and overcharging against advertised prices to proxy advertisements. ART clinics have often inflated their success rates without regulatory provisions. The ICMR guidelines required the clinics to inform couples of the success rate of the procedure intended to be used (ICMR Guidelines, 2005, Guideline 3.3.10). In the significant case of Dr. Malpani, the clinic promised a refund for failed treatment. While deciding the matter, the Medical Council of Maharashtra suspended the registration of Dr. Malpani's clinic for three months. In another case, the complainant claimed that despite incurring substantial expenses, she did not achieve the desired result of conception. She argued that the clinic's advertisement, which claimed a 70% success rate for IVF procedures, influenced her decision to seek treatment there. However, during the proceedings, the clinic admitted that the success rate was only 15-20%. The Commission deemed this discrepancy misleading and held the clinic accountable for providing deficient service. It also ordered the clinic to compensate the petitioner for the financial loss and emotional distress caused by the misleading advertisement and failed treatment. (*Malpani v. State of Maharashtra,* 2016) . However, instances of false advertising persist, as reported in the case of *Mhan Kumari*, wherein the consumer court awarded compensation and addressed the deceptive nature of advertisements by IVF clinics, which often inflate success rates without specifying whether they apply to per-cycle treatments or the use of fresh or frozen embryos (*Mhan Kumari v. Base Fertility Medical Science Pvt. Ltd.*, 2016).

Another challenge was false reviews. To cater to this problem Consumer Protection (Direct Selling Rules state that fertility clinics should not make false reviews (The Consumer Protection (Direct Selling) Rules*, 2021, Rule* 5(13)) or proxy advertisements (The Consumer Protection (Direct Selling) Rules*, 2021,* Rule 6). According to the Ministry of information and broadcasting advertisers shall self-certify that there are no misleading claims and that services are only offered at the advertised price (The Consumer Protection (Direct Selling) Rules*, 2021,* Rule 5(a)). Further, free treatment advertisements were prohibited if consumers had to pay additional costs. (The Consumer Protection (Direct Selling) Rules*, 2021,* Rule 7).

Furthermore, disclaimers made by ART clinics must not conflict with the substantial claim expressed (The Consumer Protection (Direct Selling) Rules, *2021,* Rule 11(1)(a)) and must have refrained from trying to conceal important information (The Consumer Protection (Direct Selling) Rules, 2021, Rule 11(1)(b)). They should have refrained from attempting to fortify an advertisement's false claim (The Consumer Protection (Direct Selling) Rules, 2021, Rule (11(1)(c)). The language (The Consumer Protection (Direct Selling) Rules*,* 2021*,* Rule (11(2)(a)) and typography (The Consumer Protection (Direct Selling) Rules*,* 2021*,* Rule 11(2)(b)) of the disclaimer and the advertisement should have been the same. The disclaimer must have been placed in a conspicuous area (The Consumer Protection (Direct Selling) Rules*,* 2021*,* Rule 11(2)(c)) which needed to be played at the same speed as the advertisement's initial assertion (The Consumer Protection (Direct Selling) Rules*, 2021,* Rule 11(2)(d)), it must be visible, readable and clear (The Consumer Protection (Direct Selling) Rules*, 2021,*11(2)(e)). Another concern was keeping relevant information to themselves. The clinics never cite the children born with any anomaly. In one such case, improper screening of a commissioning mother caused the premature birth of a child, resulting in severe abnormalities (*Sushil Kumar v. Javitri Hospital and Test Tube Baby Centre*, 2018)

Beyond other stakeholders, the Rules also made the endorsers liable. Ensuring the responsibility of the endorsers, the Apex Court also held that celebrities would be equally liable for endorsing misleading information through advertisements (*Indian Medical Associations & Another. v. Union of India & Others,2022*). Furthermore, the endorser might also be prohibited from advertising for a period ranging from one to three years for misleading advertisements (Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022, Rule 21(2)).

Importantly, if the advertisement was deceptive or false, the Central Consumer Protection Authority (CCPA) had the authority to order the concerned advertiser to stop advertising it or change it (Consumer protection Act, 2019, § 21(1)) and impose a penalty of up to ten lakh rupees and up to fifty lakh rupees for each successive violation (CPA§ 21(2)). Further, the Rules provided that anyone disregarding any directive from the CCPA might face a maximum confinement of six months and a maximum sanction of twenty lakh, or both (CPA, § 88).Thus, CPA covered a significant concern of false advertisements, wherein the absence of provisions under the ART Act and the SRA led to the clinics continuing to lure couples by citing fake success rates. A generic penal provision of Section 34 of the ART Act could not justify the coverage of the challenge.

To stop fake advertisements, ICMR can conduct regular checks on clinic advertisements and can consider blacklisting repeat offenders. Also, success rate claims should be audited before they can be advertised. It should be ensured that all advertisements include clear, unambiguous disclaimers (Ramaraju & Muvvala, 2023).

4.3. Informed consent:

Before initiating any medical process, it is imperative to have relevant information for making a choice, especially when it involves substantial money and physiological challenges. However, it is disregarded, wherein the couple and the surrogates are given fragmented knowledge about the procedures, medications, side effects, and expenses (Nadimpally et al., 2011, p.4).

In the pre-ART legislation era, the ICMR guidelines had a directory provision for informed consent for commissioning couples and not for others. (ICMR, 2005, Guideline 3.2.4). When the ART Act was enacted, it required clinics to counsel couples, surrogates, and donors about the implications and success rate (ART Act, §21(c)(i)). It also mandated written informed consent from all the parties (ART Act, §22(1)(a)). Furthermore, permission was also required to cryopreserve human embryos or use any human reproductive material (ART Act, §22(2)) to collect gametes posthumously (ART Act, §24(f)), donate embryos to the laboratory or conduct research (ART Act, §25(2)(a)). Moreover, the commissioning couples also had the right to withdraw their consent before the implantation of the embryo (ART Act, §22(4)).

Even the Supreme Court has decreed that it was the binding obligation of the doctor to inform the recipient of medical services of the perils involved, and failure to do so was medical negligence (*Samira Kohli v. Dr. Prabha Manchanda*, 2008). In one such case of negligence regarding the mixing up of sperm, the National Consumer Disputes Redressal Commission imposed a massive penalty against the hospital. It made DNA profiling compulsory for all fertility clinics (*Priyanka Tandon v. Bhatia Global Hospital*, 2023). However, there have been cases where the commissioning couples failed to establish a lack of informed consent and the courts dismissed their case (*Sabbani Lavanya v. Hedge Hospital*, 2023).

The SRA also prescribes prior informed consent for the surrogate, whereby all the side effects had to be explained to her. (The Surrogacy (Regulation) Act, 2021, §6(1)(i)) giving her the freedom to withdraw consent before the implantation of the embryo (SRA, *2021*,§6(2)). Additionally, as per the CPA, the commissioning couples had the right to information about the cost, standards, and quality of services (CPA, 2019, § 2(9)(i)), the right to be heard, and the assurance that their concerns would be considered in the appropriate forums (CPA, 2019*,* §2(9)(iv)).

Also, for performing any pre-natal technique on expecting women, the Pre-Conception and Pre-Natal-Diagnostics Techniques Act of 1994 mandated informed consent (Pre-Conception and Pre-Natal Diagnostic Techniques Act*,* 1994, § 5). This law did not provide similar preconditions for surrogates; however, the SRA did.

In the backdrop of these malpractices, the law of torts comes in handy, making the medical practitioner liable for trespass if the patient's consent was not obtained in an informed manner (Nandimath, 2009). Despite the above-stated provisions, informed consent was still a formality, as evident from a recent case where the All-India Institute of Medical Sciences' doctor handed over the eggs of an IVF patient without her consent to two other women. Still, the doctor was acquitted with a warning rather than penalised (Sharma, 2023). The ART Act prohibited donor gametes from triggering underground dealing in the gametes (Rao, 2022). However, with the latest amendment allowing donor gametes, such malpractices will subside. (Surrogacy (Regulation) Amendment Rules*, 202*4).

4.4. The Violation of age criteria:

In the pre-ART legislation era, the ICMR guidelines did not put a maximum age limit for availing of ART, leading to the misuse of technology by older women (Perappadan, 2019). To tackle such problems, The ART Act prescribed the upper age limit as 21-50 years for females and 21-55 for males (ART ACT, 2021, §21(g)). However, the Act does not explicitly state the punishment for violating the age criteria. Section 34 of the Act addresses the

miscellaneous violations, making them punishable under Section 33 (2). However, in the instant case, the Kerela High Court permitted a married woman aged 46 to undergo ART via donor gametes even though her husband was 55 years old (*XYZ & Others v. Union of India & Others*, W.P.(C) No. 31161 of 2024). Similarly, the Calcutta High Court allowed the couple to seek aid from ART, where the husband had crossed the age limit while the wife met the age criteria (*Saswati Mohury v. Union of India*, 2023). However, in another matter, (*Sri H. Siddaraju v. Union of India*, 2023) the Bench did not allow for the relaxation of the age limit for surrogacy, as the upper age limit for men is 26–55 and for women is 23–50 to avail surrogacy (SRA, 2021, §4(iii)(c)(I)).

Here, the court formulated three tests to determine the ability of the couples to raise a child. Firstly, the father's genetic test for testing the strength of the sperm; secondly, the family's economic stability to secure the child's future; and thirdly, the physical ability of the couples to assure that they were physically capable of taking care of the child. Still, overage couples resorting to ART have been reported, like in the case of late singer Moosewala's parents (Vasdev, 2024). In another case, the court emphasised the fundamental right to procreate, stating that any restrictions must be reasonable and justifiable. Due to the absence of transitional provisions in the ART Act, individuals already undergoing treatment were permitted to continue. In contrast, others were instructed to wait for further directives from the central government (*Nandini v. Union of India, 2022)*. To address the issue of age violation, the National Registry for ART procedures could track donor and patient age to prevent fraudulent entries, and clinics should display the age criteria in their advertising content.

4.5. Improper Grievance Redressal Mechanism:

The grievance redressal mechanism is a means to note, investigate and respond to a complaint. It is generally a civil remedy ensuring compensation, damages or suspension of licence and registration of a practitioner or clinic. Further, it must be speedy, fair and effective (World Bank, n.d.).There were provisions for regulatory, investigating, and redressal bodies.

In the pre-ART legislation era, the ICMR guidelines provided for the registration of complaints by the commissioning couples as a matter of right, and it was the duty of the ART clinics to nominate a person to investigate the complaints, without much clarity on the person's affiliation and qualification, indicating a mere lip-service and protection of medical practitioners (ICMR Guidelines, 2005, Guideline No. 3.2.0).

In the given gap, the Supreme Court held that services rendered by doctors would fall within the ambit of the CPA, enabling aggrieved patients under the ART to seek redressal under the Act. (*Indian Medical Association v. V.P. Shantha, 1996*). The CPA provided for consumer protection councils and regulatory bodies at the central (CPA, 2019, §3), state (CPA, 2019, §6) and district levels (CPA, 2019, §8). Further, the CCPA was established (CPA, 2019, §10) to stop violations of the rights of customers (CPA,2019,§18(a)), prevent unfair practices (CPA, 2019,§18(b)), impose penalties for misleading advertisements (CPA,2019§18(c)), discontinue services that pose a risk or are unsafe (CPA,2019,§20(a)), pay back the costs of services that were recalled to those who purchased them (CPA,2019, § 20(b)), stop unfair practices that harm the interests of consumers provided that the individual concerned was given a chance to be heard before the issuance of an order (CPA,2019,§20(c)). Nevertheless,

the right to investigate and undertake inquiries was subject to "prejudice to the public interest or the interests of consumers as a class." It was up for interpretation and judicial review as to whether imposing this requirement would limit the CCPA's jurisdiction to only situations involving numerous claims.

Furthermore, an Investigation Wing was established (CPA, 2019, §15), which had the power to access any of the fertility clinics, look for any records or other types of evidence and take them (CPA,2019,§22(1)(a)), demand that someone make a record (CPA, 2019,§22(1)(c)) and anyone who disobeyed the order was punishable with a one month to a three-year sentence, a fine of a minimum of twenty-five thousand rupees to a maximum of one-lakh rupee, or both. (CPA, 2019, §72(1)). Section 17 of the Act stipulated that the complaint had to be sent to the district collector, who might further report the matter to the CCPA or Regional Commissioner following a suitable investigation. However, it was unclear if the CCPA was bound by the district collector's investigation and findings after receiving a "positive report" about an allegation of a violation of consumer rights (Singh & Singh, 2020). Other adjudicating bodies include the National Consumer Disputes Redressal Commission (CPA,2019, §53), the State Consumer Disputes Redressal Commission (CPA, 2019, §42) and the District Disputes Redressal Commission (CPA, 2019, §28).

The commissions had the authority to decide consumer disputes and issue binding rulings. They also had the authority to bring any book, account, or necessary item before them. They could also permit an officer to enter and search any fertility clinic; the seizure must have been reported to the appropriate commission (Consumer Protection Rules, 2020, Rule 9). National Commission was empowered to investigate abuses such as failure to issue a cash memo, providing inferior assistance or reimbursing the funds and disclosing a customer's personal information to any other individual unless required by current laws or in the public interest. (Jhabakh et al., 2020). The Act also provides for a mediation cell, although mediation could be used to resolve cases involving medical malpractice that resulted in severe damage or death. (CPA, 2019, §74). Further, the ART Regulations mandate appropriate authorities (ART Regulations, 2022, Rule 11) to complete an investigation within seven days (ART Regulation, 2022, Rule 9.2.3), suspend or cancel the clinic's registration if found guilty, without prejudice to criminal action (ART Act, 2021, §18) and maintain a grievance cell (ART Regulations, 2022 at Rule 11). Furthermore, under Section 33 of the Act, specific actions were explicitly prohibited, such as abandoning children born through ART, selling or engaging in the import and export of human embryos or gametes, or operating agencies involved in such trade, exploiting commissioning couples, women, or gamete donors in any form, transferring human embryos into male individuals or animal, using intermediaries to procure gamete donors whereby first-time offenders were subject to a fine ranging from five lakhs to ten lakh rupees and subsequently for a term between three to eight years and a fine ranging from ten lacks to twenty lakh rupees. Additionally, Section 37 of the Act held the executive head of an ART clinic or bank accountable for offences committed under the Act unless they could prove that the offence occurred without their knowledge or that they exercised due diligence to prevent it. Further, aggrieved parties can also seek remedy under the Indian Medical Council Act, 1956, which allows the council to suspend or cancel the clinic's registration (Indian Medical Council Act, 1956, § 20A).

Despite these provisions, people were accessing justice through consumer commissions, as reported in a case whereby the couples approached the commission regarding the denial of

treatment at the crucial delivery stage, citing the lack of ICU and blood bank facilities. In this case, the hospital had collected advance payments for delivery services but did not fulfil their obligations, causing the patient to incur additional expenses elsewhere. This abrupt referral to another hospital during active labour was deemed negligent. Consequently, the commission held the IVF hospital guilty of negligence in their duty of care towards the patient and ordered them to pay compensation under various heads to the complainant (*Poonam Matlani v. Indira IVF Hospital Pvt. Ltd., 2022)*.

Thus, the legal efficiency of the ART Act and SRA is not visibly present. However, the CPA Act has created fear among IVF clinics about their liability to pay compensation, as in most cases of false advertisement, couples have been compensated by the clinics. Even after more than three years of the implementation of the Act, not all the ART clinics and banks have registered themselves with the Registry, nor is there any audit of the same. Further, informed consent is being obtained on a surface level. Furthermore, the ART Act has not been able to prevent availing the facility to overaged couples. Finally, the grievance redressal mechanism through ART clinics has given little benefit to the people; only in some instances has the CPA helped speedy remedy and monetary relief.

To address the people's grievances related to ART and surrogacy, the Government should establish ombudsman services, online and offline Grievance Portals, 24/7 helplines, and fast-track courts to tackle the claims arising from ARTs.

Conclusion

The ART industry is expanding in terms of the number of people accessing ART and, thereby, in terms of turnover. With growing scope, opportunities for various segments of society have opened, even leading to malpractices affecting different stakeholders. Although statutes such as the ART Act and the SRA have been enacted, there are various gaps concerning these legislations mandated to ensure the rights of the stakeholders, wherein the CPA has created fear among IVF clinics about their liability to pay compensation. Further, even though the ART Act required the registration of the clinics and banks within six months of its enforcement, the same remains unenforced. Furthermore, informed consent is superficially complied with. Also, availing of the facility by overaged couples is still reported. Moreover, the grievance redressal mechanism through ART clinics has not been complied with. However, in some instances, the CPA has ensured speedy remedy and monetary relief.

Thus, we can say that the ART, practised for over four decades without legal provisions, was mildly covered by ICMR Guidelines in 2005 and recently by the ART Act and SRA in 2021. The CPA has provided primary coverage of fake advertisements, medical negligence in informed consent, and grievance redressal. These gaps, therefore, need to be covered for effective ART regulation. For this, the following suggestions may be made. Firstly, the registration process can be streamlined by reducing bureaucratic hurdles. Secondly, surprise inspections and audits should be conducted, and unregistered clinics should be shut down. Thirdly, smaller clinics may keep registration costs low to encourage adherence. Fourthly, awareness about the risks of seeking treatment from unregulated clinics may be raised. Fifthly, an easily accessible registry for commissioning couples can enable them to verify the credentials of the clinics. Sixthly, regulatory bodies, like the National ART and Surrogacy Registry and the ICMR, can collaborate, and only one can regulate registration and compliance. Seventhly, to stop fake advertisements, ICMR can work in association with the

Medical Council of India (MCI) and conduct regular checks on the clinic's advertisements, both online and offline and can consider blacklisting repeat offenders from advertising altogether. Also, success rate claims should be audited before they can be advertised. To ensure compliance with informed consent uniform, comprehensive consent forms should be developed that clearly outline the procedures, risks, benefits, and alternatives.

Ninthly, to address the issue of age violation, the National Registry for ART procedures could track donor and patient age to prevent fraudulent entries. Additionally, the clinics should display the age criteria in all patient agreements and advertising content.

Subsequently, to address the people's grievances related to ART and surrogacy, the Government should establish ombudsperson services, online and offline Grievance Portals, and 24/7 helplines for patients, donors, and surrogates to report issues in multiple languages. Also, free legal support to couples, donors or surrogates who experience malpractice or exploitation should be provided. Lastly, fast-track courts should be established to tackle the claims arising from ARTs.

The above-stated suggestions may take the regulation of ART to the next level, where all the stakeholders, especially the commissioning couples, would be able to take the best out of the ART industry.

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