The Practice of *In-Vitro* Fertilization in Developing Countries: Medico-Legal Issues Arising

By

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Abstract

In vitro fertilization (IVF), an assisted reproductive system is primarily a process for bringing succor to couples who are victims of involuntary childlessness. Being a relatively new frontier in reproductive technology, its practice and propriety have generated widespread controversy along religious, cultural and moral lines. The foregoing scenario makes the issue topical. The practice of IVF in developing countries is characterized by a mirage of challenges, which include high cost of treatment, inadequate trained physicians in reproductive health technology, lack of proper Government policy on reproductive health, lack of comprehensive guideline, regressive regulatory standard, lack of political will and legislative framework on IVF to streamline practice, ensure standards and compliance amongst other. These anomalies encourage quack doctors to exploit and encroached on the rights of vulnerable couples with little regard to legal or ethical principles. In view of these challenges, this paper highlights the need for adequate regulatory and legislative framework for surveillance of physicians offering IVF in developing countries, in order to prevent exploitation of sufferers of involuntary childlessness. This paper concludes by advocating the need for developing countries to adopt similar templates on reproductive health policies and practice in the mode of what obtains in developed jurisdictions.

Introduction

In vitro fertilization is an example of exponential progress in medicine which has revolutionized reproduction and given succor to couples experiencing involuntary childlessness. The development of in-vitro fertilization[1] technology has strengthened the frontiers of assisted reproductive technique which at inception generated widespread controversies that made it almost unpopular at first instance in most developing countries. Despite this challenge, in vitro fertilization has evolved as the cornerstone of fertility treatment in developing countries (including Nigeria)[2] for couples experiencing delay in conception[3]. Currently, over four million children have been born through this technique[4]. In Nigeria the clamor for the treatment has increased amongst couples who have become victims of involuntary childlessness[5]. According to experts, one in every four couples in Nigeria has difficulty achieving conception through natural means.[6]

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[1] Hereinafter called IVF

[2] Reference would be copiously made to Nigeria (as case study) being a classical example of a developing economy which possesses virtually all the characteristic of a typical developing economy.

[3] Otherwise referred to as involuntary childlessness.

[4]Ajayi, R, IVF: Ajayi makes case for regulation in Nigeria, http://www.smsforhealth.com/news/details.php accessed 10/7/2017

[5] Involuntary childlessness is the inability to fulfill the desire to have a biologically related child. Such physical inability can be caused by one's reproductive dysfunction (e.g. low sperm count or blocked fallopian tubes), the reproductive dysfunction of one's' partner.

[6] Onche, O, IVF still an all comers affairs in Nigeria, http://www.geneticsandsociety.org/article.php accessed 10/7/2017

Regulations governing IVF treatments vary from one country to another. In the United Kingdom, it is a legal requirement for clinics which administer fertility treatment (that involve human gametes) such as IVF to be licensed[7]. Unfortunately, no such requirement or regulation exists in Nigeria and most developing countries. This uncomplimentary situation has provided a safe platform for quakes and unprincipled medical personnel to infiltrate the practice, compromise standards and thrive in this crucial area of medical practice with impunity. The patients are left with no option, but to yield to the unconscionable bargains by those who render such services. Above all, no assurances are provided for the success of the treatment. In the event of failure of such treatment, the patient is made to pay full charges all over for any repetition.

In the United Kingdom, the Human Fertilization and Embryology (HFE) Authority[8] is the statutory body with the responsibility for overseeing compliance with the relevant laws and professional guidelines on IVF technology. The body also performs annual audit of result of treatment from all licensed clinics, and the results are published annually. Furthermore, all licensed clinics are mandated to ensure that there is no mix up of human semen. Strict guidelines exist for the creation, manipulation and use of gametes. Criminal sanctions are provided for infringements on the set guidelines. Unfortunately, there is no such regulatory body to ensure standards or discourage quackery in Nigeria and most developing countries.

Conceptual Overview of In-Vitro Fertilization

In vitro fertilization is a treatment in which eggs are removed from a woman, fertilized with sperm outside the body and inserted into the uterus of the same or another woman. This procedure includes extraction of eggs, collection of sperm, fertilization in culture and introduction into the uterus at the eight-cell stage. In a successful procedure, pregnancy begins when the embryo is implanted into the uterine wall. However, the most common challenge associated with IVF is failed implantation.

The practice of artificial insemination or manual introduction of sperm into the cervix according to Bracewell J, *in re (B) (parentage)*[9] has long been known as a possible means of human conception. The first creation of live human embryos outside the human body through IVF which resulted in a successful live birth was in 1978[10]. Joy Louise Brown was the first child to be conceived through IVF in July 1978. Since Louise Brown's birth, nearly four million babies have been born through this assisted reproduction technique.[11] Her birth evoked vociferous condemnation; this prompted the government to set up "The Warnock committee" on human Fertilization and Embryology[12]. In the United Kingdom, IVF treatment is governed by the Human Fertilization and Embryology Act of 1990 which was amended by the British parliament in 2008. The Act lays down stringent conditions for obtaining a license from the Human Fertilization and Embryology Authority.

[7] Section 3(1) of the human fertilization and Embryology act 1990
[8] The Human Fertilization and Embryology Authority is a statutory licensing body set up section 5 of the human fertilization embryology act 1990.
[9] [1996] 2 F.L.R. 15 AT 21
[10] Professor Robert Edwards pioneered in vitro fertilization technique. He worked alongside a renowned Dr Patrick Steptoe to produce the world's first test tube baby.
[11] Birthday honors: test tube baby pioneer knight, BBC news, June 10 2011, http://www.geneticsandsociety.org/article.php accessed 10/7/2017
[12] Committee on Human Fertilization and Embryology (1984 cmmd 9314, chairman dame Mary Warnock)

The English Human Fertilization and Embryology Act 1990

The principle underlying the Human Fertilization Embryology Act 1990 was modeled after the Warnock Committee Report Recommendation on Human Fertilization and Embryology. Although the Act was amended in 2008[13] following new scientific development, legal and ethical issues have continued to trail the rationale behind the regulatory framework on in-vitro fertilization treatment in the United Kingdom till date. The 1990 Act provides for the establishment of a statutory regulatory authority known as the Human Fertilization and Embryology Authority[14]. The body is saddled with the responsibility of ensuring compliance with applicable laws, and enforcement of penal sanctions against offenders. The authority ensures that fertility treatments are administered in accordance with laid down procedures, structured, complex web of discretion, restraints, control and accountability[15]. The body is also responsible for the issuance of licenses to practitioners under a strict code of practice[16]. A breach of the code of practice by any practitioner may result in the revocation of his license[17]. The act also vests the authority with the powers to grant or withhold licenses, formulate policies and issue mandatory discretion[18]. Failure to comply with any of the mandatory discretions constitutes an offence.[19]

Under section 3(1)[20], IVF treatment can only be carried out under license from the human fertilization Embryology Authority. The section provides that no person shall:

"Bring about the creation of an embryo; or keep or use an embryo except in pursuance of a license."

Schedule 2 paragraph (1) provides:

"A license under this paragraph may authorize any of the following in the course of providing treatment services;

- Bring about the creation of embryo in vitro;
- Keep embryos;
- Use garment;
- Practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for this purpose;
- Placing any embryo in a woman"

Under Schedule 2 paragraph 5, a license is granted for a period not exceeding five years

[13] Human Fertilization Embryology Act 2008
[14]The Human Fertilization and Embryology Authority (hereafter referred to as HFEA)
[15] Montgomery, J., *Rights, Restraints and pragmatism, London,* cited in Stauch, M, et al, Sources on Medical Law 2nd ed., London: Cavendish, 2002, p. 373.
[16] License for the creation of an embryo outside the body is provided for under section 3(1)(a) and 1(2) of the 1990 act. License for the storage or use of embryos is provided for by section 3 (1) (b) 1990 act. Section 4 (1) (a) provides for license for the storage of gametes. The HFE Authority granted license for cell nuclear transplant in August 2004.
[17] Section 18(1)(c) HFE Act 1990.
[18] Section 22, and 24 HFE Act
[19] Section 41(2) HFE Act
[20] The Human Fertilization and Embryology Act 1990 of England (as amended in 2008)

Consent to Use or Storage of Gametes or Embryo

An important aspect of the 1990 Act is the weight accorded to acquisition of consent from gamete providers. Schedule 3 of the Act provides that

> "Consent under this schedule must be given in writing and in this schedule, 'effective Consent' means a consent which has not been withdrawn[21].

Under schedule 3 paragraph 2(1) consent to the use of any embryo must specify one or more of the following purposes: -

a) Use in providing treatment, services to the person giving consent or that person and another specified person together;
b) Use in providing treatment services to person not including the person giving consent; or
c) use for the purpose of any project of research and may specify condition subject to which the embryo may be used.

Schedule 3 paragraph 2 (2) provides that consent to the storage of any gamete or embryo must:

a) Specify the maximum period of storage (if less than the statutory storage period); and
b) State what is to be done with the gametes or embryos if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it and may specify conditions subject to which the gametes or embryo may remain in storage.

Thus, by Schedule 3 para.2 (2) (b) consent to storage, given by gamete provider can be varied, revoked or withdrawn.[22] However, such consent cannot be withdrawn or varied once the gamete or embryo has been used for treatment[23].

The meaning of the word "used" was considered in *Evans v. Amicus Healthcare*[24]. In this case, Natalie Evans wished to have an embryo implanted that had been created from her eggs and the sperm of the man from which she had subsequently separated. Since these embryos were created just before she had hysterectomy.[25] Her only chance to have a genetically related child was to have the embryo implanted. The man had written to the clinic to notify it of the separation and requested that the embryos be destroyed. Natalie challenged this position. The Court of Appeal held that the embryos could only be said to have been used once they were implanted. In his judgment, Arden, L.J. stated: In the context of the withdrawal of consent under Schedule 3 paragraph 4, the word "use" refers to the final stage. It was therefore held that the embryos had not been used since no implantation had been done, and the man who provided the sperm could still withdraw his consent to the storage and use of the embryo.[26]

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[21] Schedule 3 Para 1(3)1990 Act.
[22] By schedule 3 Para. 4 (1) 1990 Act, the terms of any consent under this schedule may from time to time be varied, and the consent may be withdrawn by notice given by the person who gave the consent to the person keeping the gametes or embryo to which the consent is relevant.
[23] Schedule 3 Para. 4(2) 1990 Act.
[24] [2004] EWCA Civ 727
[25] This means the removal by operation of ovaries of a woman.
[26] The 2008 Act has made modification to the law on withdrawal of consent. Schedule 3 Para. 4A introduced into the 1990 Act a one year "cooling period" this provision allows the embryos or gametes to be lawfully stored to allow the party withdrawing consent to change his or her mind, if not, after expiry of the one year period, the embryo is allowed to perish. See Shaun, D, Pattinson, Medical Law and Ethics, 2nd ed. London Thomas Reuters, 2009,281.

Natalie Evans subsequently lost her application to the European Court of Human Rights and, ultimately, the Grand Chamber of the European Court of Human Rights[27]

In-Vitro Fertilization and Subsequent Use of Embryo

Schedule 3 paragraph 6 (1) of the 1990 Act provides that

"A person's gamete must not be used to bring about the creation of any embryo in vitro unless there is an effective consent by that person to any embryo the creation of which may be brought about with the use of those gametes being used for one or more of the purposes mentioned in paragraph 2(1) above".

Under sub paragraph (2) "An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) above of the embryo".

Further, under sub paragraph (3) "An embryo the creation of which was brought in vitro must not be used for any purpose unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo for the use of that purpose and the embryo is used in accordance with that consent".

Consent to Storage of Gametes and Embryos

Schedule 3, paragraph 8, of the 1990 Act Provides for storage of gametes and embryos in the following terms;

> (1) "A person's gamete must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with that consent".
>
> (2) "An embryo the creation of which was brought about in vitro must not be kept in storage unless there is an effective consent, by each person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents".
>
> (3) "An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent".

The provision of the 2008 Act is *in pari materia* with that of 1990 Act, although with some modifications. As stated earlier, the consent of the gamete provider must be obtained in order to continue storage of their gametes/embryo. Such storage could be by cryopreservation (freezing).[28] However, The Human Fertilization and Embryology Act 2008 now fixes the statutory storage period for gametes/embryos for 10 years instead of the five-year period under the 1990 Act.

[27] *Evans v. UK* (6339/05) (2008)46 E.H.R.R.34 (April 10, 2007, Grand Chamber) affirming: (2006)43 E.H.R.R.21.

[28] The 1990 Act allows for the freezing of gametes and embryos under license see ss.2 (2) and 14 (1)

The new Human Fertilization and Embryology (Statutory Storage Period for Embryos and Gametes) Regulation 2009[29] made it possible to extend storage of gametes[30] and embryos[31] for a maximum of 55 years[32] subject to certain conditions. Thus, research centers are under obligation to carry out checks every 10 years to ensure that patients or gamete providers meet laid down conditions. Furthermore, the maximum age for which implantation can be carried out on a woman is 55 years.[33]

From the foregoing, it is apparent that consent for the use or storage of gametes or embryos can be revoked. Thus, in *Centre for Reproductive Medicine v. Mrs. U.* [34] The defendant's husband, after initially agreeing to the posthumous use of his sperm to treat his wife, later revoked his consent. The Court of Appeal rejected the defendant's argument that the clinic unduly influenced her husband's change of mind and held that she was not entitled to use the sperm.

The withdrawal of consent by either of the providers to the continued storage of any embryo formed with their gametes (for example following a divorce by the couple) would mean discontinuance of further storage. In such cases, the genetic material must be allowed to perish or destroyed[35]. The court interpreted this principle in the British case of *Human Fertilization and Embryology Authority ex parte Blood*.[36] Mrs. Blood sought judicial review of the Human Fertilization Embryology Authority's refusal to license infertility treatment of her with sperm of her dead husband. The sperm has been taken from Mr. Blood as he lay in coma shortly before his death from Meningitis. Consequently, his written consent for storage or use of his sperm was not obtained as stipulated in the Human Fertilization and Embryonic Act, 1990. According to Lord Wolfe M.R.:

As to storage, section 4(1) makes it clear that it must always be pursuant to a license. That means that storage can only takes place lawfully in accordance with the requirements of the licensed which for the present purpose are contain in schedule 3. This means that there must be consent in writing (paragraph 1 and paragraph 8 which complies with paragraph 2(2) and paragraph 3) before the storage can lawfully take place[37].

In the circumstance, it was held that Although Mrs. Blood could not be lawfully treated with her husband's sperm in Britain. She was entitled to export it and receive treatment in Belgium pursuant to her rights under article 49 of the European Commission Treaty[38].

[29] Formally, The Human Fertilization and Embryology (Statutory Storage period for Embryos and Gamete) Regulation, 1996
[30] Regulation 2(1)(2) under section 14(4) of the act specify the maximum storage period in respect of an embryo
[31] Section 14 (3) in respect of gametes regulation
[32] Regulation 3 ensures that embryos lawfully stored from 1 October 2009 by virtue of the Human Fertilization and Embryology (supplementary provision) order 2009 fall within Regulations 3 of the 2009 regulations, and therefore become eligible for extended storage period provided under criteria in that regulations are met.
[33] Regulation 2 (1)
[34] [2002] E.W.C.A. Civ, 565, [2002] I FLR 927
[35] Davis v. Davis (1992) 842 S.W 2 d, 588, 597
[36] (1997) 2, W.L.R 807
[37] See review of the common law provision relating to the removal of gametes and of consent provisions in the HFE Act 1990
[38] Staunch, M., el al, "Medical Law", 382

Other statutory legislations regulating in vitro fertilization in the United Kingdom are;

(i) The Human Fertilization and Embryology (Procedure for Revocation, Variation or Refusal of Licenses) Regulations 2009. This regulation provides for circumstances under which the human fertilization authority can revoke, vary or refuse licenses to clinics.

(ii) The Human Fertilization Embryology (Appeals) Regulation 2009 provides for conditions under which clinics can appeal HFE Authority decisions.

(iii) The Human Fertilization and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 proposes how identifiable information may be disclosed for research purposes.

In-vitro Fertilization in Nigeria

Although IVF is currently practiced in Nigeria, there is neither any legislation regulating IVF treatment, nor is there any regulatory framework on donor egg, donor sperm or donor embryo. There are no guidelines to determine or limit the maximum number of embryo that can be transferred into a woman's uterus; the implication of the foregoing is that the number of embryos that can be deposited in a woman's womb is at the doctor's discretion, notwithstanding the attendance adverse physical and psychological health implications.

There are also no guidelines on the issue of consent, storage period of gametes, embryo freezing or surrogacy. This has encouraged the proliferation of sub-standard fertility clinic manned by non-experts in fertility and reproductive health. Some practitioners even locate their clinics in unclean environment. This worrisome state of affairs has raised credibility issues about claims of success, thus resulting in loss of confidence in the practitioners and the treatment they administer.

Up till now, Nigeria policy makers in the health sector are yet to formulate any policy on IVF technology. The health ministry has no defined enlightenment program on the treatment and no monitoring team specifically set up to monitor the activities of medical practitioners who administer the treatment. The establishment of such regulator body is long overdue. We are not aware of any intention by the Nigerian legislature to formulate a legal framework for the regulation of IVF treatment in the near future. The absence of relevant laws on IVF treatment has grave and negative social implications. Many tend to see the exercise as being socially non-permissible and admission of incompleteness by couples who seek the treatment. The situation is further compounded by the high level of illiteracy, high incidence of poverty among the populace, inadequate qualified medical personnel , high cost of IVF treatment , low level of awareness on the importance and benefit of the treatment and many more. It is instructive to note that the scenario exemplified by the Nigerian situation is typical of almost all the developing countries around the world.

In most developed countries, defined legal and institutional frameworks exist to ensure the regulation, standardization and affordability of IVF treatment. It is apposite to mention the role of globalization in medical care having regards to the fact that we are in an age of medical pluralism, thus no discussion on IVF can ignore the development of medical tourism[39] which has culminated in the movement of deserving couples from developing countries to other countries where IVF treatment is available, legally recognized , affordable and reliable. In the British case of *Human Fertilization and Embryology Authority ex parte*

[39] India is a hub for vitro fertilization treatment and surrogacy.

Blood,[40] where Mrs. Blood had to travel to Belgium for posthumous insemination with her husband 's sperm in order to evade regulatory restriction in Britain. In the absence of an enabling law, it would be near impossibility for government to monitor the activities of medical personnel who administer the treatment sometimes in ill-equipped and unlicensed fertility clinics. Therefore, it is imperative for government to adopt a harmonized, comprehensive regulatory framework that conforms with international best practices on the administration of the treatment as it obtains in the United Kingdom and many other developed countries.

Lessons from Other Jurisdictions

Laws regulating IVF treatment vary from one country to another. While some countries like the United State of America and Japan have legislations and guidelines for the regulation of IVF treatment, countries like Nigeria, Greece and Canada have neither legislation nor guidelines for the regulation of IVF treatment. Countries like Saudi Arabia and Egypt forbid all forms of assisted conception treatment using donor egg, donor sperm, donor embryo and surrogacy, but countries like Japan and Norway allow donor sperm while prohibiting egg or embryo donation and surrogacy.

The United Kingdom, France, Germany and Australia have legislations and regulatory mechanism that prescribe the maximum number of embryo that can be transferred into the womb. In the United Kingdom, the Human Fertilization and Embryology Act 1990 provides that the maximum number of embryo that can be transferred into a woman who is 35years or younger in her first IVF treatment is two , and three for 40 years and above or those with perniciously failed IVF treatment. According to the IFFS surveillance 2010 which looked at the roles and regulations relating to assisted conception of more than 100 countries, it found that 14 countries had an upper limit of three embryos, 12 had a limit of four and 6 countries had a limit of 5. Kuwait had a limit of six embryos, while Panama had no limit on the number of embryos transferred[41]. In 2003 China banned the use of IVF by unmarried woman or couples with certain infectious diseases. The law also prohibits availability of in vitro fertilization to lesbian couples.

Costa Rica has a complete ban on IVF technology. The technique is perceived as a violation of life and lack of respect for the embryo, thus upholding the view that the embryo should never be handled or manipulated outside the body. In Germany, legislation was enacted to prohibit IVF clinics from removing and fertilizing more eggs than could be implanted in one cycle. Thus, there is no 'spare' embryo in Germany.

Ethical Issues

In vitro fertilization treatment is a sensitive ethical and moral issue against the background of increased and fast paced medical and scientific developments . Although this technology is now generally accepted as a means of addressing involuntary childlessness, it is still not without controversy. Some objectors to IVF contend that only the supreme being has power to give a child, arguing that scientists should not be allowed to play god. According to this group, insemination through artificial means separates the conjugal act from the procreative act, thus threatening the institution of family. The school of thought further

[40] (1997) 2 W.L.R 807

[41] Dr Marcus, Laws and Regulations Governing Assisted Conception, http://www.ivf-infertility.com/ivf/standard/regulations.php accessed 11/7/2015.

expressed concern about the ownership and legal status of the embryo in the event of divorce or death of either of the couple.

The Roman Catholic Church opposes all kinds of in vitro fertilization and contraception. It posits that IVF is unnatural and constitutes a threat to the unity of the family and the dignity of the human person. The church is of the view that it is not objectively evil to be infertile, it therefore advocates adoption as an option to assisted reproduction as in IVF.

Concluding Remarks

In this paper, we have highlighted the socio-legal perspectives to IVF technology, with emphasis on its role in ameliorating the emotion trauma of desperate couples who hitherto suffered involuntary childlessness. This article has identified the major challenges confronting the administration of IVF technology in most developing economics including Nigeria, the most crucial being the absence of any set standards for the administration of the treatment due to lack of defined legal framework on IVF, high and unaffordable cost of treatment, inadequate medical personnel and modern facilities. This uncomplimentary scenario has constrained many desperate couple to fall easy to prey to unprincipled and avaricious medical practitioners who most times exploit this vulnerable class with impunity to a point of penury, without any assurance of positive result and quality service delivery for the treatment. It is suggested that Nigeria and other developing economies should adopt the United Kingdom model of IVF treatment. By this way, woman reproductive autonomy and right of self-determination would be guaranteed.

Recommendations

The foregoing exposition of the socio-legal, cultural and legal challenges in the practice of IVF in Developing Economies render imperative the following recommendations as a panacea for the implementation of a sustainable regime of the treatment in developing countries.

a. African Governments must address institutional and infrastructural deficiency through a purpose driven policy on in vitro fertilization technology and address the issue of quack doctors, brain drain. By so doing, developing countries would align its policy with the progressive stance of developed states that have enacted stringent regulations governing IVF treatment.

b. Need for enactment of effective legislation for the administration and regulation of IVF treatment, backed by enforcement and sanction for breach.

c. There is also a need for the establishment of monitoring and evaluation units in the relevant ministries. This will ensure compliance with standards by medical personnel involved in the administration of IVF treatment. The units would also be responsible for ensuring that only professionally qualified medical personnel are allowed to administer IVF treatment to deserving patients. This will reduce quackery in the profession, promote standards and restore confidence.

d. There is need for adequate funding and subsidy of IVF treatment. Such funding must be properly harnessed and managed for the advancement of cost effective, efficient and affordable IVF treatment for impoverished couples desiring such care.

e. Further, Government must encourage a coalition of input from medical professional and encourage cross national and transnational collaboration especially in the area of medical research as this will foster and promote proficiency in IVF technology

f. Emphasis must be placed on educational and sensitization enlightenment programs of the public on the advantages of IVF as an alternative to natural reproduction. These would change the negative mindset and disposition to the treatment.

g. Provision of adequate medical equipment in government hospitals, and training of medical personnel to render qualitative services to patients.

There is no doubt that a pragmatic implementation of the suggestions above, would promote the use of IVF, and make it affordable to a vast majority of couples from developing countries who find it unaffordable on account of lack of funds. Finally, emulating the progressive model of IVF regulation in developed jurisdictions would protect vulnerable couples from exploitation.