

Perception of Key Ethical Issues in Assisted Reproductive Technology (ART) by Providers and Clients in Nigeria

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Purpose: In the past decade, developments in the field of Assisted Reproductive Technology (ART) have intensified the hopes and the desires of infertile people to overcome infertility, resulting in an increasing demand for such services worldwide. However, as developments in ART have evolved rapidly, so have ethical, social, and political controversies surrounding many aspects arisen. It is known that societal ethics is dependent on the values and culture of a given group. We sought to explore how practitioners and clients in Nigeria perceive some Key ethical issues surrounding ART.

Materials and Methods: This was an explorative descriptive study involving in-depth interview of three ART providers and eight female ART clients, all domiciled in Southeastern Nigeria. Sampling was by purposive and snowballing techniques for providers and clients, respectively. Ethical approval was obtained from University of Ibadan/University College Hospital and University of Nigeria Teaching Hospital Research Ethics Committees. Responses were grouped into themes for ease of discussion.

Results: Providers and clients were in support of sex selection for family balancing, and multiple embryo transfers. They also perceive that the health of the woman should be the factor considered and not biological age for service provision. However, views differed on marital status as an access factor. Participants were in support of legally binding regulations to guide practice.

Conclusion: A culturally sensitive national regulation is recommended to guide practice in this vital area of reproduction.

Keywords: new conception methods, societal ethics, national regulation, practitioners, patients

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Introduction

Of the reproductive tract morbidities, infertility produces profound social consequences for African women.¹ It affects 8–12% of couples worldwide.² In Nigeria, infertility rates vary across ethnic groups. Jegede & Fayemiwo (2010),³ reported a prevalence rate of 13.5 to 14.3% for Hausa, Fulani, and Kanuri of the Northern Nigeria while 14% were reported for the Yoruba of Southwest, 10% for the Tiv, 10.5% for the Nupe and 6.9% for the Chambas of the Middle Belt. The range is much higher in the eastern block of Nigeria where 19.1% was recorded for the Igbos and 16% for other ethnic groups of the Cross River State. The prevalence of infertility in Enugu is 12.1%, with pregnancy rate following conventional treatment being extremely poor,⁴ and

18.5%⁵ in Nnewi, Anambra State. The commonest female factor is tubal blockage and there are no facilities for microsurgical techniques leaving Assisted Reproductive Technology (ART) as seemingly the only hope of bearing a biological child. The introduction of ART as an effective intervention for infertility has brought hope to millions of people. However, ART is associated with numerous challenges to both clients and practitioners.

These challenges range from issues of number of transferred embryos, sex selection, need for regulation, cost, age, marital status, sexual identity, traditional notions of parentage, commodification of human reproductive cells, amongst others.⁶ Another key issue is the monitoring of outcomes of ART as a primary component of providing adequate ART services in any country. This includes information on access, safety, efficacy, and quality of services to aid patients in decision-making about treatment alternatives as well as aid society in clinical policy adjustments through proper regulation and resource allocation.⁷ ART is a highly complex technology that requires expertise and should not be experimented with by non-experts or ill-equipped practitioners. It involves significant medical side effects such as maternal depression, ovarian hyperstimulation syndrome, ectopic pregnancy, and complications of multiple pregnancy.

Unlike developed nations, Nigeria, like most countries in Sub-Saharan Africa had no form of regulation until recently when the Association for Fertility and Reproductive Health, an umbrella body coordinating the activities of fertility practitioners in Nigeria instituted non-legally binding practice guidelines for its members.⁸ This has resulted in a lack of uniformity in practice across the country with the risk of inappropriate practice,⁹ due to the absence of legal enforcement or sanctions for non-compliance. Practitioners and Clients remain important stakeholders in the framing of any practice guidelines since their views and experiences in the field act as a guide to key areas for legislation. Though a few studies,^{3,9–12} have looked at the views of Nigerian Stakeholders on the ethical issues in ART, there remain a dearth of data on the perception of practitioners and clients about ethical issues in ART practice. Thus, the objective of this study was to explore the perspectives of Nigerian ART providers and clients on some key ethical issues surrounding ART practice in Nigeria.

Materials and Methods

Study Design

An exploratory research design was used for the study, with in-depth interviews for data collection.

Ethical Approval

The Research Ethics Committees of University of Ibadan/ University College Hospital, Ibadan (NHREC/05/01/2008a) and University of Nigeria Teaching Hospital, Enugu (NHREC05/01/2008B-FWA00002458-IRB00002323) gave ethical approval for the study as one of the study objectives of an MSc Dissertation on Practitioners' and Clients' Perspectives and Experiences on the Regulation of ART in Nigeria.

Study Population and Location

The study population were ART providers who were also clinic directors of ART clinics located in Southeastern Nigeria, and ART married female clients who had an ART procedure in any part of Nigeria within two years prior to the onset of the study and were living in Enugu.

This study was conducted in Enugu and Anambra States, both in the Southeast geo-political zone of Nigeria. Enugu State is located at 6°30' North of Equator, and 7°30' East of Latitude. It is plus one-hour (+1hr) GMT on the World Time Zone. It has a total population (2006 Census) of 3,267,837. The population of women of reproductive age (15–49 years) was put at 716,600 and annual fertility was put at 6 children per woman and contraception remains low.¹³ The females constitute 50.1% of the population. At the time of the study, there were three established registered ART clinics. The present Anambra State is bounded in the West, South, East and North by Delta, Imo and Rivers, Enugu, and Kogi States, respectively. According to Anambra State Government (ANSO) 2019 estimation, the total population is ten million and eight hundred thousand (10,800,000) inhabitants, in a total area of 4844 km² (1870 sq mi), and an estimated average density of 1500–2000 persons per square kilometre. There was only one registered ART clinic in Awka, the capital city of Anambra state at the time of the study, with over 2.5 million inhabitants (2018 estimate). The city is located midway between two major cities in Northern Igboland—Onitsha, and Enugu.

One ART provider in Enugu and one married female ART client, were used for the Pre-Test survey and were not part of the study. Their responses helped to refine the

questions ensuring that they were easily understandable and able to answer the research question. Two registered ART providers/clinic directors in Enugu and the only registered ART provider/clinic director in Anambra State were included in the study. Other participants in the study were eight married female ART clients who had an ART procedure within two years prior to the study. Data collection was from November 2019 to January 2020.

Sampling Technique

A purposive non-probability sampling was used to select the ART practitioners/clinic directors while the ART clients were recruited by the snowballing technique, where an ART client who consented to the study gives the researcher the name of a potential participant in confidence, snowballing into as many clients as agree to take part in the study.

Data Collection Procedure

The aim of the study was explained to the research participants and a written informed consent obtained. Consent included the publication of anonymized responses. They were informed that the interview was to be recorded on tape, with notes taken by a research assistant and that their confidentiality was assured. Interview was in English and Igbo languages.

ART practitioners' interview (as Key Informant Interviews, KIIs) took place at their clinics by fixed appointment, while the ART clients' interview (as In Depth interviews, IDIs) was in their homes or an agreed location of choice by the clients (churchyard or school playground). An interview guide was used to collect information on their views on key ethical issues. The study was conducted in accordance with the Declaration of Helsinki.

Data Management Procedure and Analysis

All tapes and notes taken were reviewed after every interview session to ensure that correct responses were recorded by going through some of the questions randomly with the participants. The recordings were transcribed verbatim. To confirm reliability, some of the tapes were re-transcribed by another person to ensure correctness of information obtained.

Thematic analysis of the interviews was done by two senior researchers in qualitative methodology. Following

discussion and agreement on the emerging issues, these were arranged in themes to answer the research question.

Results (Table 1)

Demographic Characteristics

The age-range of the ART providers/clinic directors was 47–57 years, with a mean of 52.7 years. They were all Obstetrician/Gynaecologists with certification in Assisted reproduction from India. They were all Igbos and Christians by tribe and religion. The duration of ART practice ranged between 2 and 9 years.

The age-range of the female ART clients was 30 to 52 with a mean of 41.9 years. They all had at least secondary education, with 62.5% having university education. Fifty percent of them were of Roman Catholic Christian denomination, while others were Anglicans and Pentecostals. They were from Igbo, Hausa and Igala ethnic groups and of different occupations/socioeconomic class.

Reason for ART Use

The ART providers said the reasons clients seek their services range from age-related infertility to unexplained infertility following failure of conventional treatments. They noted that many of the patients wait for far too long using conventional treatments with no success and by the time they present for ART, the female clients have advanced in age with a significant reduction in success rate of the technology. They advised that health practitioners should refer infertile patients for ART as early as possible to improve their chance of success as success of ART is greatest at age 25 to 35 years. An ART provider said:

More than half of the clients in my practice present at 45 years and above, wasting time on other unsuccessful treatments. Most were not referred for ART by their physicians. They keep encouraging them to persist in trying the conventional treatments (47-year-old ART provider)

The ART clients also noted that many women seek for ART after many years of trying other treatments to achieve pregnancy. One of the clients said:

Our first baby was 7 years ago. Despite trying to conceive the normal way, we had no success. We went to different doctors but had no success despite the different drugs we were given. We then decided to try ART (38-year-old businesswoman, Igbo)

Most of the ART clients had infertility ranging from 3 to 13 years, prior to seeking ART treatment. They kept

Table 1 Summary of ART Providers and Clients Opinions on Key Ethical Issues

Key Ethical Issues	ART Providers/clinic directors (3 in number)	ART Clients (8 in number)
ART Access	It should be on demand since clients pay out-of-pocket.	1. It should be available on demand (6 clients) 2. It should be for legitimate reasons like infertility, genetic disorders, or cancer treatment (2 clients—(43-year-old medical practitioner, (48-year-old laboratory scientist
Source of information on ART	Mostly previous successful clients.	Relatives and friends who had successful treatment.
Sexual orientation and type of marriage	1. It is unacceptable because LGBTQ is against the Nigerian Law (2 providers) 2. Sexual orientation should not preclude access. It is one's choice (54-year-old ART provider)	1. There should be non-access for LGBTQ because it is against cultural/religious belief (7 clients) 2. There should be no discrimination (30-year-old immigration officer)
Marital Status	1. Offers to only married couples ((57-year-old ART provider) 2. Single women are expected to come with a partner (47-year-old ART provider) 3. Marital status should not be a discriminatory factor (54-year-old ART provider)	1. Single women should adopt (6 clients) 2. It is a woman's right to access any means of having her own baby (37-year-old Igala businesswoman; 30-year-old immigration officer)
Family balancing	1. It should be encouraged particularly in Africa where a family is incomplete without a male child (2 Providers) 2. Sex selection is unacceptable even for genetic disorders, couples should adopt (57-year-old ART provider)	It is a welcome opportunity because without a male child, a woman has no share in her matrimonial home.
Female Age	Female age should not be a discriminatory factor because donor gametes can be used.	This is Africa and every woman irrespective of age should be helped to have a child of her own.
Acceptable number of transferred embryos	5 embryo transfer per cycle among practitioners though 3 is the number allowed in the AFRH guideline.	5 embryos and welcome multiple pregnancy
Cryopreservation	1. Acceptable because it reduces cost, and the complications of re-stimulating the ovaries should there be a failed cycle and client wants to try again (2 providers) 2. It is unacceptable due to the risk of congenital anomalies that may result during the thawing process (57-year-old ART provider)	1. It is acceptable because it not only reduces cost but also prevents the risks from hormonal stimulation (6 clients including 2 Roman Catholic clients) 2. It is unacceptable because it does not respect the dignity of the embryo (48-year-old laboratory scientist; 44-year-old pharmacy rep, both Roman Catholics)
Cost	It is expensive because ART is mostly private sector driven and it is unsubsidized by government.	It is expensive and clients save for long periods, borrow money, or sell property.
Information disclosure	Adequate informed consent and risk disclosure paramount.	Based on experience in centres accessed, 1. Information disclosure inadequate 2. No discussion on number of eggs retrieved or embryos made 3. Transcript of information given only after transfer made (30-year-old immigration officer) 4. Consent signed only after final transfer phase
Need for regulation	To avoid abuse, ART practice should be regulated by the State	Government should regulate ART to avoid women being exposed to inappropriate practice.

hoping that conventional treatment will solve the problem. According to an ART provider:

Many of my clients present for ART after 8–10 years infertility, giving reasons such as lack of awareness, high cost, as well as cultural and religious bias (57-year-old ART provider)

This was corroborated by an ART client:

My husband and I went to hospital about 2 years into our marriage when pregnancy was not forthcoming. We were given several options including ART. However, it took us about 5 years to accept to go for ART being practicing Catholics. Our religion is against it (44-year-old Pharmacy Rep, Igbo)

The ART providers also noted that some clients seek their services for medical and non-medical reasons apart from infertility. Non-medical reasons include across-the-continent unions where the male partner is usually unavailable to fertilize the female partner through genital intercourse, and male sex selection for family balancing. Medical reasons include cryopreservation of gametes prior to cancer treatment and pre-implantation genetic diagnosis (PGD) in couples or individuals with inheritable genetic disorders. According to an ART provider:

A 40-year-old client of mine just cryopreserved his sperms last week in preparation for orchidectomy for treatment of Prostate cancer (47-year-old ART provider)

Similarly, an ART client said:

My sister-in-law convinced her husband who live and work in Malaysia to cryopreserve his sperms and she now has a set of twins from this technology (37-year-old businesswoman, Igala)

Access to ART

Most of the respondents opined that access to ART should be on demand. Every woman who wants a child through this technology should have access. According to an ART provider:

Pregnancy is a part of one's reproductive right. It should be available on demand (54-year-old ART provider)

Similarly, an ART client said:

Provided a couple or even a woman can afford it, it should be available on demand (43-year-old businesswoman, Hausa)

However, a few respondents noted that it should be limited to those with legitimate reasons of infertility, genetic disorders, or cancer treatment. According to an ART client:

It should not be for frivolous reasons such as male sex selection or wanting to be pregnant at a particular time in the year (43-year-old medical practitioner, Igbo)

Source of Information on ART Center

According to the ART providers, clients are occasionally referred to them by fellow gynaecologists and a few got information from their organization websites. However, successful clients were the greatest source of information on which center to access. An ART provider said:

Most of my clients are referrals from previous clients who had successful pregnancies from my center (54-year-old ART provider)

This was confirmed by the ART clients. They noted that information about centers to access was from relatives and friends who has successful treatments. An ART client said:

My husband and I had four girls and we wanted a male child. A lady working in my office gave me the address of a clinic in Lagos where sex selection services are offered (48-year-old laboratory scientist, Igbo)

Sexual Orientation and Type of Marriage

The ART providers opined that presently ART for the LGBT (Lesbian, Gay, Bisexual and Transsexual) community is against the Nigerian law. According to an ART provider:

In Nigeria, it is against the law for two men or two women to have marital relations (47-year-old ART provider)

Similarly, most of the ART clients corroborated this view. An ART client said:

The Nigerian law punishes homosexuality by 10 years imprisonment (43-year-old businesswoman, Hausa)

In addition, most of the participants agreed that it is also against the religious beliefs of the Nigerian State. According to an ART provider:

The Bible and Koran are against homosexuality (57-year-old ART practitioner)

Similarly, an ART client said:

There is no religion I know that encourages same-sex unions. Christianity and Islam which are the major ones abhor such behaviour (37-year-old businesswoman, Igala)

Most of the respondents also noted that culturally, homosexuality is unacceptable in Nigeria. According to an ART client:

It is an abomination. There is no Nigerian ethnic group that allows such (44-year-old Pharmacy Rep, Igbo)

However, this view was refuted by an ART provider who said,

Sexual orientation is a question of choice and should not preclude access to ART (54-year-old ART provider)

Similarly, an ART client said:

Gay-men can employ nannies, and lesbians can use donor sperm (30-year-old immigration officer, Igbo)

Marital Status

Most of the ART providers were of the view that though single women were not prevented access to ART by the Association for Fertility and Reproductive Health (AFRH) ART guideline, they, as practitioners do not encourage single women accessing ART in their practices. Single women are expected to come with a partner to access services. According to an ART provider:

Our culture and religion are against single parenthood. We need to think of the stability of the marriage and raising of the child. I attend to partners who after interviewing I am convinced will care for the child together (47-year-old ART provider)

Another ART provider said:

I offer to traditional couples only. It is more natural (57-year-old ART provider)

This view was supported by some of the ART clients. An ART client said:

Single women should adopt. If the child asks for his/her father, what will she answer? (52-year-old laboratory scientist, Igbo)

However, there were dissenting voices among the ART providers and clients. They believe that with the current reality of increasing number of women not marrying at all or marrying late, single women should have access to the

technology provided they are able to care for their babies. According to an ART provider:

We are now seeing many single women who are capable of raising children and so should not be discriminated against because of marital status. Times are changing (54-year-old ART provider)

An ART client also said:

A woman may not want to have a man in her life, or she may be getting older without finding a husband to settle down with. It's all about choice, it is her right to access a means of having her own baby (37-year-old businesswoman, Igala)

Family Balancing

Some of the ART providers were in support of preimplantation genetic diagnosis (PGD) for sex selection. They noted the importance of family balancing in Africa. This view was supported by the ART clients. They however said that there should be some measure of control. They agreed that PGD should be focused primarily on the diagnosis of genetic disorders with sex selection for family balancing being secondary. According to an ART provider:

Couples want to have a boy because inheritance and perpetuation of the family name is through the male line (47-year-old ART provider)

This view was corroborated by ART clients. An ART client said:

Without a male child, a woman has no share in her matrimonial home (43-year-old medical practitioner, Igbo)

However, there was a dissenting voice against use of PGD for sex selection or diagnosis of genetic disorders. An ART provider said:

It is wrong to do sex selection because it leads to destruction of the unwanted sex embryos. I am not in support of fetal biopsy even in cases of genetic disorders. The couple should adopt. (57-year-old ART provider)

Age

The ART providers agreed that while age is a factor in the success of implantation of the transferred embryo, it should not prevent access to ART. Medical fitness should be the criterion rather than age. This was echoed by the ART clients. Women whose eggs are aged can be offered donor gametes. Donor gametes are usually from young

women 20–30 years and men less than 40 years of age. According to an ART provider:

65-year-old women have been known to have successful pregnancies following use of donor eggs or embryos. A 58-year-old client of mine had a successful IVF pregnancy carried to term using donor eggs and husbands sperm' (54-year-old ART practitioner)

Similarly, an ART client said:

Nkem bu nkem (mine is mine). This is Africa where every woman wants a swollen belly (30-year-old immigration officer, Igbo)

Another ART client also said:

The people around her will help her raise the child. People who go for this procedure have no option and some succeed, and the joy is a lot (37-year-old businesswoman, Igala)

Acceptable Number of Transferred Embryos

The ART providers noted that the standard number of transferred embryos acceptable is three. However, in practice they transfer as many as five. The reasons they gave for requiring transfer of more than three range from age of female partner, couples rejecting embryo cryopreservation or destruction for religious/cultural reasons, and lack of cryopreservation facilities in some centers. According to an ART provider:

The older the female recipient, the more likely multiple embryos will be transferred (57-year-old ART provider)

Another ART provider also said:

Many faith-based organizations especially Roman Catholics frown at freezing or discarding embryos, and prefer all be transferred (47-year-old ART provider)

Most of the ART clients corroborated this view. An ART client said:

As a Roman Catholic, I told them to transfer all my embryos irrespective of the status because I did not want any to be frozen or destroyed (48-year-old laboratory scientist, Igbo)

The ART providers also noted that the higher the number of embryos transferred, the higher the chance of implantation especially in Nigeria where payment for services is out of pocket. According to an ART provider:

ART is expensive, and transferring multiple embryos increases the chance of at least one successfully implanting (47-year-old ART provider)

They however frowned at transferring more than five as this may lead to intrauterine death of one or more of the fetuses and its attendant maternal complications and risks to the alive fetuses. An ART provider said:

The number of embryos transferred should not be more than five, or else the risks will be higher than the gain (54-year-old ART provider)

They also noted that in our environment there is no facility for selective feticide where one or more of the fetuses are destroyed to make room for the others to survive in cases of high order multiple pregnancies. In addition, even if facilities were available, abortion in whatever form is frowned at. An ART provider said:

I do not know of any facility in Nigeria where fetal reduction is done (57-year-old ART provider)

Another ART provider added:

Where I trained, fetal reduction is acceptable but here many women will see it as abortion despite the risks retaining all the fetuses may pose for such women and their unborn babies (47-year-old ART provider)

Handling of Gametes and Embryos

All the respondents were of the view that it is the clients' decision to use their own gametes or accept known or unknown donor gametes/embryos. According to an ART provider:

The clients decide on whether to use their own/donor gametes or embryos. Our job is to counsel them based on their test results (47-year-old ART provider)

This view was corroborated by all the ART clients. An ART client said:

After our laboratory tests showed that my husband's semen was low, we were offered donor sperm which my husband rejected. The doctor referred us to another doctor who treated my husband for about 9 months until his sperm count increased, and we went back to the ART centre' (38-year-old businesswoman, Igbo)

Another ART client said:

The doctor told us that based on my age, my eggs may not be adequate for the procedure and offered us donor eggs.

My husband and I agreed and told him to go ahead before the procedure (52-year-old laboratory scientist, Igbo)

All respondents also agreed that clients should decide on the fate of their excess gametes or embryos, with regards to cryopreservation, discarding or donation to other infertile couples. Cryopreservation attracts different amounts at different centers ranging between 100,000 naira for 999 years in one center and 250,000 naira for 5–6 months in another centre. The issue of cryopreservation was acceptable to most of the participants. An ART provider said:

During the one-on-one counseling, I offer all clients freezing of their embryos which reduces the cost should they have a failed cycle and want to try again (47-year-old ART practitioner)

This view was corroborated by most of the ART clients. An ART client said:

I was told to pay 100,000 naira extra if I need my embryos preserved and I did. I was lucky that the procedure was successful the first time. I am happy that I won't go through the stimulation process again now we are planning for another child' (37-year-old businesswoman, Igala)

However, according to a dissenting ART provider,

I do not offer cryopreservation in my center because of the risks of congenital anomalies from imprinting problems following freeze-thawing processes (57-year-old ART practitioner)

Similarly, some ART clients also opined that cryopreservation of the embryos is against human dignity as they are living beings. An ART client said:

According to my Faith, cryopreservation and discarding of embryo is not acceptable I was successful on my third attempt. Each time I started from the beginning and the three attempts cost us more than 5 million naira (48-year-old laboratory scientist, Igbo)

In addition, the view among all participants was that there should be no fixed maximum number of cycles. It should be determined by the client's purse. An ART provider said:

Children are important in our society hence people are obsessed with having a baby. Placing a limit to the number of cycles will be viewed as wicked (54-year-old ART provider)

Similarly, an ART client said:

I was successful at my 7th attempt. Imagine if there was a limit to the number of cycles (43-year-old medical practitioner, Igbo)

Cost

All the ART providers were of the view that ART in Nigeria is expensive. The reasons given include the fact that ART in Nigeria is mostly private sector driven for now, not subsidized by government, lack of insurance, and that equipment and consumables are imported. An ART provider said:

This technology is expensive and most patients who need it cannot afford it (47-year-old ART provider)

Similarly, another ART provider said:

Most ART centers are privately owned businesses and only a few are within the government hospitals. This is one of the reasons it is expensive (57-year-old ART provider)

This was also echoed by the ART clients, noting that it is not within the reach of the average infertile couple. Many couples save for years for the necessary funds, which is why they tend to wait and present at advanced age for ART treatment. An ART client said:

The cost is too much. Most infertile women are poor (38-year-old businesswoman, Igbo)

This was corroborated by another ART client who said:

If it is less expensive, many more people will go for it. There will be less problem in society from infertility (37-year-old businesswoman, Igala)

According to the ART clients, the cost depended on whether the couple were using donor or own gametes. It also differed from one center to the other, and from one city to another. Use of couples' gamete was on the average 1.3 million naira for own gametes and 2 million naira for donor gametes in Enugu. In Abuja, the Federal Capital Territory of Nigeria, it costs about 2.5 million and 3 million naira for couples' gametes and donor gametes/embryo, respectively. The clients were expected to pay an initial deposit via bank-draft, followed by pay-as you-go for investigations and drugs. An ART client said:

I was successful at my third attempt and in total we paid more than 5 million naira. (She shrugs and breathes in and out) (48-year-old laboratory scientist, Igbo)

However, most of the clients interviewed said the cost is worth it because children are priceless in our environment. An ART client said:

ART helps. All you need do is save. Onwe ro ife ka nwa (nothing is greater than a child) (30-year-old immigration officer, Igbo)

The ART providers believe that unless some of the consumables can be locally sourced, the cost of ART is unlikely to come down soon. However, they noted that due to the devalued rate of the naira, there is an increase in transatlantic request for ART services in Nigeria. An ART provider said:

Currently, cost is moderate in Nigeria compared to other countries as patients come from outside to have it done in Nigeria (54-year-old ART provider)

Similarly, another ART provider said:

The devaluation of the naira has made the services more accessible to outsiders whose currencies are stronger (47-year-old ART provider)

Information Disclosure

The ART providers opined that the informed consent process should consist of information on what the procedures entail, with risks involved at every stage of the procedure explained. The benefits and challenges should be explained to the couples at every level of the procedure. They noted that the clients should be given the literature on the procedures and consent form to take home. This gives them adequate time to digest the information and take decision without undue pressure. An ART provider said:

After the one-on-one counselling of the clients on the procedure and possible risks, I give them written literature explaining the procedure to take home and read, so they can ask questions for further clarification (57-year-old ART provider)

Another ART provider said:

The informed consent form is given to the clients to take home, digest it and bring it back and we advise them never to sign it if they do not understand any of the procedures or their questions have not been fully answered (47-year-old ART provider)

However, some of the above claims were refuted by the ART clients. An ART client said:

No risks or side effects were mentioned, except that it may fail. Maybe the doctors think that patients may change their minds (44-year-old Pharmacy Rep, Igbo)

Most of the respondents believe all risks no matter how rare should be discussed. According to an ART provider:

Clients should be informed of all possible risks, because you never know who may inadvertently develop even the rare ones (47-year-old ART provider)

An ART client also said:

It is better to know what all the risks are and prepare oneself before going for these procedures (38-year-old businesswoman, Igbo)

This view was refuted by an ART provider saying:

Things like cancer, and death may be left out, but haemorrhage, ovarian hyperstimulation, infection, congenital anomalies, implant problems, lack of fertilization, cycle cancellation, miscarriages, etc. should be discussed (54-year-old ART provider)

Some of the ART clients believe that no matter the extent of risks the physicians tell them the procedures entail, most infertile women would still opt for any procedure that may give them children. An ART client said:

Even if doctors explain the risks to women, they will still go for it. Most are not bothered by the risk. Women are ready to sell their souls to the devil and even sleep with other men to have a child regardless of risks involved (30-year-old immigration officer, Igbo)

According to the ART clients, the policy of the ART clinics they accessed was generally 5 embryo transfers in a cycle. They also agreed that cryopreservation, discarding or donation of embryo were discussed, and the decision was that of the client couple. They agreed that they were told that an additional sum was to be paid for cryopreservation. However, the number of retrieved eggs were not disclosed during the procedure. Only one client was given a transcript of eggs retrieved, embryos made, and number of embryos transferred after the embryo-transfer procedure. Their input was not sought regarding the number of eggs to be retrieved or transferred. According to an ART client:

There was no discussion regarding the number of eggs to be retrieved or embryos to be transferred (37-year-old businesswoman, Igala)

The ART clients added that all the information about the procedure at every stage of the process, including the number of eggs retrieved, number of embryos after culture, and number (s) to be transferred prior to transfer should be given to clients. In addition, there should be signed consent for each stage of the ART process. Most of the respondents said they only signed consent during the final transfer phase, even though they did not fully understand the explanations. According to an ART client:

They just give the drugs and tell them to come to the clinic and they sign consent but not informed. The clients should understand what they are signing (52-year-old laboratory scientist, Igbo)

Another ART client said:

My husband and I signed a consent form only during the embryo transfer stage (48-year-old laboratory scientist, Igbo)

Challenges in Access and Provision of ART

The areas of greatest challenge according to the ART providers were equipment maintenance, which is costly since they are imported, epileptic power supply hence the need to provide alternative energy from generating plants and solar, as well as continued medical education of personnel in the form of in-house/outside training. An ART provider said:

None of the equipment we use are locally made, hence they are not only expensive, but the cost of maintenance is high since all spare-parts are imported (54-year-old ART provider)

Another ART provider said:

There is need for continuing medical education in this area both for the doctors and ancillary staff. All these require money (57-year-old ART provider)

Other challenges identified are poverty and the stigma attached to infertility especially within the South-Eastern states. An ART provider said:

Society has no package for the infertile woman. People sell their property to access a treatment that may not work (47-year-old ART provider)

Similarly, another ART provider said:

Women are abandoned by their husbands once no child is forthcoming. Hence, there is a rising incidence in cryptic

pregnancy and illegal adoption which is now common in the Eastern states (54-year-old ART provider)

Need for Regulation of ART

All the study participants were of the view that there is a need for Government oversight in the ART clinics to prevent abuse.

The ART providers noted that self-auditing by the Association for Fertility and Reproductive Health (AFRH), while important is not enough. Only Lagos State enforces the contents of the guidelines through its Health Regulatory Agency, but other states are yet to follow suit. They agreed that the centres need to be regularly monitored and quality assurance should be periodic.

According to an ART provider:

Childbearing has a strong demand in our country and culture. Every couple without a child thinks their marriage has not succeeded and this leads to increased demand for ART. To avoid abuse, there should be a national regulation (54-year-old ART provider)

Similarly, another ART provider said:

Adoption is chaotic, everything is done secretly due to the stigma and ART is unregulated. This is not acceptable (57-year-old ART provider)

The ART clients also corroborated these views. An ART client said:

Government should be involved so that women are not defrauded. Trial and error are common in Nigeria. They say 'Madam, it is not our fault'. Doctors should be certified and there should be periodic hospital checks (37-year-old businesswoman, Igala)

The ART providers noted that there is need for government to designate centres in Nigeria where training can be obtained instead of training outside the country. An ART provider said:

The country now has well trained ART specialists and there is need for Government to designate some of these centres for training (54-year-old ART provider)

In the area of cost, most of the ART clients believe that an increase in the number of government owned facilities will help reduce cost. An ART client said:

Equip government hospitals with ART services because most are private. It will be cheaper, and the less fortunate ones can access it (43-year-old businesswoman, Hausa)

Some participants believe that the increased spate of cryptic pregnancy is due to the lack of regulatory oversight, leaving the market free for all. According to an ART client:

I know of a woman who went for ART but ended up being sold the idea of cryptic pregnancy and illegal adoption. Government should regulate it to avoid desperate women and couples being at the mercy of fraudsters (43-year-old medical practitioner, Igbo)

Similarly, an ART provider said:

An increasing number of women claim to be carrying cryptic pregnancy which they wrongly believe is a form of assisted conception. The unregulated market is responsible for exposing them to illegal practitioners (47-year-old ART provider)

Discussion

The views of the ART providers and clients discussed below have ethical implications which should be considered in instituting a national regulation for the practice of ART in Nigeria.

Age

Age is an important factor in the success of ART. In the available Nigerian National Summary Report (2017), using own eggs, those who were less than 35 years had the highest livebirth rate of 17.6%, followed by age 35–37 years with 15.7% live birth rate (LBR). This agrees with the age range of 25–35 years proffered by the ART providers in this study. Ages greater than 42 years had only 1.1% LBR. Use of fresh donor eggs across all ages from 775 recipient cycles gave a 22.7% LBR.¹⁴ However, there are stories of women in their late sixties giving testimonies of delivery of twins and triplets. One of the practitioners reported that he managed a 58-year-old postmenopausal client of his with donor eggs and she had a successful term pregnancy.

Majority of the ART clients in this study are in support of access to ART services irrespective of age provided the woman is fit to carry a pregnancy. However, the question of how ethical it is for a 60-year-old woman or female partner in a traditional union to seek assisted conception services for infertility issues remain. No case illustrates the ethical dilemmas involved better than that of Maria Bousada, a single mother who conceived and delivered twins using donor-egg IVF at age 66 and died 3 years later, leaving her 2-year-old twins orphaned.¹⁵

Despite this scenario, arguments in favour of making donor-egg IVF available to postmenopausal women is that

not doing so will contradict societal values of equality and personal freedom. According to the specialists in the present study, the most important factor is the medical fitness of the woman. With the availability of donor eggs, donor sperms and even donor embryos, infertile individuals and couples can have their dream of having a genetic offspring. However, the question remains as to whether it is ethical to have a child knowing that one may not be present to raise the child, either from ill-health or death.

Like some of the study clients noted, children are raised in a communal manner in Africa which was echoed in the American Society for Reproductive Medicine (ASRM) committee opinion noting that it is not uncommon for grandparents to raise children as they often bring economic stability, parental responsibility, and maturity to the family unit.¹⁶ If society considers it acceptable for grandparents—postmenopausal women and men of the same age—to raise children, then it follows that for older people (who are not physically or psychologically capable) to raise their own children should likewise be considered acceptable. The people around the woman will help her raise the child as noted by the ART clients, but meanwhile she would have confirmed her womanhood.

Another point is that it is discriminatory to prevent older women from having children if it is considered acceptable for men to procreate late in life. One could argue that allowing men and women to have equal reproductive possibility would contribute to a more egalitarian society. In addition, society recognizes individuals' rights to make reproductive choices regardless of their life expectancy or age; there is no prohibition placed on people, for example, with terminal illnesses that shorten their life spans or careers that jeopardize their safety. Therefore, it would be discriminatory to deny only older women the opportunity to fulfill their desire to become parents by procreating.¹⁷ This is especially relevant in Nigeria, where payment for services is out-of-pocket.⁹

Arguments against postmenopausal pregnancy are equally compelling including that despite the social acceptance of grandparents raising children, parenting poses significant emotional and physical demands that some people of advanced age may not be able to handle. Additionally, there is a high likelihood that the children may experience the loss of one or both parents before reaching adulthood. Given the evidence that children who experience the loss of a parent have a greater chance of depression and drug abuse,¹⁸ knowingly subjecting children to the probable loss of both parents early in life

is to expose them to likely harm as well as posing a greater risk of obstetric and neonatal complications to both mother and child.¹⁹ Also, from the standpoint of the child's welfare, it can be argued that the possible harm to a child who is likely to suffer the loss of a parent at an early age may outweigh the harm to parents of not being able to exercise reproductive autonomy. The AFRH-ART guideline recommends 54 years as the maximum age for female recipients of donor eggs.

Marital Status

Marital status as an access factor in ART remain controversial. In this study, single women accessing ART was not acceptable to two of the clinic directors as well as some clients. However, some writers have stated that physicians should not use patients to express their views about the social context of parenthood, since the medical profiles of these clients are no different from that of their married counterparts.²⁰ This implies a limitation of physician autonomy in the provision of ART services which goes against their own rights.

Nigerians still see children as products of a stable marriage and people frown at an unmarried woman becoming pregnant. This has been carried into ART, which was confirmed by some of the clients who wondered what response a single mother will give as to paternity of her offspring. The AFRH guideline is silent on whether single women should access ART, thereby leaving service provision based on marital status to the discretion of the clinic directors. In practice, many clinic directors are interested in ensuring there is a father-figure in the life of the child. Most societies are no longer fastidious on whether a woman is single or not and are more interested in the ability of the woman to care for the child as opined by a clinic director.

According to the World Health Organization, reproductive rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. They also include the right of all to make decisions concerning reproduction free of discrimination, coercion, and violence. Therefore, the single woman has the same right to ART as the married. Restricting access to ART on basis of marital state is viewed internationally as discriminatory 21st century medicine and reflects a cultural bias which should not be present in this age.²¹

Sexual Orientation

While there is debate as to whether same sex couples are infertile, the fact remains that they are unable to conceive due their social circumstances.²² In Nigeria, homosexuality is illegal, and thus access to services is prohibited, invoking the concept of fitness to parent. However, many societies recognize the right of individuals to choose their sexual orientation. The views of our respondents were varied. While a few believed that sexual orientation should not deny them access, others maintained their limitation to access for cultural and religious reasons. One may argue that presently a lesbian or gay couple may be silent about their homosexual lifestyle while accessing ART as individuals, using surrogate mothers and anonymous donor sperms as applicable. They may therefore not be fully honest with the demographic characteristics given to the ART clinics. This may affect the validity of the data collected in the different centers and invariably the national data. Nigeria, being a highly religious country is unlikely to recognize the rights of homosexuals to assisted reproduction in the foreseeable future.

The regulation of reproductive freedom is not a new phenomenon, dating as far back as the 1900 with forced sterilization of those it deemed unfit.²³ The Human Rights Treaty, the International Covenant on Economic, Social and Cultural Rights (known as the Economic Covenant) adopted by the United Nations General Assembly in December 1966, and entered into force in January 1976, has however since recognized the right of everyone to enjoy the benefits of scientific progress and its applications, and the right of everyone to enjoy the highest standard of physical and mental health.²⁴ Freedom in the pursuit of the right to health means that people are not denied access to services. Any restriction on access should be justifiable and defensible, and shown as not violating peoples' human right to health.

Religion

Religion affects both ART service provision as well as ART seeking behavior. Some of the practitioners will not offer cryopreservation and embryo disposal, but preferably offer embryo donation to their clients. Their reasons stem from their belief that the embryos are potential living beings and as one practitioner opined, the problem of congenital anomalies and imprinting issues are an ever-present risk. However, the impact of ART techniques on imprinting errors is still debatable because it is thought

that infertility itself may confer an independent risk factor for defects in expected epigenetic patterns.²⁵

The Roman Catholic Church has publicly emphasized its opposition to ART several times, claiming it replaces the love between husband and wife, and might also cause disposal of embryos which are believed to be individuals with souls, and should be treated as such.²⁶ According to the Donum Vitae document:

“Techniques involving only the married couple (homologous artificial insemination and fertilization) are perhaps less reprehensible, yet still remain morally unacceptable. They dissociate the sexual act from the procreative act. The act which brings the child into existence is no longer an act by which two persons give themselves to each other, but one that entrusts the identity and life of the embryo into the power of doctors and biologists. Such a relationship of domination is contrary to the dignity and equality that must be common to parents and children.”²⁷

As far as the Catholic Church is concerned, it is not objectively evil for someone to be infertile, and advocates adoption as an option for those who still want to have children.

The Anglicans and Pentecostal denominations are more receptive of all facets of ART. The Church of Jesus Christ of Latter-Day Saints (LDS) however, while discouraging sperm donation and use of donor eggs or sperms also note that such decisions are personal matters and are left to the judgement of the husband and wife. No disciplinary action is advised for married couples who make use of ART. Muslims also accept ART but decline third party reproduction which they believe is tantamount to adultery²⁸ except among the minority Shi'ites.²⁴ Orthodox Judaism allow use of own gametes for ART but has issues regarding modesty and sexuality with strong emphasis on verifiable lineage.²⁹

Our findings show that infertile women or couples access ART for infertility treatment irrespective of their religion. It may be that to them, considering the physical and psychological burden they are willing to go through, and the financial cost they are willing to pay if they can afford it, their infertility is seen as a life-threatening condition.³⁰

Non-Medical Sex Selection

Many couples and individuals seek assisted reproduction for infertility issues. However, there remain some who request it for male sex selection. In most developed countries, non-medical sex selection is prohibited except in the

form of sperm sorting for sex-linked genetic disorders.³¹ The clinic directors interviewed noted that many clients seek ART services for sex selection and family balancing.

Inheritance is patrilineal in Nigeria, as obtains in many parts of Sub-Saharan Africa.³² As a result, many families do not feel complete in the absence of a male child to carry on the family name. Women bear the greater brunt of lack of a male child in the family and will go to any length to get one. Some women suffer various degrees of intimate-partner violence as a result and may even be sent out of their matrimonial homes. If it happens that a spouse dies, the woman is not entitled to any of her husband's property by customary Law.³³ Though this may be changing somewhat, due to the different international conventions of which Nigeria is signatory, a lot still needs to be done.³⁴ While sex selection may not be bad, especially for family balancing, there is the risk of destruction of the female embryos which some argue is ethically wrong and leads to discrimination against female gender.

Sex selection technologies have been condemned on the ground that their application is to discriminate against female embryos and fetuses,³⁵ thereby perpetuating prejudice against the girl child³⁶ and social devaluation of women. For instance, the Convention on Human Rights and Biomedicine of the Council of Europe provides that:

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided³⁷

The Workshop of the Council of Europe endorsed the condemnation of such discrimination and devaluation but considered that universal prohibition would itself risk prejudice to women in many present societies, especially while births of sons remain central to the woman's well-being. The Workshop considered that an application for preimplantation genetic diagnosis (PGD) for sex selection may not be favoured in principle, but there should be room for resolution on its merit.³⁸ This may have informed the decision of the AFRH in stating that while PGD can be used for medical sex selection, non-medical sex selection should be considered individually on its merits and practitioners should have an ethics committee in-house to assess such requests.⁸

However, as stressed by the World Health Organization, the availability of sex selection technologies should not be regarded as the root cause of these problems.³⁹ The root cause is the culturally embedded

preference for male offspring the world over (less so in Western societies), accentuated by fertility decline and population control, with technology as a facilitator.⁴⁰

Non-medical sex selection remains a hotly debated topic with one view claiming it is fundamentally at odds with a human rights perspective based on the equality between the sexes, and the other insisting that its restriction goes against the rights of reproductive choice and may have the unintended and morally adverse effect of contributing to sex-selective abortions because of forbidding all forms of sex selection for non-medical reasons prior to pregnancy.⁴¹

Number of Transferred Embryos

In this study, the ART practitioners noted that as many as 5 embryos are transferred per cycle. They claimed that the higher the number of embryos transferred, the higher the chance of implantation. The need to increase the chance of implantation stem from the fact that most clients pay out of pocket in the presence of endemic poverty as noted by Fathalla (2002).²⁴

At present, the AFRH insist that not more than three embryos should be transferred per cycle, with automatic suspension being penalty for violation. This reduces the incidence of higher order multiples (HOM) pregnancies. This penalty is for now only enforceable in Lagos State. However, most developed countries now favour elective single embryo transfer,⁴² to avoid the risks of multiple gestation and prematurity, which lead to a reduction in birth-admission costs and ultimately savings for government. During the past 10 years in Europe, especially within the last five years, a variety of measures have been employed to greatly limit the number of embryos that can be transferred.⁴³ Most recently, studies from Sweden, Denmark, the Netherlands, and Belgium have shown that single embryo transfer (SET), especially when combined with frozen/thawed embryo transfer (FET) in a subsequent cycle, achieves pregnancy and live birth rates equivalent to the transfer of two and even three or more embryos, without the complications of twin and higher order multiple (HOM) pregnancies and births.

Several countries now have firm guidelines or regulations allowing only SET for certain categories of patients. The United Kingdom regulatory body has put in place measures to ensure that national and clinic-specific multiple pregnancy rates are maintained at below 10% of all IVF births. Thus, increasingly, practitioners are advocating the transfer of a single embryo. The evidence from the

2016 International Federation of Fertility Societies (IFFS) Survey supports the notion that there has been an increase in the proportion of countries with legislation or clinical guidelines restricting the number of embryos permissible for transfer to women undergoing IVF/ART cycles (59% vs 38% in 2013).

Despite the challenges of out-of-pocket expenses for ART and client request for multiple embryo transfer in our environment, we as a community should aim for elective single embryo transfer (eSET) in a fresh cycle, and if there is failure of implantation, it is followed by a single thawed frozen embryo in the subsequent cycle, as it is associated with a dramatic reduction in the rate of multiple pregnancy. Studies have also shown that eSET significantly increases the chance of healthier livebirths compared to (DET) double embryo transfer.⁴⁴ The risks associated with multiple pregnancy coupled with the advancement in the effectiveness of ART leading to successful pregnancies should make all men of goodwill to lend their voices to a medically supported call to reduce the number of embryos transferred. This is in keeping with the principle of non-maleficence and beneficence.

The issue of a cultural love for multiple pregnancies should take a backstage in the health of our women and offspring. According to the European Society of Human Reproduction and Embryology (ESHRE) and American Society for Reproductive Medicine (ASRM) Best Practices,⁴⁵ a successful IVF treatment has moved away from the outcome of a single cycle toward the concept of the singleton birth rate per initiated cycle over a given time period, including patient distress, complications and costs, thereby indicating that a single healthy baby is the true measure of success and twin gestation is an adverse complication of IVF.

Cost

The ART directors and clients agree that cost is exorbitant for this technology. Virtually all European countries have some form of cost coverage. Six countries—Denmark, France, Hungary, Russia, Slovenia, and Spain—have complete coverage via national health plans, while Austria and Finland have two-thirds and forty percent coverage via their national health system. However, coverage depends on patient characteristics.⁴⁶ Coverage in Spain is for instance only available for women up to age 40. Slovenia covers six cycles for the first child and four cycles after a first live birth, but only for women up to age 42. In some parts of the United Kingdom, women who are obese are being denied coverage.⁴⁷ All Western healthcare systems

both public and private, set restrictive eligibility criteria that limit consumers' access notwithstanding some state subsidization in most of the countries of Western Europe.⁴⁸ The financial burden is even higher in low resource countries where state-subsidization rarely exists. In these countries, the cost of a single cycle was more than half of an average individual's annual income, which agrees with our findings of an average cost of 1.5 to 3 million naira for ART procedures. Payment for services in Nigeria is out of pocket as confirmed by the ART practitioners. There is no insurance coverage or government subsidization. This is not surprising in a country where the world bank data gives current national health expenditure (% of GDP) as 3.89 (2018 value).

The high cost of ART in Nigeria according to the clinic directors is because equipment is bought outside the country including consumables. In addition, majority of the ART centers are private sector driven though a few public tertiary health establishments including National Hospital, Abuja (2006), University of Benin Teaching Hospital (2007), University of Ilorin Teaching Hospital (2012), Lagos State University Teaching Hospital (2013), University of Lagos Teaching Hospital (2016), University of Port-Harcourt Teaching Hospital (2017), and Federal Medical Centre Umuahia (2018) now have ART centers.

Despite the high cost of ART, infertile couples see it as their last hope and believe that considering the stigma attached to not having their own child, they will rather borrow or sell their property to obtain this priceless "commodity"—a child. This was echoed by one of the clients saying "Onwe ro ife ka nwa" (nothing is greater than a child).

The ART practitioners also noted that there seems to be an increase in transatlantic demand for ART probably because the cost in Nigeria is comparatively low due to the diminished strength of the Naira. There is no regulation regarding transatlantic ART service production as obtains in most developed and some developing countries. This cross-border reproductive care has implications for equity of access to ART since the poor majority would be outpriced from the market.⁴⁹

Informed Consent

Both the practitioners and the clients agreed on the importance of full disclosure of what the clients are to expect from the ART process. Informed consent is one of the most important components of an ethical ART service provision, the elements of which consist of information

in an understandable language about the procedures to be undertaken, anticipated results, alternative treatment, all foreseeable risks, and discomforts (physical, psychological, social, economic, inconvenience), and benefits. Substantial understanding means recognition of consent as an act of authorization.⁵⁰

In clinical practice, the physician offers recommendation, provide information, patient makes the decision and signs the consent form. Informed consent is a process during which the physician provides information, and the patient asks questions to clarify ambiguities, which helps the physicians to understand the values the patients choose to promote while undergoing treatment. The physician-patient interaction enables the physician to understand the clients' preference about shared decision-making or if they prefer to be kept informed but leave the decision-making to the doctor or their family. This openness has the advantage of creating long-term trust in the patient-physician relationship. Because informed consent is a process, clients have a right to withdraw consent anytime they wish without negative repercussions.

The study participants were of the view that consent forms should be signed at every point in the ART process. This is a documentation that the procedures were authorized, and while it does not prove that informed consent was obtained, it does protect the practitioners from legal action provided there was no gross negligence on their part.

In terms of handling of the excess embryos, the views of the practitioners and clients were that decision should be that of the clients. This is the acceptable standard of practice worldwide since the clients are the owners of their genetic materials. Individuals or couples for whom gametes or embryos were stored can in conjunction with their clinicians decide on what to do with their gametes/embryos if they no longer need them in storage. As a result, policies must be established by clinics that document the basis of discussion about gamete/embryo disposal. The AFRH guidelines recommend that clinics must ensure that for the period of storage stipulated in the consent form, gametes and embryos must be kept safe. Following this time, if the person responsible for the gametes and /or embryos cannot be reached for further direction, in accordance with the policy of the clinic, gametes or embryos may be discarded, used for research or training purposes. Sufficient effort backed with proper documentation must have been made to get in touch with the individuals concerned, allowing adequate time for

them to respond before discarding. Cryopreservation of fertilized oocytes and embryos are permitted at all stages through blastocyst development in most developed countries except Italy, which permits oocyte cryopreservation but not embryo freezing.⁴³

In the Nigerian environment with epileptic power supply, the clinic directors must ensure that there is continuous electricity supply bearing in mind that any disruption could lead to depreciation in the cryopreserved tissues (gametes and embryo).

Regulation of ART

In this study, both the ART clients and practitioners emphasized the need for regulation of ART in Nigeria. Only South Africa has a national regulation in Sub-Saharan Africa, and until recently (May 2019), Nigeria had no guideline. Nigeria is the first Sub-Saharan African country to perform in-vitro fertilization in 1984 followed by South Africa in 1986 and Ghana in 1995.⁵¹ As at 2001, there were only 8 ART centers in Nigeria, but there has been a rapid proliferation in the last 10 years, with non-doctors and non-specialists setting up ART centers. At present, there are more than 70 ART centers in Nigeria.⁹

The UK is the first nation to have a well-coordinated regulatory body for assisted reproduction, which it does through the Human Fertilization and Embryo Authority (HFEA), backed by the HFE Act (1990).⁵² HFEA regulates activities by means of licensing, audit, and inspection of fertility centers and maintaining the Code of Practice, which ensures the optimum undertaking of licensed activities by fertility centers.⁵³ While some nations now have similar regulatory bodies as the UK, many have only professional guidelines which is not legally binding on the ART practitioners.⁴³ Nigeria belongs to the latter group. Majority of Nigerian ART practitioners were practicing in a legal vacuum but with the AFRH guideline of May 2019, they can now all have a minimum reference standard for practices offering ART services in Nigeria. Nevertheless, this guideline is not binding on all practitioners except for those who are members of the Association of Fertility and Reproductive Health. Lagos State, the former capital of Nigeria and currently Nigeria's commercial center has the greatest number of Fertility centers, with many being run by uncertified and unaccredited specialists.⁸ The State government therefore saw the need to enforce the contents of the guidelines through its health facility monitoring and accreditation agency (HEFAMAA).

The experience with Reproductive Technology Accreditation Committees in Australia has demonstrated that self-regulation can work. Committees accredit practitioners who are qualified to perform the procedures and have adequate facilities to perform them. They also try to ensure that the accredited centers maintain the quality of their services and regularly report their results in an objective, unbiased way. Benefits of self-regulation include its flexibility. It can respond to new developments in a rapidly advancing field.²⁴

In the United States, the existing regulation focuses on quality control. The Centers for Disease Control and Prevention (CDC) collects and publishes data on ART procedures. The Food and Drug Administration (FDA) controls approval and use of drugs, biological products, and medical devices and has jurisdiction over screening and testing of reproductive tissues, such as donor eggs and sperm. The Centers for Medicare and Medicaid Services (CMS) is responsible for implementation of the Clinical Laboratory Improvement Act to ensure the quality of laboratory testing. The only Federal legislation on ART is the 1992 Fertility Clinic Success Rate and Certification Act which does not establish any penalties for non-reporting clinics except to list them as such in the yearly report.⁵⁴ While there are laws used by States to regulate ART, many States choose not to regulate ART at all and leave regulation to medical societies like American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Medicine.⁵⁵ Though standards set by members of the profession for the practice of reproductive medicine are widely followed and successful, some instances have occurred in which professional guidelines have been breached such as the Octuplet pregnancy in California.⁵⁶ These have led to calls for greater regulations ensuring clinics follow ASRM guidelines and comply with federal reporting and certification requirements.

In Nigeria, self-regulation is likely not to work in the absence of legal backing. The participating clinic directors are of the opinion that the AFRH guidelines are insufficient. This is because it has no bite in other states of the federation. While it may work in Lagos state, other states are exempt. The ingenuity of Nigerians may be such that the illegal clinics will move to other states of the country and continue to cause havoc. Rather than regulation per state, there are arguments for a national regulation which will be binding on all practitioners. Each State Assembly passing a bill will take a longer time with the attendant

negative effects on desperate women and couples who will be at the mercy of fraudsters. As the ART clients in the study noted, in the absence of oversight functions, based on their experience and discussion with fellow infertile colleagues, ART providers will continue to practice according to their conscience and not all consciences are well-formed. However, some writers have suggested that the problems with self-regulation can be circumvented by separating the regulatory and professional divisions of the profession such that the regulatory division would undertake the task of promoting the interests of the profession and balancing those interests with the public interest in safety while it continues to operate separately from the broader professional group.⁵⁷

The AFRH-ART guidelines require that clinic directors be medically qualified at not less than 10 years post-qualification, with not less than 5 years post-specialization as an obstetrician and gynaecologist. The team necessary for a good outcome in ART is multidisciplinary, consisting of doctors, nurses, embryologists, and counsellors. These are in line with the current minimum standards by ASRM for practices offering assisted reproductive technologies,⁵⁸ and HFEA Code of Practice for ART practitioners.

Currently, pilot programs for training and certification of ART nurses have started at University of Port-Harcourt as well as for training and certification of gynaecologists (PF-IART) which started in Oct 2019 at Nisa Premier & Garki Hospitals Abuja in collaboration with West African College of Surgeons (WACS). Training of clinical embryologists is available through ESHRE/post graduate programs abroad as it is yet to be initiated in Nigeria. Medical education programs as being instituted in Nigeria is welcome. This will go a long way to standardize and update the knowledge of Nigerian ART specialists.

While the AFRH guideline as presently available is a welcome development, a supplement to these guidelines in the form of government legislation, which are sets of rules codified by law that come with penalties for violation, will better serve the Nigerian population.

Strengths and Limitations

The Strength of the study lies in the fact that it employed an in-depth exploration of the views of Providers and Clients in the ART process to answer the research questions. In addition, the clients were of different ethnic groups and obtained their ART services from different

centers in different states across the Federation, four of the six geopolitical zones.

However, the study has some limitations. The small sample size may have influenced the opinions obtained making the results not to be totally generalizable to the whole country. This is a preliminary qualitative report that requires confirmation of its findings through a larger study. The snowballing sampling technique may have led to bias in the study responses since the women by proposing each other may have more similarity and interests than a random sample of women. In addition, the fact that all the women were married may have biased the study sample. The views of the men were also not represented. Larger sample studies involving all genders and marital status is recommended.

Conclusion

The views of the ART providers and clients in this study are supportive of making ART available to all who need the technology on demand, while calling on the government to subsidize the cost as it is beyond the reach of the average Nigerian person. While the guideline instituted by the Association for Fertility and Reproductive Health for its members is a welcome development, the lack of legal enforcement continues to expose ART clients to the risk of inappropriate practice by providers.

There is a need for continued effort on the part of all stakeholders to ensure the passage of the Nigeria Assisted Reproductive Technology Bill which has been in the House of Assembly since 2012.⁵⁹ This Bill should take cognizance of the findings from the study including:

1. The legislation should clearly state that free and informed decision-making is central and imperative in all ART procedures.
2. Eligibility criteria for ART services must be clearly stated:
 - a. whether it should be available to men and women in stable unions or inclusive of single women, not left at the discretion of the ART practitioners as is the case in the AFRH-ART guideline presently.
 - b. Fifty-four years is the maximum access age for female clients recommended by the AFRH-ART guideline but needs an upward review considering the views of practitioners and clients on the cultural need for women to be allowed to access ART provided they are medically fit to carry a pregnancy.

3. There should be legislation on non-medical sex selection bearing in mind the patrilineal inheritance system in Nigeria to have a uniform standard of practice, that is not dependent on the religious diversity and differences in moral and cultural perspectives of the ART providers.
4. There should be provision governing claims of conscientious objection by providers, without them suffering any disadvantage because of their objection. However, the providers should be mandated to inform the clients of the conflict and promptly refer them to other providers where they can obtain the needed service.
5. Cost of ART should be subsidized by provision of ART services in many more government owned medical establishments and by in-cooperating ART provision into the National Health Insurance Scheme so that payment of services will no longer be out-of-pocket, thereby improving access.
6. Information on available ART centres should be readily available to the populace without them depending only on relatives, friends, acquaintances, or referral by physicians. The list should be easily accessible from government and association websites.
7. The maximum of three-embryo transfer per cycle of IVF recommended by the AFRH-ART guidelines need to be enforced and defaulters punished to check quackery and protect clients from the risks of higher order multiple pregnancies and being faced with fetal reduction with possible loss of all fetuses. However, there is need to encourage single embryo transfer, which is safer, avoids the risks of multiple pregnancy, and is the international standard of care.

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