Enforcement of ethics and standards amongst practitioners of ART in Nigeria

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The definition of ethics as the branch of knowledge that deals with moral principles make the subject esoteric and the seeming concern of only the very few people interested in philosophy and other academic subjects that relate to the fundamental nature of knowledge and behaviour. Most practitioners of In Vitro Fertilisation (IVF) feel remote to this subject and consider it academic at the best of times. My impression is that most practitioners feel that ethical considerations have little to do with their practice.

The objective of this presentation is to change this conceptual position and bring ethics from the esoteric to the exoteric and contextualize it within daily aspects of patient management. Medical ethics is a system of moral principles that define values for the practice of medicine and scientific research. It is a system based on a set of values that guide professionals when they need to resolve difficult situations which they may encounter in practice. These values include:

- Respect for autonomy (right to self-determination)
- Non-maleficence (do no harm)
- Beneficence (do good) and
- Justice (fairness) [1]

There are many such codes in medicine. The Hippocratic Oath is a pledge on ethics that used to be taken by all physicians. It required the physician to swear by healing gods to uphold specific standards of behaviour [2]. One of the critical elements of the oath is *primum non nocere* - First, do no harm [2]. The oath served to codify and unify expected behaviour and all doctors were required to swear the oath before starting their medical practice. This is no longer the case but the importance of ethics in the medical profession cannot be overemphasized.

Human beings come with different value frameworks, and the objective of ethical discussions is to define a framework that meets the needs of our patients while at the same time protects the reputation and integrity of the profession. In IVF treatment, it focuses the medical practitioner on the needs of the woman, her partner, the child to be born as well as ensuring that the cultural needs of the society are upheld. Potter Stewart, associate justice of the United States Supreme Court, defines "*ethics as knowing the difference between what you have a right to do and what is right to do*" [3]. This concept is crucial when one considers the balance of power in the doctor-patient relationship. The doctor has all the power and the patient could be open to abuse and to quote James Madison Jnr, the American statesman, lawyer, diplomat, philosopher and Founding Father – "The truth is that all men having power ought to be mistrusted" [4].

These issues are critical, especially, when one considers the economics of the healthcare market. A free market is one where there is an open exchange of goods and services without any interference except by the forces of demand and supply [5]. The healthcare industry operates under the state of market failure [6, 7]. Market failure occurs when the price mechanism fails to account for all of the costs and benefits necessary to provide and consume goods or services. The market will fail by not supplying the socially optimal amount of products or service. There are four probable causes of market failures; power abuse as in a monopoly, improper or incomplete distribution of information, externalities and public goods.
I will focus on asymmetric information - when one person knows more than somebody else for the purpose of this essay. Asymmetric information is the specialisation and division of knowledge, as applied to any economic trade. For example, doctors typically know more about medical practices than their patients. After all, physicians have extensive medical school educational background that their patients generally don't have.

The effect of this asymmetry of information on an industry has been elegantly described by George Arkelof [8] in his seminal paper "The Market for Lemons: Quality Uncertainty and the Market Mechanism". In this paper, Arkelof examines how the quality of goods traded in a market can degrade in the presence of information asymmetry between buyers and sellers, leaving only "lemons" behind. Arkelof's theory applies in all markets where information asymmetry occurs between buyers and sellers and healthcare is a particular case in point.

- Providers may overwhelm patients with information about individual treatment options, and the patients may end up with unnecessary treatment.
- The doctor can also pretend to be competent in specific procedures and provide substandard care.
- Providers may use a price incentive to lure patients into receiving substandard services.

There are many more examples. The overall effect is a steady decline in the quality of service and the state of the industry. There is anecdotal information that despite the growth we have seen in the IVF industry in Nigeria with over 70 practitioners providing IVF services [8]. The level of distrust in services is such that most people that can afford to travel abroad for service will prefer to do so rather than receive treatment locally [8]. We need to protect our industry from charlatans and restore trust to drive growth.

One of the ways to manage the downward spiral of standards that could be driven by information asymmetry is to ensure that practitioners work within strict guidelines. These guidelines are sets of instructions which inform us of the manner service is rendered. Regulations, on the other hand, are rules which are authorised by legislation. I must commend the foresight of the past president of the Association for Reproductive Health (AFRH), Nigeria, Dr. Faye Iketubosin for inaugurating an ethics committee of the AFRH and for the honour and the privilege he afforded me to chair a committee of very able practitioners, namely, Dr Patrick Okonta, Dr Kehinde Bamgbopa, Dr Kingsley Onwuzurigbo, Dr Chizara Okeke and Mrs Rose Ogbeche. Over a period of a year, we participated in a stakeholders' workshop and garnered viewpoints of leaders across different segments of society as well as the opinions of IVF practitioners. The information gathered was synthesised, and the conclusions documented. Indeed, some of these findings have been published [9, 10] in peer review journals.

The president of AFRH received the final report on April 14, 2018. The information we provided formed part of the guidelines launched by the association and the Lagos Ministry of Health on May 6, 2019, by the immediate past Honorable Commissioner for Health, Dr Jide Idris. The ministry went one step further on July 12, 2019, and adopted the guidelines to the Health Facility Monitoring and Accreditation Agency (HEFEMMA) of the Lagos State Government. A monitoring committee was set up under the distinguished leadership of Professor Emeritus Giwa Osagie, Professor Oladapo Ashiru and Professor John Ikimalo. The objectives were to inspect IVF practices in Lagos State and ensure they conform to the published guidelines. They undertook to publish a list of the clinics that have met these guidelines. These are steps in the right direction, and they will go a long way in addressing the issues outlined above about lack of trust in the industry.

Unfortunately, the guidelines have not been written into law, and it will be difficult to enforce these guidelines as the adoption of the standards will be optional unless there is a legal framework to enforce compliance. While we wait for regulations by the law, I believe that we need to make a case for the importance of the adoption of ethical standards on a self-regulatory basis. Self-regulation is something we have adopted at Bridge Clinic. We operate as if regulation already exists, and the rest of this article shares the experience at Bridge Clinic. The hope is that other practitioners may be stimulated to start to self-regulate in the absence of regulation and within the framework of the values of medical ethics - beneficence (do good), non-maleficence (do no harm), justice, and autonomy.

At Bridge Clinic, we have come to understand that a critical driver of ethical practice is the implementation of a quality management system. Quality means fitness for purpose and quality management are all the systems we put in place to ensure that our services are fit for purpose and that our value proposition delivers to all stakeholders. The concept of quality management underpins the ethical approach to patient care.

ADOPTING INTERNATIONAL FRAMEWORKS

Bridge Clinic does not believe in reinventing the wheel. Our organisation has adopted various existing guidelines for good practice of IVF especially the Human Fertilisation and Embryology Authority (HFEA) supported by the European Society for Human Reproduction (ESHRE) and the United Kingdom (UK) National Institute for Clinical Excellence (NICE) IVF Guidelines. These guidelines clearly define the parameters of 'good practice' and are regularly reviewed to stay relevant with the advancements of ART.

ETHICS COMMITTEE

To ensure cultural relevance within Nigeria, we set up a local ethics committee to review practice on a case by case basis and to ensure our practice remains culturally acceptable in Nigeria.

The first chair of the ethics committee was the distinguished legal practitioner Dr Myma Belo Osagie. Other members were the late Reverend Canon Adenuga (Christian perspective), Justice Okunu Shuaib (legal as well as Islamic perspective), the late Professor Akinla (a Gynaecological perspective), Mrs Peju Adebajo (a laywoman), Chief Uwensuyi Edosomwan (a layman) and Professor Olorode (a professor of sociology).

Under the guidance of the ethics committee, Bridge Clinic was able to explore and adopt the treatment of the single woman, IVF surrogacy, and the use of donor eggs and donor sperm in IVF treatment, practices that are common abroad but may pose challenges within our society. The ethics committee was instrumental in supporting Bridge Clinic in achieving many firsts in Nigeria, including the first birth by IVF surrogacy in Nigeria (11).

These practices have become well established now, but we had to be careful twenty years ago, and the support of the ethics committee was invaluable. As the practice of IVF matured in Nigeria, the decision was made to transfer the functions of the external committee to an internal committee chaired by the clinic's medical director. A defined framework is used to assess individual cases that are more complex. More contentious issues are escalated and deliberated by the Clinical Governance Subcommittee of the Board of Directors for guidance and decision making.

QUALITY MANAGEMENT SYSTEM

I attended the 18th Annual Conference of ESHRE in Vienna in 2002 and listened to a talk about the importance of establishing a quality management system in IVF clinics. A few German clinics had embarked on this journey, and they were sharing their experience at the conference. Bridge Clinic was an early mover with quality management certification, and we became the first clinic in the English-speaking world to adopt a quality management system. We received our first certification in 2004 following an international audit and verification of meeting the requirements for ISO 9001:2000. At the time, this was ahead of all the clinics in the UK.

We were re-audited according to the ISO 9001:2000 standards in 2005 and 2006. By continuously improving our systems, we were inspected and certified in line with ISO 9001:2004 standards in 2007, 2010 and 2011. Bridge Clinic received certification for ISO 9001:2008 standards in 2013 and 2017 and further improved our systems to align with ISO 9001:2015 standards in 2018 and 2019. These certifications are carried out by an independent team that visit Nigeria from Quality Austria.

I must state that I believe it is easier to have a quality management certificate than it is to drive a quality management philosophy across the organisation. Nevertheless, the implementation of quality management has made it much easier to drive consistency in our delivery of IVF services to our patients.

DEFINE STANDARDS FOR ALL TOUCHPOINTS

The underlying philosophy of quality management is to define standards for all touchpoints on the customer journey. Applying risk management principles help to identify hazards and eliminate them to drive consistency of service delivery to all patients.

The essential approach is Plan, Do, Check, and Act (PDCA). This approach is an iterative four-step management method used in business for the control and continuous improvement of processes and products. It is also known as the Deming circle/cycle/wheel, the Shewhart cycle, or the control circle/cycle. In its most essential form, it means that you plan what you want to achieve, and you perform it. You then measure the outcome/achievement and continuously adjust the plan to ensure improvement. The approach is iterative because the philosophy is a continuous journey that you embark upon to drive improvements without a definite destination.

RECRUITMENT

Quality management starts with recruitment within an organisational structure where the delivery of service is beyond a key man. It is crucial to take the time to employ for fit or role suitability rather than competence. There are many competent doctors and nurses, but they may not commit to driving a quality management system if this does not resonate with their values. The importance of taking the time to employ the right staff cannot be overemphasised. The induction and on-boarding processes must similarly be well defined and implemented to assure the service expectation are met as should the training and competency certification system.

DOCUMENTATION

Documentation is a crucial element of quality management, and Bridge Clinic maintains a robust quality management documentation system that is easily accessible by all staff.

1. *Quality Policy*

   The Quality Policy defines the objectives for the year and what the organisation hopes to achieve.

2. *Patient's Charter*

   The Quality Policy supports the Patient's Charter, which captures the patient's expectations of us in terms of service delivery.

3. *Quality Manual*

   The Quality Manual codifies the general objectives of the organisation, and the organisational structure and resources required to meet the defined goals.

4. *Standard Operation Procedures (SOPs)*

   All procedures and processes are outlined and summarised in individual documents known as Standard Operating Procedures (SOPs). These SOPs are developed to drive the value proposition. These documents must be viable, tested and accessible to all staff. All documents are available on our electronic medical record system (EMR).

PERFORMANCE MANAGEMENT

Various initiatives are in place to regularly measure individual and organisational performance and to act on the findings.

1. *Customer Satisfaction*

   We measure customer satisfaction through surveys and a complaint management system.

2. *Incidence Management*

   We monitor process performance and conformance to all defined standards through regular internal and external audits. Bridge Clinic deploys a robust incidence management system to address anything that goes wrong. Incidences are classified into three categories.

   2.1 Incident

   An incident is a procedure or action that does not conform to the defined standard a has a limited direct impact on the patient's outcome or system.

   2.2 Severe Adverse Event

   A severe adverse event (SAE) is an incident that directly affects the patient's outcome or system negatively.

   2.3 Near Miss

A near-miss has the potential to have a direct negative impact on the patient's outcome or system, but at the time of the recorded incident, did not have any effect.

On the one hand, there is a system to manage process failures which may be as a result of system failures that are due to inadequate training or lack of processes. In these cases, SOPs may need to be created or reviewed, and in cases where guidelines do not exist, new policies are written. On the other hand, the system could be in place, but the staff did not do the right thing in which case the course of action guidelines for disciplinary action. Ultimately, incident management is about learning a lesson from occurrences and taking systemic measures to prevent future recurrence. Following this approach leads to organisational learning and the building of intellectual property for the organisation.

PROCESS CONFORMITY

One of the requirements of the ISO standards is process conformity, and this means that the processes as defined achieve what they are set out to do. The ultimate result of an IVF clinic is the pregnancy rate. In the UK and other, more regulated countries, clinics are mandated to report the results of their treatment to the HFEA, and these results are published. There is no such requirement in Nigeria. A similar system has been set up in Bridge Clinic to ensure that we operate as if we are working under regulation. Bridge Clinic invites the verification department of the financial services firm Alexander Forbes to audit and publish the results of all treatment at Bridge Clinic annually. The results of these audits are available on Bridge Clinic's website.

LEVERAGING ON INTERNATIONAL ORGANISATIONS

New advances are rapidly changing the science of IVF. It is difficult for a clinic in Nigeria to be part of this momentum, drive innovation, do research and development, and ensure that we can provide our patients in Nigeria the latest treatments that are available on the international stage. We felt that it was important to operate in affiliation with an organisation that was on the cutting edge of the science of IVF and able to implement new developments into our practice in Nigeria as they came through. We set up a collaboration with IVF Centres Prof. Zech (Next Clinics) from Austria for this particular reason. Our relationship means we more or less have a 'plug and play" with new developments in the science of IVF. Our staff either travel to Austria to learn or where necessary, the Austrians travel to Nigeria to implement the changes.

Furthermore, we have defined benchmarks for all laboratory and clinical procedures. We review our performance against these benchmarks monthly and work with the staff of IVF Centres Prof. Zech to address any discrepancies. We look at our indices such as the average number of oocytes per patient, the stimulation dose to achieve that rate, the average fertilisation rate, the blastocyst formation rate to name a few and where these indices do not meet the benchmarks, we troubleshoot and work assiduously to rectify the situation.

Conclusion

A focus on continuous improvement and benchmarking means that we will always deliver consistent and superior pregnancy rates as we have all the systems in place to make sure the patients' outcome is assured

irrespective of the doctor managing the patient. The total of this is consistent performance and improvement in our pregnancy rates over the years, which ensures our value proposition to our patients.

Quality management drives the philosophy of primum non nocere - first, do no harm, and as a corollary assures the philosophy of doing good. This value is the basic requirement of anyone practising medicine. It is essential in IVF treatment in Nigeria to earn the trust of our patients. Furthermore, it will drive the growth of a practice as it improves the chances of patient satisfaction.

There is much work to be done to ensure an integrated and effective regulatory framework for the practice of medicine in Nigeria, and while we wait for that, I hope that I have been able to show that we don't need to have regulation in place to enforced standards and that we can drive standards by self-regulation.

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