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INTRODUCTION

The availability of fertility treatment in Kenya is on the increase and its regulation is imperative since one in every four couples in developing countries is affected by infertility. Kenya is no exception. In the 1980's, fertility was high at 8.0 children per woman but the growth rate has since declined (1).Infertility is defined as "having the desire for a biological child and attempting pregnancy through unprotected sexual intercourse without success, for at least one year if the woman is under 35 years of age, or six months if the woman is 35 years of age or older (2). Women who consider themselves infertile often require medical intervention in order to conceive. In such intervention, they need to give their consent for various interventions and treatment. This consent is commonly referred to as 'informed consent'. As the name suggests, informed consent means the permission which a patient gives to a physician to perform a certain healthcare intervention to include examinations, tests and treatments (3). Informed consent is also required in medical research (4). Similarly in research, participants in clinical trials willingly consent to be used in the testing of various drugs before they are approved for the market. This article argues that whereas patients in Kenya consent to fertility treatment, they do so without being fully informed of all the treatment options available. It is imperative that doctors inform patients of all the options that they have so that the patient can in turn give informed consent for any consequential treatment. The development of informed consent in the practice of medicine has evolved to be an integral requisite for good medical practice. The essential elements of a valid informed consent and the practice of obtaining informed consent from patients during fertility treatments in Kenya should be exhaustive but precise. With the introduction of newer modalities of fertility treatments including in vitro fertilization, use of donor eggs and surrogacy it is

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6. Faith Kasiva. Robbed of Choice: Forced and Coerced Sterilization Experiences of Women Living with HIV in Kenya. African Gender and Media Initiative. 2012; https://profiles.uonbi.ac.ke/kihara/files/report-on-robbed-of-choice-forced-and-coerced-sterilization-experiences-of-women-living-with-hiv-in-kenya.pdf accessed 20th April 2017

imperative for the patients to have a detailed and adequate information of all available options, so as to make an informed consent. In relation to In Vitro Fertilisation consent is critical especially in relation to gamete or embryo donors and in cases of surrogacy where disputed parenthood is of grave concern. In relation to cryopreservation of human embryo's ethical and legal issues may arise and in particular ownership status in these situations should be clearly defined and understood. Legitimately the two party's involved in surrogacy can claim the reproductive rights in these situations. It is paramount to avoid any ethical and legal dilemmas by clearly defining and documenting ownership in these situations. In all these scenarios success rates have to be clearly indicated and the risks of multiple gestations & hyper stimulation and similar complications be mentioned. The Medical Practitioners and Dentists Board of Kenya, the regulatory body for Medical Practice, has an obligation to ensure such and to have a pro-active role in relation to the regulation of informed consent in Kenya.

Historical Development of the Doctrine of Informed Consent:

Generally speaking, 'informed consent' is a relatively new concept in the practice of modern medicine and research (5). The primary goal of Medical practice is "first to do no harm ". The physician has the role to inspire confidence to the patient, provide of details of side effects, risks of any intervention any undesirable effects and the mandate to seek an alternative opinion. Physicians should avoid any form of coercion, being paternalistic in nature and that any consent obtained from patients should not be defensive in nature. Patients have every right to be involved in the decision making process regarding the treatment they would be offered and should make a voluntary decision (6).

Informed Consent in the Twentieth Century:

Whereas many countries started off without a doctrine of informed consent, the same was nonetheless slowly instilled into medical practice over the years. The 1914 American case of Schoendorff v Society of New York7 Hospital is a case in point. In that case, Justice Benjamin Cardozo (as he was then) stated as follows;

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits a battery for which he is liable."

In the aforesaid case, the Plaintiff consented to an abdominal examination under general anaesthesia but was not informed of a tumour which was removed by the surgeon. She had not been informed about the adverse risk of removal of the tumour. In this case, it is clear that Justice Cardozo used the doctrine of battery to instil into medical practice the fact that a surgeon can be liable for battery if he or she performs a surgical procedure on their patient without their express consent.

It was the horrendous research experiments by physicians in Nazi Germany in the 1940's that contributed to the urgent need by the international community to address the issue of consent in medical research and practice. The shocking research experiments led to the preparation and adoption of the 'Nuremberg Code' by the United Nations in 1948. Regardless of the fact that many countries which were party to the UN treaties had agreed to the use of informed consent in medical research and in the practice of medicine, many countries were still conducting research unethically and physicians were not keen to obtain informed consent from patients. In the USA for instance, vaccines for dysentery were tested on orphans and mentally retarded patients and penicillin was tested on prisoners.

It is obvious that the thinking at the time was that findings of the research, albeit unethically obtained, were for the greater good of society. The 1957 British Case of Bolam v Friern Hospital Management Committee8highlights the resistance to the informed consent doctrine by physicians and the courts alike. In that case, a voluntary patient at the Defendant Hospital, sustained injuries during treatment provided to him. He sued the Defendant hospital claiming inter alia that the hospital failed to warn him of the risks involved with the treatment. The defendant's stood on their ground that it was not their common practice to warn their patients of the risk of treatment (which in this instance it believed to be small) unless the patient specifically asked about this. The court held that;

"A professional person is not necessarily negligent if he conforms to a practice accepted as proper by some responsible members of his profession, even if other members would have taken a different view. FHMC was not in breach of duty because it had acted in a way regarded as proper by a responsible body of opinion."

In the 1970's however, there was a renewed cry for informed consent during medical research. The USA government conducted a medical study between 1932 to1972 in Tuskegee with the aim of studying the natural progression of untreated Syphilis in rural African-American men in Alabama. Six hundred black men were enrolled in the study. Whereas researchers were aware that penicillin could cure syphilis, they knowingly failed to treat the patients they were studying. A whistle blower brought out the researcher's hideous unethical practices and the same culminated in the institution of a committee to investigate the said malpractices. The committee's report, which is commonly referred to as the 'Belmont Report', expanded the definition of informed consent, making sure that participants were kept informed throughout the experiment and more fully understand risks and benefits. It also stated that individuals with a lower capacity for making decisions, such as children, the elderly and the developmentally disabled needed to be protected.

It is now widely accepted today that informed consent is an integral element of patient's rights. In fact the 2015 English Supreme Court Case, Montgomery v Lanarkshire Health Board9has now set the pace in relation to the same. In that case, the Bolam test, which asks whether a doctor's conduct would be supported by a responsible body of medical opinion, no longer applies to the issue of consent. The law now requires a doctor to take "reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments." In that case, the mother of a child born with cerebral palsy, sued Lanarkshire Health Board arguing that her treating consultant should have warned her of the particular risks to her and her baby of shoulder dystocia occurring during delivery. She also argued that she should have been advised about the alternative possibility of delivery by caesarean section, which would have avoided these risks and prevented her child's injury.

Elements of Informed Valid Consent: Essentially, consents must be voluntary, the patient must have had the capacity to consent and the patient must have been properly informed.

Voluntary Consent: Medical treatments, especially in the Kenyan context, patients are more so often coerced into accepting treatment by third parties such as their spouses, parents, relatives, third party payers or even insurance or government agencies. It is therefore mandatory for the Physician to assure themselves that the

patient is consenting voluntarily to a said treatment. A case in point relates to family planning treatment. In order to appreciate the issue relating to voluntary consent, it is imperative that we examine voluntary consent during sterilization procedures. Whereas the Kenya National Family Planning Guidelines for Service Providers (2010) emphasizes informed and voluntary consent prior to female surgical sterilization women are often forced to accept these procedures without their consent. In October and November 2011, the African Gender and Media Initiative in partnership with Women Fighting Aids in Kenya and two other organizations, conducted a study wherein the experiences of 40 women living with HIV were documented. In the said publication, the 40 women describe how they were either forced or coerced to accept permanent sterilization procedures (bilateral tubal ligation) in healthcare facilities in Kenya. These procedures were carried out when the said women visited health facilities to give birth either through natural or caesarean section. In some instances, sterilization was required as a condition for receiving free or reduced-price medical treatment or receiving food and medical aid for their children, especially milk and anti-retroviral medications. Whereas these medical procedures relate to sterilization other than fertility treatment, they nonetheless highlight the extent to which physicians disregard voluntary consent of patients.

Capacity: An interesting issue arises where a mentally compromised person, one of unsound mind requires medical treatment. Does such a person have legal capacity to provide valid informed consent? Legal capacity refers to one's ability to enter into a contract or take legal action on their own behalf.

Legal capacity can be affected by ones state of mind or their age. From a medical perspective, an individual who can ably understand the nature of proposed treatment and its likely effect, its alternatives, and also understand the effects of refusing the proposed treatment is considered to have the necessary capacity to give valid consent. In a country like Kenya, where it is clearly documented that about 44.8% of 1.330,312 million persons with Disabilities are of unsound mind, physicians have to be vigilant when obtaining a valid informed consent in these circumstances.

The Mental Health Act and the Children Act provides for a guardianship system that allows guardians, trustees and estate managers to be appointed when a Person with Mental Disability is incapable of taking care of himself and his life affairs. This is commonly referred to as substituted decision making. The problem is that in Kenya, people with mental disabilities are treated as "objects of pity" who require help and sympathy from the society as opposed to rights holders with interests, preferences and desires. This is in direct contrast to Kenya's obligations under the United Nations Convention on the Rights of Persons with Disabilities (CRPD). Article 12 of the said treaty mandates Kenya to guarantee the right to equal recognition before the law for people with disabilities, women with intellectual disabilities and women with mental health issues. Regardless of the provision of the law regarding legal capacity of mentally disabled persons, various studies conducted overtime have revealed that persons with mental disability continue to be vulnerable to being coerced into sterilisation procedures. EyongMbuen, Rea Maglajlic and Oliver Lewis (2014) under the auspices of the Mental Disability Advocacy Centre (MDAC) which is based in Budapest, conducted a study in Kenya titled, 'The Right to Legal Capacity in Kenya' which documented accounts of women forced into undertaking a sterilization procedure. From the aforesaid report, it is clear that whereas

Kenya has enough laws regulating issues relating to disabled persons, discrimination and inequality remain due to social prejudices are also apparent in the way that people with mental disabilities are treated in practice by both State and private entities.

Being Properly Informed: Assuming the treating physician has obtained voluntary consent from a patient and that the patient is not incapacitated in any way, the physician must still adequately explain to the Patient about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision. The significance of properly informing a patient has been highlighted in many court decisions world-wide. This article casts light on the famous case of Canterbury v Spence.10 In that case, a young man was advised to undergo a laminectomy in an effort to alleviate back pain. Whereas the physician was aware paralysis was a possible outcome of the said treatment, the physician feared that the Patient might reject the treatment and therefore did not advise him of the same. As fate would have it, after undergoing treatment, the patient fell from his hospital bed and was paralyzed. After deliberation on this matter, the court held that to establish true informed consent, a physician is now required to disclose all risks that might affect a patient's treatment decisions. The particular pieces of information that a physician must disclose include the following; (1) condition being treated; (2) nature and character of the proposed treatment or surgical procedure; (3) anticipated results; (4) recognized possible alternative forms of treatment; and (5) recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment, including non-treatment. Whereas all these pieces of information are critical to informed consent, the thrust of this article is directed towards informing patients of all possible alternative forms of treatment in the context of infertility.

Informing Patients of Infertility Treatment Options in Kenya: Given that there is no single factor which causes infertility either in men or women, it also means that there is no one size fits all infertility treatment. Causes of infertility range from tubal, ovarian, anatomical, endometriosis, cervical, psychological, idiopathic to various male factors and should be explained and discussed with relevant patients. Treatments including ovarian stimulation, IVF and surrogacy should be adequately highlighted. Based on a research conducted in Kenya by Shieshia, OdworiMildre11, it was found that 82.7% of the information provided to patients related to diagnosis. Almost no information was provided in relation to the options of treatments available. Those who have undergone IVF treatment know that it can be a harrowingly expensive and emotional process. It is therefore imperative that doctors inform their patients of all their treatment options.

Informed Consent: Role of the Medical Practitioners and Dentists Board in Kenya

In order to ensure that patients are sufficiently informed of all treatment options and that valid informed consent is obtained, it is imperative that the Medical Practitioners and Dentists Board (MPDB) takes a lead role in the same. The MPDB is the regulatory body for the practice of medicine and dentistry in Kenya.

It is a statutory authority established

10. 409 U.S. 1064 93 S. Ct. 560 34 L. Ed. 2d 518 1972 U.S.

11. Shieshia, Odwori Mildred. An investigation of informed consent in clinical practice in Kenya. Kenyatta University Institutional Repository. 2011; http://ir-library.ku.ac.ke/handle/123456789/1750 accessed 20th April 2017

under Cap 253 Laws of Kenya and its mission is to ensure the provision of quality and ethical health care through appropriate regulation of training, registration, licensing, inspections and professional practice. One of its functions is to inspect private and public premises of medical and dental practice. Inspection as to whether informed consent is offered must be a critical element to its role.

In relation to fertility treatments, it is imperative that the MPDP ensures that patients are made aware as to all the treatments available. It should be made mandatory that all registered gynaecologists produce a list of treatment options available for all the infertility causes to the patients. Such a list ought to emanate from the Medical Practitioners and Dentists Board. In order to facilitate the same, a specific law relating to informed consent ought to be enacted so that the modalities of achieving the same are carefully spelt out. As it is at the moment, Kenya does not have any specific enacted legislation addressing the issue of informed consent in medical practice, a Health Bill was recently tabled in parliament. . Section 9 (2) of the said Bill provides that;

"a health care provider must take all reasonable steps to obtain the user's informed consent".

Further, Section 9 (1) states that;

"no specified health service may be provided to a patient without the patient's informed consent except in special circumstances such as the emergency treatment, if the court so orders or if failure to treat the patient (s) will result in a serious risk to public health.

A close examination of the aforegoing provisions indicate that the elements constituting valid consent and enforcement of the same have not been addressed. They nonetheless are not specific enough. The (MPDB) must spearhead the process of ensuring that the proper laws are put in place and that the same are implemented and take a very patient oriented approach and aims to protect patients and improve medical education for the benefit of patients as consumers and at the same time take a lead role on informing doctors about the significance of informed consent in their practice as well as the implementation of the same.

CONCLUSION

From the aforegoing, it is clear that valid informed consent is a critical patient's right. The mandate to ensure that all medical practitioners obtain such consent from patients should be safeguarded and all practitioners should offer treatment options which only benefit the patient. The MPDB should spearhead the process of ensuring that parliament enacts a law which specifically deals with the issue of informed consent as a statute.

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