A REVIEW OF THE EXTANT LAW AND PRACTICE OF INFORMED CONSENT IN MEDICAL PROCEDURES IN NIGERIA

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Abstract

Informed consent which is a fundamental principle in medical ethics and law ensures that patients fully understand the risks, benefits, and alternatives of medical procedures before giving their consent. This paper thoroughly examines the current legal framework and practices governing informed consent in medical procedures in Nigeria. The paper scrutinizes statutory provisions, case laws, and practical applications based on primary and secondary data sources. It identifies several discrepancies and shortcomings in Nigeria's approach to informed consent. The paper's key findings indicate that while legal requirements for obtaining informed consent are in place, their implementation and enforcement vary significantly, often resulting in inadequate patient comprehension and autonomy. The crucial role of medical practitioners is underscored, yet it is frequently undermined by insufficient training and awareness of informed consent protocols. Building on these findings, the article proposes the establishment of more explicit, robust guidelines, improved training programs for healthcare providers, and importantly, more robust enforcement measures to ensure adherence. These recommendations are intended to harmonize Nigeria's informed consent practices with international best practices, ultimately enhancing patient safety and autonomy.

Keywords: Informed Consent, Healthcare, Patient, Patient's right, Medical ethics

1.0 Introduction

Black's Law Dictionary describes informed consent as 'a person's agreement to a recommended medical procedure with full knowledge of the risk involved and the alternatives¹. Informed consent is key in medical law and ethics which represents the right of a patient to autonomy over healthcare decisions. In other words, for a patient to give his informed consent, the patient must understand the proposed medical intervention including any potential benefits, risks, dangers, available options and the option to refuse treatment². The consent must be free, not manipulated or coerced, prior and well informed. Informed consent is basic as it goes beyond signing of a consent form but a comprehensive process of communication between the patient and the physician. The physician is obligated by virtue of the fiduciary relationship with his patient, to ensure that the patient clearly comprehends the proposed medical procedure or intervention thereby satisfying the ethical

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² D Pattinson, Medical Law and Ethics (Sweet & Maxwell Ltd. London 2006) 129

requirements of the autonomy of a patient. Ironically, as crucial as this is to the treatment of patients, it is often relegated to the back of the patient's hospital folder even when the information contained therein maybe inadequate, uninformative, or incomplete³.

The elements of informed consent are

- (1) The nature of the procedure
- (2) The risks and benefits and the procedure
- (3) Reasonable alternatives
- (4) The risks and benefits of alternatives
- (5) An assessment of the patient's understanding of elements 1 through 4.
- (6) Instruction that the person is free to withdraw his consent or to discontinue treatment or participation in the project or activity at any time without prejudice to the subject.

Consent may be given expressly by a patient either in writing or orally although the written form is preferable. Consent can also be given impliedly by the act or demeanor of the patient⁴.

The healthcare system in Nigeria encounters a range of challenges such as limited resources, varying levels of patient education and diverse cultural attitudes towards medical authority. These factors can make it difficult to implement informed consent protocols effectively. Despite legal frameworks intended to safeguard patient rights, inconsistencies in applying and enforcing these laws often undermine the informed consent process. This can result in patients undergoing medical procedures without a comprehensive understanding of the implications, potentially jeopardizing their autonomy and safety. Informed consent is very essential in health care for the following reasons:

- (a) It gives legal protection to health care practitioners from legal liabilities
- (b) It respects patient's right's to self-determination in healthcare decisions.
- (c) It conforms with ethical medical principles
- (d) Patients who are well informed are likely to cooperate which may lead to a better outcome on the other hand, patients who are not aware are likely to neglect the physician's advice.

In Nigeria, there are several laws and regulations on informed consent in medical procedures. The relevant legal frameworks include

1.1 The 1999 Constitution of the Federal Republic of Nigeria (As Amended)

The Constitution is the supreme law of the land which has its binding force on all authorities, institutions and persons⁵ and it provides for fundamental human rights which citizens are to enjoy. The Court held in *Chief Francis Igwe & Orsv Mr. Ezeanochie &*

^{3 .} Z. Lawal, E.Garba, M.Ogirima*etal* 'The doctrine of informed consent in surgical practice' Annals of African Medicine Vol. 10, No. 1; 2011:1-5 ile:///C:/Users/pc/Downloads/ajol-file journals_51_articles_67176_submission_proof_67176-601-137129-1-10-20110615.pdf accessed 6th August 2024 4A Ojo 'The Right to Patients' Informed Consent in Nigeria and South Africa: A comparable Discuss' (2021) *Journal of Research and Humanities and Social Science*https://www.questjournal.org accessed 10th August 2024

⁵Constitution of the Federal Republic of Nigeria, 1999.

Ors⁶ that fundamental human right is certainly a right which stands above the ordinary law of the land. Section 34 provides for respect and dignity of human person and no person shall be subjected to torture or to inhuman or degrading treatment which includes protection against non-consensual medical procedures. By virtue of Section 34(1)(a), any medical treatment administered without a patient's informed consent can be construed as a form of violation of the patient's right to human dignity. There is a worth placed on the sanctity of human live which should be protected at all cost by ensuring that patients' rights are protected by ensuring that medical treatments are administered ethically and legally. Although the Constitution did not specifically mention informed consent, subsidiary legislations and administrative instruments have been enacted, geared towards giving full effect to the provisions of the Constitution⁷.

1.2 National Health Act (2014)

The National Health Act is the principal legislation regulating health care delivery⁸. Healthcare professionals form a significant component of health care systems and are important in the delivery of smooth, efficient, effective and quality health care services. Section 23 of the Act provides that every health care provider shall give relevant information to a 'user' pertaining to the users health status, range of diagnostic procedures and treatment options, the benefit risk, cost and consequences generally associated with each option the users right to refuse health care services and explain the implications; risk obligations of such refusal, it further states that this information must be explained to the user in the language, the user understands taking into cognizance the user's level of literacy. A 'user' is explicitly defined in Section 64 as the person receiving blood or blood products or using a health services and if the person receiving treatment or using health services is (a) below the majority age, "user" also includes the person's parent or guardian or another person authorized by law to act on the first mentioned person's behalf when the person is incapable of taking decisions. "User" includes the person's parent, grandparent, adult child, brother, sister⁹. The Act prescribes the process of obtaining consent before any medical intervention is carried out on the patient.

1.3 Patient Bill of Rights

Bill of Rights is a set of claims that determines the status and needs of patients during the provision of health services and obligations of healthcare providers towards the patients and patient relatives¹⁰. A patient has the right to receive complete information about diagnosis, treatment and prognosis from the physician in terms that are easily understood.

⁶⁽²⁰¹⁰⁾ WRN 43

 $⁷ A A delugba \ {\it Constitution\ and\ Rule\ of\ Law\ in\ Nigeria\ (Lagos,\ Rothan\ Press,\ 2011)},\ p.81.$

⁸National Health Act CAP N LFN 2004

⁹C Ekechi. Agwu: Regulating assisted reproductive Technologies (ART) in Nigeria: Lessons from Australia and the UK African Journal of Reproductive Health December [2020].

¹⁰A Sheikhtaheri, M Sadeq 'Nurses Knowledge and Performance of the Patients' Bill of rights. PubMed

^{2015&}lt;a href="https://www.researchgate.net/publication/277782513">https://www.researchgate.net/publication/277782513- nurses-knowledge-and-performance-of- the Patients'-Bill- of- rights>accessed 7th August 2024

However, if it is medically inadvisable to give such information to you, it will be given to a legally authorized representative. In addition a patient have the right to receive information necessary to give informed consent prior to any procedure or treatment any potential risks or benefits, the probable duration of any incapacitation and any alternatives with exception to cases of emergency¹¹. The patient has the right to know who shall be responsible for authorizing and performing any procedure or treatment. When a patient is to be used for human experiment, research for educational purposes, he/she has the right to be fully informed and also reserve the right to refuse to engage in such¹².

Unfortunately, most patients are not aware of these rights or the laws protecting them. Emphasis should be placed on awareness and patients' involvement in making decisions regarding their treatment choice. Patient should be able to institute civil or criminal actions against health practitioners who infringe on their rights.

1.5 Child Rights Act

The Children's Rights Act¹³ expands the human rights bestowed to citizens in Nigeria's 1999 constitution to children. Children belong to one of the most vulnerable members of the society and are to be protected and it has been discovered that some acts engaged in, whether knowingly or unknowingly, are infringements against the rights of a child. Section 13(1) Protects the right of children to health services, which includes the requirement for informed consent from a parent or guardian for medical procedures involving minors. Where a Child cannot provide informed consent however parents are to permit treatments and intervention. However, notwithstanding the definition of a child to be a person below 18 years, wherein a child can understand the medical intervention being carried out on him or her, the child's consent is to be requested for. In *Dr Rom Okekearu v Danjuma Tanko* 14 informed consent by children was analyzed by the Supreme Court. The plaintiff had his finger amputated in the Defendant's hospital. The consent of the 14 years old boy was not obtained directly from him rather relied on the consent he purportedly obtained from the plaintiff's aunt as follows "carry on with whatsoever treatment necessary" the Supreme Court held that since the boy was 14 years and rational enough to have given a valid consent, efforts should have been made to obtain his consent after being adequately informed before seeking the consent of the Aunt which did not amount to a valid consent. 15 In every action concerning a child whether undertaken by an individual, public or private body, institution of service, court of law or administrative or legislative body, the best interest of a child shall be the primary consideration¹⁶

¹¹Clinicial Centre America's Research Hospital 'Patient Bill of Right' https://clinicalcentre.nih.gov/participate/patientinfo/legal/bill-of-rights.html accessed 7th August 2024

¹² Larkin Health System '(Patients' Bill of Rights: Patients' Rights and Responsibilitieshttps://larkinhealth.com/en/patients-bill-of-rights/accessed 7th August 2024

¹³ Child's Right Act 2003

^{14 (2002)}LPELR- SC73 1998

¹⁵ O Agbo 'My Body My Decision' https://gremile.wordpress.com/2017/10/05/my-body-my-decisioin/ accessed 10th August 2024 16Article 4 (1) of the African Charter on the Rights and welfare of a Child.

1.6 Code of Medical Ethics¹⁷

This is a subsidiary legislation made under the Medical and Dental Practitioner's Act¹⁸ which spells the rules of professional conduct for medical and dental practitioners including the requirement to obtain informed consent and fully inform patients about their treatment options. Rule 19 provides that Practitioners involved in procedures requiring the consent of the patient, his relation or appropriate public authority must ensure that the appropriate consent is obtained before such procedures, either for surgery or diagnostic purposes are done, be they invasive or non-invasive. Consent forms should be in printed or in written form either as a part of case notes or in separate sheets with the institution's name boldly indicated. Explanations to patients from whom consent is being sought should be simple, concise and unambiguous about expectations. Proper counseling should precede the signing of the consent form. Where the patient is under age, (below eighteen years (18) by Nigerian law), or is unconscious, or is in a state of mind constituting a mental impairment, a next-of-kin should stand in. In the absence of a next-of-kin, the most senior doctor in the institution can give appropriate directive to preserve life¹⁹. In special situations, a court order may need to be procured to enable lifesaving procedure be carried out. Discussion and explanation to the patient with the health practitioner must be in the language in which the patient is fluent and when necessary, through a competent interpreter. The MDCN designed some consent forms as a standard format for procedures and certain interactions that deserve specific and expressly defined documentation. This form is the precedent to be used by registered by all registered health practitioners in Nigeria.

This is in a bid to enhance patients' rights as no clinical examination can be carried out without the patient being adequately informed and failure to comply with provisions of the code may amount to infamous conduct and if found guilty will be punished. *In Medical and Dental Practitioner Disciplinary tribunal v Dr. John Nicholas Okonkwo*²⁰involving the refusal of a blood transfusion by the Jehovah's witness on religious grounds. The Supreme Court upheld the patient's right to refuse treatment, emphasizing the importance of respecting patient autonomy and informed consent. Also in *Nigerian Medical and Dental Practitioner Council v Dr Emeka*²¹the Court underscored the necessity for medical practitioners to obtain informed consent from patients before performing any medical procedure.

These laws and regulations collectively provide a framework for informed consent in Nigeria, emphasizing the importance of informed consent²² and the need for clear communication between healthcare providers and patients, the protection of patient autonomy, and the ethical obligations of medical practitioners. However, challenges

¹⁷Code of Medical Ethics of Nigeria 18CAP M8 Laws of the Federation 2004

¹⁹ Section 19 MDCN Act

^{20 (2001) 7} NWLR (Pt. 7111) 206

^{21 (2001)10} NWLR (Pt 722)689

²²Medical and Dental Practitioner Disciplinary tribunal v Dr. John Nicholas Okonkwo

remain in ensuring consistent application and enforcement of these provisions across the country.

1.7 Challenges in Implementing Informed Consent

Despite the legal provisions of the law on informed consent, there are challenges prevalent in our clime on its implementation these includes:

- (a). Religion has a big role to play in securing informed consent from patients. Nigeria is a highly religious country wherein people believe what will be will be and that there is s Supreme Being who manages and controls the affairs of men²³. Consequently, in cases where a patient is to make a decision or take a stand, the patient rather submits their fate to God, vitiating the principle of informed consent, however, notwithstanding the decision taken by the patient, the patient must be well informed based of the elements of informed consent and the patient must be acting autonomously.
- (b). Illiteracy/educational status of patients is a key factor as study has shown that knowledge of informed practice increased with the level of educational background of the patients some health practitioners may opt for partial disclosure. Some patients even see health practitioners as authority figure that should be obeyed; they tend to depend completely on the judgment of the health practitioner. This should however not deter a health practitioner from respecting the patient's right to autonomy by simplifying the informed consent process and an informed ns obtaining and valid consent from the patient²⁴.
- (c). Poverty is another inhibiting factor which affects a large population of Nigerian. It goes hand in hand with Illiteracy. When the rights of a patient have been infringed, poverty will allow such person to institute an action against the Health practitioner.
- (d). Family relationship and affinity can affect the right to autonomy of a patient especially in cases where family members play a major role in the health care financing of its members, the individual financing the care, is privy to the health information becomes a decision maker for the patient.
- (e). Limited health care resources, time constraints and overburdened healthcare facilities can hinder the consent process.
- (f). There is limited remedy available in Nigerian law to patients whose right have been infringed upon²⁵

²³ S ArinzeUmobi, G Okeke'A Review of Socio Cultural Factors affecting Patients' Right To Informed Consent and Autonomy in Medical Practice in Nigeria AJLHR 4 (1) (2020) https://journals.ezenwaohaetorc.org accessed 10th August 2024

²⁴ K Agu, E Obi,B.Eze "Attitude Towards Informed Consent Practice In A Developing Country: A Community Based Assessment Of The Role Of Educational Status' BMC Med Ethics

⁽²⁰¹⁴⁾https://www.ncbi.nlm.nih.gov/pmc/articles/pmc4216367/ accessed 10th August 2024

²⁵ P Gbobo M Oke - Chinda ' An Analysis of the Doctrine of Informed Consent in Nigeria's Health care Services

vol. 69 (2018) Journal of Law, Policy and Globalization

 $https://www.iiste.org/journals/index.php/JLPG/article/view/40837 accessed \ 10th \ August \ 2024$

1.8 Sufficiency of the Extant Laws on Informed Consent in Nigeria

While the 1999 Constitution which is the foundation of the legal frame work for human rights provides for the right to dignity of human person, it unfortunately does not address informed consent directly. There are still some significant inadequacies in our laws as far as addressing the questions of informed consent and patients' autonomy are concerned. There is no standalone specific legislation solely dedicated to informed consent consequently leading to inconsistencies in practice, enforcement and increased risks of medical claims. Even in cases where this concept is acknowledged, there are few efficient procedures to uphold patients' rights and make healthcare practitioners liable for violations as the case may be. The remedies available under the Nigerian law are quite limited and also marred with bureaucracy²⁶. The victim can maintain an action for damages in court. He can also complain to the appropriate Regulatory Bodies. Whereas some case laws have touched on informed consent, there is paucity of comprehensive judgments to establish clear legal standards thereby leading to vulnerability of patients more particularly, when health practitioners fail to balance patient autonomy with clinical judgment.

1.9 Conclusion and Recommendation

Patients' rights are continually evolving, their safety being a major focus in health care and one of the ways to secure that is through informed consent. Therefore, ensuring that all elements of informed consent are met will result in fewer medical malpractice cases, patients' satisfaction and an enhanced professional reputation. In order to address the inadequacies of our laws, the following are recommended

- (a) The development of specific comprehensive legislation and regulations governing informed consent would be necessary to fully realize its potentials.
- (b) The strengthening of enforcement mechanisms in the event of breach of the law and in addition to this, the judiciary should continue to set precedents for practicing health practitioners.
- (c) Patient education and public awareness advocacies/ outreaches to educate the public about their rights should be encouraged and there should also be a healthcare provider continuous training on informed consent and ways to enhance communication skills.
- (d) For true autonomy of patients to exist, consent forms should be standardized, clear and understandable to the patients so they can make voluntary decisions.

Nigeria can move towards a healthcare system that prioritizes patient autonomy and ensures that medical interventions are administered ethically and within the confines of the law.

²⁶ P Gbobo M Oke – Chinda 'An Analysis of the Doctrine of Informed Consent in Nigeria's Health Care Services Vol. 69 (2018) *Journal of Law, Policy and Globalization*