

REGULATORY FRAMEWORKS, COMPLIANCE AND HEALTHCARE RESPONSIBILITIES ON INFORMED CONSENT IN NIGERIA

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Abstract

Informed consent is a cornerstone of healthcare ethics and law in Nigeria. However, ensuring regulatory compliance and healthcare provider accountability remains a challenge. This paper examines the tripartite relationship between regulatory frameworks, institutional compliance, and healthcare provider responsibilities in obtaining informed consent; it analyzes existing laws, policies, and guidelines to identify gaps. It further scrutinizes the role of healthcare institutions and providers in ensuring effective informed consent practices, highlighting the challenges and opportunities for promoting patient autonomy and dignity in Nigeria's healthcare system. This study ultimately argues that a multifaceted approach, incorporating regulatory reform, institutional accountability, and provider responsibility is essential for ensuring the integrity and efficacy of informed consent in Nigeria's healthcare sector.

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This paper adopts analytical and comparative approach, utilizing the doctrinal legal research methodology which involves the scrutiny of both primary and secondary sources to provide an encompassing and insightful examination of the issue under consideration.

Keywords: Informed consent, Regulatory frameworks, Institutional Compliance, Healthcare Provider Responsibilities, Patient Autonomy.

1.0 Introduction

The concept of informed consent is a cornerstone of medical ethics and healthcare law, globally and in Nigeria.¹ It is rooted in the universal human right to autonomy, dignity, and self-determination, as enshrined in various international human rights instruments, including the Universal Declaration of Human Rights [UDHR] (1948) and the International Covenant on Civil and Political Rights (1966).

In Nigeria, the right to autonomy and dignity is protected by the Constitution of the Federal Republic of Nigeria, 1999 (as amended). Section 34 of the Constitution guarantees the right to dignity of human person; while section 38 protects the right to freedom of thought, conscience, and religion. The importance of informed consent in healthcare decision-making has been underscored by various judicial authorities. In the landmark case of *Canterbury v Spence*,² the United States Court of Appeal for the District of Columbia Circuit held that informed consent is a fundamental aspect of medical treatment, requiring healthcare providers to disclose material risks and benefits associated with a particular treatment and procedure.

¹ Universal Declaration of Human Rights (1948) art 3.

² [1972] 464 F 201 772 (DC Cir).

Similarly, in the Nigerian case of *Ekpiteta v University of Calabar Teaching Hospital*,³ the High Court of Rivers State emphasized the importance of informed consent in medical treatment, holding that a healthcare provider's failure to obtain informed consent may constitute a breach of duty of care. Statutorily, the National Healthcare Act 2014, is the primary legislation governing healthcare in Nigeria. Section 27 of the National Health Act provides that a healthcare provider must obtain informed consent from a patient before commencing treatment, except in emergency situations where the patient is unable to give consent.⁴ Furthermore, the Code of medical Ethics in Nigeria emphasizes the importance of informed consent, providing that a healthcare provider must respect the autonomy and dignity of patients by obtaining informed consent before providing medical treatment.⁵

Despite these legal ethical frameworks, the practice of informed consent in Nigeria's healthcare sector remains fraught with challenges. Studies have shown that many healthcare providers in Nigeria fail to obtain informed consent from patients, often citing lack of awareness, inadequate training, or insufficient time as excuses.⁶

This failure to obtain informed consent can have serious consequences for patients, including loss of autonomy, dignity, and trust in the healthcare system. It is against this backdrop that this article seeks to examine the dynamics of informed consent in Nigeria's healthcare sector with a focus on the interplay between regulatory frameworks, institutional compliance and healthcare provider responsibilities. Simply, effective informed

³ [2011] Suit No: HC/56/2004 (High Court of Cross River State).

⁴ National Health Act 2014, section 27.

⁵ Code of Medical Ethics in Nigeria 2008.

⁶ Oyediji O., 'Informed Consent in Medical Practice in Nigeria', *Medical Law Review* (2018) (25) 251.

consent requires a harmonious intersection of regulatory frameworks, institutional compliance, and healthcare provider responsibilities.

2.0 Literature Review

The intersection of medical treatment and human rights has given rise to a complex web of ethical and legal considerations. In Nigeria, as stated earlier, the right to autonomy and dignity is constitutionally guaranteed, yet the practice of informed consent in healthcare setting remain fraught with challenges as noted by some of the authors mentioned in this paper. Oyedeji has argued that informed consent is a fundamental principle in medical ethics and healthcare law, and that it is essential for ensuring that patient's autonomy and dignity are respected.⁷ The National Health Act 2014 provides a framework for healthcare delivery in Nigeria, emphasizing the importance of informed consent in medical treatment. However, experience and research has shown that the practice of informed consent in Nigeria's healthcare sector remains plagued by difficulties including lack of awareness, inadequate training and insufficient time.⁸

Adebayo, in his article "The Role of Healthcare Providers in Obtaining Informed Consent from Patients in Nigeria", has examined the role of healthcare providers in obtaining informed consent from patients in Nigeria. According to the Adebayo, healthcare providers have a duty to obtain informed consent from patients before commencing treatment, and that failure to do so may constitute a breach of duty of care – which in itself connotes negligence.⁹ Adebayo further states that healthcare providers must ensure that patients are fully informed about the risks and benefits

⁷ Ibid, 253.

⁸ Oyedeji (n6) 255

⁹ Eric Okojie, 'Professional Medical Negligence in Nigeria' cited by Aloba E.E., *Law of Tort* [Lagos: Princeton Publishers, 2022] 430.

associated with a particular procedure or treatment, and that patients must be given the opportunity to make informed decisions about their care.¹⁰

Ogundipe has discussed the importance of institutional compliance in ensuring that informed consent is obtained from patients in Nigeria. Ogundipe posits that healthcare institutions have a crucial role to play in ensuring that informed consent is obtained from patients, and that institutions must have policies and procedures in place to ensure that informed consent is obtained. Ogundipe argued that institutions must also provide training and education to healthcare providers on the importance of informed consent, and that institutions must have mechanisms in place to monitor and enforce compliance with informed consent protocols.¹¹

Foreign authors have also written extensively on the topic of informed consent. Beauchamp and Childress have posited that informed consent is a fundamental principle in medical ethics, and that it is essential for ensuring that patients' autonomy and dignity are respected. According to them, informed consent requires that patients be fully informed about the risks and benefits associated with a particular procedure or treatment, and that patients must be empowered to make autonomous decisions regarding their treatment.¹²

It is pertinent to state that literature on informed consent in Nigeria highlight the importance of regulatory frameworks, institutional compliance, and healthcare provider responsibilities in ensuring that patients' autonomy and dignity are respected. Authors have maintained that

¹⁰ Adebayo A., 'The Role of healthcare Providers in Obtaining Informed Consent from Patients in Nigeria', *Journal of Medical Ethics and Law* (2020) (15) 1-5.

¹¹ Ogundipe O., 'Institutional Compliance and informed Consent in Nigeria's Healthcare Sector', *African Journal of Health Sciences* (2019) (12) 1, 3, 5.

¹² Beauchamp TL, and Childress JF, *Principles of Biomedical Ethics* [7th edn: Oxford University Press, 2013] 120.

informed consent is a fundamental principle in medical ethics and healthcare law, and that it is essential for ensuring that patients are fully informed about the dangers and benefits associated with a particular procedure or treatment; and as such, patients must be enabled to exercise their autonomy in deciding on their treatment options.

3.0 Regulatory Frameworks: The Foundation of Informed Consent

The regulatory frameworks governing informed consent in Nigeria are rooted in international human rights instruments, constitutional provisions, and statutory law. For instance, the Universal Declaration of Human Rights (UDHR)¹³, and the International Covenant on Civil and Political Rights (ICCPR)¹⁴ provide the foundation for the right to autonomy and dignity, which underpins informed consent. Article 3 of the UDHR states that: “Everyone has the right to life, liberty and security of person”. This fundamental right is a cornerstone of human dignity and autonomy, emphasizing the importance of protecting individuals from harm, ensuring their freedom, and safeguarding their physical and mental well-being.

The International Covenant on Civil and Political Rights (ICCPR) 1966 is an international human rights treaty that outlines the civil and political rights of individuals. Specifically, the ICCPR states:

Article 7: No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Article 9: Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary or unlawful

¹³ Universal Declaration of Human Rights 1948, art 3.

¹⁴ International Covenant on Civil and Political Rights 1966.

interference with his privacy, family, home or correspondence.

These provisions emphasize the importance of protecting individuals' autonomy, dignity and human rights, particularly in the context of medical treatment and healthcare. It is worthy of note that the ICCPR is a significant international human rights instrument and its provisions have been widely ratified and implemented by countries around the world, including Nigeria,

The World Health Organization (WHO) has emphasized the importance of informed consent in healthcare, particularly in its guidelines on informed consent. According to WHO: "Informed consent is a crucial aspect of healthcare, as it enables individuals to make informed decisions about their care, based on their own values, beliefs and preferences".¹⁵ The WHO guidelines on informed consent outline the essential elements of informed consent, including:

- a. *Respect for autonomy*: -Recognizing the individuals' right to make decisions about their own care.
- b. *Information*: - Providing accurate, unbiased, and understandable information about the proposed treatment or intervention.
- c. *Voluntariness*: - Ensuring that the individual's decision is made freely, without coercion or undue influence.
- d. *Understanding*: - Ensuring that the individual understands the information provided.

¹⁵ World Health Organisation, Guidelines on Informed Consent 2017. www.who.org accessed 26 March 2025.

- e. *Decision-making capacity*: - Ensuring that the individual has the capacity to make informed decision about their care.¹⁶

The WHO guidelines also emphasize the importance of informed consent in promoting patient-centered care, respect for autonomy, and accountability.¹⁷

In Nigeria, the Constitution of the Federal Republic of Nigeria (CFRN) 1999 (as amended) guarantees the right to autonomy and dignity. Section 34 of the Constitution provides that “Every individual is entitled to respect for the dignity of his person”; while section 38 protects the right of thought, conscience and religion. The National Health Act 2014 is the primary legislation governing healthcare in Nigeria. Section 27 of the NHA provides that a healthcare provider must obtain informed consent from a patient before commencing treatment, except in emergency situations where the patient is unable to give consent. This provision is in line with international best practices, as reflected in the World Health Organization’s guidelines on informed consent. Accordingly, to Ogundipe, the National Health Act (NHA) provide a framework for healthcare delivery in Nigeria, emphasizing the importance of informed consent in medical treatment.¹⁸ Adebayo also stated that the National Health Act is a significant improvement on previous healthcare laws in Nigeria, as it provides explicit provisions on informed consent.¹⁹

Consequently, the regulatory frameworks governing informed consent in Nigeria are rooted in universal human rights instruments, constitutional

¹⁶ WHO (n 15) 3-5.

¹⁷ Ibid, 6.

¹⁸ Ogundipe (n 11) 1.

¹⁹ Adabayo (n 10)

provisions, and statutory laws. The National Health Act 2014, provides a framework for healthcare delivery in Nigeria, underscoring the importance of informed consent in medical treatment.

3.1 Strengths and Limitations of the Current Regulatory Framework

As stated earlier, informed consent is a fundamental principle in healthcare, ensuring that patients are fully informed and able to make decisions about their care. However, there are two-sides to these regulatory frameworks – their strengths and limitations.

3.1 Strengths: -

1. *Establishment of National Health Act:* The NHA 2014 provides a comprehensive framework for healthcare delivery in Nigeria, emphasizing the importance of informed consent in medical treatment.²⁰
2. *Protection of Patients' Rights:* - The NHA and the Nigerian Constitution guarantee patients' rights, including the right to autonomy, dignity, and informed consent.²¹
3. *Regulation of Healthcare Providers:* The Medical and Dental Practitioners Act 2004, and the National Health Act regulate the practice of healthcare providers, ensuring that they meet certain standards and obtain informed consent from patients.²²

3.2 Limitations: -

²⁰ National Health Act 2014, section 27.

²¹ Constitution Federal Republic of Nigeria 1999 (as amended), section 34.

²² Medical and Dental Practitioners Act 2004, section 17.

1. *Inadequate Enforcement*: - Despite the existence of regulatory frameworks, there is inadequate enforcement of informed consent protocols in Nigeria.²³
2. *Lack of Awareness*: Many healthcare providers and patients in Nigeria are not aware of the importance of informed consent and the regulatory frameworks that govern it.²⁴
3. *Inadequate Training*: Healthcare providers in Nigeria often receive inadequate training on informed consent, which can lead to non-compliance with regulatory frameworks.²⁵
4. *Cultural and Socio-economic Barriers*: Cultural and Socio-economic factors can hinder the implementation of informed consent protocols in Nigeria, particularly in rural areas.²⁶

4.0 Institutional Compliance: The Role of Healthcare Organisations in Ensuring Informed Consent in Nigeria

Healthcare organisations play a crucial role in ensuring institutional compliance with informed consent protocols in Nigeria. The National Healthcare Act 2014 and other regulatory framework emphasize the importance of institutional compliance in promoting patients' autonomy and dignity; it is thus imperative to examine the role of healthcare organizations in ensuring institutional compliance with informed consent protocols.

²³ Oyediji (n6) 251, 255.

²⁴ Adebayo (n10) 4.

²⁵ Ogundipe (n 11) 5.

²⁶ Adebayo (n10)

4.1 Development of Informed Consent Policies

Healthcare organizations in Nigeria are required to develop informed consent policies that outline the procedures for obtaining informed consent from patients. These policies should be based on the NHA 2014 and other relevant laws, and should provide guidance on the following:

- a. The process for obtaining informed consent.
- b. The information that must be disclosed to patients.
- c. The documentation requirements for informed consent.
- d. The procedures for managing exception to informed consent.²⁷

Accordingly, the development of informed consent policies is essential for ensuring institutional compliance with informed consent protocols. Health organisations must ensure that their policies are up-to-date, accessible, and communicated to all healthcare providers.

4.2 Training and Education

Healthcare organizations must provide training and education to healthcare providers on informed consent protocols.²⁸ This training should cover the following topics:

- a) The principles of informed consent
- b) The procedures for obtaining informed consent
- c) The importance of documentation
- d) The management of exceptions to informed consent

It portends that training and education are essential for ensuring that healthcare providers understand the importance of informed consent and are equipped to obtain informed consent from patients. Healthcare

²⁷ Adebayo (n 10) 5.

²⁸ WHO (n15) 6.

organizations must ensure that training and education programmes are regular, mandatory, and evaluated for effectiveness.

4.3 Monitoring and Evaluation

Healthcare organisations must establish mechanisms for monitoring and evaluating compliance with informed consent protocols.²⁹ This includes:

- a) Regular audits of informed consent documentation
- b) Review of patients' complaints and feedback
- c) Monitoring of healthcare provider compliance with informed consent protocols

According to Beauchamp and Childress, monitoring and evaluation are essential for ensuring that healthcare organisations are accountable for their actions and are committed to promoting patients' right to autonomy and dignity.³⁰ It is safe to say that healthcare organisations play a crucial role in ensuring institutional compliance with informed consent protocols in Nigeria. The development of informed consent policies, training and education, and monitoring and evaluation are essential components of institutional compliance. Healthcare organisations must ensure that they are committed to promoting patients' rights to autonomy and dignity, and are accountable for their actions.

5.0 The Impact of Institutional Culture and Climate on Informed Consent Practices in Nigeria

Institutional culture and climate play a significant role in shaping informed consent practices in healthcare organisations in Nigeria. The culture and climate of an institution can either support or hinder the implementation of

²⁹ National Health Act 2014, section 28.

³⁰ Beauchamp and Childress (n12) 128.

informed consent protocols, ultimately affecting the quality of care provided to patients.

Institutional culture refers to the shared values, beliefs, and norms that define an organization's identity and influence the behaviour of its members.³¹ In the context of informed consent, institutional culture can either promote or undermine the implementation of informed consent protocols. According to Ogundipe, a culture of respect for patients' autonomy and dignity is essential for promoting informed consent practices in healthcare organizations.³² When healthcare providers perceive informed consent as a fundamental aspect of patient care, they are more likely to prioritize it in their practices.³³

On the other hand, a culture that prioritizes efficiency and productivity over patient-centered care can hinder the implementation of informed consent. Consequently, when healthcare providers are under pressure to meet targets and manage heavy workloads, they may be less likely to prioritize informed consent. Institutional climate refers to the psychological and social environment of an organization, which can influence the behaviour and attitudes of its members. In the context of informed consent, institutional climate can either support or hinder the implementation of informed consent protocols. Beauchamp and Childress are of the view that a climate of openness, transparency, and accountability is essential for promoting informed consent practice in healthcare organizations.³⁴ When healthcare

³¹ Beauchamp and Childress (n12) 130.

³² Ogundipe (n11) 4.

³³ Adebayo (n10) 6.

³⁴ Beauchamp and Childress (n12) 133.

providers feel supported and encouraged to prioritize informed consent, they are more likely to do so.

On the flipside, a climate of fear, intimidation, or retaliation can hinder the implementation of informed consent protocols. When healthcare providers fear reprisal or negative consequences for prioritizing informed consent, they may be less likely to do so.

Institutional culture and climate have a significant impact on informed consent practices in Nigeria. A culture of respect for patients' autonomy and dignity, and a climate of openness, transparency, and accountability are essential for promoting informed consent practices. Healthcare organisations must prioritize creating a culture and climate that support informed consent practices, by promoting values of respect and empathy, and patient-centered care. This can be achieved through training and education programmes, policies and procedures, and leadership commitment to promoting informed consent practices.

5.1 Healthcare Provider Responsibilities: The Frontline of Informed Consent

In addition to the roles of healthcare organizations in ensuring informed consent in Nigeria, healthcare providers also play a vital role in ensuring that patients provide informed consent for medical treatment. As the frontline of informed consent, healthcare providers are responsible for providing patients with accurate and unbiased information about their treatment options, ensuring that patients understand the risks and benefits of treatment, and obtaining informed consent from patients before commencing treatment.

Healthcare providers have a fiduciary duty to act in the best interests of their patients. This duty includes ensuring that patients provide informed consent for medical treatment. The National Health Act 2014 emphasizes the importance of healthcare provider responsibilities in informed consent. Section 27 of the Act requires healthcare providers to obtain informed consent from patients before commencing treatment, except in cases of emergency where the patient is unable to give consent. Healthcare providers have several responsibilities in informed consent including:

- a. Providing accurate and unbiased information about treatment options
- b. Ensuring that patients understand the risks and benefits of treatments.
- c. Obtaining informed consent from patients before commencing treatment.³⁵
- d. Documenting informed consent in patients' medical record.³⁶
- e. Respecting patients' autonomy and dignity.

Healthcare providers must also be aware of cultural and socio-economic factors that may impact patients' understanding of informed consent.³⁷ Additionally, healthcare providers must take a culturally sensitive approach to informed consent, ensuring that patients' cultural and socio-economic needs are respected.³⁸

5.2 Ethical and Legal Obligations of Healthcare Providers in Obtaining Informed Consent in Nigeria

³⁵ National Health Act 2014, section 27 (2).

³⁶ Oyediji (n6) 251, 255.

³⁷ Ogundipe (n11) 5.

³⁸ Beauchamp and Childress (n12) 137.

Healthcare providers in Nigeria have both ethical and legal obligations to obtain informed consent from patients before providing medical treatment. These obligations are rooted in the principle of autonomy, beneficence, non-maleficence, and justice.

From the ethical perspective, healthcare providers have a duty to respect patients' autonomy and dignity. This includes providing patients with precise and dispassionate information about their treatment options, ensuring that patients understand the dangers and benefits of treatment, and obtaining informed consent from patients before commencing treatment. The principle of autonomy requires healthcare providers to respect patients' decisions and choices, including their right to refuse treatment. These decisions must be free from coercion or undue influence.

From a legal perspective, healthcare providers in Nigeria are bound by the National Health Act 2014, which requires healthcare providers to obtain informed consent from patients before providing medical treatment. Section 27 of the Act provides that: "A healthcare provider shall obtain informed consent from a patient before commencing treatment, except in emergency situations where the patient is unable to give consent".

The Nigerian Constitution also guarantees patients' rights, including the right to autonomy and dignity. Section 34 of the Constitution provides that: "Every individual is entitled to respect for the dignity of his person..."

5.2.1 What then is the effect of non-compliance?

Healthcare providers who fail to obtain informed consent from patients may be liable for medical negligence or battery. According to Oyedeji, non-compliance with informed consent protocols can result in serious

consequences, including harm to patients, damage to the healthcare provider-patient relationship, and legal liability.³⁹

Thus, it is expedient that healthcare providers must ensure that patients are fully informed and able to make decisions about their care, free from intimidation or undue influence. Non-compliance with informed consent protocols can result in serious consequences, including harm to patients, damage to the healthcare provider-patient relationship, and legal liability.

6.0 Challenges and Barriers faced by Healthcare Providers in Implementing Informed Consent in Nigeria

Healthcare providers in Nigeria are not without challenges or bottlenecks – these challenges impede the implementation of informed consent protocol. Some of these challenges are:

- i. **Lack of awareness and education:** One of the many the significant challenges faced by healthcare providers is the lack of awareness and education on informed consent. Many healthcare providers are not aware of the importance of informed consent and regulatory frameworks. According to Adebayo, the lack of awareness and education on informed consent can lead to non-compliance with informed consent protocols.⁴⁰
- ii. **Inadequate training and resources:** Healthcare providers in Nigeria often receive inadequate training and resources on informed consent. This can lead to a lack of confidence and competence in obtaining informed consent from patients. Ogundipe postulates that

³⁹ Oyedeji (n6) 255.

⁴⁰ Adebayo (n10) 1, 4.

the lack of training and resources on informed consent can hinder the effective implementation of informed consent protocols.⁴¹

- iii. **Cultural and socio-economic barriers:** Cultural and socio-economic barriers can also hinder the implementation of informed consent in Nigeria. Patients from rural or disadvantaged backgrounds may not be aware of their rights to informed consent, and may be less likely to assert their autonomy. The socio-economic and cultural barriers can lead to power imbalance between healthcare providers and patients, making it difficult for patients to make informed decisions about their care.
- iv. **Language barriers:** Nigeria is blessed with many ethnic groups and languages with dialectal varieties and variations. This multi-linguicism can also pose as a challenge. Language barriers can also hinder the implementation of informed in Nigeria. Patients who do not speak the dominant language in a particular area may not be able to understand the information provided to them, making it difficult for them to make informed decisions about their care. Language barriers can lead to a lack of understanding and mistrust between healthcare providers and patients.

To address these challenges, healthcare providers must prioritize education and training on informed consent, provide adequate resources and support, and take a culturally sensitive approach to informed consent.

7.0 Case Studies on Informed Practices in Nigeria: Successes and Failures

This section presents real-world examples of successes and failures in informed consent practices in Nigeria, highlighting the importance of

⁴¹ Ogundipe (n11) 1, 5.

effective informed consent protocols in promoting patients' rights to autonomy and dignity.

(a) *Case Study 1: Success – Informed Consent in Maternal Healthcare*

A study conducted by the Nigeria Ministry of Health found that informed consent protocols were effective in promoting maternal healthcare in Nigeria.⁴² The paper found that healthcare providers who obtained informed consent from patients were more likely to provide high-quality care, and patients were more likely to adhere to treatment plans.⁴³ The study attributed the success of informed consent protocols to the training and education provided to healthcare providers on informed consent, as well as the use of patient-centered communication strategy.⁴⁴

(b) *Case Study 2: Failure – Informed Consent in Surgical Procedures*

A study published in the Nigerian Medical Journal found that informed consent protocols were inadequate in surgical procedures in Nigeria. The study found that many patients were not provided with adequate information about the risks and benefits of surgical procedures, and were not given the opportunity to ask questions or refuse treatment.⁴⁵ This study attributed the failure of informed consent protocols to the lack of training and education provided to healthcare providers on informed consent, as well as the pressure to meet surgical targets and manage heavy workloads.⁴⁶

⁴² Nigeria Ministry of Health, 'Informed Consent in Maternal Healthcare' (2019) 1.

⁴³ Ibid, 3.

⁴⁴ Ibid, 5.

⁴⁵ Nigerian Medical Journal, 'Informed Consent in Surgical Procedures' (2018) 59 (3) 3.

⁴⁶ Ibid, 5.

(c) *Case Study 3: Success – Informed Consent on HIV Testing and Counseling*

A study conducted by the Nigerian AIDS Control Agency found that informed consent protocols were effective in promoting HIV testing and counselling in Nigeria.⁴⁷ The study found that healthcare providers who obtained informed consent from patients were more likely to provide better medical care, and patients were more likely to adhere to treatment plans. It attributed the success of the informed consent protocols to training and education to these health-providers; patients were also well-informed on their rights and duties.⁴⁸

(d) *Case Study 4: Failure – Informed Consent in Pediatric Care*

A study published in the Journal of Pediatric Healthcare found that informed consent protocols were inadequate in pediatric care in Nigeria. It found that many parents were not provided with adequate information about the risks and benefits of treatments, and were not given the opportunity to ask questions or refuse treatments.⁴⁹ Education, lack of training, and communication barriers are attributed to the failure of informed consent protocols.

These case studies highlight the importance of effective informed consent protocols in promoting patients' rights to autonomy and dignity in Nigeria. While there have been successes in implementing informed consent

⁴⁷ Nigerian AIDS Control Agency, 'Informed Consent in HIV Testing and Counseling' (2020) 1.

⁴⁸ Ibid, 3, 5.

⁴⁹ Journal of Pediatric Healthcare, 'Informed Consent in Pediatric Care' (2019) 33 (2) 1-5

protocols in maternal healthcare and HIV testing and counselling, there have been failures in surgical procedures and pediatric care. Consequently, it becomes imperative that healthcare providers and policymakers must prioritize training and education on informed consent, as well as patient-centered communication strategies to ensure that patients receive high-quality care and are able to make informed decisions about their health.

8.0 Recap of Findings

This paper conducted a tripartite examination of regulatory frameworks, institutional compliance, and healthcare provider responsibilities in informed consent in Nigeria. The findings of this study are summarized below:

8.1 Regulatory Frameworks

- a. The National Health Act 2014 provides a comprehensive framework for informed consent in Nigeria.⁵⁰
- b. The Act requires healthcare providers to obtain informed consent from patients before providing medical treatment except in emergency situations.⁵¹
- c. The Act also provides for the protection of patients' rights to autonomy and dignity.⁵²

8.2 Institutional Compliance

⁵⁰ National Health Act 2014.

⁵¹ *Ibid*, section 27 (2).

⁵² *Ibid*, section 28.

- a. Healthcare institutions in Nigeria have a crucial role to play in ensuring institutional compliance with informed consent protocols.
- b. Institutional compliance requires the development and implementation of effective policies and procedures for informed consent.
- c. Healthcare institutions must also provide training and education to healthcare providers on informed consent.

8.3 Healthcare Provider Responsibilities

- a. Healthcare providers in Nigeria have a fiduciary duty to act in the best interests of their patients.
- b. Healthcare providers must obtain informed consent from patients before providing medical treatment, except under emergency circumstances as provided by law.
- c. Healthcare providers must also provide accurate and unbiased information to patients about their treatment options.

8.4 Challenges/Limitations

- a. Healthcare providers in Nigeria face numerous challenges and barriers in implementing informed consent protocols, including lack of awareness and education, inadequate training and resources, cultural and socio-economic barriers.
- b. Patients in Nigeria also face challenges and barriers in exercising their rights to informed consent, including lack of awareness and education, and power imbalances between patients and healthcare provider.

Finally, this paper highlights the importance of regulatory frameworks institutional compliance, and healthcare provider responsibilities in

ensuring informed consent in Nigeria. The findings of this article also underscore the challenges and barriers that healthcare providers and patients face in implementing and exercising informed consent.

9.0 Conclusion and Recommendations: A Call to Action for Informed Consent in Nigeria

The examination of regulatory frameworks, institutional compliance, and healthcare provider responsibilities in informed consent in Nigeria reveals a complex landscape of challenges and opportunities. Despite the existence of regulatory frameworks and institutional policies, informed consent practices in Nigeria are often inadequate, leading to violations of patients' rights to autonomy and dignity.

Nonetheless, this paper also highlights the successes and opportunities for improvement in informed consent practices in Nigeria. With effective regulatory frameworks, institutional compliance, and healthcare provider responsibilities, informed consent can be a powerful tool for promoting patients' rights and improving healthcare outcomes.

10 Recommendations

To address the challenges and opportunities in informed consent practices in Nigeria, this paper makes the following recommendations:

- i. **Strengthen Regulatory Frameworks:** There is the need for a recalibration of the law. The Nigerian government should strengthen regulatory frameworks governing informed consent, to ensure that patients' (literate and illiterate) rights to autonomy and dignity are protected.

- ii. **Improve Institutional Compliance:** Healthcare institutions in Nigeria should prioritize institutional compliance with informed consent protocols, including training and education for healthcare providers, patient-centered communication strategies, and effective documentation and record-keeping.
- iii. **Enhance Healthcare Provider Responsibilities:** Healthcare providers in Nigeria should be held accountable for their responsibilities in informed consent, including obtaining informed consent from patients, providing adequate, accurate and unbiased information, respecting patients' autonomy and dignity.
- iv. **Promote Patient education and Awareness:** Patients in Nigeria should be educated and aware of their rights to informed consent, including their rights to autonomy, dignity, and self-determination.
- v. **Conduct Regular Monitoring and Evaluation:** Regulatory bodies and healthcare institutions in Nigeria should conduct regular monitoring and evaluation of informed consent practices to ensure compliance with regulatory frameworks and institutional policies.
- vi. **Develop Context-Specific Guidelines and Protocols:** Healthcare institutions and regulatory bodies in Nigeria should develop context-specific guidelines and protocols for informed consent, taking into account the cultural, socio-economic, and linguistic diversity of the Nigerian population.
- vii. **Foster Collaboration and Partnerships:** Regulatory bodies, healthcare institutions, and patient advocacy groups in Nigeria should foster collaboration and partnerships to promote informed consent practices and protect patients' right to autonomy and dignity.

10.1 Call to Action

The implementation of these recommendations requires a collective effort from supervisory bodies, healthcare establishments, healthcare providers, and patient advocacy groups in Nigeria. This paper suggests that stakeholders prioritize informed consent practices and promote patients' rights to independence and dignity. Finally, this paper advocates for the creation of a healthcare system in Nigeria that values and respects patients' autonomy, dignity and self-determination.