

MEDICAL NEGLIGENCE AND EMERGING INNOVATIVE TREATMENTS AND PROCEDURES***Abstract**

As technology advances, the question of whether or not legal liability arises when a physician deviates from routine medical practices and employs an innovative medical treatment or procedure is inevitable. Using the doctrinal method of research, this paper examines the concept of negligence in medical practice and discusses the relevance of innovative treatments. It further discusses the standard of care required when an innovative treatment has been employed by a medical practitioner. The paper finds that case laws, particularly in English courts, have settled the requirements to be fulfilled in proving a case of medical negligence involving innovative treatments, which are that: there is a usual and normal practice; the defendant has not adopted that practice and; the course the professional had adopted is one which no professional person of ordinary skill would have taken if he/she had been acting with ordinary care. However, the standard of care for innovative treatments remains unclear in some countries like Nigeria and America. The main recommendations are the filling of the lacuna in Nigerian laws regarding the standard of care for innovative treatments through adequate legislation by adopting a liberal interpretation of the malpractice standard of care to encourage medical innovation.

Keywords: Medical Negligence, Innovative Treatments, Technology, Standard of care

1. Introduction

The principle underlying negligence was first expressed in the English case of *Donoghue v Stevenson*.¹ In that case, Lord Atkin expressed the view that ‘a man has a duty of care to conduct himself in such a way as to avoid harm to others, where a reasonable man would have seen that such harm could occur’. The court in *Lochgelly Iron & Co. v M'mullan*² defined medical negligence as ‘the failure of the healthcare provider to exercise the ordinary care and skill a reasonably prudent and qualified person would exercise under the same or similar circumstances’. Thus, the underlying principle in medical negligence is that anyone who holds himself out as having professional skill is legally expected to demonstrate the amount of competence associated with the proper discharge of duties of the medical profession. If he falls short of that and injures someone in the process, he is not demonstrating the requisite ability and is ipso facto liable.³ The introduction of technology has made great impacts in many sectors of the economy, the health sector inclusive. The healthcare industry has experienced a proliferation of innovations aimed at enhancing life expectancy, quality of life, diagnostic and treatment options, as well as the efficiency and cost effectiveness of the healthcare system.⁴ The adoption of a new medical device or innovation by a physician carries with it some degree of malpractice liability risk. The legal standard for malpractice varies from place to place, but generally requires an evaluation of the physician’s conduct either against that of a hypothetical ‘reasonable physician’, or else against professional custom. Where the use of a new device involves a significant departure from traditional modalities of care, and a bad clinical result follows, questions may arise about whether the legal standard for malpractice has been violated.⁵ Whether a doctor could be found negligent for deviating from the orthodox practice would depend on the justification of the particular act in question. As a general rule, the court will consider evidence of its novelty, previous trial of the procedure, dangers inherent in it, previous response of the patient to orthodox treatment, the seriousness of the patient’s ailment and the patient’s attitude to the novelty and risk of the unorthodox procedure.⁶

The focus of this paper will therefore be on determining whether a physician can be liable for negligence simply because he deviated from the orthodox medical procedures and employed any of the emerging innovative treatments and procedures.

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¹(1932) AC 562.

² 1934 AC At 72.

³J.A. Dada, *Legal Aspects Of Medical Practice In Nigeria* (2nd Edition, University Of Calabar Press 2002) 126.

⁴V. Omachonu And N. Einspruch, ‘Innovation In Healthcare Delivery Systems: A Conceptual Framework’ [2010] (15)(1) *The Innovative Journal: The Public Sector Innovation Journal*; 1.

⁵MD. Greenberg, ‘Medical Malpractice And New Devices: Defining An Elusive Standard Of Care’ [2009] (19) (423) *Health Matrix: The Journal Of Medicine* <http://Scholarlycommons.Law.Case.Edu/Healthmatrix/Vol19/I_Ss2/19> Accessed 21/11/2018.

⁶F. Emiri, *Medical Law And Ethics In Nigeria* (1st Edition, Malthouse Press Limited 2012), 280.

2. Proof of Medical Negligence

A plaintiff who brings an action for medical negligence must establish or prove the existence of the following; First, the duty of care must be established and this duty has been imposed by law once there is a physician-patient relationship. This relationship commences once a physician accepts responsibility for the care of a patient and undertakes treatment.⁷ The physician's duty of care covers consultation, diagnosis, medical advice as well as treatment.⁸ Second, it must be established that there has been a breach of duty through the examination of the conduct of the physician. Thus, there must be a finding that the physician's conduct fell below the acceptable standard of care. Generally, in determining the standard of care, the court examines whether the defendant physician has omitted to do 'something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs would do or doing something which a prudent and reasonable man would not do'.⁹ The determination of the relevant standard of care involves an assessment of the level of skill, knowledge and experience that could reasonably be required of a practitioner with the same professional standing as the defendant. The English court generally accords priority to the 'standard of practice recognised as proper by a reasonably competent body of opinion'.¹⁰ In the more recent case of *Bolitho v City and Hackney Health Authority*,¹¹ Lord Browne-Wilkinson indicated that 'the court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis'. It is noteworthy that more than one standard may be applicable in a given case. In such a case, the court must determine which of the standards should be applied in the particular situation. The courts may approve of the standard of care adopted by a physician even though the medical approach implemented by the physician is not accepted or practised by the majority of his or her colleagues. Third, the defendant's breach of duty resulted in damage or harm to the plaintiff. In order to be successful, the plaintiff must show that the resulting damage was reasonably foreseeable at the time of the commission or omission of the relevant act. Furthermore, a finding of negligence requires proof of causation. This implies that the court must find a nexus between the defendant's negligent action or omission and the plaintiff's injury. The plaintiff must thus demonstrate that the defendant's conduct caused the injury suffered. The court generally employs the 'but for' test, which implies that the plaintiff must establish that 'but for the tortious conduct of the defendant, the plaintiff would not have suffered the injury complained of'.¹² In proving causation, the plaintiff can invoke the maxim *res ipsa loquitur*, an evidentiary rule that means 'the fact speaks for itself'.¹³

3. Meaning of Innovative Treatments and Procedures

Innovation can be defined as the intentional introduction and application within a role, group, or organization, of ideas, processes, products or procedures, new to the relevant unit of adoption, designed to significantly benefit the individual, the group, or wider society.¹⁴ Generally, the phrase innovative treatment refers to significant departures from standard medical therapy which have not been validated by reliable research methods, or where there is simply insufficient evidence to support the safety and efficacy of the innovative procedure, method or device.¹⁵ It significantly emphasizes a distinction from variations or adaptations of existing standard therapy to suit individual patient circumstances. Thus, in offering innovative treatment, the physician is working on a hunch or scientific theory that has not been adequately investigated or researched. Such medical procedures are administered for the benefit of a specific patient but have uncertain outcomes.¹⁶ Conceptually, a more comprehensive definition has been offered as follows:

Innovative therapies generally represent uncontrolled, often single, interventions intended to manage or solve particular problems. They are not ordinarily designed to test hypotheses.

⁷E. Okojie, 'Professional Medical Negligence In Nigeria', <[Http://www.Nigerianlawguru.Com/Articles/Torts/PROFESSIONAL%20MEDICAL%20NEGLIGENCE%20IN%20NIGERIA.Pdf](http://www.Nigerianlawguru.Com/Articles/Torts/PROFESSIONAL%20MEDICAL%20NEGLIGENCE%20IN%20NIGERIA.Pdf)> Accessed 10 December 2018.

⁸MA. Jones, *Medical Negligence* (Sweet And Maxwell 1991), 112.

⁹*Hazel V British Transport Commission* (1958) 1 WLR 169 Per Pearce J.

¹⁰*Bolam V Friern Hospital Management Committee* (1957) 1 WLR 583 At 586.

¹¹(1996) 4 All ER 771.

¹²*Snell V. Farrell* (1990) SCJ No 73, 72 DLR (4th) 289.

¹³*Cassidy V Minister Of Health*, (1951) 2 KB 343; (1951) 1 All ER 574 CA.

¹⁴V Omachonu & N Einspruch, 'Innovation In Healthcare Delivery Systems: A Conceptual Framework' [2010] (15)(1)*The Innovative Journal: The Public Sector Innovation Journal*; 1.

¹⁵R. Levine, *Ethics And Regulation Of Clinical Research* (2nd Ed. Yale UP, 1986), 3-6.

¹⁶S. Erdun-Jones & D. Weissstüb, 'Drawing The Distinction Between Therapeutic Research And Non-Therapeutic Experimentation: Clearing A Way Through The Definitional Thicket' In D. Weissstüb Ed., *Research On Human Subjects: Ethics Law And Social Policy* (Pergamon, 1998) 95.

Additionally, they are not undertaken in order to gain new knowledge beyond the needs of the patient. Although the use of innovative therapies may lead to new knowledge, this consequence is secondary to their primary purpose of benefiting patients.¹⁷

An innovative treatment or procedure could be situated at any point of the continuum from genuine innovation with no precedent, such as using a new procedure or drug, to relative innovation representing a small variation from standard therapy, such as extension of therapy beyond the standard duration; or using a conventional treatment in a different context.¹⁸ Essentially, innovation in healthcare connotes providing ‘more for less’, meaning more value, better outcomes, greater convenience, access and simplicity, in a less complex and time consuming manner.

4. Medical Negligence and Emerging Innovative Treatments

Negligence and malpractice doctrine generally make it clear that standards of care are evolutionary rather than static, and also that providers of medical care have an obligation to stay abreast of new techniques and developments. By implication, the malpractice standard in 2019 is different from what it was in 1979, not because of any changes in the law but because of changes in medical knowledge and in new technologies. Broadly speaking, the malpractice standard of care assumes, and depends upon this kind of innovation in medical treatment. Legal ambiguity around what the standard of care really means in this kind of circumstance implies that physicians and their lawyers may genuinely not know the degree of malpractice risk that is associated with adopting a new clinical technology. This may present a problem for judges in determining appropriate rules for apportioning liability fairly. More important, though, is the potential for far-reaching effects on physicians (and other care providers) in their willingness to adopt new technologies, given ill-defined but perceived malpractice liability risks associated with doing so. By implication, malpractice law may sometimes present a deterrent to medical innovation, and a market barrier to demand for new technologies, even where those technologies offer broad social benefits in the form of superior clinical outcomes and/or reduced administrative costs.

4.1 Proof of Medical Negligence for Innovative Treatments and Procedures

In proving medical negligence generally, the English tort law case of *Bolam v Friern Hospital Management Committee*¹⁹ is often applied. In this case, the court concluded that a doctor might be able to avoid a claim for negligence if he can prove that other medical professionals would have acted in the same way.²⁰

However, the case of *Hunter v Hanley*²¹ is the Scottish equivalent to *Bolam*. It sets out a slightly different test applicable to professional negligence cases under the laws of Scotland. In the case, Hanley was given an injection but suffered an injury when the hypodermic needle broke. She subsequently alleged that the accident had been caused by Hunter who had failed to exercise the standard of care and competence which it was his duty to observe in giving the injection. More specifically, it was alleged that the type of needle used by Hunter was not of suitable and adequate strength for that type of injection. The court held that deviation from ordinary professional practice is not necessarily evidence of negligence and it would hinder progress in medical treatment if the law were to hold otherwise. Even a substantial deviation from normal practice may be warranted by the particular circumstances of a case. In order to establish liability in circumstances where deviation from normal practice is alleged, the court in this case, set out three facts which have to be established:

1. It must be proved that there is a usual and normal practice;
2. It must be proved that the defendant has not adopted that practice; and
3. Most importantly, it must be established that the course the professional had adopted is one which no professional person of ordinary skill would have taken if he/she had been acting with ordinary care.

The onus thus rests on the plaintiff to establish these three facts, and without all three, his case will fail. It was further held in *Landau v Werner*²² that ‘a doctor might not be negligent if he tried a new technique, but that if he did,

¹⁷D.H. Cowan, ‘Innovative Therapy Versus Experimentation’ [1985] *Torts & Insurance Law Journal*; 619.

¹⁸A Eyadhy & S Razack, The Ethics Of Using Innovative Therapies In The Care Of Children, [2008] (13)(3) *Paediatrics Child Health*; 181.

¹⁹(1957) 2 All ER 118.

²⁰All Answers, ‘The Bolam Test In Clinical Negligence’, <<https://www.lawteacher.net/free-law-essays/medical-law/bolam-test-clinical-negligence.php>> Accessed 5 February 2019.

²¹1955 S.C. 200.

²²(1961) 105 Sol. Jo. 1008.

he must justify it before the court. Successes were the best justification for unusual and non-established treatment'. In *Clark v MacLennan*,²³ the court held that a doctor owed a duty to his patient to observe the precautions which were normal in the course of the treatment he gave. Where a patient suffered damage after there had been a departure from the orthodox course of treatment, the court has to inquire whether the doctor had taken all proper factors into account prior to taking action in order to determine whether that departure was justified. If it was not, that departure was a breach of the duty owed to the patient.

In relation to burden of proof when there is a deviation from a usual medical practice, Mustill LJ in *Wilsher v Essex Area Health Authority*²⁴ expressly disagreed with the proposition in *Clark v MacLennan*²⁵ that in certain cases there is a general burden of proof on the doctor. This view was affirmed on appeal.²⁶ The proper law therefore is that the burden of proof remains that of the patient. It can shift to the doctor if the patient establishes that the procedure used is not orthodox. Such a suit may thus succeed unless the doctor leads proper evidence of rebuttal.

An instance in which the highest United Kingdom court found that guidelines drawn up by a responsible body of opinion can offer a degree of protection to clinicians in the eyes of the law can be found in the case of *Airedale NHS Trust v Bland (Guardian ad litem)*.²⁷ The guidelines in question were developed by the Medical Ethics Committee of the British Medical Association (BMA), and suggested safeguards to be observed before discontinuing artificial nutrition and hydration to patients in the Persistent Vegetative State (PVS).²⁸ Although the Bland case was not a legal action in negligence, it was stated that the requirements of the Bolam test were met because they amounted to 'guidance from a responsible body of professional opinion'.²⁹

In the case of *Loveday v Renton and Wellcome Foundation Ltd.*,³⁰ the court held obiter that failure to observe particular contraindication guidelines when administering whooping cough vaccination would not in itself constitute negligence because there was a respectable and responsible body of medical opinion that some contraindications should not be observed because the risk of disease outweighed any actual or possible risk from the vaccine. Even if it had been possible to establish in the Loveday case that pertussis vaccine could cause brain damage (which the case left unproved), the judge clearly believed that the third and crucial condition set out in the earlier case of *Hunter v Hanley*³¹ could not be established, despite the breach of official guidelines, namely that the course the doctor adopted was one that 'no professional man of ordinary skill would have taken if he had been acting with ordinary care'.

Deviation from a guideline would unlikely be accepted as evidence of negligence by a United Kingdom court, as long as the particular deviation is approved by a responsible body of doctors. However, a finding of negligence cannot be excluded where deviation from an accepted guideline does not accord with approved responsible clinical practice.³² In *Cranley v Medical Board of Western Australia*,³³ Dr. Cranley had deviated from the Australian National Methadone Guidelines and, as a consequence, was found guilty of 'infamous and improper conduct'. However, the Supreme Court of Western Australia upheld his appeal when it heard of a minority medical opinion in Australia which supported treatment of opiate addicts as he had done.

²³(1983) 1 All ER.

²⁴(1986) 3 All ER 801 At 815.

²⁵Supra.

²⁶(1988) 1 All ER 871 At 879, Per Lord Bridge.

²⁷(1993) AC 789.

²⁸A Condition In Which A Medical Patient Is Completely Unresponsive To Psychological And Physical Stimuli And Displays No Sign Of Higher Brain Function, Being Kept Alive Only By Medical Intervention.

²⁹B. Hurwitz, 'Can Deviation From Guidelines Constitute Negligence?' <<https://www.guidelinesinpractice.co.uk/your-practice/can-deviation-from-guidelines-constitute-negligence/300395.article>> Accessed 5 February 2019.

³⁰(1990) 1 Med LR 117; (1990) 1 MLR 1.

³¹Supra.

³²B. Hurwitz, 'Can Deviation From Guidelines Constitute Negligence?' <<https://www.guidelinesinpractice.co.uk/your-practice/can-deviation-from-guidelines-constitute-negligence/300395.article>> Accessed 5 February 2019.

³³(Supreme Court WA) (1992) 3 Med LR 94-113.

Clinical guidelines for innovative treatments may remove the need for expert testimony in the court's deliberations to determine a physician's liability.³⁴ As clinical guidelines become more universally adopted, guideline-informed care may be viewed by the courts as some evidence of the standard of care required. While it is extremely unlikely that the existence of protocols will lead to the elimination of the Bolam test altogether, there could be a strong argument for reversing the burden of proof in cases where guidelines are not followed. A doctor who had decided not to follow the definitive guidelines produced by experts in his field would be required to justify his decision. He could prove his actions through expert witnesses but 'the burden of proof would be on him and not the patient'.³⁵ The effects of any such changes in legal emphasis could well be to encourage adherence to clinical guidelines.

4.2 Standard of Care for Innovative Treatments and Procedures

According to Tindal CJ,³⁶ the question here is not what could have been expected of the defendant but what could have been expected of 'a man of ordinary prudence'.³⁷ Speaking generally, then, the standard of care is not determined with regard to the peculiarities of the defendant, but rather by reference to a creation of the law: the ordinary reasonable person. On its face, it seems that the objective standard is adopted for convenience rather than from a concern for justice. This is because, at first glance, a subjective standard that holds a defendant negligent only if he were personally culpable seems preferable from the standpoint of justice. Conversely, the objective standard seems based on policy concerns, most likely convenience of proof. It is possible to read Tindal CJ's claim that if a subjective standard were applied then 'liability for negligence should be co-extensive with the judgment of each individual, which would be as variable as the length of the foot of each individual' in this manner.³⁸ If a subjective standard were adopted, then it would be too difficult to prove that the defendant was negligent.³⁹ However, the objective standard is not based on this policy. In fact, the objective standard is not merely consistent with corrective justice; corrective justice demands the adoption of an objective standard. First, it is important to recognise that the objective standard is not always harsh on defendants. If the defendant is an ordinary reasonable person in the relevant respect, then he will be asked to do no more than he is able to do.

Moreover, if the defendant has abilities superior to those of the ordinary reasonable person, then the objective standard will ordinarily impose a standard of care on the defendant that is easier to meet than a subjective standard would be. Hence, in such circumstances the objective standard will impose fewer obligations on the defendant than ethics does. From the perspective of ethics, this may appear soft on the defendant and harsh on the claimant. The objective test is not claimant friendly, rather, least in the usual cases; it is a 'one size fits all' standard that sometimes benefits claimants, but sometimes benefits defendants over a subjective standard.⁴⁰ The point of the objective standard is to mediate between the interests of the parties by setting an impersonal standard by which to judge the defendant's actions.

In *Bolitho v City and Hackney Health Authority*,⁴¹ the House of Lords made it clear that the negligence of medical practitioners is not to be determined solely by reference to conventional medical practice. Thus, courts must ensure that the expert opinions relied upon has a logical basis and has weighed the risks and benefits of such procedures before coming to a conclusion. The standard of care to be expected of medical practitioners seeks to do justice between parties and not restrict the thinking of medical practitioners.⁴²

The Bolam test is applied in circumstances where an action is brought in negligence. In the context of innovative treatments, it may be difficult to determine a 'responsible body of professional opinion'. A surgeon performing an innovative procedure may be at the frontier of medical science so that no other experts may be found to constitute a 'responsible body' who are then able to assert an authoritative opinion. It is settled law that deviation from approved

³⁴SK. *Clinical Guidelines And Negligence Liability*. In: *Clinical Effectiveness: From Guidelines To Cost Effective Practice*. DM Hitch (Eds) (Earlybrave Publications Ltd, United Kingdom 1995), 127-35.

³⁵B. Hurwitz, 'Can Deviation From Guidelines Constitute Negligence?' <<https://www.guidelinesinpractice.co.uk/your-practice/can-deviation-from-guidelines-constitute-negligence/300395.article>> Accessed 5 February 2019.

³⁶*Vaughan v Menlove* (1837) 3 Hodges 51, 132 ER 490, 493.

³⁷*Ibid.*

³⁸*Ibid.*

³⁹S. Todd, 'Negligence: Breach Of Duty' In S. Todd (Ed), *The Law Of Torts In New Zealand* (3rd Edition, Brookers Wellington 2001), 383.

⁴⁰A. Beever, *Rediscovering The Law Of Negligence* (Hart Publishing, 2007); 74.

⁴¹(1996) 4 All ER 771.

⁴²A. Beever, *Rediscovering The Law Of Negligence* (Hart Publishing, 2007), 85.

practice does not necessarily amount to negligence, and in *Simms v. Simms*⁴³ it was recognised that it would be against the public interest to impede medical progress just because of the absence of a Bolam endorsement.

It remains to be tested as to how the courts would assess the legal standard in a case of alleged negligence involving the use of an innovative surgical or interventional technique. Some factors that might be considered would be the extent to which its use was justified in the circumstances, whether there was evidence of previous trials of the treatment, the seriousness of the patient's condition and the extent of the foreseeable risk in the procedure.⁴⁴

The general standard of care in malpractice involves some variation on the reasonableness of a physician's conduct, usually as determined by comparison to what other physicians would do in similar circumstances. A narrow interpretation of this standard could put a heavy burden onto the early adoption of a specific new medical device, since most other physicians would not yet be using that device, and any departure from customary practice might plausibly be construed as unreasonable. But a more nuanced perspective on the standard of care would recognize that clinical practices obviously do change over time, and that physicians frequently do employ new technologies and new techniques. By implication, the reasonableness of using a new device cannot be judged simply from the fact that it has not yet been widely adopted. Rather, a 'reasonableness' or even a 'customary' analysis would have to reflect on the circumstances under which physicians generally adopt and use new devices, even where those adoptions entail a substantial change from customary care. In practice, the risks associated with a new device will often be somewhat ambiguous to physicians, because experience with the new device will be limited. The greater the ambiguity in clinical risk, the more difficult it becomes for physicians to know how the malpractice standard of care will apply. By corollary, the potential for malpractice liability becomes greater.⁴⁵

In the United States, only few cases have been decided on the standard of care in connection with the adoption of new medical technologies. In 1993, for example, a court in Louisiana held a physician who had performed a femoral arteriogram using a new imaging technology liable, based on the principle that 'it is a breach of the standard of care... to subject a patient to a particular test or procedure which has any risk of injury... if that doctor knows or reasonably should know that the procedure will be of no benefit to the patient.'⁴⁶ There have been some cases in which defendants were held liable for their failure to adopt new technologies or procedures.⁴⁷ These judgements reserved the duty of determining the reasonableness standard in relation to defendants' conduct, to the courts⁴⁸ and prove two important points. First, they show that legal standards of care do change over time as technology changes. Risky procedures may therefore eventually become attractive and even compulsory. Second, the 'reasonableness' and the malpractice standard depend on how narrowly or broadly a particular treatment of the physician is viewed. A broader view, for example, will acknowledge the fact that medical science can never be static and must allow innovations.⁴⁹

However, United States case law has not established distinct principles for evaluating the malpractice standard of care in the context of new medical devices or procedures, as opposed to other clinical situations involving alleged malpractice. Neither have the courts established any distinction between applicable malpractice standards connected with new devices that are believed to offer unique therapeutic benefit, as opposed to new devices whose primary advantage is reduced cost when compared to conventional treatment.

⁴³[2003] 1 All ER 669.

⁴⁴JK Mason & RA McCall. *Law And Medical Ethics* (Butterworths London 1983), 218-229.

⁴⁵MD. Greenberg, 'Medical Malpractice And New Devices: Defining An Elusive Standard Of Care' [2009] (19) (423) *Health Matrix: The Journal Of Medicine* <[Http://Scholarlycommons.Law.Case.Edu/Health_Matrix/Vol19/Iss_S2/19](http://Scholarlycommons.Law.Case.Edu/Health_Matrix/Vol19/Iss_S2/19)> Accessed 05/02/2019.

⁴⁶*Riser V American Medical International, Incorporation*, 620 So.2d 372 (1993). In This Case, The Defendant Physician Reportedly Did Believe That There Was Some Potential Benefit In The New Procedure To The Patient, But The Record Of Expert Evidence Actually Produced At Trial Failed To Support His Point Of View.

⁴⁷*Helling v Carey*, 519 P.2d 981 (1974), Where An Ophthalmologist Was Held Liable For An Injury That Could Have Been Prevented Through A Glaucoma Pressure Test; *Washington V Washington Hospital Center* 579 A.2d 177, (D.C. 1990), Where A Hospital Was Held Liable For Failing To Use Continuous Oximetry Technology To Reduce The Risk Of Anesthesia-Related Brain Injury.

⁴⁸RA. Epstein, 'Legal Liability For Medical Innovation' [1987] (8) (1139) *Cardozo Law Review*.

⁴⁹Michael D. Greenberg, 'Medical Malpractice And New Devices: Defining An Elusive Standard Of Care' [2009] (19) (423) *Health Matrix: The Journal Of Medicine* <[Http://Scholarlycommons.Law.Case.Edu/Healthmatrix/Vol19/Iss2/19](http://Scholarlycommons.Law.Case.Edu/Healthmatrix/Vol19/Iss2/19)> Accessed 5 February 2019.

A pertinent issue in determining negligence when innovative treatments are employed is consent. Consent cannot be used as a defence in medical negligence cases as a patient cannot consent to negligent treatment. A medical practitioner can be liable for negligence based on inadequate information being given to the patient.⁵⁰ It is essential therefore that the patient is informed of any uncertainty regarding the risks, all reasonably foreseeable risks and an open discussion should be entered into regarding alternative established surgical procedures. Thus, the need for patient consent raises particular and unique complexities in the context of therapeutic innovation. The fact that the procedure has had limited application precludes the provision of critical information that a patient may expect including an individual surgeon's success rates. Performance data of a surgeon may be a material factor for a patient in the consent process. An honest portrayal of the lack of available information must be made clear. In order to legitimise innovative care, consent based upon adequate information is mandatory.

In the United States, much of the litigation involving novel surgical techniques have revolved around lack of adequate consent and not being informed that the technique was experimental in nature.⁵¹ In Europe, such practice could form the basis of a legal challenge founded on the violation of Human Rights. Lack of informed consent prior to innovative treatment could breach Articles 3 and 8 of the European Convention on Human Rights.⁵² Autonomy, as protected by Article 8, could be violated through compromising self-determination as a result of inadequate information being provided. Furthermore, a recipient of novel treatment might allege a violation of Article 3, which prohibits inhumane and degrading treatment, in the absence of full information disclosure.

Surgeons should, therefore, be diligent in ensuring that patients are fully aware that the proposed procedure is innovative in nature, and that they understand that the clinician may be uncertain of outcome. Failure to do so would be contrary to good medical practice and could lead to litigation.⁵³

5. Conclusion and Recommendations

Medical negligence is one of the most recurring issues and a major challenge hindering the effective delivery of health care services in Nigeria and other parts of the world. Attempts have been made to regulate medical practice through legislations and case laws in order to ensure that medical practitioners deliver medical services diligently and cautiously by imposing on them a duty of care. Advancements in medical care are an essential aspect of a modern health service and, as such, should be encouraged and facilitated. When a physician adopts and uses a major piece of new medical technology with a resulting shift in the nature or delivery of clinical care, the result is the potential for a new set of malpractice risks. Liability for medical malpractice is based on whether a physician meets a legally required standard of care. That legal standard is usually defined by medical custom, or else by what other reasonable physicians would do when confronted with similar circumstances but medical innovation, however, sits in a perceptible lacuna. While it is clear that regulation and control is necessary in order to prevent risk to patients, control cannot be imposed to such a degree that innovation is stultified and progress stopped. However, in the absence of a regulatory framework, there is a real danger that patients might be inadvertently harmed. With the advent of technology, new medical techniques have unfolded and are still unfolding, giving rise to the need to determine the standard of care required when a medical practitioner opts for an innovative treatment and deviates from standard or routine procedures. There is also the need to determine whether or not such a deviation would amount to medical negligence. This aspect of medical negligence is however not adequately regulated especially in Nigeria but other countries like England have regulated this aspect through case laws.

To improve the current situation in Nigeria concerning medical negligence and the emerging innovative treatments and procedures, the following recommendations are proffered:

Bridging the Gap in Nigerian Medical Malpractice Legislations

This paper has successfully brought to limelight the fact that Nigerian legislations do not make provisions for medical negligence regarding innovative treatments and procedures. This study thus recommends that the

⁵⁰*Sidaway v Board Of Governors Of The Bethlehem Hospital And The Maudsley Hospital* (1984) AC 871.

⁵¹*Anderson V George H. Lanier Memorial Hospital* (1974) 493 F 2d 408 (US CA, 5th Cir); *Estrada v Jaques* 321S.E. 2d 240 (N.C. Ct App 1984).

⁵² 1950, Signed 1953.

⁵³Healey Samanta, 'When Does The 'Learning Curve' Of Innovative Interventions Become Questionable Practice?' [2008] 36 *European Journal Of Vascular And Endovascular Surgery* 253-257.

machineries of government should take adequate measures to ensure that medical negligence regarding innovative treatments is legislated upon and adequately regulated, also ensuring that the legislations are implemented. This gap in our legislations needs to be bridged so all forms of ambiguity regarding this subject matter will be cleared, leaving room for precision and specificity of the laws in this regard. Bridging this gap would be favourable to the medical practitioners as they would now be aware of the liability if any, which they would incur if they decide to deviate from routine medical practices. Clarification of the malpractice standard by policymakers, and of the steps that reasonable physicians should take in connection with using new medical devices and equipment, could help substantially in reducing the ambiguity around device-related malpractice risks.

A more Liberal Interpretation of the Malpractice Standard of Care

In the United Kingdom, the standard of care for innovative treatment revolves around “reasonableness of such a treatment” in the sense that such treatment must be justifiable else it has fallen below the standard of care. For such a country and other countries which have spelt out their malpractice standard of care, a liberal interpretation of such a standard of care is recommended. This is because a too rigid or too strict interpretation of the malpractice standard of care would hinder future innovations as medical service providers would be reluctant to try out new techniques due to the fear of being held negligent. In a country like Nigeria where the malpractice standard of care for innovative treatment is unknown, it is recommended that such standards are established, a liberal interpretation is appropriate and even necessary to avoid the potential for perverse disincentives to technical innovation in medicine.

Education on Patient Rights and its Enforcement

Every patient is deemed an autonomous being, meaning every patient has the right to make medical decisions on his own, except in special circumstances such as mentally ill patients or minors. Treating a patient as an autonomous being implies according the patient his rights such as consent, right to information, inter alia. A medical practitioner can be liable for negligence based on inadequate information being given to the patient. It is essential therefore that the patient is informed of any uncertainty regarding the risks, all reasonably foreseeable risks and an open discussion should be entered into regarding alternative established surgical procedures. Patients should be educated on their rights, so that before any treatment or procedure is carried out on a patient, especially an innovative treatment, the patient would insist that all relevant or material facts about the treatment should be disclosed. This will give the patient the opportunity to make an informed and well thought out decision on whether or not to go through with the treatment, considering the risks and benefits involved. The test of materiality or relevance of information regarding a treatment is whether a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor should reasonably be aware that the particular patient would be likely to attach significance to it.

Encouragement of Research and Technological Advancement in the Health Sector

Although this paper was not focused on the need for technological advancement in the health sector, the importance of technological advancement was explained. Technological advancement is inevitable and necessary for development in all sectors of the economy, the health sector inclusive. Research should be encouraged in the health sector and more attention should be paid to the health sector in general, so that there can be general improvements in the Nigerian health care delivery system. The government can ensure this by providing adequate funding to the health sector for research and other developmental purposes.