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Review Article

Ethico-legal aspects of hospital-based blood transfusion practice; implications of professional negligence to medical practitioners: a review

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ABSTRACT

Background: Blood transfusion is predominantly a hospital-based practice in many resourceconstrained economies like Nigeria, wherein the sourcing, storage, processing and clinical use of blood and blood products resides in the often financial and manpower constrained hospitals. Aim: To identify the ethical and legal issues related to hospital-based blood transfusion practice for medical practitioner. Methods: Relevant articles retrieved via PubMed/MEDLINE and Google scholar search engines were used. Results: This review found that, medical practitioners are directly or vicariously liable in professional negligence in hospital-based transfusion injuries. The potential weaknesses in hospital-based blood transfusion practice as ethically identified include; transfusion transmissible infections, blood group incompatibility, haemolytic transfusion reaction, failure to obtain informed consent and challenges of haemovigillance. However from the cases considered, medical practitioners are more professionally liable where they withhold a transfusion or transfuse blood group incompatible transfusion or fail to obtain an informed consent for blood transfusion especially amongst Jehovah's Witness adherents. Conclusion: Medical practitioners at hospital-based transfusion centres are professionally liable for negligence due to blood transfusion injuries by their clinical, laboratory or general administrative oversight at different levels of hospital management. It is recommended that, they carry out this duty cautiously. While error reporting should be encouraged, litigations against them should be pursued cautiously in order not to encourage defensive blood transfusion practices in fear of claims or litigations to the disadvantage of the patients. Mediation or arbitration systems which are faster, less expensive and often less punitive but help strengthen the blood transfusion services should

Key words: Professional negligence, medical practitioner, hospital-based, blood transfusion, liability, Nigeria

INTRODUCTION

"Blood transfusion is like marriage: it should not be embarked upon lightly, unadvisedly or wantonly or more often than is absolutely necessary". Blood transfusion is a cornerstone of modern medical practice essential in almost every field of clinical

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practice either in emergency situations or as a necessary adjunct to modern and emerging Medicare. [2,3,4] As with any treatment, however, transfusion of blood or blood components must be ordered and administered safely and appropriately. Transfusion is more than a single discrete event—it is a process.[5] The transfusion chain begins with donor considerations (whether their donation is safe for them to make and whether the donation is safe for any patient to receive). Once blood is collected, the safety of the blood product is a focus of activity (infectious disease testing, compatibility testing, necessary modifications such as irradiation or leukocyte reduction). The end-point of the transfusion process involves recipient considerations (proper identification of the unit and the patient, appropriateness of blood as the best treatment modality, administration of the unit and evaluation of the recipient).[5] Unlike in many countries in Africa like South Africa, Burundi, Malawi, Central African Republic and Botswana where safe blood is efficiently collected and distributed centrally through their country's National blood Transfusion Service, (NBTS) many resources constrained economies like Nigeria are yet to effectively run nationally coordinated services to meet the blood needs of their populace. [6,7] Therefore, hospital-based blood transfusion is the prevailing practice wherein the sourcing, storage, processing and clinical use of blood and blood products resides in the confines of hospitals most of whom have financial and manpower constraints. In keeping with the advances in knowledge, technology and medical skills, medical law too has evolved and has seen the development as well as the refinement of important medico-legal concepts. [8] The revolution in blood transfusion practice has particularly created religious, moral, ethical and legal dilemmas. [2,9] These challenges coupled with the fact that, it is a form of transplant and associated with injurious complications to blood donors or recipients, calls for a critical assessment particularly that, some complications may be predictable and potentially prevented while others may go unnoticed only to present as blood transfusion injury. The risk associated with this essential service and the need for great caution in blood transfusion practice has been canvassed by many workers. $^{[1, 6, 10, 11]}$ Therefore, one of the vital yet challenging responsibilities hospitals in countries engage in is the provision of blood services. Medical practitioners who order blood

for their patients are faced with the challenge of managing the blood transfusion needs of the patient in an evidence-based approach and balancing the expected clinical benefit with the medical and legal risks inherent in the transfusion of blood. [4]

It is therefore, no longer acceptable to maintain a laissez-faire approach by accepting only the benefits of blood transfusion and ignoring its inherent risks. [12] Considering that, in many developing countries of the world, it is not unusual to go through a medical school without acquiring a sound knowledge of medical ethics, [13] the feared grossly inadequate knowledge of medical ethics by medical practitioners[14] and the view of blood transfusion in legal jurisprudence, as a professional service for which the actions of the practitioner should be viewed against that of a "reasonable professional",[15] medical practitioners who make fatal mistakes or are negligent at hospital-based blood transfusion service may be liable for professional negligence. The decided cases on hospitalbased blood transfusion service as determined in some courts, including ethical and legal issues for which medical practitioners may be liable are reviewed using internet and print material literatures on Nigeria and other commonwealth member nations preferably. This review also includes, stare decisis (previous court decisions) and related Medical and Dental Council of Nigeria (MDCN) Disciplinary Tribunal rulings.

METHODOLOGY

A review of the ethical responsibilities of medical practitioners in hospital-based blood transfusion practice with respect to the medical code of ethics, the international blood transfusion codes for best practices, the national regulations on blood transfusion practice and the constitutional provisions as well as the legal implications of negligence in hospital-based blood transfusion practice were considered. We searched PubMed, MEDLINE and google scholar databases for articles (original, review, commentaries and case reports) using key search terms including; ethics + legal + blood transfusion; ethics + legal aspects + hospital-based transfusions; law suits + negligence + hospital-based transfusions; ethics +court decisions + hospital transfusions and law suits + medical practitioners + hospital blood transfusion. Our search generated a total of 654 related articles out of which 606 were excluded due to unavailability of full text manuscripts in English language or its contents did not meet our review criteria. Following this we included 48 articles relevant to the ethical consideration and 18 court (*stare decisis*) and the Medical and Dental Council Investigation and Disciplinary Tribunal decided cases related to this study.

REVIEW

Hospital-based blood transfusion and legal basis for practice by medical practitioners

Medical practitioners are noble professionals, required to possess a particular level of learning, knowledge, expertise and skill and to maintain a reasonable degree of care and caution, while performing their duty of taking care of the sick and ill including blood or blood products transfusion. [16,17,18] In Nigeria, medical practice is regulated by the Medical and Dental Council of Nigeria (MDCN) established by the Medical and Dental Practitioners Act CAP 221, Laws of the Federation of Nigeria, 2004 or CAP M8 Laws of the Federation of Nigeria 2004. [13,16,19] This Act empowers the MDCN to make rules of professional standards and code of medical ethics for medical practitioners in Nigeria and to establish Disciplinary Tribunals and Investigating panels for the enforcement of these rules. [15] Under the Act; "Only persons who have undergone the course of training based on the curriculum for medical and dental education as approved by the MDCN and have certificates approved obtained the recognized by the Council, and who beside all these have registered and licensed by the Council shall practice as a Physician or Dental Surgeon in Nigeria."^[19]A medical practitioner on oath at graduation pledges to consecrate his/her life to the service of humanity, practice the profession with conscience and dignity and to take the health of his patient as the first consideration irrespective of color, religion, gender, political affiliation and any other differences. [19] Besides these, s/he is regulated by the current general Code of Medical Ethics including those relating to the care of the sick which stipulates among others that; His primary responsibility of care is to his patient, his obligation at all times shall always be to preserve human life, shall owe his patient complete loyalty and all the resource of his science. [19] In the case of private hospitals, the

Private Hospitals Act, CAP.537 Laws of the Federation (LFN) 2004 additionally provides that, registration of private hospitals must be under the supervision of a qualified medical practitioner. [19] Therefore, medical practitioners are statutorily responsible for patients care in all private and public hospitals/clinics owed by individuals, governments, faith-based and nongovernmental organizations (NGO). Any breach of this care may render him or her guilty of infamous conduct professionally or negligence. While the medical profession appreciates and respects the contributions of other health care givers and allied professions in some care services and treatments including blood transfusion, the "doctor-patient fiduciary relationship" is the foundation of a valid legal duty of care to any patient in the hospital setting [20,21] It is also required of a hospital that, all the dealings in blood transfusion practice must always follow national and international guidelines.^[22] In recognition of these and in pursuance of blood safety strategies in Nigeria, blood transfusion is well regulated by medical code of ethics, [17] ethics in blood transfusion practice, [23] national guidelines for blood transfusion^[24] and the Nigerian Constitution.^[25] Additionally, Lagos State government, [26] has pioneered a stateowned blood transfusion service that is effectively providing safe blood for her inhabitants. Furthermore, all hospitals are required to put in place blood transfusion policies, hospital transfusion committee, employ best practices and be proactive in providing an oversight on all blood transfusion processes. All these measures are aimed at blood assuring safe transfusion safeguarding the hospital, blood banks, medical practitioners and other health professionals against negligent liability in blood transfusion practices. Only suitably qualified medical practitioners are ethically allowed to oversee blood donation and direct clinical blood usage at hospitals.^[23] Also, the code of medical ethics[19] stipulates that, in public and private employments, these conditions of the law apply to medical practitioners who work therein. Therefore, the actions and inactions of all other support staff in blood transfusion practice in Nigeria including nurses, laboratory scientists' technicians' attendants have legal implications on the medical practitioners. Any deviation from blood transfusion standards may result in an error or mistake termed a "malpractice". While some malpractices may

not be particularly fatal and readily ignored or go unnoticed, others may be fatal and cannot be ignored in law and may be proven to be a negligent act with personal liability. Therefore, medical practitioners are responsible for safe blood transfusion in hospitals and may be liable in blood transfusion injuries not only by their personal or direct actions and inactions but also for their administrative, laboratory and clinical oversight functions. This was manifest in 2006 when some medical practitioners in authority at a premier Teaching Hospital in Nigeria including a Chief Medical Director Medical (CMD), Chairman Advisory Committee(C-MAC) and Head of Department of Hematology and Blood Transfusion (HOD) had their appointments suspended indefinitely for their vicarious liability in a neonatal Transfusion Transmissible-HIV (TT-HIV) case. At that instance, the Nigerian Minister of Health Professor Eyitayo Lambo emphasized; "we are determined to put a stop to negligent practices in our health institutions." [27]

Blood transfusion practices and ethical guidelines

Ethics refer to rules and principles that ensure right conduct. [20, 28] The word "ethics" is derived from the Greek word "ethos" that means customs and habits. [28] It is a branch of philosophy dealing with values relating to human conduct, with respect to the rightness and wrongness of certain actions and to the goodness and badness of the motives and ends of such actions. Ethics is therefore that science of knowledge, which deals with the nature, and grounds of moral obligations, distinguishing what is right from what is wrong as required of a group or persons. [13,20] Ethical principles revolve around; respect for persons i.e. autonomy, self-determination, protection of vulnerable groups, informed consent etc, or beneficence, that is, equitable distribution of risk and benefits, equitable recruitment of study participants, special protection of vulnerable groups, and justice, that is physical, mental and social well-being, minimal risks. and responsibility of caregiver to patients. [20] Every profession or calling has ethical codes which are more often than not universally observed and in medicine, there is hardly any area that does not have its ethical aspect. The practice of transfusion medicine involves a number of ethical issues because blood is a precious human resource with a limited shelf and with inherent risks.[29] Medical

practitioners are guided by at least two ethical codes. The first being the medical code of ethics^[19] applicable to all medical practitioners in general and the second being the Ethics of Blood Transfusion practice. [23] Medical Code of ethics are professional ethics applicable to medical practitioners and refers to the medical oaths and codes that prescribe a physician's character, motives and duties which are expected to produce a right conduct and which should guide the members of the medical profession in their dealings with professional and non-professional relationships including that with their colleagues, other health care professionals their patients and with the state. $^{[20,\ 29,\ 30]}$ The medical code of ethics upholds the wellbeing of the patient even above that of the practitioners themselves. Part B1 section 29, in particular provides for constituents of professional negligence and these imply explicitly in blood transfusion practices. Also, the Ethics in Blood Transfusion^[23] defines ethical principles and rules to be observed in the field of transfusion medicine. The legal implication of any ethical breach depends on the circumstances of each case. While some ethical breach would amount to commission of crime, other amount to civil wrong, while again, others are neither here nor there. [17] In 1980, the international society for blood transfusion (ISBT) formally endorsed the first code of ethics governing the practice of blood transfusion and this was later adopted and approved by the WHO, the league of Red Crescent societies and the General Assembly of ISBT on 5th September 2006. [23] The Ethics of Blood Transfusion is an 18-item ethical guideline broadly divided into two sections; the first part relates to responsibilities of blood centres to blood donor and donations while the second part is concerned with the responsibilities of hospitals with respect to care and protection of patients. The ethical code stipulates in item 18 that, only agencies competent and authorized to carry out blood transfusion services including hospitals could do so but, such operations must comply with the ethical codes and regulations. Also, ethics 7 and 14 requires that only suitably qualified registered medical practitioner can be responsible and accountable for all donations and for transfusion therapy in hospitals. Therefore, maintaining ethical standards in hospital-based blood transfusion service is a responsibility of medical practitioners and a failure of such

professional duty may be the basis for professional negligence. Also, obtaining informed consent to medical treatment generally is a human right of any individual and violation of this may constitute ground for battery in the law of tort. The medical code of ethics also stipulate that, it is mandatory to obtain an informed consent in some medical treatment and surgery before such is carried out. Ethics 1 require that, an informed consent is obtained from blood donors before blood donation and for the use of his/her donated blood. Related to this, ethics 12 also requires the patient to give an informed consent before being administered any form of blood therapy and any valid advance directive on blood transfusion must be respected. requirements of an informed consent vary from country to country but broadly suggest a full disclosure and discussion of the proposed medical intervention like blood transfusion.[20] Ethics further buttresses that. components of a valid informed consent must include education on risks, complications, alternatives or implications of refusal of such consent and the reasonable expectations for actions and inactions. [23] As a general rule, parents must give their consent before transfusion therapy is administered to their minor children. [8] However, minors who are married, pregnant, or emancipated, and who are in need of treatment may usually give valid consent for their own medical or surgical treatment. [8] Informed consent is a sensitive issue which ought not to be trivialized since it legally, implies that a consensus or a meeting of minds has been met and is not a mere completion of a form. [8,20] Unfortunately most practitioners do not appreciate the enormity of problems that may result from obtaining consent inappropriately.[20] The medical practitioner obtaining the consent, should either be the person that will be administering the treatment including blood transfusion (e.g. the medical consultant) or another senior member of the team who clearly understands the proposed treatment, otherwise, it is not a valid consent.^[20] Therefore, it is expected that, the medical practitioner under whom the blood donor donates his blood or the blood recipient receives such a therapy (ethics 7 and 14) is responsible for providing adequate information to enable the patient decide to accept the blood donation/transfusion or otherwise. It is also his responsibility to educate the donor on the risks to others of donating infected blood

(ethics 5) before deciding on blood donation. Even though an informed consent could be verbal, written or implied^[31] and it is not mandatory in many instances to document it in order to make it valid in law, for the avoidance of legal responsibilities wherein patients or blood donors deny giving an oral informed consent, it is advisable that, all informed consents be documented and witnessed by a third party including the relevant contacts of all the parties involved. But above all medical practitioners appreciate that, informed consent like every part of medicine is dynamic and must keep abreast with current developments with respect to it since ignorance is no excuse in law.[20] It is also ethically required that, any harm to a patient or blood donor must be reported (ethic 9) even if it is undetected by the sufferer. An adequately organized blood bank runs an effective haemovigillance process with "look-back" and "look-forward" on all blood transfusion processes including harm suffered by patients, donors and hospital staff related to blood transfusion. Such a system also encourages prudent use of blood and blood products avoiding unnecessary wastages (ethics 17). Where the motive for running and maintaining the blood transfusion service is not driven by profit making as stipulated in ethics 2 and 16, reports of suffered harm is readily made available to the concerned public. Harm reporting of this nature helps in strengthening the blood transfusion processes at hospitals for a better and improved service delivery.

Hospital-based blood transfusion practice in Nigeria: challenges and implications for medical practitioners

Currently, Nigeria's NBTS is unable to meet the nation's blood needs. Consequently, most hospitals, many of which are bedeviled with financial, logistics and manpower constraints are de facto in donor mobilization and selection, blood collection, transport, storage and transfusion. The lack of constant and guaranteed electricity supply, inadequate storage facilities for donated blood, limited capacity for blood component preparations and usage at hospitals is rife. These setbacks have prevented economy of scale obtainable with bulk purchases of blood consumables in NBTS, raised the costs for blood procurement and have promoted unnecessary transfusion of whole blood rather than specific component therapy. [7] In addition to these, the absence of an effective oversight over hospitals by the

Nigerian NBTS has compromised the quality in blood transfusion processes. Haemovigillance at hospital-based blood services is deficient in Nigeria. Haemovigilance is a risk monitoring system integral to the practice of transfusion medicine whose ultimate purpose is to improve the quality and safety of transfusion therapy. [32] Coupled with these, there is a general paucity of blood transfusion professionals in the country which has, paved way unprofessional, unsupervised and segmented blood transfusion services at hospitals with a feared compromise to safe blood supply and professional negligent liability.[7] But more worrisome is the dominance of "family" or "family-replacement" allogeneic blood donors rather than the desirable voluntary nonremunerated and benevolent blood donor population at hospital-based blood transfusion centres. A family donor donates blood to a particular patient on request, persuasion or coercion and are motivated by financial, material gains or for other undisclosed reasons and without true benevolent or altruistic Characteristically, such directed donation from related or unrelated individual is used to meet the transfusion needs of the index patient at the time. On the other hand, the donation from a "family-replacement donor" though similar to a 'family donor', is used to replace an already used blood by his/her relative or patient. Quintessentially, the donor has already received a blood transfusion and a "family-replacement donation" is used for a replacement. Many paid blood donors disguise as either "family" or "family-replacement" donors by denying their financial inducements and donating poor quality blood which is unsafe and at risk of harming a blood recipient in the hospital with attendant risks of transfusion injuries and negligent liability. In any of these, the cost of donor recruitment is entirely borne by the patient needing that blood transfusion. [33] In an attempt to overcome these challenges and promote voluntary donation, blood donors who voluntarily donate blood community blood through mobilization outreaches organized by hospitals are motivated to become repeat, voluntary nonremunerated blood donors. However, many hospitals cannot effectively pursue this noble task due to lean finances and logistics. For instance, besides the perceived high cost of organizing blood drive outreach programmes, there is the fear of blood wastages if blood units are excessively collected as a result of

inadequate infrastructure and equipment for storage and processing of bulk blood collected at outreaches. Sometimes, lean budgets prevents accepted logistic components like paying return of transport fares for voluntary blood donors who come from far distances or refreshments and other acceptable necessary for blood recreational services hospital. These donor retention in the challenges have made identification, education, mobilization and retention potential voluntary repeat blood donors difficult and have further contributed to the prevailing spade of unsafe blood supply to hospitals. In the wake of these, there is a serious apprehension to blood transfusion due the new and emerging transfusion transmissible infections. These have culminated into varied religious beliefs, psychological and moral dilemmas in accepting blood transfusion and constitute potential weaknesses for litigations against medical practitioners who are central to all blood transfusion activities in hospitalbased transfusion services. In the midst of these, there are concerns of poor record keeping and poor quality control programmes at hospital based blood banks in Nigeria. [34] These have created great concerns for blood safety in most hospital-based transfusion services.

Blood transfusion practices and professional negligence

In his commentaries in the law of England in 1768, Sir William Blackstone coined the term "mala praxis" relating to injuries patients suffer and are caused by physicians due to professional neglect or want of skill. [16] In 1847 when the American Medical Association and standards of practice for medical practitioners were established, licensed physicians became exposed to malpractice litigations.[16] The significance of the term "malpractice" is that it is used to differentiate professionals who do harm although not willfully from nonprofessionals who do similar wrongs and for purposes of applying certain statutory limitations of tort liability. [16] In Nigeria, the medical code of ethics^[19] define malpractice as "......that act by a registered practitioner for whom he or she is found guilty by the statutory procedure, to have failed to meet the professionally accepted standards, method or decorum in any aspect or area of professional practice..." It is not all mistakes of medical practitioners engaged in blood transfusion

practices in hospitals that are punishable in law but those that occur from carelessness and negligence. Generally, whether in the context of a conduct inquiry, an inquest or a civil claim for damages that, the law does not aim to punish medical practitioners for all their mistakes except where it is established that his/her conduct amounted to negligence.[17,35] In South Africa, the test of negligence is an objective one and is based on the REASONABLE PERSON TEST. [35] In this regards, the finding of negligence against a person will arise if a reasonable person who finds himself or herself in the same circumstance as those of the person involved would have foreseen the reasonable possibility of his or her conduct injuring another and would have taken reasonable steps to guard against such an event but the person nevertheless failed to take such steps to guard against the event in question.[35] A medical practitioner cannot be said to be negligent by reason of a mere fact that, he or she made a mistake except if the error is one which a reasonably competent practitioner could not made.[35] Similarly, the medical cannot be held criminally practitioner responsible for a patient's death unless it is shown that s/he was negligent or incompetent, with such disregard for the life and safety of his patient that it amounted to a crime against the State. [17] According to Baron Alderson in Blyth v Birmingham waterworks, [36] negligence is "the omission to do something which a reasonable man would do or doing something which a reasonable prudent man would not do". [17] Sir Lord Denning MR in $Hucks\ v$ Cole,[37] ruled that, in order to reach the conclusion that a medical practitioner is negligent, his conduct should be deserving of censure or it should be inexcusable. Similarly, Hon Justice Ogbuagu of the Nigerian Supreme Court[38] defined negligence as "failure to exercise the standard of care that a reasonable prudent person would have exercised in a similar situation; any conduct that falls below the legal standard established to protect others against unreasonable risk of All these opinions by learned justices' highlight the facts that, the medical practitioner should always do what is right and not fail in doing what ought to be done with reasonable care to avert harm and such actions or inactions must be acceptable to the body of experts in the field of medicine to avert negligent liability. This was demonstrated in

Barnet Management ruled that "A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art." [39] Negligence is a question of fact and each case depends its peculiar facts upon circumstance.[17] Therefore, medical negligence accesses the action exhibited or exercised by the medical practitioner in comparison with other members of the profession acting under similar conditions. An expert testimony is usually required to establish it.[15] In professional negligence, an expert's opinion in the field of transfusion medicine is often required on the prevailing standards in the field including existing government regulations and applicable private standards and guidelines.[15] This is contrastingly different from ordinary negligence in which the actions of the practitioner are accessed based on "the reasonable man of ordinary providence" i.e. whether the actions of the medical practitioner negates what an ordinary person would have done in such a given circumstance. [15] Yet, some courts have broadened the evidence that can be introduced to establish the prevailing standard of care to include evidence about practices of other practitioners, hospitals and transfusion services of equivalent statues. [15] Additionally, the "Bolam test" lays a legal foundation for assessing the appropriate standard of reasonable care in negligence cases involving skilled professionals like medical practitioners^[39] and requires that "If a medical practitioner reaches the standard of a responsible body of medical opinion, he is not negligent".[17] Therefore, where the medical practitioner accused of a negligent act has represented himself or herself as having more than average skills and abilities, in line with the provisions of the medical profession, the bolam test expects the standards to be in accordance with a responsible body of opinion and therefore negligence cannot be proven.[17] Quintessentially, ethics form the legal basis for blood transfusion practice and any deviation may make a medical practitioner who is responsible for prescribing, administering and overseeing the production of blood services in hospital professionally liable negligence. In Nigeria, negligent litigations due to blood transfusion injuries by medical practitioners are generally not yet widely

decided. The adjudication system by the MDCN investigating panel and disciplinary tribunal of Medical experts may address blood transfusion injuries suffered by aggrieved patients, donors or their relatives. On the other hand, an adversarial system in a law court either without prior recourse to MDCN or as appeals of MDCN investigating and disciplinary tribunal decisions may be employed. In this later system, majority of malpractice suits are considered as tort actions of civil liability. [13,16] A "tort" is defined as any wrongful act, damage, or injury done willfully, negligently, or in circumstances involving strict liability, but not involving breach of contract, for which a civil suit can be brought, and which makes the perpetrator of the act liable under law to pay damages to the injured party. [20] Torts, in contrast to criminal cases, are private civil wrongs usually between individuals in which the remedy is a common law action for damages. [13,20] In this respect, a medical practitioner can only be held criminally responsible for a patient's death where it is proven that s/he was negligent or incompetent with such disregard for life and safety of his patient that it amounts to a crime against the state. [16,17] Historically, negligence was grounded on fault based liability where, the negligent action had to be proven to cause the injury [15] In this instance, the aggrieved or injured person has to prove that, the medical practitioner was negligent in his act and therefore liable for his faults. In India, the judgment between the Indian Medical Association v V.P. Shantha brought the medical professionals within the ambit of "service" as defined in the Consumer Protection Act, 1986. [30] In this judgment, "Service" includes the provision of facilities for a fee but does not include the rendering of any service free of charge or under a contract of personal service while "Deficiency" means any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service. Therefore, medical practitioners may be liable in their deficiencies at blood transfusion services in the hospital. In cases where the services offered by the doctor or hospital do not fall in the ambit of 'service' as defined in the Consumer Protection Act,

patients can take recourse to the law relating to negligence under the law of torts and successfully claim compensation. [40] Thus, the law of torts under civil laws takes over and protects the interest of patients at a point where the Consumer Protection Act ends and this applies even if medical professionals provide free services. $^{[15]}$ The onus is on the patient or the injured party to prove that, the medical practitioner was negligent and that the injury was a consequence of such negligent act. [15] Such cases of negligence may include transfusion of blood of incorrect blood groups.[41] Although three types of liabilities; personal, vicarious and strict liabilities exist for which the medical practitioner could be negligent, strict liability does not apply in the provision of blood transfusion service. This is because blood is a living tissue inherently variable and incapable of being rendered uniform or completely safe. [15] Therefore, the concept of "blood shield statues" is usually applied in blood transfusion practices to remove the practitioners from strict negligent liability. Strict liability was usually applied to hold manufacturers accountable for poorly designed products just by proving that, the product design by the manufacturers was faulty. Even in jurisdictions where blood shield statues have not been adopted, courts can decide that, strict liability should not apply in blood collection and storage. [15] Medical practitioners may hence be held liable for their insufficiency in services. Maiority professional negligence litigations are for personal liability based on allegations by the injured party contending that, the medical treatment s/he received did not conform to the standards imposed on the medical practitioner by law. [42] A medical practitioner may be liable for failure to attend to a patient urgently needing a blood transfusion or not providing a blood transfusion to a patient promptly in a timely manner or for administering a blood transfusion at a negligent rate or transfusion of wrong blood to a patient for whatever reason. Other times, the legal actions for which the medical practitioner could be subjected to in blood transfusion practice would be assault and battery (lack of an informed consent in blood donation or blood transfusion outside emergency situations); fraud and deceit (including running a blood transfusion service as merchandise for profit margins only, that is and selling of blood); imprisonment (holding or detaining the patient

until the bill for blood transfusion received at hospital-based blood service is paid); libel and slander (written or oral information published by the medical practitioner or the blood bank capable of damaging the reputation of a blood donor or recipient); invasion of the right of privacy (taking photographs and publicizing a blood recipient or donor without his or her express permission); and breach confidential communications (where the medical practitioner or his subordinates divulge information about a blood donor or recipient which he learned under the physician-patient privileged relationship). Besides vicarious liability may be held against a medical practitioner in blood transfusion practice not related to his or her direct actions or inactions but by an indirect action of others, usually those under his or her supervision, headship or leadership. This is based on the principle of "respondeat superior" implying that let the superior respond for the negligent act of his or her employee or subordinates because such superior is assumed to gain benefits through the actions of the employee. [15] In this regard, a Medical/Surgical Consultant (a medical practitioner fully trained to specialize in patients care in a particular branch of medicine and who accepts total responsibility for patients care in the hospital) share a collective responsibility with house officers, resident doctors, subordinates and technicians under his or her supervision to deliver safe and appropriate care to patients and may be vicariously liable for inadequate supervision. [16,42] However, in order to establish liability, the complainant must prove the allegation against the medical practitioner by citing the best evidence available in medical science and by presenting expert opinion. [15] In some instances, the complainant can invoke the principle of "res ispa loquitur" or "the thing speaks for itself". This is particularly used where the injury suffered by the complainant is truly obvious. There is a negative correlation between competence and the likelihood of being sued with statistics showing that a competent specialist is as likely to be sued as a less competent general practitioner will. [42] The negligence equation can be expressed as: Duty of Care+ Breach of Duty +Damages arising thereof = NEGLIGENCE. [17] Therefore, for negligence to prevail against a medical practitioner it must be established that; the medical practitioner had a duty of care, there was a dereliction or breach of that duty, the

dereliction of duty resulted in damage to the patient; and consequently, the plaintiff was, in fact, damaged by the above act.^[15]

Duty of care in blood transfusion practice

Once a patient has enrolled and is accepted for treatment in the hospital, a duty of care arises as there is already a doctor-patient fiduciary relationship. The doctor-patient fiduciary relationship is one of the unique and privileged relationships based on mutual trust and faith. [16, 17] In the case of Dr. LaxmanBalkrishna Joshi vs. Dr. Trimbark Babu Godbole and Anr., AIR 1969 SC 128[43] and A.S.Mittal v. State of U.P., AIR 1989 SC 1570, [44] it was laid down that, when a medical practitioner is consulted by a patient, the doctor owes to his patient certain duties which are: (a) duty of care in deciding whether to undertake the case, (b) duty of care in deciding what treatment to give, and (c) duty of care in the administration of that treatment. A breach of any of the above duties may give a cause of action for negligence and the patient may on that basis recover damages from his doctor. [18] It has also been held in Abatan v Awudu (2003)^[45] that, "the relationship between a doctor and his patient is one of trust and confidence; a relationship where one has the power and duty to treat and restore the other to mental and physical well-being". This is the basis of all treatment in the hospital. Besides this, there is a consensual relationship between the patient and the medical practitioner. This consensual relationship however implies that, the patient's decisions are sacrosanct and he or she makes personal decision about the medical treatment or procedure he is being provided including any form of blood transfusion while the role of the medical practitioner is limited to advisory and guidance. [16, 17] Although a form of contractual relationship usually exists between the medical practitioner and his patient, the actions in blood transfusion practice are not usually based on contract. [15] The medical practitioner may be considered to agree impliedly to treat the patient in an appropriate manner only without assurances of a cure. [16] The legal theory in a contract exist where the medical practitioner entered into a contract with the patient for a successful treatment of the patient, and if the patient does not get such at the end of a blood transfusion, it is contended that a contract had been breached and that the patient should recover. [15] Hence, only few

courts agree with the application of contractual relationship theory in blood transfusion practices because there is no assured outcome. [15] However, suits are allowed on breach of contract, if the medical practitioner guarantee a result from his treatment.^[15,16] specifically promised to effect cure Generally, the legal platform considered by the is the doctor-patient fiduciary relationship and the malpractice actions as considered to be "tort" in nature whether the duty grows out of a consensual relation or has its origin in contract.[15] A Los Angeles court ruled in Patin v, The Administrators of the Tulane Educational Fund that, the transfer of blood from Touro Infirmary to Tulane did not fall within the Malpractice Act because there was no such health care provider-patient relationship between Touro Infirmary and Plaintiff. [46]

Breach of duty in blood transfusion

Before considering if there was a dereliction of care, the standard of care must be established. In an action against a hospital for alleged injury resulting from the receipt of blood products, the standard of care was defined as "that reasonable measure of safety and blood testing exercised by like and similarly situated facilities......"[47] Blood donors may sustain injuries for which negligence may be established but, most commonly, infringement of the desirable standard relationship is more pronounced between the medical practitioners and patients who are blood recipients. Medical practitioners who fail to prescribe or provide a blood transfusion when indeed the patient needs it or provides negligent services may be liable for breach of duty of care. In the Nigerian case of Okezie V Chairman Medical and Dental Practitioners Disciplinary Tribunal [MDPDT], [48] Dr Okeize was found guilty by the Medical and Dental Practitioners Disciplinary Tribunal of infamous conduct and gross professional negligence in 2001 and was suspended from practice for six months. The charges against him included among others failure to provide cross-matched blood as a of post-operative complications. Although this judgment was later set aside in court, it emphasized the value of blood transfusion as a duty of care. In Kalyani Dutta v. Tirath Ram hospital, the Delhi State Consumer Commission held that, not providing blood to a patient who could die if blood transfusion is delayed for some time or not

providing it at all is deficiency or a failed duty.[17] The Indian, Supreme Court viewed the transfusion of wrongly grouped blood to a patient as medical negligence upholding a compensation of Rs. 2 lakh ordered by the State Consumer Disputes Redressal Commission and confirmed by the National Commission to the husband and children of a woman who died due to transfusion of wrong blood group. [49] A medical practitioner who fails to examine a patient may fail in identifying the blood needs of the patient and consequently result in a blood transfusion injury, may be liable for negligence. In Surgeon Captain C.T Olowu v. The Nigerian Navy [50] a medical practitioner employed by the Nigerian Navy was held to be liable for failure to examine a patient who was admitted into the hospital. Besides these, other fallible points for medical practitioners may include; inappropriate blood request and negligent rate of blood transfusion, failure to inform blood donors who are harmed by blood transfusion through quality programme of haemovigillance, "look back" or "look forward". Another breach in the duty of care is existent in a consensual relationship where medical practitioners failure to obtain an "informed consent" before embarking on blood donation or transfusion.[16] This is breach of the patients' fundamental human rights to blood donation or transfusion. Also, where a patient or a blood donor withholds consent and the medical practitioner goes ahead to do the opposite, the medical practitioner may be liable in the tort of assault withstanding battery not improvements that may have been noticed with the treatment. The decision in Sideway v. Board of Governors Bethlem Royal Hospital, [51] that, "...the courts should not allow medical opinion of what is best for the patient to override the patient's right to decide what is best for himself, whether he will submit to the treatment offered him" laid the foundation in Okekearu v. Tanko[52] where a tort of battery was made out against a medical practitioner who treated a patient without obtaining an informed consent. Generally, the Nigerian Constitution guarantees a right to privacy of all persons and also the right to freedom of thought, conscience and religion found in Sections 37 and 38 of the 1999 Constitution of the Federal Republic of Nigeria as amended. [17, 25, 53] In the case of Abi v CBN, [54] a patient sued his doctor and the hospital for negligently diagnosing, prescribing

administering a drug on him.... Although his appeal failed on the grounds that he failed to call medical expert witness and for not pleading reps ipsa loquitor instead, it is submitted that a wrong diagnosis and administration of drugs where the side-effects compared against the benefits has not been communicated to the patient may lead to an Blood is a drug and actionable wrong. therefore, its administration must be evidencebased to avert negligent liability. It is important to provide proofs that there is a deficiency or a breach in service delivery either in the concept of ordinary negligence, medical negligence or In Williams v. professional negligence. Jackson Parish Hospital, the Louisiana Supreme Court, held that the pre-1982 claims in strict liability arising out of a defective blood transfusion are not traditional medical malpractice claims and, therefore, not governed by the Medical Malpractice Prescription Statute but were governed by the General Tort Prescriptive Statute. [55] However. in George vs. Our Lady of Lourdes Regional Medical Center, Inc where the Plaintiff fell down the steps of the mobile unit after donating blood, the 3rd Circuit Court of Appeal held that, the plaintiff's claim did not fall within the medical malpractice act stating that to constitute malpractice, health care professional services must be rendered to a patient.[56] In the Nigerian case of Tega Esabunor v. Faweya (2008)[57] where a medical practitioner was sued for providing medical relief to an under-aged child whose mother, being a Jehovah Witness adherent, had refused to agree to blood transfusion to save the life of the child. The medical practitioner was held not to be negligent haven acted pursuant to a court order obtained to that effect. A consideration of a religious objection to blood transfusion involves a balancing of several interests which includes; constitutionally protected right of the individual which is paramount, the state interest in public health, the safety and welfare of the general society and the interest of the medical profession in preserving the integrity of medical ethics and thereby its collective reputation. A medical practitioner faced with a dilemma of blood transfusion refusal in an adult of full age without mental incapacity or other incapability hindering him from making a decision could refer such a patient to an institution where the particular situation can be better tolerated as exemplified in M.D.P.D.T v.

Okonkwo.[58] An alternate approach is to provide treatment agreeable with the choice of the patient and admit him on those terms. This may be applicable in dying patients whose prognosis may not be influenced significantly by a blood transfusion. A similar position was maintained in Superintendent of Belckerton State School v Sackewiz^[59] where it was noted that, 'the dying are more in need of comfort than treatment'. Similarly, in M.D.P.D.T v Okonkwo, ^[58] the medical practitioner, Dr Okonkwo of Jeno Hospital admitted and gave his patient her chosen method of treatment until her death. Also, as it relates to over-riding public interest, medical practitioners who have under-aged children or minors that are denied blood transfusion against the interest of the society or medical profession can seek a court order or direction in order to be properly guided in his actions and guard against a claim in negligence or any other related tortuous or criminal liability as was held in Tega Esabunor v Faweya.^[57]

Proof of injury and incurred damage from a breached duty

It is crucial to establish that, the breach of care of duty through blood transfusion or otherwise most likely caused the injury directly or proximally. In considering causation, the concept of "foresee-ability" is relevant in determining whether certain actions or in actions constitute negligence. When the manner in which an injury occurs is so improbable or unpredictable such that the defendant could not have "foreseen" it, then the injury is not negligent. The more the foreseeable an untoward outcome is or was, the greater the potential exposure to negligent liability.[15] A cause may be defined as something that is necessary and or sufficient to determine a specific outcome. [12] This is called deductive deterministic causation and usually applies in criminal jurisprudence or criminal cases. In such instances, a jury requires necessary and sufficient conditions to be met sufficiently deliver a guilty verdict.[12] Circumstantial and forensic evidences could be necessary to support the proof of guilt beyond reasonable doubt. [12] Most commonly professional negligence is based on tort which is a civil jurisprudence and therefore, causation is usually based on probabilistic definition as it is also applied in statistical association in science. [12] Negligence as in civil cases is decided on the balance of probabilities.[12] The

court must be convinced that an alleged negligent act was directly or proximately associated with the injurious outcome and on the balance of probabilities, the outcome would not have occurred in the absence of the act. [12] The difference between legal and scientific probabilities is the definition of the probability threshold. In civil cases, at least 50% probability as evidence of causation is sufficient for a judges conviction of guilt whereas in scientific statistical methods, 95% probability p<0.05 is required.[12] The final element is to provide the proper measure of damages due to the blood transfusion injury suffered. These are called compensatory damages which may be economic or non-economic in nature. [15] An economic damage includes lost wages and medical expenses and other damages that can truly be attributed documented financial costs. Non-economic damages on the other hand are more subjective and may include pain, sufferings and physical impairments, emotional torture, loss of society inconveniences, companionship, humiliation, etc. which do not have definite financial costs. In order to determine the amount of damages, it is appropriate to consider the past, present and future economic and non-economic damages. [15] However, where the hospital, medical practitioner or the blood transfusion service can prove that the patient or blood donor engaged in high risk activities before the blood transfusion or donation and that, the morbidity or mortality could have been caused by a different source, it becomes difficult to establish the element of causation or attribute damages. [15] In his ruling at Indian Supreme Court, the lead Judge submitted that, "Although the patient survived for about 40 days after receiving a mismatched blood transfusion, it cannot be said that there was no causal link between the mismatched transfusion of blood and her death. [49] Wrong blood transfusion is an error which no hospital/doctor exercising ordinary care would have made. Such an error is not an error of professional judgment but in the very nature of things a sure instance of medical negligence..."^[49] Consequently, damages were granted to be paid to the husband and children of the deceased woman. [49]

Obtaining evidence in blood transfusionrelated cases against medical practitioners: limitations, progress and the future

Generally, even though there is a need for care and caution in prosecuting medical practitioners in the interests of society, the Courts have never stated till now, that they can never be prosecuted for negligence. [17,20] The Nigerian case-laws for instance suggest that, while the professional tribunal of MDCN has been very strict on reported cases of ethical breaches against her members, the Nigerian courts have been more liberal in their approach to cases of ethical breach against medical practitioners and have repeatedly quashed the decisions of the professional tribunals. [17] Justifiably, a certain amount of immunity is allowed to medical practitioners considering the noble service rendered by them and in view of the reports that some complainants often use criminal cases to harass or to extract unjust compensation. [17] Therefore, medical practitioners accused of rashness or negligence may not be arrested just because he or she has been charged for it but only if it is necessary to further investigate, or for the purpose of collecting evidence, or if there is a fear of absconding.^{117]} However, as patient's are becoming more aware of their fundamental rights, ethics and the law with respect to blood transfusion practice through travels and technological advancements, those who suffer any form of professional negligence may wish to seek appropriate redress but, they are often shrouded with limitations. A medical testimony is often required in professional negligence related to blood transfusion practice to prove that, the acts or omissions by the accused medical practitioner were in fact negligent. [42] It is the onus of the injured party or person to cite the best evidence available in medical science and accommodate expert opinions in the field of blood transfusion to establish a liability. These are often difficult to obtain due to scarcity of practitioners or lack of cooperation from those concerned. Therefore, in order to overcome the difficulty encountered in obtaining expert witnesses, courts in some jurisdictions now permit the introduction of medical textbooks, publications, treatises, hospital bylaws, and other accrediting and licensing bodies rules and regulations to establish deviation from standard medical practice.[42] Previously such materials were not permissible as evidence as they were held to be "hearsay" evidence, due to the fact that their authors were not present in the courtroom to be questioned and cross-examined. [42] Also medical practitioners in practice outside the local community may now testify about the standards of medical practice including blood jurisdiction.[42] another transfusion in Previously, the courts had held that only local physicians could testify to the standard of care in their local community. [42] Some courts have become more liberal in recognizing situations in which negligence by allowing the doctrine of res ipsa loquitur thereby dispensing with the burden on the plaintiff to produce expert medical testimony to support his case. [42] Previously this doctrine was applied primarily in foreign-body cases but now all the plaintiff has to do is to prove that the defendant medical practitioner was in control of the procedure alleged to have caused the injury. [42] These may deter plaintiff from successful litigation.

notwithstanding, professional These negligence in medical practice have been on the increase. [13] In developed countries, legal actions due to blood transfusion injuries have increased over the years. [60] Even in developing countries like India, [22] and Nigeria, [20] as the world is becoming a global village, medical litigations are becoming more popular. The reasons for the increase in medical liability suits in recent years are not fully understood. It is however obvious in recent times to identify medically negligent errors particularly by utilizing decided cases. [61] These have made possible the availability and documentation of cases which hitherto were not universally available. Additionally, there seem to be vast advances in knowledge and medical skills which has evolved and refined medical law including some medico-legal concepts in blood transfusion practice. [8,12] For instance, where enlightened care seekers perceive the actions of the medical practitioners as failing to measure up to the blood transfusion service obtained in another facility within the country or abroad or as depicted in television shows without considering local standards. These have made the appreciation of transfusion related injuries more glaring. Some of the other reasons for the increasing litigation suits includes: medical practitioners not admitting their limitations either in training or experience in blood transfusion practices and instead, adopting practices beyond their scope or those offering

blood transfusion as a default without recourse to true evidence-based benefits; loss of respect and confidence on the practitioner because of personality crisis or perceived incompetence or a breached communication with patients or blood donors that creates suspicion. Also, where medical practitioners insist payment for family replacement blood donations transfused to their clients by non-legal measures adopting including detention in hospital and physical assault as indemnity measures or failure to obtain an informed consent in blood donation or transfusion and where a client is given a false assurance of cure to be achieved following a blood transfusion which is eventually not achieved. In other respects, thoughtless remarks made by one medical practitioner against another or failure of medical practitioners to pursue and embrace an alternative conflict resolution to settle blood transfusion litigations out of court possibly contribute to the increased spade of blood transfusion related litigations. Undoubtedly the threat of professional liability suits in the hospital-based blood transfusion service may cause medical practitioners a move away from compassion-centered care towards so-called defensive medicine, [62] discourage the performance of new procedures which might be helpful to a patient [42] as well as devastating emotional effects on these practitioners who are affected in malpractice suits. [63] However, some have led to beneficial changes in blood transfusion practices in order to avert negligent liability. These include many time-consuming chores that seemed unnecessary in blood transfusion practice including record keeping, inventory and general public health concerns in the hospital blood bank or transfusion centres. In general, these and emerging legal challenges are re-defining blood transfusion practice, and it is hoped that, as evidencebased medicine rapidly evolve, transfusion will no longer remain unquestioned or be regarded as being essential in the management of many medical and surgical situations.[12]

CONCLUSION AND RECOMMENDATIONS

Blood transfusion is beneficial in many circumstances and may even be life-saving if carried out on precise and evidence based indications. Our findings in this study show that, medical practitioners at hospital-based

blood transfusion services are directly or vicariously liable for professional negligence and that, potential weaknesses exist at hospital-based blood transfusion practice for which s/he may be culpable including; transfusion transmissible infections, blood group incompatibility, haemolytic transfusion reaction, failure to obtain an informed consent as well as challenges of haemovigillance. Also, decided court/tribunal decisions medical practitioners including withholding a blood transfusion when in deed the patient needs it or transfusing group incompatible blood transfusion or failure to obtain an informed consent for blood transfusion Witness Jehovah's adherents including indicate that, the weight of professional negligence in blood transfusion practices does not spare the medical practitioner.

The supply of safe blood and adherence to best practices in blood transfusion is undoubtedly, a panacea to preventing litigations due to negligent hospital-based blood transfusion practices. Therefore, medical practitioners who are at the fulcrum of all transfusion safety programmes must rise up to their bidding by embarking on blood transfusion cautiously even when there are proven evidence-based benefits and effectively overseeing the organization and operations of all hospital-based blood transfusion services.

For the safety of blood transfusion, step by step procedure must be adopted in hospital-based transfusion centres in Nigeria. This should include informed consent, immune-haematological results, and specific prescription about quantity and quality of blood products. [22,64]

It is also apt that, the indications and the planned transfusion including all issues relating to the blood transfusion must be recorded in the patients` hospital case file and kept in safe custody for a particular period of time as the law require for the land. In the absence of such laws in Nigeria, these records should be kept for 30 years as it is done in some developed countries like France^[19,62] as these may avert possible blood transfusion related litigations.

The MDCN has recognized that the quality of care declines as physicians are further out of training and has taken steps toward annual recertification of all medical practitioners on their competence to practice the profession in Nigeria through the "continuing professional development (CPD)". The implementation of this activity has provided an opportunity for updated knowledge on emerging Medicare including blood transfusion and ignorance will not be an excuse in law and medical found to be practitioners professionally negligent in blood transfusion practice, risk being prosecuted by the MDCN for infamous conduct with consequences of suspended practice or premature termination of lifelong aspirations to practice medicine if his/her name terminated from the medical register. Besides these, guilty medical practitioners could incur losses through compensations or appropriate criminal sanctions. Therefore, policing and purging of the medical profession from within is apt and should be sustained as this will be better than from outside. [42]

However, it must be realized that, it is through the lessons of our everyday errors that we can design our work environment to be less error prone and more error tolerant. [65] Therefore, litigations due to blood transfusion injuries may appear punitive attracting damages to the liable medical practitioner but, could also help strengthen blood bank practices and ensure safer blood supplies for the communities particularly at hospital-based transfusion centres. There are concerns that, over zealous application of the precautionary principle exert undue influence on decision making and in contribute to increased costs of Therefore, the adjudication systems should be mindful and protect the medical practitioners who may be too careful in protecting themselves against litigations and shy away from some interventions in blood transfusion practice at hospital-based blood transfusion centres at the detriment of the patients or blood donors. In this light, mediation and arbitration systems which are less expensive, faster in resolution and managed medically knowledgeable by individuals, [16] should be encouraged.

Finally, the implementation of a compulsory insurance policy for medical practitioners though expensive remains the best approach for medical practitioners in the event that, there are proven medical negligence charges to be indemnified.

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