



# **Informed Consent in Transfusion Medicine: An Ethical Obligation Or a Legal Compulsion to Avert Liabilities for Negligence to the Health Care Provider**

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## **Authors' contributions**

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## **ABSTRACT**

Blood transfusion is oftentimes life-saving but associated with risks which ought to be disclosed by the health care provider as an ethical obligation and legal requirement. The practice of informed consent to transfusion medicine is quite new and few studies have comprehensively x-rayed its historical, ethical and legal implications with an in depth consideration of professional negligence using decided cases by the adversarial and arbitration systems. PubMed, PubMed Central, Google Scholar, African Journal on Line (AJOL) electronic databases were searched using combined keywords like; "Blood transfusion and informed consent" "informed choice to transfusion medicine practice", "consent in transfusion medicine", "health care giver and consent to transfusion therapy",

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“transfusion consent and the health care seeker”, “liability and informed consent to transfusion” and “contemporary issues in medical negligence”. Relatedly, printed materials were considered. The 91 studies that met the inclusion criteria were considered with highlights showing that, informed consent to medical treatment generally is an age long practice running from roman civilization to the present but its advocated practice in transfusion medicine a recent event. The practice is also generally low in comparison with informed consent taken for other treatments in similar settings. The consequences of dereliction including infamously conduct amongst professionals or negligence with direct and vicarious liabilities in adversary systems has been set in precedent judgments. These in addition to the present day patient-centered care model as global best practice and quality in health care delivery is compelling for health care providers to imbibe the practice not as a form of defensive medicine but a repertoire to quality and responsive Medicare service.

*Keywords: Informed consent; blood transfusion; transfusion medicine; professional negligence; liabilities; health care-seeker; health care-provider.*

## 1. INTRODUCTION

Blood Transfusion as a medical procedure whereby blood is collected from the circulation of one individual and infused into another for practical therapeutics indications, is a relatively new specialty with relevant medico-legal concepts like the informed consent process. Blood is included on the list of the World Health Organizations (WHO) essential medicines and in the United States of America (USA), is deployed as a life-saving medication in more than 10% of all hospital stays that include a procedure [1-4].

Few institutions consider separate informed consent for blood transfusions; rather, the patient gives this consent as part of a more comprehensive statement [5]. In many developing countries a specific requirements of the informed consent in transfusion is not compulsorily sought by stakeholders in transfusions i.e. patients, health care providers, hospitals, governmental agencies etc. Countries like the USA, have adopted the practice, while others like the United Kingdom (UK) are reportedly lacking the legal requirement with greater emphasis on patient involvement and choice about medical treatment without corresponding emphasis on blood transfusion consent. Obtaining specific informed consent in blood transfusion is an important step towards "recognizing the importance of patient autonomy in the context of decision making about medical treatment" [6]. Proponents to this view question on whether the low risks of 0.019% being the calculated serious adverse events associated with blood transfusions practice in UK is justifiably high enough to pursue specific informed consent in blood transfusion [6]. However, many developing countries with low health care delivery services and high

prevalence of diseases, poverty and illiteracy may not be covered by this view.

The Institute of Medicine Committee of Healthcare defined informed consent to transfusion medicine as being a patient centered care; “providing care that is respectful of and responsive to individual patient preferences, needs and values and ensuring that patient values guide all clinical decisions. It emphasizes on an effective dialogue between the health care provider and health care seeker or patient in the decision making process [7-8]. Many of the risks to transfusion recipients including immunological and non-immunological have long been recognized. Recently emerging transfusion transmissible infections (TTIs) not routinely detectable in donor blood, residual infections even in routinely screened TTIs occasioned by the quality of test kits, infrastructure and manpower competencies that differs between developed and developing economies has raised deeper concerns on the choice of transfusion related therapies to be more care seekers based. Relatedly, whole blood donation earlier believed to be free of adverse effects has been shown to be otherwise [9-11].

A report of informed consent among physicians found that, twenty-one percent of respondents had been sued, and in 42% of these instances, the informed consent process was an issue [12]. With the current global advances in technology the practice of Medicine, knowledge and spread of medical information is at a high pace revolution with the medical law and e legal concepts including the informed consent playing central roles in litigations against health care providers [13-16]. This globally rising trends has been identified in some developed and developing economies [15,17-20].

The practice of informed consent to transfusion medicine is quite new and there are few studies to the best knowledge of the authors that comprehensively x-rayed its historical, ethical and legal implications with emphasis on professional negligence and negligent liability to the health care provider using the decided cases in the judicial systems. The aim of this study is to review the historical developments, ethical and legal implications associated with the informed consent in transfusion medicine to the healthcare provider with reference to the settled or decided cases by the courts and decisions of arbitration disciplinary panels for infamous conduct or misconduct by professionals in medical disciplines.

## 2. METHODOLOGY

The review was carried out through a literature search on PubMed, PubMed Central, Google Scholar, African Journal on Line (AJOL) electronic databases were searched using combined keywords like; "Blood transfusion and informed consent" "informed choice to transfusion medicine practice", "consent in transfusion medicine", "health care giver and consent to transfusion therapy", "transfusion consent and the health care seeker", "liability and informed consent to transfusion" and "contemporary issues in medical negligence". Relatedly, printed materials were considered where applicable. All literature retrieved together with judicial decisions and rulings or awards of arbitration panels of professionals in disciplinary tribunals set for professional negligence against care givers in the field of medicine were all considered in line with the aim of the review. Only materials (hard or soft copies) whose contents met the criteria for the review were included while others were excluded. A total of about 2368 literature searches were retrieved and about 91 that met the criteria for inclusion in this research were utilized.

### 2.1 The Informed Consent and Transfusion Medicine: Historical Perspectives

"*Informed consent*" is a legal and ethical doctrine derived from the principle of respect for the autonomy or independence of the patient or health care seeker.

The "Health care provider" is considered a person, partnership, limited liability partnership,

limited liability company, corporation, facility, or institution licensed or certified by this a state to provide health care or professional services as a physician, hospital, nursing home, community blood center, tissue bank, dentist, registered or licensed practical nurse or certified nurse assistant, offshore health service provider, certified registered nurse anesthetist, nurse midwife, licensed midwife, nurse practitioner, clinical nurse specialist, pharmacist, optometrist, podiatrist, chiropractor, physical therapist, occupational therapist, psychologist, social worker, licensed professional counselor, licensed perfusionist, licensed respiratory therapist, licensed radiologic technologist, licensed clinical laboratory scientist, or any nonprofit facility considered tax-exempt [21]. Similarly, a "care seeker" or "patient" is defined as a natural person, including a donor of human blood or blood components and a nursing home resident who receives or should have received health care from a licensed health care provider, under contract, expressed or implied [21].

Generally two rights derived from autonomy are accorded legal protection. The constitutional right to life and the right to the dignity of the human person, followed by the right to bodily well-being, protected by professional negligence rules. Therefore healthcare providers owe care seekers a duty to seek and obtain an effective autonomous authorization before a treatment or procedure is undertaken on him or her failure of may amount to dereliction [10,22]. The expression "informed consent" has simply been transposed in Italian and roughly translated in an ambiguous fashion into "*consenso informato*" when, on the contrary, it should be referred to as "*informazione per il consenso*" "information for consensus" not only to respect the concept but, surely, for a more correct deciphering and a more precise interpretation related to the numerous concepts it presupposes and implies [23].

Reports suggest that as early as the Roman civilization, consent was sought by physicians. Greek and Roman, documents have documented how the doctor's intervention had, in "some way", first to be approved by the patient. The Hippocratic physician respected a principle of professional responsibility which was more religious and of a moral type, but, from a legal point of view, very weak inasmuch as it depended upon regulations elaborated by human beings [23-24]. Plato, in ancient Greece, connected consent with the quality of a free

person. In Alexander the Great's era and later on in Byzantine times, not only was the consent of the patient necessary but physicians were asking for even more safeguards before undertaking a difficult operation. Sometimes a symbolic affirmation was carried out by the patient by way of offering a "sword" or "lancet" to the surgeon. This signified that, "if God heals the patient, the doctor boasts but if not, the doctor is not considered responsible [25].

During the medieval also called the dark period of Western culture the Islamic culture in this period had its big boom and the contributions of Hippocrates (d. ca. 375 BC) received attention from Muslim physicians and other works were produced during this period by the Islamic intellectuals. This development formed the basis for the European Renaissance in many aspects including the Islamic medical ethics that had considerable influence on the initiation and development of the European medical ethics in many of its aspects [26-27]. In the post renaissance period, reports on informed consent to medical treatment first appeared in the United States of America (USA) at the beginning of the 18th Century. It was however rather focused on and limited to the simple rights of the patient to give his/her approval of the health intervention. This emergence and prominence of the care seekers autonomy deviated from the initial thought that the physician or health care provider is all knowing and only acting in the interest of the patient or health care seeker who was considered an ignorant person not having the knowledge, intellectual capacity or moral authority to oppose or disagree with the wishes and decisions of the physician or health care provider [23-24].

In the early part of 20<sup>th</sup> century, the German government's guidelines in 1931, emphasizing on present day requirements of informed consent and independent ethics review, were flouted by physicians. The shocking Nazi human experiments gave rise to the much-acclaimed code—the Nuremberg Code. Among its 10 principles the longest principle is on informed consent. Later, the Helsinki Declaration stated the importance of having an ethics committee review a research proposal, which included an informed consent document comprising patient/participant information sheet and informed consent form [24] The Tuskegee trial in US about 7 years later led to the Belmont Report for human protection and the informed consent [24]. It is pertinent to note that, the practice of

obtaining informed consent has its history in, and gains its meaning from, medicine and biomedical research but many of the initial discussions on informed consent were not specifically targeted at transfusion medicine.

In *Schloendorff v Society of New York Hospitals*, [28] the New York Court of Appeals held that, carrying out surgery on a patient without his or her "consent" amounted to assault. However, the term "informed" emerged in *Salgo v Leland Stanford, Jr University Board of Trustees* [29] where the court ruled that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment, i.e. "informed consent". Following this, serious discussion on the meaning, import and the jurisprudence of informed consent thus began in medicine, research, law, and philosophy around 1972 [30]. When the American Red Cross blood donor service was inaugurated in 1941, the consent practiced in donation was merely a legal document absolving blood service providers of any liabilities for blood donation and not a true consent in itself [10]. The publication of the American Association of Blood Banks (AABB) in 1957 also omitted consent for blood donation, and specific inclusion of informed consent to blood donation only became introduced in the AABB standards for blood bank services in 1976 [10]. However, the revision of the laws and the definition of malpractice in the USA in 1976 specifically included liabilities arising out of defective transfusion as follows; "*any unintentional tort or any breach of contract based on healthcare or professional service rendered or which should have been rendered by a health care provider to a patient and also includes all legal responsibilities of a health care provider arising from defects in blood tissue transplant drugs and medicines*" [21]. This implied that, defects in the informed consent to transfusion medicine was specifically recognized.

## 2.2 Ethical Considerations of the Informed Consent in Transfusion Medicine

Professional ethics as they apply in transfusion medicine has been described as the moral bond that links a profession, the people it serves, and the society [31]. Generally, ethical principles exists in medicine, law and research which revolves around; respect for persons (autonomy, self-determination, protection of vulnerable

groups, informed consent); beneficence (equitable distribution of risk and benefits, equitable recruitment of study participants, special protection of vulnerable groups), non-maleficence (avoiding harm) and justice (physical, mental and social well-being, minimal risks) as responsibilities of care providers to care seekers [32].

Ethical provisions rigidly regulate transfusion medicine practice because blood is a perishable resource, costly to acquire and requiring good inventory practice for quality service delivery, product availability and for the related implications for liabilities for negligence [33-35]. Internationally, the Ethics of Blood Transfusion of International Society for Blood Transfusion (ISBT) of 5<sup>th</sup> September 2006 included the informed consent which specified in ethics 1 that, an informed consent should be obtained from blood donors before donation and for the use of his/her donated blood. In ethics 12 it specified that, patients should give an informed consent before being administered any form of blood therapy and any valid advance directive on blood transfusion must be respected. Again, ethics 3 further buttressed on the components of a valid informed consent to include education or disclosure on risks, complications, alternatives or implications of refusal of such consent and the reasonable expectations for actions and inactions [36]. The National Guidelines for Blood Transfusion in some countries also prescribe to the informed consent process prescribed by the ISBT ethical code [16,37-38]. The revised version of the ISBT Ethics of Blood Transfusion, published in 2017 further advised health care provider in transfusion medicine to avail care seekers any required knowledge on the subsequent legitimate use of their donations and if it encompasses both possible commercialization of the products derived from the donation and whether the donation might be used in research i.e. not just the attendant risks of the donation procedure itself but also the potential repurposing of surplus donated blood for research bio-banks and the sale of fractionated plasma components [39]. Similarly, the ethical standards for blood banks and transfusion services of the American Association of Blood Banks (AABB ) specifically indicates that, at a minimum, the elements of the informed consent shall include the following; a description of the risks, benefits and transfusion alternatives including (non-treatment); the opportunity to ask question; the right to refuse or accept transfusion[40-41].

The major elements of the informed consent consist of disclosure (benefits, risks, costs, implications of treatment and non-treatments etc.), comprehension (ability to understand information put forward in a language best understood and if possible by a family member in familiar dialectal ascent for full comprehension), voluntariness (freedom of coercion and the care seeker given sufficient time frame to make decisions), competence (above legal age requirements and not suffering from any mental health disorder) and decision or authorization (acceptance or decline) [15,42]. Professionals like medical practitioners, Nurses, Medical Laboratory Technicians and Scientists and other health care providers competent in the informed consent process owe the ethical obligations of providing the informed consent process to care seekers in their different lines of duty [43-48].

### **2.3 Legal Effect of Informed Consent to Transfusion Medicine; Malpractice, Negligence and Negligent liabilities**

The Black's Law Dictionary, defines informed consent as *"a person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives."* It is also *"a patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure"* [49].

The informed consent otherwise also termed *"knowing consent"* to transfusion medicine relates to the right to respect the voluntarily, independent and informed decision of the patient or care seeker on adequate comprehension of the risks involved and the benefits thereof in a mentally stable individual without any form of coercion or undue influence for the donation or transfusion service. In case of minors, informed consent must be obtained from their surrogate designates or in line with the law. In the event that specific consent cannot be obtained in transfusion therapy especially in unconscious and in emergency, the basis for treatment by transfusion must be in the best interests of the patient. Any valid advance directive declining a blood transfusion must be respected. Globally, the operations of blood transfusion services are guided by extant laws, Acts, Regulations or statutes which in turn helps in shaping blood transfusion services [16,44,50-51]. Any

contravention of the provisions of such legal instruments constitutes an offence under the law. In the UK, the informed consent must be by trained health care provider fully conversant with the practice and procedure, including specialized nurses, medical doctors etc [52]. In the USA however, the Supreme Court judgment in *Campbell M. Montgomery v Lanarkshire Health Board*, [53] held that; “the requirement of ‘informed choice’ or ‘informed consent’ by patients in medical treatment rests fundamentally on the duty of disclosure by medical practitioners” [53] Relatedly, in some countries like Nigeria [51] and South Africa [16], the responsibility of oversight to all blood donation and transfusion is vested on the medical practitioners who also bears the responsibility of obtaining an informed consent to blood transfusion from care seeker.. The hospital or institution who employs such health care professionals (or permits them to practice in their facilities) also share in the responsibility of selection, education, retention and supervision of her staff to practice in line with global best practices in order to avert liabilities for negligence to such institution, organization or hospital [16,34]. Where the extant laws, regulations or code of ethics of a particular country requires the medical or healthcare provider responsible for blood transfusion to inform a patient of the need to transfuse blood to him or her, such healthcare provider is under an obligation to do so failing which it will be viewed as a of the breach under the law. Such healthcare provider may then be liable for negligence should the care seeker seek redress. It is also important to note that whether a particular law or regulation or code of ethics prescribe that the care seeker be informed of the blood transfusion or not, it remains a moral obligation to be adhered to by such concerned healthcare providers. A deviation from the informed consent process may result in an error or mistake termed a “malpractice” and this term “malpractice” differentiates professionals who do harm although not willfully from non-professionals who do similar wrongs. It is also useful in the application of certain statutory provisions of liabilities in tort [51]. The health care provider cannot be held criminally responsible for a patient’s death unless it is shown that he or she was negligent or incompetent, with such disregard for the life and safety of his patient that it amounted to a crime against the State [54].

Sir William Blackstone coined the term “mala praxis” relating to injuries caused by physicians

due to professional neglect or want of skill for which he reported in his commentaries in the Laws of England in 1768. However, licensed physicians only became vulnerable to malpractice litigations by virtue of their practices when the American Medical Association and standards of practice for medical practitioners were established in 1847 [51,55-57]. In the landmark judgment of Baron Alderson in *Blyth v Birmingham Waterworks* 1856 , the court affirmed that, “Negligence is the omission 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 [58]. The Court in this judgment distilled further the essence of basic negligence stating that, the mere fact that someone has been injured by another or another’s property does not mean negligence has occurred. Rather, one must act or fail to act in a way that someone of ordinary prudence would not act or fail to act. Otherwise, there is no fault and no liability. This definition was also adopted in *Ojo v Dr Gharoro* [59], and *Odinaka & Anor. v. Moghalu* inter alia [60]. The initial definition of negligence as provided in the UK court decision in *Bolam v Friern Hospital Management Committee* [1957] [61] therefore laid down the typical rule for assessing the appropriate standard of reasonable care in negligence involving skilled professionals such as doctors and known as the BOLAM TEST. Bolam test stipulated that “if a doctor reached the standard of a responsible body of medical opinion, he or she is not negligent”. In this sense, medical negligence accessed the actions of the health care provider in comparison with other members of the profession acting under similar conditions. The expert’s opinion is often based on the prevailing standards in the field including existing government regulations and applicable private standards and guidelines [62]. Relatedly, Sir Lord Denning MR in *Hucks v Cole*, [63] 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. The initial concept of negligence as determined in the US judiciary based on the “bolam test,” was however changed in *Canterbury v Spence* (1972) from a ‘professional practice standard’ to a ‘reasonable person standard’ which undermined the tradition and practice of physicians not willing to testify against each other, and largely opening the floodgates to the far more litigious medico-legal culture today [64]. Currently, it is considered as the “the omission to

do something which a reasonable man would do or doing something which a reasonable prudent man would not do" [54].

In another judicial pronouncement, the Court 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 harm" [65]. Similarly, the test of negligence in South Africa, is based on the *reasonable person test* wherein the proof of negligence against a person will arise if a reasonable person who finds himself or herself in the same circumstance as that 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 [66]. Relatedly, the judgment of the UK Supreme Court departed and overruled the earlier House of Lords case in *Sidaway v Board of Governors of the Bethlem Royal Hospital*, in reconsidering the duty of care of a doctor towards a patient on medical treatment and also changed the *Bolam test* in medical negligence by introducing the general duty to attempt the disclosure of risks [53].

In *Indian Medical Association v V.P. Shantha* the duties of medical professionals were brought within the ambit of "service" as defined in the Consumer Protection Act, 1986 [67]. In this judgment, "Service" was defined to include the provision of facilities for a fee but does not the rendering of any service free of charge or under a contract of personal service. "Deficiency" on the other hand was defined as any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be 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 [54]. Given this scenario, medical practitioners and health care givers became liable in their deficiencies at blood transfusion services. In cases where the services offered by the health care provider do not fall in the ambit of 'service' as defined in the Consumer Protection Act, patients often took recourse to the law relating to negligence under the law of torts and successfully claimed compensation such that, the law of tort took over and protected the interest of patients at a point where the

Consumer Protection Act ended. The tort applies even if medical professionals provide free services. Besides the adversarial system, the arbitration system may be used to try professionals is some by professions in a medical field who err in their practices. Therefore, whether in the context of a conduct inquiry by professional disciplinary tribunals or an inquest or a civil claim for damages, the law does not aim to punish health care providers for all their mistakes except where it is established that his/her conduct amounted to negligence [51,66]. The basic elements of proof in negligence are: the defendant owed a duty of care to the plaintiff; the defendant breached the duty; the plaintiff's injury was directly or proximately caused by the breach; and the plaintiff suffered damages as a result. The negligence equation can be expressed as:

Duty of Care+ Breach of Duty +Damages arising thereof = NEGLIGENCE [54].

Negligence under the law is a therefore a civil wrong or tort 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. Torts, in contrast to criminal cases, are private civil wrongs in which the remedy is a common law action for damages [54]. Therefore, obtaining an informed consent from a care seeker before commencement of treatment is a constitutionally acclaimed fundamental right of the care seeker which may constitute the grounds for battery in the law of tort or criminality in cases of violation. It is a sensitive legal requirement, implying that a consensus or a meeting of minds has been met and is not a mere completion of a prepared consent form.

#### **2.4 Duty of Care Related to the Informed Consent in Transfusion Medicine**

The broad doctor-patient relationship, one of the unique and privileged relationships based on mutual trust and faith forms the legal basis for which medical care activity takes place between the care provider and care seeker [68]. This relationship extends to transfusion medicine with a general acceptance that the doctor (and the blood transfusion service) owe a 'duty of care' to the patient and is in a unique position to prevent harm if responsible steps are taken to make the blood supply chain as safe as possible [16].

Therefore, whether in the context of blood donation or transfusion, a duty of care arises on the basis of this "doctor-patient" fiduciary. This consensual relationship empowers the health care seekers' decisions to be sacrosanct over the health care providers or giver'. He or she makes personal decision to the health care giver about the medical treatment or procedure he is being provided including any form of blood transfusion while the role of the medical personnel is limited to advisory and guidance [51,54]. Per Regina Obiageli Nwodo, J.C.A in Nigeria had ruled that, for a claim in negligence to succeed the appellant must prove that the respondents owed him a duty of care and was in breach of that duty [69]. In *Abatan v Awudu* [70] the court reiterated this duty of care as follows "*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.*" In *Caparo v Dickman* [71] the absence of a relationship of "proximity" prevented a proof of negligence against Dickman. Similarly, a Los Angeles Court ruled in *Patin v The Administrators of the Tulane Educational Fund* [72] 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 [73]. Similarly, in *George vs. Our Lady of Lourdes Regional Medical Center, Inc* [74] where the Plaintiff fell down the steps of the mobile unit after donating blood, and sued for negligence one of the grounds of the failure to adequately warn a first time blood donor like her of the risks and side effects associated with blood donation (informed consent); the 3<sup>rd</sup> Circuit Court of Appeal held that, the plaintiff's claim did not fall within the medical malpractice Act because health care or professional services were not rendered to a patient according to law since the duty of care post donation could not be established.

However, in *Smith v Hospital Authority of Walker Dade and Catoosa* [75], where Smith sued the hospital seeking damages for alleged negligent act committed by its technicians, nurses, employers and agents while extracting blood from the plaintiff and as a direct result of which the plaintiff allegedly sustained serious and permanent injuries to the median nerve of his left arm. The court of Appeal held that, even though the hospital argued that the blood donor voluntarily agreed to the withdrawal of his blood as a donor and at the time of doing so had

executed a written release absolving the hospital from any liability from the procedure, this release was void as a violation of public policy and could not shield the hospital from any negligent acts it engaged in during the withdrawal of the plaintiffs blood. It further states that: "*once a donor is unquestionably placed under the control of the hospital personnel and he must rely on their professional skills as in any other hospital-patient relationship*".

The actions in blood transfusion practice are not usually based on contract. A legal theory in a contract exist where the health care practitioner enters into an agreement with the care seeker for a successful treatment, and if the care seeker does not get such at the end of a blood transfusion, it is contended that a contract had been breached. In this instance, the suit is allowed on breach of contract, because the health care practitioner specifically promised to effect cure or guarantee a result from his/her treatment. Since this is not usually the case the application of contractual relationship theory in blood transfusion practices is not usually applied, rather, the legal duty of care necessitating the health care practitioner to give an informed consent to transfusion medicine stem from this "doctor-patient fiduciary" relationship.

## **2.5 Breach of Duty of Care in the Informed Consent in Transfusion Medicine**

In considering if there was a dereliction of duty of care to give an informed consent to transfusion therapy, the standard of care must be established. The adequacy or the required standard for informed consent is determined by the state with three acceptable legal approaches; (a) Subjective standard: *What would this patient need to know and understand to make an informed decision?* (b) Reasonable patient standard: *What would the average patient need to know to be an informed participant in the decision?* (c) Reasonable physician standard: *What would a typical physician say about this procedure?* Many jurisdictions use the "reasonable patient standard" because it focuses on what a typical patient would need to know to understand the decision at hand [76]. The courts rely on "reasonable patient test" to see if adequate information was given to the patient for a valid informed consent [24]. The South African Supreme Court judgment in "*Castell v. De Greef* [77] defined the "reasonable patient" standard for disclosure in an informed consent process



defining a risk as being material if "in the circumstances of the particular case: (a) a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or (b) the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it." Relatedly, in this case the Court blended the "reasonable patient" test with the individual patient's "additional needs test" and determined the standard of care as being in accord with the fundamental right of self-determination and individual autonomy [77].

In an action against a hospital for an alleged injury resulting from the receipt of blood products to suggest dereliction of duty, the standard of care was defined as *"that reasonable measure of safety and blood testing exercised by like and similarly situated facilities"* [78].

The healthcare provider who fails to obtain an "informed consent" before embarking on blood donation or transfusion or administers a form of transfusion therapy even where a patient or a blood donor withholds consent and the care provider still goes ahead to undertake the opposite action on him or her is in breach of the duty of care in the existent consensual relationship notwithstanding any improvements that intervention may have produced with the given treatment. In *Reibl v Hughes* [79] the Court stated unanimously that *"unless there has been misrepresentation or fraud to secure consent to the treatment, a failure to disclose the attendant risks, however serious, should go to negligence rather than to battery."* The case also marked the creation of a standard whereby a care provider must give the patient sufficient information so that an objective, reasonable person in the patient's position would be able to make an informed choice about a medical procedure. The case also settled the issue of when a physician may be sued for battery and when it is more appropriate to sue the doctor in negligence [79]. The decision in *Sideway v. Board of Governors Bethlem Royal Hospital*, [80] also reaffirmed that, *"...the courts should not allow medical opinion of what is best for the patient to over-ride the patient's right to decide what is best for himself, whether he will submit to the treatment offered him"* The New York Supreme Court, Appellate Division, reversed the judgment of the Supreme Court, New York County, and found that the right of a patient to determine her medical treatment included the right to refuse a blood transfusion based on religious beliefs [81]. Relatedly, in

*Okekearu v. Tanko* [82] a tort of battery was established out against a medical practitioner who treated a patient without obtaining an informed consent and resulted in amputation of a finger. In the ruling of the Court; *"...whatever way and from whatever angle one looks at the matter, it is clear that no consent was sought and obtained to amputate Tanko's finger, a duty which clearly rested on the appellant. He was negligent..... the appellant intentionally amputated the finger of Tanko, an act which amounted to battery"* [82].

In *Tega Esabunor v. Faweya* [83] a medical practitioner was sued for providing medical relief to an under-aged child whose mother, being a Jehovah Witness adherent, had refused to consent to blood transfusion to save the life of the child a case of dereliction of duty was not supported because it was carried out on the directive of the court. Similarly, Denise Nicoleau, a Jehovah's Witness, refused to consent to blood transfusions following a cesarean section. Despite her objection, the Supreme Court of Suffolk County authorized the hospital to administer the transfusions. The state argued that it had an overriding interest in preserving the life of a young, otherwise healthy person and an even more substantial interest in protecting an infant from loss of its mother, and further argued that a patient's right to decline lifesaving treatment should be limited to cases of terminal or degenerative disease [84]. A consideration of religious decline of consent to blood transfusion involving minors requires balancing of several interests which includes; the 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. 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 guide against dereliction of duty of care as was held in the two cases above [83-84]. Any health care practitioner faced with a dilemma of blood transfusion refusal in an adult of full age without mental incapacity or other incapability hindering him or her from making a valid decision and who are limited in their available alternatives to transfusion therapy could refer such a patient to an institution where expertise could be accessed and better care offered as exemplified in *M.D.P.D.T v. Okonkwo*

[85]. in order to avoid a dereliction of duty. Respect to the informed consent in transfusion medicine is sacrosanct and care providers should provide such treatment agreeable to the patient and admit him or her on those terms. In *Superintendent of Belckerton State School v Sackewiz* [86] the court ruled that, 'the dying are more in need of comfort than treatment' while in *M.D.P.D.T v Okonkwo* [85], Dr Okonkwo admitted and gave the patient her chosen method of treatment when she declined blood transfusion even until her death. Health care providers have a responsibility of honouring advance notice refusing blood transfusion even in emergency situation in order to avert dereliction of duty in the informed consent negligent cases. In *Malette v. Shulman* [87] liability for Battery was awarded against Dr. Shulman for tortuously violating his patients' rights over her own body by acting against the Jehovah's Witness card presented in hospital and for administering blood transfusion all the same without consent in the interest of the patient [87].

## **2.6 Proof of Causation, Measure of Damages and Application of Liabilities Related to the Informed Consent to Transfusion Medicine**

In establishing a case of negligence, Lord Atkin's advanced three necessities; the claimant and the defendant being in a relationship of proximity, the concept of reasonable foreseeability of harm, and more loosely, it being fair, just and reasonable to impose liability on the defendant for his or her actions [88]. The proof of and pronouncement of verdict for professionals may be through the adversary system in a conventional court or by the arbitration or mediatory system through the professional disciplinary tribunals against offenders in a given profession. Medical negligence comprises the majority of professional negligence lawsuits and is usually decided by establishing the basic four elements— the FOUR Ds: A. Duty owed to the patient, B. breach of the standard of care (Deviation), C. causation (Direct cause), and D. Damage to the patient. A party accused of medical negligence defends itself either by showing that one of these elements is missing or by establishing an affirmative defense. An affirmative defense is a legal argument in which the defendant admits the existence of all required elements, but argues that his or her actions should be excused nonetheless [89].

In considering causation, the concept of "foresee-ability" is relevant in determining whether certain actions or in actions constitute negligence. Where the manner in which an injury occurred is so improbable or unpredictable such that the defendant could not have "foreseen" it, in which case then the injury is not negligent. The more the foreseeable an untoward outcome is or was, the greater the potential exposure to negligent liability [62]. However, a failure to obtain a consent does not have any indemnity related to foresee-ability. Whether harm was caused or not, failure to obtain an informed consent in itself an infraction of the law and a dereliction of duty by the health care provider.

Causation is frequently divided into two separate inquiries: 1) whether the professional's actions in fact caused the harm to the patient, and 2) whether the professional's actions were the proximate cause of the patient's harm. Courts generally find it difficult applying this principle in deciding on cases of medical negligence as the most important factor in deciding such is the proximate cause and which can only be identified by medical expert [89]. Therefore, failure to avail an informed consent to the care-seeker for a consent or decline is truly a proximate cause of a harm in transfusion therapy. The proof of causation is defined as that necessary and or sufficient factor to determine a specific outcome. This is called deductive deterministic causation and is usually applied in criminal cases. In such instances, a jury requires necessary and sufficient conditions to be met to sufficiently deliver a guilty verdict. Circumstantial and forensic evidences could be necessary to support the proof of guilt usually beyond reasonable doubt [17]. The proof of causation as applied in most cases of professional negligence including that related to the informed consent is based on tort and a civil wrong is usually based on probabilistic definition. The negligence in civil cases is decided on the balance of probabilities and 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 such action or in action [17]. The difference between legal and scientific or civil probabilities is the definition of the probability threshold. At least 50% probability as evidence of causation in civil cases is sufficient for a judges conviction of guilt whereas in criminal cases, a scientific statistical methods of 95% probability  $p < 0.05$  is required to prove beyond reasonable doubts [17].

Determining the amount of damages in failure to obtain an informed consent is sometimes difficult and dependent on the case. Such consideration may require the past, present and future economic and non-economic damages associated with the act [62]. An economic damage includes lost wages and medical expenses and other damages that can truly be attributed as documented financial costs. On the other hand, non-economic damages are more subjective and may include pain, sufferings and physical impairments, emotional torture, inconveniences, loss of society and companionship, humiliation, etc. which do not have definite financial costs. Negligence relating to the informed consent in transfusion medicine generally falls within the professional negligence with three types of liabilities; personal, vicarious and strict liabilities which are possible against the health care giver or practitioner. Since blood is a living tissue, inherently variable and incapable of being rendered uniform or completely safe, the standard of 'strict liability' generally does not apply. The concept of "blood shield statutes" is usually applied in blood transfusion practices to remove the practitioners from strict negligent liability and even in jurisdictions where blood shield statutes have not been adopted, courts can decide that, strict liability should not apply in blood collection and storage [62]. On the other hand, strict liability is usually applied to hold manufacturers accountable for poorly designed products just by proving that, the product design by the manufacturers was faulty. Relatedly, in *Williams v. Jackson Parish Hospital* [90]. the court ruled that, the claims of 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. Instead it was governed by the General Tort Prescriptive Statute.

Health care providers may be liable for failure to give an informed consent in transfusion medicine for their direct deficiencies personally or vicariously but majority of professional negligence litigations are hinged on personal or direct liability [91]. Besides these, vicarious liability may be held against a health care provider for failure to obtain an informed consent in blood transfusion practice for cases not directly related to his or her actions or inactions but by others, usually those under his or her supervision, headship or leadership. Therefore, failure to obtain an informed consent from a healthcare seeker by a junior in rank health care

giver under supervision may cause the senior in rank health care provider like a resident doctor, nurse or technician could attract vicarious liabilities to the superior healthcare provider. This is based on the principle of "*respondeat superior*" implying that let the superior answer or be liable for the negligent act of his or her employee or subordinates performed or committed in the ordinary course of his employment; because such superior is assumed to be the principal and gain benefits through the actions of the employee [51]. Such superior under the law thus shares a collective responsibility with his or her supervisee's to deliver safe and appropriate care to patients and may be vicariously liable for inadequate supervision including where an informed consent is not obtained for a blood transfusion or donation or its wrongly applied [51,91]. Relatedly, vicarious liabilities may apply to hospitals and blood sourcing agencies and non-governmental organization. Rarely, blood transfusions may also give rise to criminal liability for the common law crime of culpable homicide and perhaps even assault if for instance a patient dies as a result of negligence on the part of the practitioner, or of the blood transfusion service, the individuals involved may be charged and convicted of the crime of culpable homicide – which entails the wrongful and negligent causing of the death of another person. This will particularly be useful where an informed consent was not obtained ab initio.

Negligence related to the informed consent to transfusion medicine may be hinged on the doctrine of *res ipsa loquitur*. This doctrine is premised or predicated on the mere fact of the event happening which is based on two rebuttable presumptions, viz: [1] That the event happened as a result of a duty of care somebody owes his neighbour (b) And that somebody is the Defendant [59]. To this extent, such health care providers who owe a duty of care to obtain an informed consent but derelict are potentially liable in law.

Finally, the informed consent in transfusion medicine despite being quit a new concept, represents an ethical and legal requirement as applicable to any other procedure to be carried out on the human body in any branch of Medicine. It guides practice in order to guarantee the safety of care seekers and provide the relevant legal shields for care providers which is aimed at fulfilling the lawfulness of health assistance as a reflection and respect for the autonomy and of decisional auto-determination

of the person requiring and requesting such intervention. It is the focus of the current patient-centered quality health care delivery initiatives that also aids the care-provider in attaining responsive practice and averting negligent liabilities.

### 3. CONCLUSION

The informed consent in blood transfusion medicine is an ethical obligations and legal requirement to protect health care professionals involved in blood transfusion practice against misconduct and negligent liabilities when faithfully practiced. These implications have been demonstrated in the decided cases in adversarial and arbitration systems but, it is yet lowly practiced in comparison with consent taken for other medical treatments. The recent emergence of the informed consent as the foundation in quality Medicare through the patient-centered care model further requires that health care providers fulfil on the informed consent to blood transfusion in the interest of quality service delivery, protection against misconduct or infamous behavior in their professions and economic losses arising from negligent liabilities. Considering, the low practice globally, further researches to identify practice constraints against are required

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The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

### CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

### ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

### COMPETING INTERESTS

Authors have declared that no competing interests exist.

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