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Compliance with the Informed Consent to Blood Transfusion: Constraints and Physic for the Developing Africa

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

The informed consent to blood transfusion is a patient centered care where the health care provider is ethically obliged and legally compelled to disclose the details, alternatives and consequences of a procedure such as blood donation or transfusion and obtain from the patient a prior consent before it is carried out. However, this newly evolving practice is largely constrained in many developing countries of Africa and this study sought to identify constraints and advance remedies. Literature search on PubMed, PubMed Central, Google Scholar, and African Journal on Line (AJOL) as well as print material literatures where applicable was used to retrieve 66 publications whose contents met the criteria for inclusion into the study. Constraints range from nondisclosure or defective disclosure, knowledge gaps of health care providers and non-comprehension of consent-based information by patients, illiteracy, religious and cultural practices, poor funding and

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administrative bottlenecks like non provision of consent forms or consent-based information materials as well as weak structures of effective oversight for compliance of health institutions by governmental regulating agencies. Physic like deployment of contentious professional development (CPD) activities for different professionals, focused training on consent-related guidelines, public awareness and education on prevailing social, religious and cultural impediments, research and localization of institution specific challenges. Additionally, proactive economic policies like the deployment of insurance indemnity covers for healthcare workers with negligent liabilities in order to dissuade health care providers from practicing defensive medicine which is inimical to quality health care delivery. There is a need for more researches on constraints prevalent in each developing country in Africa for a more appreciable advancement of the practice.

Keywords: Informed consent; blood transfusion; health care provider; patients; constraints and physic; developing Africa; negligent liabilities.

1. INTRODUCTION

Blood transfusion is sometimes a life-saving therapy but as a form of transplant is associated with predictable and unpredictable risks for which health care providers are ethically obliged and legally compelled to obtain from the patient a prior consent before such procedures as blood donation or transfusion.

The informed consent to blood transfusion is a patient centered care associated with quality service delivery; "providing care that is respectful and responsive to individual patient preferences, needs and values through an effective dialogue between the provider and the patient in what eventually guides all clinical decisions"[1,2].

This patient centered care or 'consumer engagement' and 'consumer-centered care' are fundamental standards of safety and quality improvement in health care delivery [3,4].

The concept of informed consent comprises of ethics of five analytic components: disclosure, comprehension, voluntariness, competence and consent itself. 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) [5,6].

The advocacy for a specific consent for blood transfusion is relatively new. Unlike the case with other medical and surgical treatment procedures, most patients are not included in the making of informed decisions regarding the need for transfusion versus alternative therapies previously. Instead, consent obtained for other treatment or procedures usually is implied in blood transfusion [1].

Recent publications of the NHS Trust on "Patients' Consent for Blood Transfusion" in 2011 followed an earlier evaluation and recommendations on the blood transfusion service by the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Professional Advisory Committee on the safety of Blood Tissue and Organs (SaBTO) [7,8]. Similarly, the federal and provincial legislations in Canada did not specifically address consent to blood transfusion, until the Justice Krever's interim report of the Commission of Inquiry into the Blood System. The legal opinions related to the interim report and that of the Canadian Medical Protective Association, warranted that informed consent specific to blood and blood components be incorporated into the Canadian Society for Transfusion Medicine, standards for hospital transfusion services and the Canadian Standards Association Standards for Blood and Blood Components [9].

Some practitioners have justified the low practice of the informed consent in the UK as a reflection of the extremely low serious adverse events associated with blood transfusions which is argued, does not support the rigors, investments and costs associated with obtaining specific informed consent in blood transfusion [10]. However, this level of health care advancement is not universally available across nations especially in developing countries.

Generally, the compliance to informed consent to blood transfusion in developing countries is very

low and reports suggest that, few institutions consider separate informed consent for blood transfusions; rather, the patient gives this consent as part of a more comprehensive statement [11].

A study in Mali recorded on the disparity in the practice of informed consent process in comparison with similar studies conducted in industrialized nations highlighting on the need for more comprehensive studies with a view to identifying, targeting and addressing specific areas of miscomprehension and invariably improving the informed consent process in developing countries [12].

Much of the literatures on the informed consent process especially in developing countries have largely focused on practices in clinical research and surgical procedures [13].

The informed consent to blood transfusion is not adequately researched even as compliance to ethical guidelines, providing improvement in the quality of health care delivery and averting liability for infamous conduct or negligence in the arbitration or adversary systems is apt. This study therefore sought to assess compliance challenges to the informed consent to blood transfusion in developing countries and provide possible remedies.

2. METHODOLOGY

The review was carried out through a literature search on PubMed, PubMed Central, Google Scholar, and African Journal on Line (AJOL) as well as print material literatures where applicable.

The review employed key search words like “challenges in informed consent to blood transfusion” “informed choice to transfusion medicine and challenges”, “valid consent in transfusion medicine and difficulties”, “developing countries and consent to blood transfusion challenges”, “transfusion consent and the health care providers in developing economies”, “negligent liabilities and the informed consent to transfusion in developing countries”. Following a criteria based on relationship of content with the study aims, 66 inclusion were utilized for the review.

According to the USA Statutes for Public Health and Safety[14], 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-exemp* .[14] *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* [14].

3. COMPLIANCE CONSTRAINTS TO THE INFORMED CONSENT IN BLOOD TRANSFUSION

3.1 Disclosure by Healthcare Providers

The informed consent process requires the health care provider to disclose to the patient (blood donor or recipient) the benefits, risks, costs, implications of treatment and non-treatments, alternatives and with a view to obtaining consent for the procedure or otherwise. Some studies have reported on the value of such disclosure and posited that, even the most elite and knowledgeable patients’ still demonstrate inadequate knowledge of blood safety and are unable to understand completely all the nuances required to give their informed consent [5,15].

Patients may have differing perceptions about informed consent to blood transfusions based on their backgrounds, values and educational levels, cultural or religious beliefs, which may or may not be accurate. For instance, in a study amongst Saudi Arabians, males were reported more likely to perceive blood transfusion as a high-risk procedure while older Saudis had a more negative perception of its benefits while previous recipients and donors were more likely to have a better perception of the benefits with a more positive overall risk perception [16].

The specific healthcare professional responsible for the disclosure varies from country to country. In developing countries that adopt similar models to the USA, disclosure is a function of the clinician or medical practitioner as decided in the Supreme Court judgment in *Campbell M. Montgomery v Lanarkshire Health Board*, [17] wherein the court 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"* [17]. On the other hand, the UK model requires that, the informed consent be obtained by trained healthcare providers fully conversant with the practice and procedure. This may include Nurses, Medical Practitioners, Health Service Managers, Session Staff etc. [3,18].

For the required standard of disclosure for the informed consent, there are three acceptable legal approaches recognized; (1) Subjective standard: *what would this patient need to know and understand to make an informed decision? (2)* Reasonable patient standard*: what would the average patient need to know to be an informed participant in the decision? (3)* Reasonable physician standard*: what would a typical physician say about this procedure?* Similarly, the *types of risks* to be disclosed to patients may be; *(1) 'most common risks'* (2) '*the most serious risks'* or (3) '*all material risks'* [19]. Neither the international guidelines nor regulatory directives in transfusion medicine consistently stipulate which risks should be specifically disclosed to the patients. Therefore, contemporary practices concerning disclosure of risk vary amongst blood centers [20]. However, many States use the "reasonable patient standard" because it focuses on what a typical patient would need to know and understand in order to make the decision at hand [21].

Earlier, in *Reibl v Hughes* the Canadian jury ruled that, "failure to disclose the attendant risks, however serious, should go to negligence" [22]. Similarly, in deploying precedents, the Australian Supreme Court set the standard in a medico-legal case determined in Roger v Whitaker [23] where information disclosure in medical procedures was shifted from a "reasonable doctor" to the "reasonable patient" standard. In this case the court emphasized that providing specific information with regards to "material" risk was a necessary requirement. The Court further defined 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 [23,24]. On the other hand, in determining the standard of care in Castell v. De Greef, the South African Supreme Court blended the "reasonable patient" test with the individual patient's "additional needs test" and submitted that the standard for disclosure by the doctor in an informed consent is the "reasonable doctor" one [24].

The challenges of disclosure in developing countries may related to non-disclosure or disclosure defects. Friedman et al reported risk disclosure defects where the risks were more reported as "not discussed" than benefits [25]. A South African study reported that, although doctors had general knowledge of informed consent requirements, disclosure defects prevail in their practices [13]. Similar studies in Nigeria have also reported that, patients did not give informed consent in majority of cases not as a reflection of their illiterate statues but challenges related tom disclosure. Reasons such as the non-disclosure of the informed consent content by doctors, poor communication with the healthcare provider, noninvolvement of senior doctors knowledgeable on informed consent to spearhead consent discussions and the use of too technical language for patients, sharing too little information on the process and over reliance on signed consent forms [26-29].

A study in Uganda equally reported on the clinicians' level of knowledge as largely being limited to provision of information about and the right to consent to a transfusion while another reported that, although Uganda Cancer Institute (UCI) physicians had some basic knowledge in transfusion, most reported gaps in their knowledge, and all expressed a need for additional education in the basics of blood transfusion [30,31].

The obstacles to health care providers disclosing, seeking and obtaining a valid informed consent in South Africa has also been reported to include different cultural ethos, multilingualism, poverty, education, unfamiliarity with libertarian rights based autonomy, and power asymmetry between doctors and patients [13]. Similarly, a Nigerian study reported that factors such as low educational status/illiteracy, poor economic status, patients unduly trusting

the provider thereby preventing him or her from seeking autonomy or self-determination as well as family influences over medical care [32]. These leads to non-disclosure or defective disclosure in the informed consent process.

Cultural influences, beliefs and practices in some communities like that consistent with the traditional Navajo culture in Southwestern United States, where hózhó, the most important practice combines the concepts of beauty, goodness, order, harmony, and everything that is positive or ideal. In this culture, discussing negative information conflicts with the Navajo concept hózhó and is viewed as potentially harmful by these Navajo informants [33]. In this regard, cultures with this practice have difficulties complying with the Patient Self-determination Act while the informed consent procedures are ethically challenged [33].

Generally, although the informed consent process to medical treatments is age-long practice hinged on the patient-physician relationship that advances patients autonomy, it is a relatively new concept in blood transfusion, rudimentary in developing countries and with enormous compliance challenges related to disclosure. The practical implementation of disclosure requirements is fraught with difficulties, some of which may cause harm to the patient or be obstacles in fulfilling the moral obligation of beneficence [34]. The consequences of a failed duty of care in disclosure by the healthcare provider may amount to professional misconduct in an arbitration system or constitute a direct and or vicarious negligent liabilities in an adversarial system [35].

3.2 Comprehension Challenges by Patients

The ability to understand the information disclosed is a repertoire for an informed choice being made. Comprehension challenges may relate to noncomprehension, misinterpretation, miscomprehension, misperception or misunderstanding of the disclosed information.

Some researchers have explored the perceptions of and factors affecting the process of obtaining informed consent in a hospital-based setting and reported factors such as language and medical terminology used, insufficient time allocation, cultural/traditional reasons and low education as adverse contributors to patients not signing the consent form themselves. This study also recorded on the need for health care providers to encourage patients to sign the consent form themselves [36]. The signing of a consent form without comprehension of the relevant information disclosed is void. Therefore, the currently practice of the informed consent has shifted focus to effective communication and comprehension with lesser emphasis on consent signatures.

Communication barriers like language differences, incorrect or inadequate language translations or misrepresentation between the health care provider and the patient or between the health care provider, interpreter and patient have been reported to breed misunderstanding and non-comprehension [21,37]. The vulnerable patients including the frail elderly, people with cognitive impairment, health care consumers who do not speak or understand English etc have been reported as at risk groups capable of having their entitlements to make informed decisions overlooked and even violated, especially when being cared for in time-pressured and rapidly changing environments such as the emergency department, a busy surgical ward, or the operating room [3].

Krosin et al reported that, the degree of miscomprehension of the informed consent was related to translation, cultural differences in the notion of informed consent and village settings [12].
Blood donors have also been reported to have failed in comprehending the informed consent ignored the risks associated with whole blood donation and instead perceived the process as an assurance of blood safety [30].

3.3 Voluntariness and the Informed Consent Process

The patient's choice to donate or receive blood should be of free will, not by coercion. Coercion is present if the patient feels threatened, bullied or subjected to irresistible pressure to make a decision he or she would otherwise not make [38]. Sufficient time frame is also expected to be availed the patient to assimilate the information disclosed so as to guide the decision to accept or decline intervention.

Voluntariness is affected by cultural and religious influences in many settings. In many cultures in Africa, men are the heads of families, household guardians and providers and breadwinners with

the responsibility to protect, support and maintain their families and homes financially, culturally and religiously. To that extent, decisions of dependents are not truly voluntary. Husseini et al reported on the influence of Islam and culture on informed consent especially in medical procedures concerning a women's pregnancy or the decision to terminate a pregnancy where the husband needs to be consulted and his consent germane as the father-to-be, provider and the legal guardian of both mother and fetus. The patient's opinion or wishes are sought to ensure the objectivity of the decision made. But, when that condition is jeopardized and the decision is not sound, the physician and or husband have the right to intervene, persuade and reason with the decision maker. In doing so, there's a fine line between persuasion and coercion which is not accepted in informed consent [39].

Parents occasionally refuse blood transfusions for their children. It is a matter fundamental to the beliefs held by Jehovah's Witnesses that they, and the children for whom they are responsible, do not receive transfusions of blood products. A request for consent for blood product transfusion is likely to be refused in any circumstance. Most Jehovah's Witnesses refuse to accept the major blood fractions (Whole Blood, Red Blood Cells, Plasma (FFP) and Platelets), however the minor blood fractions (Albumin, IVIG, cryoprecipitate etc) are usually considered matters of conscience for each individual to decide.

Beliefs about what blood products are acceptable are not completely uniform among all Jehovah's Witnesses. From time to time non Jehovah's Witnesses may also refuse blood transfusions, for reasons that may include fear of contracting blood borne infections. Refusal of blood transfusion may be immediately life threatening or may risk serious long term damage to the child [40].

Many of the Jehovah's Witnesses patients who decline to consent as blood donors or recipients sometimes do so not truly on the principle of voluntariness but are coerced by the religious consequences of eternal damnation with no chance of repentance. This misconception of eternal damnation with no chance of repentance was clarified by the church's explanation in 1951 stating that where a Jehovah's Witness was to compromise their belief and accept blood transfusions, due to spiritual weakness yet still held to their beliefs, that individual would not be ostracized by the Jehovah's Witness community, rather, kindness would be shown and pastoral help offered [38].

Other researchers have recorded on the effects of communal family life style, poverty, high illiteracy levels in different cultures that allows consent by patients to be largely influenced by husbands, elders, religious leaders or other significant members of the family or village or community. In these instances consents are given in fear of the consequences of withdrawal or denial of support by other benefactors and not truly an application of autonomy in the informed consent [41-43].

Voluntariness in blood transfusion consent is also influenced by age-old medical paternalism in many developing countries. Doctors' opinions and disclosures with regards blood transfusion is usually associated with extreme fear and patients are compelled to act on the wishes of the doctor rather than a voluntary action. A study of public hospitals in an urban setting reported evidence of overuse of implied and presumed consent by doctors with implications for medical paternalism and lack of voluntariness in consent [13]. Another report also suggest that, doctors are accorded a larger role in clinical decision-making in Kashmir according to cultural and religious views of the local population thereby impeding on patient's autonomy which is the basis of modern medical ethics relating to the informed consent [44].

Some young blood donors in developing countries with a predominant pluralistic blood transfusion system, predominant hospital based transfusion services rely largely on "family donors" who are often compelled to donate for their relations or family member by external influences of parents, elders, clergy, traditional leaders etc. Similarly situations of external influences on transfusion consent also prevails in blood recipients who may not express their wishes because of the fears of their caregivers and health care financers withdrawing their support or care. Such donors and blood recipients are usually coerced by family pressures as a directive of respected family members, clergy or religious leaders or ego to consent and donate or receive blood and not truly as a voluntary consideration desired of an informed consent to blood transfusion practice. Quintessentially, illiteracy, religious and cultural influences impart on voluntariness to the informed consent to blood transfusion in many developing countries.

3.4 Competence and Decision on the Informed Consent to Blood Transfusion

The informed consent to blood transfusion requires that, no one can give consent on behalf of an adult patient with mental capacity. Such adult has full legal capacity to make decisions for themselves i.e. the right to autonomy and self-determination unless it can be shown that he or she lacks such capacity at the time the decision is to be made. They should be able to make a decision for themselves based on their understanding of the nature, risks, benefits and alternatives including that of doing nothing and the probable outcomes of both acceptance and refusal of the proposed blood donation or receipt [21,38].

Exceptions include; incapacitated patients, life-threatening emergencies with inadequate time to obtain consent, and voluntarily waived consent. In the case of critically ill patients with temporary incapacity, for example altered consciousness after trauma, clinicians must give life-saving treatment, including blood transfusion, unless there is clear evidence of prior refusal such as an Advance Decision Document. The patient record should document the indication for transfusion and the patient should be informed of the transfusion when mental capacity is regained (and their future wishes should be respected) [45,46].

In other circumstances, where a patient cannot make decisions independently or their ability to make decisions questioned or unclear, but has not designated a decision-maker, the hierarchy of decision-makers, which is determined by each state's laws, must be sought to determine the next legal surrogate decision-maker. If this is unsuccessful, a legal guardian may need to be appointed by the court [21].

Children (typically under 17) cannot provide an informed consent as such their parents or surrogate parents or guardians must permit treatments or interventions termed "informed permission" instead of "informed consent" [21]. An exception to this rule is a legally emancipated child who may provide informed consent for himself. Some, but not all, examples of an emancipated minor include minors who are; under aged but married, serving in the military, able to prove financial independence or mothers of children (married or not) [21].

As society's view of disabled citizens has evolved, the courts have increasingly upheld the child's right to life and the appropriate treatment. Physicians should also be aware of their provincial or territorial laws, medical association's recommendations and their own hospital's policy for proceeding in such cases. Where the parents or legal guardians of a child refuse blood transfusion that, in the opinion of the treating clinician, is life-saving or essential for the well-being of the child, the physician has an obligation to alert the appropriate authorities to guide his or her actions [47].

Generally, while the legislation regarding minors and informed consent varies from one developing country to another, the decision of a competent individual to accept or decline a transfusion haven been availed all the necessary information on it is universally sacrosanct and must be respected by the health care provider irrespective of religious or cultural encumbrances. A study in the USA, recorded on the need for national guidelines for the informed consent process for both the donor and the parent of a minor to ensure that adequate information is specified therein [19].

3.5 Knowledge Gaps by Health Care Providers, Administrative and Operational Bottlenecks within Health Institutions and Weak Oversight on the Informed Consent to Blood Transfusion

Unlike consent to other treatments like surgery or clinical research, the informed consent as applied to blood transfusion is new and evolving. Health care providers may not be aware of all its nuances because of the content of their medical curricula. Inadequate education on medical ethics especially relating to the informed consent by some health care providers have been reported and traced to the non-inclusion of medical ethics generally in the undergraduate medical education curriculum in many institutions [48-50]. A study found that, only 60% of respondents (medical students, residents, advanced practice providers, and attending physicians at an academic institution) felt their informed consent training was adequate. Consequently, multiple areas of difficulty in obtaining proper informed consent were identified [51].

Inadequate knowledge or non-deployment of the informed consent by some health care providers is sometimes related to the health care facility of practice. Some hospitals do not provide for informed consent to transfusion medicine in their hospitals, do not have operational systems to support the practice of informed consent. In one study, Ninety-two hospitals in a three-state mid-Atlantic region were surveyed to determine their policy toward obtaining written informed consent for transfusion and to examine the content of written consent documents and the process by which consent is obtained. This study revealed that, even though majority of respondent institutions require written informed consent, those forms, per se, do not document that the fundamental tenets of informed choice have been applied to the decision to transfuse blood [52]. This may be a problem related to the health care provider required to obtain the consent from the patient or the lack of effective oversight by the hospital managements.

It is the development of guidelines, regulations, statutes, etc related to the informed consent to blood transfusion by governments in different parts of the world that has popularization and reinvigorated interest in the informed consent to blood transfusion. The implementation of informed consent to blood transfusion is not promoted in many institutions in developing countries as reports suggest that few institutions consider separate informed consent for blood transfusions; rather, the patient gives this consent as part of a more comprehensive statement [11]. Some studies have also posited that, seeking a separate consent for blood transfusion requires time and paperwork [53].

Another study reported on the lack of institutional training and education of house staff on transfusion indications, benefits and risks which are core disclosure elements in the informed consent transfusion medicine [25].

Some researchers have also posited that, the oversight by governments in many developing countries is weak and therefore, legal frameworks supporting transfusion safety and some ethico-legal aspects of blood transfusion including the informed consent process is not prioritized and often non-existent. [32, 54].

4. REMEDIES TO THE INFORMED CONSENT TO BLOOD TRANSFUSION

4.1 Improving Educational Training Programs for Patients and Health Care Providers

The knowledge of the informed consent practice is thought to be increased with education. This may be deployed for health care providers through contentious professional development (CPD), focused training on written practice guidelines at discussion groups in units, departments within a health institution or involving aggregates of practitioners from other institution within a State, Zone or country with a view to breaching the knowledge gap of such health care providers [29,51,54]. Ethical and educational elements of informed consent for blood transfusion has also been supported to form part of the curriculum of residential training and undergraduate studies [55]. A South African study also supported continuing education in medical law and ethics to improve informed consent practices and overall quality of healthcare service delivery [13]. The effectiveness of transfusion educational intervention in Medicine core clerkship has been identified with researches supporting the use of an informed consent model as an effective educational intervention in Medicine core clerkship program [56].

Some studies have suggested improved patient information on the informed consent process through the, dissemination of information leaflets to patients. This suggested useful intervention is thought to be associated with minimal impact on the health care professionals' time as information materials could be introduced at each patient's bedside, in pre-op packs and in outpatient clinics, theatre waiting rooms, blood bank reception halls etc. The impact of these interventions could also be reassessed within appropriately planned time interval for the outcome on the intervention [57].

Some studies have also encouraged contentious patient's educational programs and information material sharing such that a poor care seekers' recollection and understanding of risks and alternatives could be continuously upgraded [58].

In this new technological age, online resource have been shown to aid healthcare professionals

involved in the transfusion process and patients gain more information that will assist in obtaining a valid consent. Use of visual and digital communication tools is being encouraged to address some the inefficiencies in the process of obtaining consent. Patients should be actively engaged as a way to enhance communication and ensure patient safety and understanding. A study introducing the video coverage of blood transfusion improved patients understanding of risks and impacted on their of giving consent for transfusion [59]. Such video coverage on the informed consent to blood transfusion could be shared at projector screens at all waiting points of the health care facility, at social media platforms of student groups, youth groups, village and community meetings in order to improve an understanding of the informed consent to blood transfusion. Transfusion training and evidence-based guidelines are needed to reduce inappropriate transfusions and improve patient care including the practice of informed consent [30,31]. Health care institutions as health care providers should educated their work force on the requirements of the informed consent to blood transfusion for effective disclosure to patients. Such members of the healthcare team should also be informed about the details of the procedures and interventions and preferably used as witnesses in obtaining informed consent. They would be able to evaluate whether all necessary information was given to the patient and quality assure that the patient has been disclosed reasonably by the provider before obtaining the informed consent [21].

Institutions should consider a written consent form different from surgical consent in order to increase patients' knowledge and autonomy on transfusion procedures [55].

Multidisciplinary and intergovernmental collaborations are necessary for improvement in the informed consent by health care providers. The patient blood management (PBM) strategy developed by a collaboration between the American Association of Blood Banks and the Joint Commission in the US has emerged as an evidence-based treatment strategy that aims to minimize the need for blood transfusion, enhance requirements for transfusion education and promotes shared decision making, including informed consent. This ultimately promotes the patient-centered model for quality health care delivery [1].

4.2 Developing Effective Communication between Patients and Health Care Providers

Maintaining a good caregiver-care seeker relationship, sharing information on the treatment being offered routinely, allowing for a patient centered decision making process and initiating private dispute resolution or treatments with aggrieved parties will likely breach misunderstandings. It has been reported that, early involvement of the patient in a dialogue concerning informed consent is necessary [60].

Disclosures related to the informed consent to blood transfusion should be in a language best understood by the patient and where possible a family member with familiar dialectal ascent be deployed for a better comprehension by the patient. Therefore, while it is necessary to make a disclosure to the patient, it must be effectively communicated and all barriers to comprehension must be scaled for an effective and valid consent. Some studies have posited that seeking a separate consent for blood transfusion requires time and paperwork. However, if done properly, benefits the patients by increasing their knowledge and autonomy in the transfusion process [53].

Where disclosure of information and informed consent are done by physicians in a defensive way for fear of malpractice suits, it defeats the essence of the act [34].

4.5 Taking Measures to Avert Litigations to Health Care Provider and Improving the Process of Seeking Redress for Breaches of the Informed Consent to Blood Transfusion for the Patient

Informed consent is essentially a legal doctrine developed partly out of recognition of a patient's right to self-determination and partly out of the doctor's duty to give the patient sufficient information to enable him or her to make an informed and prudent choice about whether to undergo a proposed treatment like blood transfusion [3].

An effective informed consent is a major focus of patient safety and also a legal shield against claims of misconduct or negligence against the health care provider who must be well versed

with the law and follow the ethical guidelines of blood transfusion [61].

Patients face the challenge of seeking redress in the failure to obtain consent in blood transfusion either through the arbitration procedure by professional associations within which the health care provider belongs. This is usually cheaper and more professional but less technical in law and patients encountering difficulties in locating the relevant place to report their grievance. On the other hand, the adversary system may be used to address grievances in allegations of negligence by the patients. In this situation, the patient is expected to produce evidence only housed by the health care provider for a favourable consideration of his or her case in the jury. To that effect, proving professional negligence due to failure to obtain an informed consent and establishing liability within acceptable probabilities often difficult to obtain [62].

In some countries, while the professional tribunals have been very justifiably strict on reported cases of ethical breaches against their members, the 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 [63].

An informed consent could be verbal, written or implied and it is not mandatory in many instances to document it in order to make it valid in law. However, for the avoidance of legal responsibilities wherein patients deny giving an oral informed consent or forgot doing so as an aftermath of an unfavourable outcome, it is advisable that, all informed consents be documented and preferably witnessed by a third party including the relevant contacts of all the parties involved. It is also advisable that the indications, risks and planned transfusion so discussed with the patient before obtaining his or her consent should be so indicated and fully documented in the patients case notes [64].

In pursuing negligent liability to the health care provider, the patient may rely on implicating evidences of medical testimony to be given through medical colleagues or related institutions to prove that, the act or omission by the accused health care provider is in fact negligent.

There are allegation of a conspiracy of silence where the professionals refuse to testify against their colleagues. The principle of "res *is pa loquitur*" or "the thing speaks for itself" in some instances is usefully applied [63,65]. Previously this doctrine was applied primarily in foreign-body cases but now all the plaintiff has to do is to prove that the defendant physician was in control of the procedure alleged to have caused the injury i.e. the care giver was in control of a procedure in transfusion medicine requiring a transfusion and he or she failed [62,65].

Another challenge prevails should the patient die of injuries sustained through blood donation or transfusion without an informed consent. The local prevailing "wrongful death statute" would apply in determining the amount to be recovered as damages but, many wrongful death statutes prescribe a limit on the amount of damages that the next of kin can recover in the event the deceased has been killed by the negligence of another [62,65].

Recently, the Joint Commission in addressing the challenges to effective informed consent employing the patient signature, emphasized that, it did not indicate an effective understanding of the informed consent process [21].

Many blood transfusion guidelines particularly in developed countries relating to the informed consent to blood transfusion now emphasize on the role of documentation and witnessing of the informed consent process, effective communication with patients and development of effective oversights. Such documents are expected to be kept in safe custody for a period of time as required by the law in that country. In France for instance, the law stipulate that these records should be kept for 30 years [64]. However, in jurisdictions where, durations are not clearly spelt out, hospital based transfusion committees could develop such template to guide practice until the true legal frameworks are in place.

Even in blood centres, it is imperative that, blood donors are availed an opportunity of an informed consent and which must be transferred to the hospital utilizing such donations in order to ensure quality and accountability in the transfusion process.

Justifiably, a certain amount of immunity is also allowed to health care givers considering the nobility of the services they render and in view of the reports that complainants often use the court cases to harass care providers to extract unjust compensation [63].

Health care providers should enroll into insurance schemes that may cover their indemnities in cases of proven medical negligence liabilities due to the informed consent. The most ethically defensible approach is to tailor and navigate the information according to the needs and desires of each individual patient in a sensitive and empathic manner. Hence, the informed consent should be a process of mutually shared responsibility by the patient and the physician, ensuring adequate and relevant information that is well comprehended by the patient, and is used correctly for his or her decision making [34].

Some researchers have argued on the non-standardization of the informed consent and it being viewed as a legal necessity rather than as an expression of patients' autonomy capable of enhancing the doctor-patient relationship. As an integral element of ethical medical practice it is often subjected to misapplication by some providers and deserve elevation to its rightful place in clinical blood transfusion in order to enhance doctor-patient relationship [35,66].

5. CONCLUSION

The informed consent to blood transfusion is a collaborative process allowing patients and healthcare providers make decisions together when more than one reasonable alternative exists. It ensures the patient's preferences and priorities are adopted haven been reasonably disclosed on the procedure by the provider.

In the developing countries of Africa, many constraints mitigate against the practice of informed consent including lack of effective disclosure by the providers, non-comprehension of consent-based information by patients and weak structural frameworks for effective oversight and measurement of compliance by health institutions and governmental agencies. Physic like focused training on consent-related guidelines and CPD to providers, research and localization of institution specific challenges, public awareness and education on constraints exists. The institutionalization of insurance indemnities to cover providers with negligent liabilities and dissuade the practice of defensive medicine by such providers which is inimical to quality health care delivery is also advocated. Compliance with the informed consent to blood transfusion has a mutual benefit to the healthcare provider and the patient (i.e., the donor or recipient). While the healthcare provider is protected from litigation by this act, the patient is assured of a safe and quality blood with minimal blood adverse effect. A time has come for developing Africa to overcome practice constraints to this mutual but legally implicating practice to the providers as it is in developed countries.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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