

Review

The doctrine of informed consent in surgical practice

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Abstract

Physicians and other professionals in the field of medicine have to perform invasive and non-invasive procedures on patients as part of their duties. There is a legal basis upon which these procedures are done; this is called 'informed consent.' Sociocultural factors have strong influence on the sick role. These factors influence the application of informed consent in Nigeria.

Key words: Health professionals, informed consent, physician

Introduction

Informed consent forms the basis of the relationship between the patient and the surgeon. It ensures the patient's autonomy and independence.

Surgeons have a special need to have a clear understanding of this important topic. The last few years have seen an increase in the number of cases taken to court for arbitration regarding the issue of consent. Informed consent may be defined as 'the legal term describing a patient's voluntary agreement to a doctor performing an operation, arranging drug treatment, or carrying out diagnostic tests'.^[1] It may also be defined from the medical ethicist's point of view as a 'voluntary, uncoerced decision made by a sufficiently competent, autonomous person on the basis of adequate information and

deliberation to accept rather than to reject some proposed course of action that will affect him or her.'^[2] The surgeon acts in a fiduciary capacity in the relationship with his patients. It is therefore necessary for him to let patients be fully informed of everything concerning their care. Whatever meaning one gives to informed consent, it is a voluntary agreement or acquiescence to what another person proposes or desires, or an agreement as to a course of action. It is a mandatory process needed in the course of treatment of all patients. Its main value is that it satisfies the ethical requirements of the autonomy of the treated individual.

While it is recognized to be an important aspect of patient care, it is often relegated to the back of the patient's folder. It may also be inadequate, uninformative, or incomplete in hospitals in our

environment.^[3] The forerunner to informed consent began to evolve in England in 1767 in a case where a certain level of professionalism was required in treating orthopedic patients in *Slater vs Baker and Stapleton*.^[4] In the US, the earliest litigation on informed consent reached the Supreme Court of Minnesota in 1905. In this case, a patient consented to an operation on the right ear. During the operation, the surgeon discovered that the left ear was in worse condition than the right. He proceeded to operate on the left ear and was held liable for battery.^[5]

It has become the norm rather than the exception that 'every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body.'^[6] A surgeon may do nothing to his patient without valid consent if that treatment, investigation, or diagnostic procedure will in any way interfere with the patient. Various forms of consent are in use by physicians around the world. Informed consent is probably the most versatile and the most commonly used form of consent. Another name for informed consent is *knowledgeable consent*.

Elements of informed consent

The bottom line is patient autonomy. The elements of informed consent in surgery include:

1. Explanation of the procedures to be followed and the purposes of each; those procedures that are experimental should be identified as such.
2. Description of any attendant discomfort and risk that can reasonably be expected.
3. Description of any benefit that can reasonably be expected.
4. Disclosure of any appropriate alternative procedures that might be advantageous to the patient.
5. Instruction that the person is free to withdraw his consent or to discontinue treatment or participation in the project or activity at any time without prejudice to the subject.

It is difficult to satisfy all the demands of an informed consent in practice. It is time consuming, it may be fuzzy and unwieldy, or the patient may not be sophisticated enough to understand what he is being told. In other situations, he may be too sick to bother.^[7] Consent must start with the patient (or his/her relative) identifying himself/herself and that he/she has agreed to undergo the investigation, treatment, or operative procedure. The person to perform this operation must be stated where feasible. The nature of what is proposed and the anticipated effect, including the significant risks and alternatives or any additional steps the surgeon may

take in the course of the operation. The patient (or relative) must state that he/she is satisfied with the explanations given regarding the surgical procedure and its possible outcome. The patient must be aware of the medical team that may participate in his or her operation. This consent must be signed by patients and witnessed by a relative or any third party after all relevant questions have been satisfactorily answered.^[8]

When a procedure is to be delegated to another physician, the patient should know about this. An informed consent is usually appropriate for all circumstances. The need for the patient to be fully informed is stronger in patients involved in research. It is usually administered by a knowledgeable member of the team in the simplest form possible. Over the last few decades, patients and their lawyers have tried creatively to expand this basic doctrine of informed consent. In a case in the US, *Truman vs Thomas*, a physician recommended that a woman should undergo a Pap smear. She refused and later developed cervical cancer. She sued the physician on the ground that he is by obligation supposed to inform her of the risk she faces by refusing the Pap smear. The court upheld her application and this case is popularly referred to as the doctrine of informed refusal. Again, in 1996, the Wisconsin Supreme Court in *Johnson vs Kokemoor* seems to extend the doctrine by requiring that a doctor should disclose his performance and experience as compared to other surgeons. In this case, the court determined that the surgeon provided misleading information by not letting the patient know his level of performance. This is now called performance disclosure.

In *Hidding vs Williams*, the court required that the surgeon should disclose his alcoholism. This case suggests that the court may consider factors other than the risk of surgery, even including the personal and professional characteristics of the attending physician, as part of informed consent.

The courts have also construed the doctrine of informed consent to include disclosure of a surgeon's HIV (human immunodeficiency virus) status. The case dealing with this matter was *Scoles vs Mercy Health Corporation of Southeastern Pennsylvania*. Scoles was an orthopedic surgeon who became HIV positive. The hospital learned of this and conditioned his clinical privileges upon his agreement to inform his patients of his HIV status prior to any invasive procedure. Scoles brought a suit against the hospital based on the Americans with Disabilities Act. The court ruled that the hospital had acted reasonably by asking the doctor to disclose his HIV status.^[9]

Conflict of interest or financial interest should be disclosed to the patient. The courts require that a physician should disclose any connection to industry or companies since this may influence his decisions to use products from a particular company. Almost all surgical procedures involve risks, which can broadly be divided into two types. The first type comprises inherent risks, which are defined as those that may materialize, which are defined as those that bear upon the patient's decision to undergo a surgical procedure. For example, hand surgery is more professionally material to a concert pianist than to a driver and, hence, the material risks are higher in the former than in the latter.

Capacity to consent

What ability does a patient have to consent to surgical procedures? Patients consent to procedures usually not because of their belief that what they assent to is the best for them. They give consent because they look up to their doctors as their authorities and hence their guardians. Serious illnesses are usually followed by losses of normal functions in many dimensions, including in the ability to reason and to act, without which autonomy cannot be guaranteed.

Capacity to consent has legal connotations. A poorly educated adult who has the mental capacity of a child may not be capable of consent. On the other hand, a young child of 7 years with the emotional and mental stability to comprehend issues can give consent. The age of maturity is rapidly becoming irrelevant in these situations. A substitute decision maker may be required when the capacity to consent is deficient. It is the duty of the physician to find out if the patient has reasonably understood what was explained. In obtaining consent, all of the above factors must be taken into consideration. It is important for surgeons and their teams to know that in the absence of consent they can be charged with assault or battery. This is as much a liable offence as when the treatment given deviates significantly from that which is intended. Assault and battery may also be said to have occurred when consent is fraudulently procured or where the truth has been misrepresented. To assault a person means to attack him/her violently by physical or non-physical means. Battery, on the other hand, may refer to unlawful touching or beating and, in medicine, unlawful treatment of an individual.^[5]

The civil laws of the United States and Canada recognize a body of law which states that all patients be informed of all medical or surgical procedures and have been upheld by the supreme courts of these countries. In the case of *Sidaway vs the Board of Governors of Bethlehem Royal Hospital*, a patient

brought an action against her doctor claiming that he failed to warn her about some inherent hazards in a form of treatment which the doctor proposed and applied to her. Since the treatment involved a substantial risk of grave consequences, the doctor ought to have warned her. Lord Scarman in his judgment stated:

'a doctor who operates without the consent of his patient is, except in cases of emergency or mental disability, guilty of the criminal offence

of assault.' The Supreme Court of Canada had ruled that in obtaining the consent of a patient for

the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions asked by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks, and any special or unusual risks attendant upon the performance of the operation. It should be added that the scope of the duty of disclosure and whether or not it has been breached are matters which must be decided in relation to the circumstances of each particular case. The Canadian Supreme Court extended the obligation of disclosure as follows: 'A surgeon must also, where circumstances require it, explain alternative means of treatment and their risks.' It is also the duty of the attending surgeon to inform patient of the possible postoperative or post-discharge complications. All the features that suggest the occurrence of early or late complications must be made known to the patients adequately; this will enable the patient seek early and appropriate medical attention.^[6]

In medicine and medical law in Nigeria there are some rulings or injunctions concerning this. Similar situations were agreed upon and followed by the Nigerian Supreme Court in the case of *MDPDT vs Okwonkwo, Uwaifo, JSC*, said 'I am completely satisfied that under normal circumstances no medical doctor can forcibly proceed to apply treatment to a patient of full sane faculty without the patient's consent, particularly if the treatment is of a radical nature, such as in amputations or other radical surgery.' So the doctor must ensure that there is a valid consent and that he does nothing that will amount to a trespass to the patient.^[8] The courts in US have recognized that the constitutionally guaranteed right to privacy of a patient encompasses his right to decline medical treatment.

In Nigeria, the doctrine of informed consent has become entrenched as a fundamental right under Section 37 and 38 of the 1999 Constitution. Section 37 provides that the privacy of citizens, their homes, correspondence, telephone conversations, and telegraphic communication, is hereby guaranteed and protected. Section 38 (1) provides that every person shall be entitled to freedom of thought,

consciences, and religion, including the freedom to change his/her religion or belief, and freedom either alone or in community with others, and in public or in private to manifest and propagate his religion or belief in worship teaching, practice, and observance.^[10] These provisions are constitutional safeguards to the right of a patient to reject a form of medical treatment based on religious beliefs. Therefore a Jehovah's witness can, on the basis of section 37 and 38 of the 1999 Constitution, object to a blood transfusion on religion grounds.

Surgical intervention against the consent of a patient would be an invasion of his right to privacy. This is regardless of the fact that the doctor may be of the opinion that such treatment would have the effect of prolonging life or that the refusal of treatment seems unwise, foolish, or ridiculous to others.

Sociocultural factors in Nigeria

Nigerian and international guidelines recognize the need for informed consent in research and medical practice.^[11] The conduct and behavior of physicians is guided by the code of medical ethics of the Medical and Dental Council of Nigeria. Rule 19 of part A deals with informed consent and agrees entirely with the definitions and discussion above.^[12] This has been affirmed by the Supreme Court of Nigeria. In the Medical and Dental Disciplinary Tribunal vs Okonkwo the Nigerian Supreme Court ruled: 'The patient's consent is paramount... (accordingly) the patient's relationship (with the doctor) is based on consensus. It follows that the choice of an adult patient of sound mind to refuse informed consent, barring state intervention through judicial process, leaves the practitioner helpless to impose a treatment.' Nigeria is a multicultural, multiethnic, and multireligious society. There is also strong belief in the extended family system. Perceptions on issues including health are influenced by these factors. Certain issues may not be directly discussed without upsetting these beliefs. These factors influence decision-making. The literacy level in Nigeria is 68% and the per capita income is US\$1188. With such demographic characteristics, many decisions will be made without clear understanding of the implications and this includes the informed consent process in surgery. One study reported that only 70%–95% of patients gave consent for their operations in a Nigerian teaching hospital.^[13] This shows the magnitude of the problem in a tertiary health institution. One can derive from this study that the problem may be higher in the secondary and primary health centers.

In northern Nigeria there is strong belief in unorthodox bonesetting. It is often resorted to as the first line of treatment despite any protests

from the patient. This is due to a strong centrally controlled feudal system that can have bearing on decisions regarding treatment. These decisions may be detrimental to the patient.

This is an erosion of the patient's autonomy and would be considered unacceptable in Western societies.^[14] The people of Southern Nigeria, mainly Yorubas and Ibos, are more educated and may comprehend the issue of informed consent better than their counterparts in the north who are mainly Hausas and Fulanis. The latter are more likely to accept mishaps and attribute them to divine doing. A signed consent form must not be considered as consent. A signed form is only evidentiary, indicating that such discussion has taken place before a witness. The physician should indicate in the patient's file that the discussion did take place. The courts accept this as evidence. If the patient can convince the courts that such discussions did not take place, then it has no legal value. It is generally accepted that in emergency situations, the patient or surrogate decision maker

(e.g., patient's relatives or the physician) must invoke the 'duty of care' concept in order to save life or limb and do whatever is immediately necessary. The physician should at all times in these emergency situations be able to demonstrate eminent suffering or danger to life or health of the patient. All treatments and or investigations must be limited to those that will salvage life or limb, or health in general.^[5] Most legal actions against physicians in respect of consent are as a result of negligence, and raise doubts as to the adequacy of consent given by the patient.

Although the physician's intentions in performing an operation may have been good, the courts will not judge him on that. The courts have repeatedly affirmed that the good intentions of the physician cannot be substituted for the will and choice of the patient. A higher standard of disclosure may be required in operations or procedures that are not entirely necessary to the physical wellbeing of the patient, e.g., cosmetic surgery.

Other forms of consent to surgery

An *implied consent* usually derives from the fact that a patient may arrange and keep an appointment and volunteer history and submit to examination without objection. It can therefore be reasonably upheld by the court that the patient has given an implied acquiescence to what is done to him.

Expressed consent may be in oral or written form and is usually preferred when a procedure is going to be more than mildly painful. Although oral expressed consent

may be adequate in most circumstances, it will be wiser if the physician demands and obtains a written confirmation. This is relevant because often patients

change their minds or have it changed for them by other people around them.

Voluntary consent is a form of consent that allows a patient to have free expression, choice of physician, mode of treatment and alternatives, which are the sole prerogatives of the patient. We would like to think however that this should be an attribute of informed consent rather than a form of consent.

Conclusion

The concept of consent is continuously evolving, and it is necessary for the surgeon to be conversant with the application of informed consent. Consent, in whatever form, should be informed. Informed consent is that given by a person of sound mind having the entire information necessary to make up his mind as to whether he would or would not accept a form of surgical treatment. Therefore, consent obtained by fraud, under the influence of drugs or anesthetics, from an insane person, or without giving sufficient information about the surgical ailment, the treatment proposed, and the attendant risks to enable the patient to understand the position fully and make an intelligent decision, is not an acceptable informed consent. Informed consent should be a simple document, adaptable to most situations. The physician must resist the urge to psychologically manipulate the patient or to convince him to give his assent. Surgeons must obtain consent from patients before carrying out any procedure, no matter how minor. The constitutionally protected right of the individual patient should be paramount at all times. A citizen's right cannot be abridged with the intention of protecting him. A patient has a right to determine his own medical treatment and that right is superior

to the surgeon's duty to provide necessary care. No surgical 'ethics' can deviate from this position.

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