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INFORMED CONSENT IS A PROCESS NOT SIGNING OF A FORM

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INTRODUCTION

Informed consent, which has been popularized in healthcare ethics and research, as result of past abuses in research and medical experimentations, is rooted in the principle of Autonomy, and supported in the American Jurisprudence that "(e) very human being of adult years and sound mind has a right to determine what shall be done with his own body…." (Mappes & Degrazia, 2001, p.93). That determination means that the person has decision – making rights, rights to hold personal views, to make choices, and to take actions based on personal values and beliefs. It also means that unwanted and unauthorized touching for whatever reason, and regardless of the toucher's profession, of another individual without that individual's consent is criminal assault and battery (Levitin, 1996. P41).

This is a shift from paternalistic healthcare to a more shared-decision making or collaborative healthcare. A shift that requires of healthcare professionals to obtain an informed consent before initiating any procedure or physical touch. It is a shift that requires the healthcare professionals to provide an enabling and conducive atmosphere for patients to take active participation in their care. It is a shift that requires the professionals to provide for the patients (or research participants) all the material information necessary for the patient to make an informed decision. A shift that requires the professional to present to the patient all the options or alternative of the treatments, their benefits and risks, and allows the patient to make his choice. An informed consent, therefore,

can be defined as "an individual's autonomous authorization of a medical intervention or of a participation in research" which "…occurs if and only if a patient or subject, with substantial understanding and in absence of substantial control by others, intentionally authorizes a professional to do something" (Beauchamp & Childress, 2001, p.78)

The words of Berlin (1969, as cited in Young, 2001) practically, succinctly, and aptly describes the meaning and concept of informed consent thus:

> I wish my life and decisions to depend on myself, not on external forces of whatever kind. I wish to be the instrument of my own, not of other men's acts of will. I wish to be a subject, not an object; to be moved by reasons, by conscious purposes, which are my own, not by causes which affect me, as it were, from outside. I wish to be somebody, not nobody; a doer – deciding, not being decided for, self – directed and not acted upon by external nature or by other men as if I were a thing, or an animal, or a slave... I wish, above all, to be conscious of myself as a thinking, willing, active being, bearing responsibility for my choices and able to explain them by references to my own ideas and purposes. (p.441)

Consequently,

> In a healthcare setting, when a patient exercises her autonomy she decides which of the options for dealing with her healthcare problems (including having no treatment at all) will be best for her, given her particular values, concerns and goals. A patient who makes autonomous choices about her health care is able to opt for what she considers will be best for her all things considered. To uphold the importance in healthcare of obtaining a person's informed consent is to recognize the value of patient autonomy. (Berlin, 1969, as cited in Young, 2001. p.442)

In other words, it assures his respect and dignity. A patient, of course, does not lose this dignity despite his medical condition. Patients come to hospitals not just as patients but first and foremost as human persons who happen to be sick and or anxious from or about something. As human persons, created in the image of God, they have inherent dignity, respect, and rights and must be treated in that way. Unfortunately, this is not always so. In our various hospitals, patients are, sometimes, treated as anything other than persons- they are often treated and referred to by bed

numbers, medical folders, as medical conditions, or worse as diagnosis. However, behind those bed numbers and folders are human beings—people's parents, children, spouses, siblings, uncles, cousins, aunts etc.

INFORMED CONSENT: A PROCESS

Many of us may have had the experience of going into the hospital and be handed over a form to sign without any time to read through it or without any explanation of the contents of the form; and most of us unfortunately and ignorantly signed. This happens in most of our hospitals in Nigeria, and it is termed informed consent.

However, this is not an informed consent. Informed consent is rather a process and not the signing of the form. The signing of the form is and should be the end of the process. It is not called "informed consent" for nothing. It is called so because it is and should be a consent or decision given or made respectively after due information has been provided and due deliberation and considerations made by the patient.

This process is very systematically and well captured by (Jonsen, et al. 2002) thus:

> When a patient consults a physician for a suspected medical problem, the physician makes a diagnosis and recommends treatment. The physician explains these steps to the patients giving the reason for the recommended treatments, and the benefits and burdens of all options. The patient understands the information, assesses the treatment choices, and expresses a preference for one of the options proposed by the physician. This ideal scenario captures the essence of the informed consent process. As an ethical basis for the patient – physician relationship, informed consent consists of an encounter characterized by mutual participation, good communication, mutual respect, and shared decision – making. Informed consent should not designate a mechanical recitation of facts or a pro -forma signature on a piece of paper…. Informed consent requires a dialogue between physician and patient leading to agreement about the course of medical care. Informed consent establishes a reciprocal relationship or therapeutic alliance between physician and patient …. A properly negotiated informed consent benefits both the physician and the patient: a

> Therapeutic alliance is forged in which the physician's work is facilitated because the patient has realistic expectations, and is more likely to be a willing collaborator in the treatment. (Pp.50-51)

As a result, for an informed consent to be a valid one the following elements of the process must be present 1) Competence 2) Disclosure (or information), 3) Understanding, 4) Voluntariness (or freedom), 5) Consent (Levitin, 1996. Pp. 42-43; Beauchamp & Childress, 2001. Pp 79-103). In other words one gives an informed consent to an intervention if (and perhaps only if) one is competent to act, receives a thorough disclosure, comprehends the disclosure, acts voluntarily, and consents to the intervention. In other words, informed consent is a process that ends in the actual consent or signing of the form.

ELEMENTS OF INFORMED CONSENT

The above elements constitute the process of informed consent. These elements do not only constitute the process but also the meaning of informed consent.

a. Competence

Competence (medically known as decision-making capacity) a legal term, is the ability, knowledge and skill to make decisions about the affairs of oneself. On the other hand decision-making capacity is a medical term that connotes a person's ability or capacity to make medical decisions or "a clinical determination that refers to whether a patient has the mental capability to: understand

relevant information, appreciate the medical situation they are in and its possible consequences, reason through risks, benefits and alternatives of treatment options, and communicate a choice freely and voluntarily based on their own values" (Vermont Ethics Network n.d)

It is not surprising that in most literatures the two terms "competence" and "decision-making capacity" have been used synonymously. The reason for that is not far-fetched because of the central word "capacity" or "ability" that define both of them-the capacity or ability to make decision. Hence, there are few facts to be noted about the word capacity thus,

- All adults are presumed to have decision-making capacity, regardless of diagnosis.
- Decision-making capacity is decision specific.
- Capacity is affected by many factors- Sleep, state of wellness or illness, medication etc.
- Patients can have capacity some of the time, and either have limited capacity or no capacity at other times.
- Decision-making capacity also includes having the ability to engage in what a chosen decision requires.
- Adults with capacity have the right to accept or refuse medical intervention consistent with their goals and values.
- Health care practitioners are obligated to promote patients to make as many decisions as their capacity allows and to do so in the least restrictive manner possible. (*Vermont Ethics NETWORK,* n.d)

From the foregone you can deduce that there is no fixed standard or criteria for assessing or determining competence (decision-capacity) of a patient. There seen to be lack of consensus on this-- some may agree on some criteria while disagreeing on others. The reason for this disagreement is due to the fact that

> Competence determinations are not essentially factual, objective, or empirical matters but rather are value laden judgments about the relative importance of autonomy and beneficence to the person, as assessed by the clinician or others…. Under the most common view, competence is not a fixed property of an individual applicable to all decisions and all potential risks, rather, competence is a context – dependent, decision-specific, interpersonal process. (Wettstein, 1995)

However, despite this disagreement on the standard or criteria for clinically determining competence (decision-making capacity) some criteria that have been adduced include "whether the person can make a choice, communicate that choice, understand relevant information about the choice and its alternatives, and rationally manipulate information about the choice and its alternatives". (Wettstein, 1995)

b. Disclosure

The concept of informed consent is legally hinged on the duty of health professionals to give patients all the information necessary for them to arrive at a decision pertaining to a particular treatment or procedure-hence the term "informed". In other words it is a "consent" or decision based or arrived at, or as a result of the information provided and understood – the patients need to be informed in order for the consent, based on the information, to be informed. It is also good to note here that if there can be informed consent, it also implies that there can also be an informed refusal. This is very important for health professionals to know, that just as patients may give their approval, permission, or consent to a certain treatment, procedure, or participation in research based on the information provided them, they can also give their disapproval, deny permission, or refuse certain treatments, procedure, or participation in a certain research based on the information given them. When that happens, especially if the

person has fulfilled the competence criteria, the professionals should know that it is within the patient's right to do so.

However, there is a shift from the legal obligation of disclosure as the basis for informed consent to a more ethical dimension of respect for patient's autonomy as the basis. The questions surrounding the element of disclosure have always been what is to be disclosed? How is it to be disclosed? Are there some exceptions to the obligation of disclosure?

To the question of what is (amount of information) to be disclosed,

> Professionals are generally obligated to disclose a core set of information, including (1) those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research, (2) information the professional, believes to be material, (3) the professionals recommendation, (4) the purpose of seeking consent, and (5) the nature and limits of consent as an act of authorization. If research is involved, disclosure should generally cover the aims and methods of the research, anticipated benefits and risks, any anticipated inconvenience or discomfort, and the subjects' right to withdraw, without penalty, from the research. (Beauchamp &Childress, 2001)

Emphasis should be laid on the no 1 of the core set of information to be disclosed to patients which talks of those material information that are necessary for patients to give consent. The question will be what are this material information? They include, though not limited to, the following:

> … the nature and purpose of the proposed procedure, attendant risks of the proposed procedure, the possibility of success, your prognosis if the procedure is not performed, and the benefits and limitations of available treatment alternatives. Anticipated costs of treatment and possible effects on your lifestyle, such as mobility limitations, dietary restrictions, and ongoing monitoring requirements, should also be discussed. If your doctor proposes a new medication regimen, you should be told why the medication is needed, why the prescription is being changed, possible side effects, and the availability and advantages or surgical and non-surgical alternatives. (Levitin, 1996.p.43)

The above information are very material to the process of decision-making or consent giving for the patient.

To the question of how information's are to be disclosed to patients three different standards have been proposed. They are; the professional standard, the reasonable person standard and subjective standard, hence "(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?" (National Library of Medicine, n.d)

There is really no measure to the amount of information to be given to patients by professionals. The only guiding principle should be the informational need of the particular patient which differs from patient to patient. Every information should be tailored to the informational need and materiality of the information to the patient's decision.

c. Understanding

Understanding is an essential element of the informed consent process. No matter the amount of information disclosed to a patient, for clinical treatment or procedure, or to a participant, in research, without proper understanding and comprehension by the patient or participant, any decision based on this improper and inadequate understanding or comprehension, renders that decision or consent invalid.

As a result the professional must devise ways or means to communicate these information to the patient in a way and manner that he or she would understand. In other words, the professional must come to the patient's level of understanding. The patient must be able, in his own terms, language and level of understanding, to understand "diagnoses, the nature and

purpose of the intervention, alternatives, risks, and benefits and recommendations" (Beauchamp & Childress, 2001.p.89)

d. Voluntariness

Coercing, pressuring or unduly influencing a patient, in any way, form or manner to consent to a procedure, treatment or research, renders such consent invalid. Hence, a person can only rightly be said to have voluntarily consented to a procedure if he had acted "voluntarily to the degree that he or she wills the action without being under the control of another influence", (Beauchamp & Childress, 2001, p. 93) and if his ability to voluntarily make such decisions has not been affected by his medical, psychological, economical and even religious state or condition.

e. Consent/refusal

Here comes the last stage of the process which unfortunately many people think is the only one component process of the informed consent – that is giving consent or refusal, or signing of the form or refusing to sign it. I want to reemphasize again that informed consent also entails informed refusal.

It is only when a patient or a participant, in research, has been judged competent or of having decision-making capacity, the core material information, pertaining to the procedure or research, disclosed to him, the patient demonstrates adequate understanding of the information disclosed, and judged to be under no undue coercion, influence and pressure, that he can now be in a good position to consent (sign the form) or refuse to consent (not sign the form) to the treatment or research. So I repeat the informed consent is a process and not signing of the form.

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EXCEPTIONS TO THE REQUIREMENT OF INFORMED CONSENT

It is important to note that it is necessarily required that informed consent be taken from every competent, and voluntary adult patient before any treatment or procedure, or before participation in research. The loss of competence or consciousness does not automatically deny such a person the right of informed consent. In such cases, such right is transferred to and held in custody, and exercised for the patient by surrogate (a relative, a friend, guardian etc.) who makes decision on behalf of the incapacitated or unconscious patient. However, there are some popular legal exceptions to this legal and ethical requirement (some of which are still debatable, controversial, and may only be used in rare cases and with caution to avoid abuse).

Such exemptions include (1) Emergency situations where immediate treatment is necessary because patient's life or health is at risk, patient is incapacitated (unable to give consent or unconscious), and no surrogate (family member or friend) is a available to provide consent (2) Public health interests where mandatory reporting of infectious diseases is required, cases of outbreak control (like during the time of Ebola and Covid-19) where contact tracing or quarantine measures are required; cases of vaccination programs against such highly infectious disease that threaten public health safety through mandatory immunizations; and cases of mandatory screening programs (such as mandatory testing for blood donors) (3) In cases of Legal requirements such as court-ordered treatment for mental health treatment for individuals deemed a risk to themselves or others; mandatory reporting of child abuse, elderly abuse, or certain crimes; and public safety laws like Breathalyzer tests for suspected drunk driving, (4) In cases of "therapeutic privilege" where disclosure might severely cause emotional distress or harm a patient (this is very rarely used and very controversial because it is open to abuse), and lastly (5) In cases of implied consent

which includes routine medical procedures where patients' actions may indicate consent such as vital signs, and basic exams (Levitin, 1996 pp. 44-45).

CONCLUSION

I have tried to argue in this paper that informed consent is more than a signature on a form. Rather it is an ongoing process of communication and shared decision-making. By prioritizing transparency, understanding, and patient autonomy, healthcare providers can uphold ethical standards and improve outcomes. It is time to shift the focus and change our attitude from mere documentation to meaningful dialogue. Healthcare professionals should have it in their mind in respect of the principle of autonomy and its consequent process of informed consent that they can only go to the extent a competent, adult, and informed patient is willing to go with them.

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