THE EPISTEMOLOGICAL IMPORT OF INFORMED CONSENT IN CLINICAL RESEARCH

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ABSTRACT: This paper attempts to establish the epistemological import and limits of informed consent in clinical research. It points out that informed consent is a necessary requirement in clinical research because it ensures adequate participation of care receivers in issues relating to their health. Besides ensuring that care receivers have knowledge of whatever medical intervention they are consenting to, informed consent, as an ideal, provides assurance that care receivers and others are neither coerced nor deceived. While the question of the value of informed consent in health care delivery is not so much controverted, in contest is the question of whether or not complete and wholly specifically informed consent can indeed be realized in medical intervention. Two orientations are identified in this debate. One insists that an individual will be able to make an informed decision and make reasonable choices amongst alternatives when fully informed. The other orientation sees as an epistemic illusion, achieving full informed consent, and rather opts for informed request. This paper examines this debate by clarifying the notion of informed consent, its components and its nexus with knowledge. The position of the paper is that informed consent is not only an ethical ideal in clinical research and health care; it is also an epistemic virtue that must be continuously strived towards. This paper establishes that health care receivers can only have an epistemic claim of their medical situation if all requirements of informed consent in health care delivery such as provision of adequate information, the risk and benefits of treatment, avoidance of vague/ambiguous statements, voluntariness, etc. are met.

Keywords: informed consent, epistemology, autonomy, health care, clinical research

INTRODUCTION: Epistemology and ethics are interrelated areas of philosophy. In the area of philosophy of medicine, this nexus plays out as well, though unusually recognized. In this paper, our intent is to critically discuss the epistemological import of informed consent in health care delivery. In doing this, the paper shall delve into the meaning and features of informed consent in relation to health care. In exploring the epistemological implications and limits of informed consent, conceptual analysis of knowledge and its conditions is provided. Consequently, the paper examines the connection between informed consent and knowing with some concluding critical notes.

INFORMED CONSENT: SOME CLARIFICATIONS: Aderogba, a 58 year barrister had received treatment for prostate cancer. At the time of diagnosis, investigations revealed local spread of the disease but there was then no evidence of systemic spread. Following initial treatment, he remained well for one

year when the picture changed radically. The cancer had spread to several bones and, in particular, his spine. He was told of his diagnosis which he accepted in due faith. Because of his situation, he viewed life has a great mystery. Few months after, his physician told him about some researchers who visited the hospice where he was. The intent of the research team was to conduct certain research on prostate cancer. His physician wanted him to participate in the research but he failed to fully inform him of the risk of participating. The only picture he had of the research was a positive one. Aderogba ignorantly consented and signed the informed consent form given him by the physician.

The above clearly shows the case of a research participant who consented to research procedure without information and knowledge. What then is informed consent?

Informed consent is very much prominent in modern bioethical discussions. It is a concept that recognizes the importance of the patient in health care system. Ideally, a patient who visits a physician is meant to divulge certain medical history about himself to the physician and the physician is equally meant to carefully digest the information given to him by the patient. This information is meant to assist the physician in the process of diagnosis. This is also applicable to research in health care delivery where prior information given to the patient is important in decision making. As an ethically acceptable medical practice especially when taking actions that concern others, informed consent can either be on medical treatment or on research on human subject. For the purpose of this paper, informed consent is used and understood in the latter sense.

Voluntary request and informed consent of human subjects have been the central focus of non-therapeutic research on human experimentation. There is a serious concern in research as a whole especially in relation to the involvement of research participants who are unable to consent to intervention. Research on human subject is a worrisome practice and this accounts for why there remains no satisfactory ethical justification for the inclusion of incompetent adults and children without any immediate intended benefits in the clinical research outcome. These set of individuals are seen as belonging to a vulnerable group. The inclusion of children has been extensively discussed in bioethics debates, and to this effect, it has been addressed in legislation and recommendation [1.]

We cannot dispute the fact that research on humans are vital because of the obvious and challenging problems faced in health care system on daily basis. These problems require urgent attention especially in the wake of high number of avoidable death recorded on a daily basis on health deficiency ground. Some of these problems are not new while some are recent medical problems. Medical research have led to proffering cure to all sort of diseases such as cancer, leukemia, dementia, HIV etc. This has no doubt promoted the public good hence the need for research.

On the above premise, informed consent is important and necessary in medical practices specifically in clinical research; though there are some basic difficulties confronting it. We cannot give informed consent when we are very young or very ill, mentally impaired, demented or unconscious, or merely frail or confused. Often people cannot give informed consent to emergency treatment [2]. Besides these problems, even in cases of adult with maturity of minds, we must also note that the way in which persons comprehend information differs. One may probe further the cogency of informed consent by asking whether or not a competent care receiver whose consent has been sought with full information disclosed and discussed is disposable to responding more positively to care and treatment than a care receiver without informed consent.

This is a very important question to be considered. There are two sides to addressing this vital question. On one hand, a patient who has adequate information of his health in general and who is well informed of

the research procedure he wants to engage in may respond positively to treatment. Some patients respond better when they are informed and know of the intended intervention. Such patients consciously decide to care less about the painful medical procedure in such research with the sole intention of achieving a positive end. For such patients, knowing is a contributing factor to their health.

On the other hand, some patients may have a different outlook of life after knowing. In fact, they make a very radical decision by not even wanting it to work. Such patients may consciously decide not to cooperate in any way with the care giver considering the fact that the cooperation of the care receiver matter a lot in care delivery. Dealing with difficult patient in the process of care can be quiet frustrating and the objective of intervention may be a mirage. However, whether knowing yield a positive result for some and yield otherwise for the other does not make knowing and information giving not worth pursuing. Informed consent in research is a medical necessity that must be pursued giving all due recognition.

COMPONENTS OF INFORMED CONSENT: Having understood what informed consent is there is a need to point out the vital features of informed consent. Informed consent consists of two major components. One is the physician's disclosure of all necessary information to the patient. This information must include diagnosis, prognosis, available and alternative treatment, and the risk, benefits, and consequences of having or refusing treatment [3]. The second component is the consent of the patient who decides whether to accept or refuse treatment on the basis of the information provided.

Informed consent in clinical research has highlighted in Ad protocol, 2005 Art.13 should include the purpose of study, study design, risk and benefits, alternative to participation, duration of study, voluntariness and confidentiality of personal data [4]. We may therefore ask if all these requirements are met before enrollment of research participants and if yes, can we be sure that participant fully get the information right.

Nuremberg Code is a response to notorious abuses in researches in the past. This code establishes voluntary and informed consent of the human subject as the grounding principle for the ethical conduct of research.

Voluntary consent according to the Nuremberg Code is defined in terms of the following:

This means that the person involved must have legal capacity to give consent should be so situated as to be able to exercise power of choice without the intervention of any element of force, fraud, deceit, duress, over reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and should have sufficient knowledge and comprehension of the elements of the subject matter involved to enable him to make an understanding and enlightened decision (Nuremberg Code) [5.]

Despite the cogency of this code, we cannot pretend as if it does not have its limitations. Deducing from the above quotation, this code says that person involved must have legal capacity to consent. But what about a situation where the concerned person is not legally competent to consent? The inadequacies in Nuremberg Code was addressed and recognized by the World Medical Association's Declaration of Helsinki. The declaration states that in case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation [6].

Informed consent goes beyond informing and consenting. There are situations where consent is given as a result of coercion or manipulation. This cannot be considered as a genuine consent even if the patient is fully informed and fully understands [7]. Coercion sounds very cruel and is something to be discouraged

in health care delivery. This is the same to paternalism in doctor patient relationship where the physician believes s/he always knows better than the patient. However, it is not all unlikely that information might be provided to the patient in a way which will lead to the patient choosing as the practitioner would wish [8.]

The above mentioned requirements of informed consent need to be further explained. In research, it is expected that the participant be given adequate information in comprehensible form. This is necessary in order to avoid participation in the absence of knowing. This is what is referred to as informed consent form. The informed consent form states very clearly all that the research is all about. These requirements are highlighted and briefly explained thus:

The Purpose of research: the informed consent form should state the purpose of the research. Why the research? What objective does it hope to attain? What are the contributions of the research to human life and existence? How can the research help develop the area of medicine and knowledge acquisition. All these need to be fully explained in the informed consent form

The protocol purpose: Research protocol is also given to research ethics committee before the approval of the research. Research ethics committee and research review board can either approve or deny the protocol as long as they are not satisfied with the content of the research protocol. This is done in order to ensure the protected of individual right and dignity.

The study design: The study design is included in the informed consent form so that patient can know and understand the pattern the research is going to take.

Risk and benefits: There is no research without its risk and benefit; therefore, the researchers should endeavor to provide the participant the likely risk in participating and also with the things to be benefited in participation. We cannot dispute the fact that there can be unexpected risk but information on the expected one should be made available in order to help in decision making in either to participate or not.

Alternative to participation: This like any other requirement of informed consent is also very important. The patient needs to know the alternative to participation. As a patient, if I am not participating, what do I lose? What other treatment is available for those who have chosen not to participate? This must be told with all sense of sincerity. The researcher does not need to present terrible situation to the patient so that he feels the best decision is to participate.

Duration of study: The patient need to know how long the research is taking. When the research is starting and when is ending. This will ensure proper planning and enable patient to have an already made mind set.

Voluntariness. In an ideal situation, it is expected or assumed that a person have the right to voluntarily accept or reject any offer. Acceptance of any proposal should be strictly voluntary and not through coercion. Equally, the patient should be allowed to exercise his or her right to refuse or to withdraw from intervention when he feels uncomfortable at any stage or phase.

Confidentiality of personal data: Certain information is needed before a person can be enrolled in research. Ideally, some research has age range. This is a convenient way of searching for those that truly qualify to participate in research. This information is meant to be kept strictly confidential and not be made available for public consumption.

It is worth noting that if any of the components is missing then, informed consent has not been met. It takes only a patient who has an in-depth understanding to either refuse or accept any intervention.

However, a combination of these components is necessary but may be difficult to attain. These components can only be attained when we spell out the necessary requirements needed for a patient to be capable of consenting. Here comes in the issue of competency. Competency in decision making is a major problem with informed consent. How can we define competency and when is a person said to be capable of consenting? Who determines a competent patient? What happens in case of incompetency? Having discussed the meaning and components of informed consent, there is a need to do a conceptual clarification of epistemology i.e. knowledge in a bit to bring out the epistemological imports of informed consent.

WHAT IS KNOWLEDGE? The concept of knowledge is the central concern of the field of epistemology. In Philosophy, there is no way we can possibly discuss knowledge without situating it in epistemology.

In the literary sense, there are two usages of knowing. The two senses are 'knowing that' and 'knowing how'. To 'know that' could mean to have a fact and information about something while 'knowing how' means the ability, proficiency and skill to do something. With this explanation, it is clear that there is a difference between 'knowing that' and 'knowing how'. It is possible to know that something is the case and may not be able to know how. For example, if I can swim, I can as well make a categorical statement that I can swim and may not be able to explain how I do it. This is not the case in Philosophy; when you claim to have a knowledge claim of something you should be able to justify further that the claim is true.

Epistemology is a branch of Philosophy that is concerned with the nature and scope of knowledge (9). The Latin word *episteme* means knowledge or knowing. Thus epistemology is knowledge or the study of knowing. Epistemology addresses questions such as what is knowledge? How is knowledge acquired? What do we know? How do we know that we know what we claim to know? How certain is our knowledge claim? While these questions can be slightly confusing for common man, philosophers ponder on these questions in an attempt at coming up with plausible answers.

Like Philosophy, there is no universal acceptable definition of knowledge because there are divergent definitions provided. Not until 1960 when Edmund Gettier wrote a provocative essay to debunk these existing criteria of knowledge, for a very long time, the traditional definition of knowledge as justified, truth, belief was greatly embraced by scholars and considered a sufficient definition of knowledge. The traditional definition of knowledge as justified, truth and belief states that 'S' knows that 'P' if and only if 'P' is true, 'S' believes that 'P' and 'S' is justified in believing that 'P'. This definition of knowledge goes in line with Ayer and Chilsom's definition of knowledge. Gettier argument is that the traditionally held notion of knowledge cannot be considered an adequate definition of knowledge because it is possible for a person to be justified in believing a proposition that is in fact false. Knowledge is more than mere belief. When you claim to know something; you must also understand what you claim to know. Epistemology also states the difference between believing something and knowing something. You can believe something but that does not need to be right or wrong. In other words, you can believe in something and it could be right or wrong. On the other hand, if you know something, it cannot be wrong, as knowledge is absolute while belief is not. You continue to believe in things only when you are not sure of them. The moment you are sure of something, in other words, the moment you are certain about something, you stop believing it, as you know it.

It is important at this juncture to establish the connection between informed consent and knowing this would assist a great deal to bring out the epistemological import of informed consent in clinical research.

THE NEXUS BETWEEN INFORMED CONSENT AND KNOWING: Informed consent is closely linked to knowing. Information gives the opportunity to know and knowing guarantees and secures consent. The patient needs to know or have knowledge of what h/she is consenting to. Knowledge opens up a wide range of understanding without which one cannot make an informed choice or decision.

Some lessons can be deduced from the citation of Isaiah Berlin. He writes:

I wish my life and decisions to depend on myself, not on external force 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 reason, by conscious purposes, which are my own, not by cause which affects 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 [10.]

The above quotation points to important thing that cannot be undermined. It shows very clearly the importance of autonomy, individual decision making capacity, and rejection of paternalism whether in clinical research or health care. In clinical research, if all the stipulated guidelines and conditions are fully explored, the potential participant cannot in any way claim ignorant during the research process because he would have been made to understand the risk/benefit of participating. Besides this, the avenue for exercising competence and autonomy would have been guaranteed. In all these, informed consent is intrinsically linked to knowledge because information produces knowledge and having the knowledge of something shows one has been informed.

Let us briefly examine the case of Mr. Aderogba. From the analysis of his case, it is clear that he consented without having the information that will enable him makes an informed decision. This can simply be termed consent void of information. The researcher in his case had failed to respect his autonomy, respect him as a person and respect his desires. This point can further be strengthened when will look closely at the components of informed consent earlier explained in this paper. We may need to ask if the purpose of research was adequately explained in the inform consent form. Does the participant understand the risk and benefit of the research? Did he give a voluntary consent? Can we say that Mr. Aderogba was duly informed prior to the carrying out of the research on him? How can we assess the competency of Mr. Aderogba in his decision? These and many more are the envisaged problems of informed consent and research in human subject. The issue here is not limited to whether the research exposes a subject to harm, but the moral wrong of using a person as a means to an end and only a means to an end [11.]

It is crystal clear from the case given above that Mr. Aderogba did not give an informed consent in the research he was made to participate in. He consented without information. This is because to give an inform consent to something, you must have a detailed and elaborate knowledge of that very thing and you must truly know the danger and likely benefit of what you are consenting to. In knowing, you must also understand what you claim to know. If understanding is lacking then it cannot be referred to as an informed consent.

Conclusion: Having thoroughly discussed the content, meaning and requirements of informed consent in research, it is deducible that informed consent is a key requirement for the ethical conduct of human subjects' research. Informed consent no doubt guarantees participants actual participation in decision

making of their health without any form of coercion medical paternalism. It is quiet unfortunate today that in many ways, care receivers are vulnerable to many medical interventions specifically in research. They are vulnerable because they do not know and cannot claim to have an epistemic claim of what they have consented to. We cannot at the same time claim ignorant that many researchers may want to use this avenue to exploit participant because research is highly important and vital to human continuous existence.

On the whole, clinical research is often the most efficient and valid method to generate valuable knowledge that improves patient care. Without it, medical knowledge becomes static and health care delivery becomes handicap. This statement poses a very serious worry. There is problem with contradictory interest; should we sacrifice the interest of the majority at the expense of protecting and ensuring the individual's interest or vice versa? If this holds, then utilitarianism as an ethical theory should be embraced. This goes to show that informed consent is not only an ethical ideal in clinical research and health care; it is also an epistemic virtue that must be continuously strived towards. It is the position of this paper that informed consent is necessary only that all requirements of informed consent should be worked towards being met in order to protect the integrity of the research and ensure the dignified interest of the research participants.

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