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Ethical Issues in Bio-Medical Research: A Re-Appraisal for Public Health Services in Nigeria

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Abstract
Public health is as essential as life and living. The onus always lies on the state to promote the physical and mental wellbeing of its citizens. Treatment consent in African communal cultures privileges decision reached by community consensus. Yet, medical research is essential to enhance public health. However, medical research, itself, must be carried on observing the basic ethical codes—broad and/or specific. The purpose of this study is to uncover such common nexus among medical research, ethical codes, and achieving public health in Nigeria. Taking the Afemai-Etsako of Nigeria as case study, it examines the place of the wider ethical codes enshrine in the Nuremberg Code, whether adult patients are allowed to refuse effective and standard treatment against their self-interest and the consensus decision without punitive measures by the doctors, the family and the community. This qualitative research found that adult males and females could (and do) refuse medical treatment and that patient consent is a precondition for treatment. This pilot study is significant because it highlights an African perspective to consent and refusal to medical treatment in global bioethics.

Keywords: Afemai-Etsako, ethics, health/public health, medicine/medical research

Introduction

While health is "the state of being sound/whole in body, mind, or spirit," public health is the "health of the community at large…the methods of maintaining the health of the community, as by preventive medicine and organized care for the sick" (Garner, 1999, p. 787). Many states have "a public health department" (or other agency) responsible for applying public health law/service and maintaining public health. However, medical practice dates back to 4000 BC. For instance, in pre-historic Egypt, medicine was practiced in the Fourth Dynasty (2900-2750). But there is no documented evidence of a code of ethics for medical practice at that time, though it might have existed (Berdon, 2006, p. 1). It was in the 5th Century BC, that the Oath of Hippocrates was formulated in Greece by Hippocrates. The Oath is generally regarded as the first ethics document with global recognition. Till date, doctors world-wide still swear to adhere to the tenets of the Hippocratic Oath (HP).

Firstly, the HP is an outline of the principle "do no harm" (*primum non nocere*) (Mason and McCall Smith, 1983: 251), and second, an explanation of what should constitute an appropriate relationship between physicians and patients. The Hippocratic Oath was silent on research involving humans. Despite this, the injunction '*first do no harm*' was to prove relevant to the development of future medical research ethics documents involving human subjects (Omonzejele, 2018).

Much research has shown that medical decisions among African cultures are made by the community (Osuji, 2014), which includes the patient, the family, kindred elder, and the African Traditional Medical doctor (ATMd). In some instances, the ATMd is a member of that community. The decision leading to consent is arrived at by consensus among the patient, the family, and kindred elder, and occasionally it includes the ATMd. Following this consensus, the consent is given, and the patient accepts the treatment. This form of informed consent where the autonomy is considered or practiced in relation to others, specifically members of the family and community, is referred to as relational autonomy in informed consent (RAIC) (Osuji, 2014). As long as the patient adheres to the consensus reached, and follows through with the treatment, there is no further problem. However, what is not certain is what happens when, against both her or his self-interest and the consensus decision, the patient refuses to follow an effective and standard treatment (Osuji, 2017).

However, in the context of Afemai-Etsako Traditional Medicine (A-ETM, i.e. a form of African traditional medicine practiced among the Afemai of Nigeria), when adult patients refuse or withdraw from effective and standard treatment against both their self-interest and the consensus decision of the family and kindred elder, and the A-ETM doctor, what are the consequences for the patients? (Osuji, 2017). There is, therefore, the need to uncover whether adult patients are allowed to refuse effective and standard treatment against both their self-interest and the consensus decision without punitive measures. The primary focus is not whether consent is informed or not, or how informed it is.

The entire *Afemai-Etsako* cpmprisess of the present Edo-North senatorial of Edo State, Nigeria. It has an estimated population of 577, 100 thousand people (NPC, 2006/16). So the scope of this study covers the three Local government areas in Afemai-Etsako division, viz., Etsako-East, Etsako-West, and Etsako Central. However, useful generalizations would be made of some claims since most traditional African communities' perceptions of reality share some similarities in their essentials. Although this work may not be the first surrounding the discourse on trado-medical and public health experiences in Nigeria, it, however, is an eye-opener of the experience among the Afemai-Etsako.

Terse Literature Review

According to Osuji (2017), most research on informed consent in Nigeria and, indeed, in Africa have concentrated on clinical research in the context of Western-styled medicine, with only a few on clinical practices in hospitals. Some of such research include those from Nigeria (Irabor & Omonzejele, 2009; Agulanna, 2008; Osuji, 2017).

Generally, informed consent can be described as a voluntary, autonomous authorization by a subject or patient to the medical professional to initiate or not to initiate; to proceed or not to proceed with a medical proposed plan or intervention for the patient. Tom Beauchamp and James Childress outline the criteria for informed consent. To have proper informed consent, other than institutional consent, according to the Biomedical ethics principle, there has to be the following process, 1. Competence, that is, the patient must be of age and capable of consent, 2. Disclosure of information from doctor to the patient, 3. Understanding by the patient of the information disclosed, 4. Voluntariness, that is absence coercion and undue

internal and external constraints, and 5. Acceptance/Refusal, that is, the patient authorizes or refuses the treatment or research (Irabor & Omonzejele, 2009, p. 37; Osuji, 2018).

Similarly, the Code of Medical Ethics in Nigeria holds a similar concept of informed consent as above and enunciates similar criteria for it as Beauchamp and Childress. It upholds the rights of a patient to accept or refuse treatment. Rule 19 Part A of the Code requires that consent be obtained from a patient or the relatives, or the public authority before treatment depending on the situation. The Code stipulates that a proper informed consent must incorporate the following, the benefits and risks of a procedure, appropriate professional advice on options, the patient's choice of preferred option, and authorization for the clinician to commence treatment by completing the form (Medical and Dental Council of Nigeria, 2004; Ezeome & Marshall, 2008, p. 139). The primary focus of this study is not whether consent is informed or not or how informed it is, but rather to discover whether adult patients can refuse effective and standard treatment against both their self-interest and the consensus decision without punitive measures (Osuji, 2017).

More so, Osuji held that:

> …the patient's consent is paramount...his relationship with the Doctor is based on consensus. It follows that the choice of an adult patient with a sound mind to refuse informed consent to medical treatment, barring state intervention through judicial process leaves the practitioner helpless to impose a treatment on the patient (2017).

Christopher Agulanna (2008) studied decision-making in communal societies of three African ethnic groups: Hausa-Fulani, Yoruba, and the Igbo. He found that decision-making in these ethnic groups is generally by consensus. He applied this consensus style to decision-making in biomedical research in Sub-Saharan Africa. Because he was concentrating on biomedical research in Western-style medicine, his work considered what he called a 'multi-step" approach to informed consent in research and clinical practice in sub-Saharan Africa (Agulanna, 2008); his' did not look into the refusal of treatment amongst the A-ETM experience.

On their part, Annas and Grodin (1998) noted that in most settings in Africa, voluntary, informed consent would be difficult, and it might even preclude ethical research (p. 562). Their reason is that where there are scarce medical facilities and services, patients will take whatever comes their way, even if it is presented as research. The people will see the research as treatment (p. 562).

The Nuremberg Code

Historically, in modern sense, the first significant regulatory guideline in research involving human subjects after the Second World War is the Nuremberg Code of 1947. The Nuremberg Code was issued as a result of research abuses committed by Nazi scientists during the Second World War. The purpose of the Code was to prevent the recurrence of such atrocities under the guise of medical research in the future (Freud, 1970, p. vii). Ten principles were listed in the Nuremberg Code to be taken into consideration before an investigator could undertake medical research, which required the use of human research subjects. Those principles for permissible medical research are:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free 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 comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision….
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature….
3. The experiment should be so designed and based on the results of animal experimentation and knowledge of the natural history of the disease or other problems under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject (The United States Government Printing Office, 1949, pp. 181-182).

Ethical Dimensions in the Nuremberg Code One could examine the above clauses to see to what extent the Code serves as an effective instrument of protection for *vulnerable* subjects from *exploitation* and *harm* in the medical research setting. Before our ethical incision, it is germane to explain the concepts of vulnerability, exploitation and risks that could possibly lead to harm; and their import in the medical research enclave; especially as those concepts fare in the Nuremberg Code instrument (Omonzejele, 2018).

Vulnerability is a complex concept to define. This is because all humans are vulnerable in one way or the other. Omonzejele (2018) quoted Kottow as saying:

> …vulnerability is a human condition, from which we all suffer, and because of its universality we all agree that equal protection is due to every member of society. As societies grow more complex, the vulnerability of its members extends beyond the fear of aggression

> or the risk of having one's right thwarted. Much support and assistance are required before we become fully integrated members of society… (2003, p. 461).

Contextual forms of vulnerability refer to situations where the inability to protect one's own interests emanates from social, cultural, political or economic circumstances. The cause of making somebody vulnerable is extraneous. The lack of choices for access to essential medicines in, for instance, rural Rwanda is a social, political and economic circumstance affecting Rwandan citizens rather than vulnerability related to specific people. If some of the affected citizens were to receive political asylum in the United Kingdom, their access to essential medicines would be guaranteed. Intrinsic forms of vulnerability, on the other hand, is when the nature of vulnerability is imbedded in the research subjects themselves, such as; in the case of incompetent mentally ill[1] or children.

Consequently, the concept of vulnerability can be defined as a contextual or intrinsic state of being incapable of protecting one's own interests under threat of harm or under threat of exploitation leading to harm. A proper appreciation of the concept of vulnerability must necessarily take those two forms into reckoning (Omonzejele, 2018).

Exploitation is the act of taking undue advantage of individuals or groups to serve one's own interests by using an imbalance of power (Omonzejele, 2011, pp. 65-72). And the elements of exploitation are: Imbalance of Power (a Necessary Condition of Exploitation); Exploitation involves at least Two Agents. But it is possible for exploitation to involve more than two parties, that is, when an exploiter (X) goes through someone else (Y) to take advantage of the circumstances of the *exploitee* (Z). Wertheimer (1999, p. 210) refers to this mode of exploitation as "mediated exploitation" (Omonzejele, 2011). Another concern is that there must be Disproportion in Benefit Accruing. Yet, a key condition for exploitation is in fact not any imbalance of benefit or harm but the role of *coercion*. One of the parties has to be in some sense *pressured* into the contract if it is to count as an exploitative one. The pressure can come in different forms. One arises out of ignorance. Another is from lack of alternatives or from perceived lack of alternatives. *Ignorance* It would seem that the ability to exploit another often times emanates from unequal *knowledge* on a given subject matter.

A second opportunity for exploitation arises from one party lacking any *alternative* to the solution offered by the would-be exploiter, thereby coercing the *exploitee* into acceptance. What this means is that exploitation is not only about imbalance of power, rather, what makes a transaction between parties exploitative is where one of the parties has a compelling need for which s/he lacks alternatives (or suffers from a perceived lack of alternatives) while the other party, the potential exploiter, is able to satisfy this *need* with the intent and means to benefit his or her own interests disproportionately. In situations where one party is suffering from a compelling need and a second party is offering an arrangement which would among other things alleviate that need, a way of avoiding exploitation would be for the second party to meet the compelling need first, before any contract is negotiated.

In addition to physical and psychological risks, research subjects may be subjected to social risks. This is the case for instance when enlisting in the research leads to stigmatisation

within one's family or community. Social risks have far reaching implications in the African context sometimes long after studies have taken place. For instance, such risks could slim down the chances of a young woman getting married even though she was merely an infant when her family was stigmatized as a result of her family's participation in research (Omonzejele, 2012, p. 84).

The Nuremberg Code attempted to address the above three concepts with a view to protecting human subjects in the research setting. Efforts made in that document as the first international research ethics guidelines proved as veritable resource to subsequent international guidelines, such as, the Helsinki Declaration and the CIOMS document. At this point, let us examine the content of the Code one after the other.

V. Ethics and Bio-Medical Research Amongst the Afemai-Etsako

The findings of this study are presented under two broad subheadings, "Refusal of Treatment by adult males, females and children" and the "Interviewees' personal experience of a patient refusing medical treatment."

a. *Refusal of Treatment by Adult Males, Females and Children :*All the Afemai-Etsako Traditional Medicine doctors (A-ETMd), interviewed said that adult patients could, and do refuse effective and standard medical treatment even against both their self-interest and the consensus decision of the family, kindred elder, and the A-ETMd without any punitive measure against the patient. All the elders interviewed said that adult patients could and do refuse effective and standard medical treatment even against both their self-interest and the consensus decision of the family, kindred elder, and the A-ETMd without any repercussion or punitive measure against the patient. For example, an elder responded thus:

> …are you going to force someone? You only force little children who do not know anything yet, because we say, they are afraid of medicine. But if you give a grown-up adult some medicine or treatment that will keep him alive and s/he refuses, you cannot force her/him.

Likewise, all the elders interviewed noted that adult patients with mental illness could be forced to receive medical treatment against their wishes but with the consent of their relations. It is the consensus decision of the family, kindred elder, and the A-ETMd in the best interest of the patient. According to them, these patients are not able to comprehend and decide what is to best promote their interests. Similarly, most female family members interviewed said that adult patients could and do refuse effective and standard medical treatment even against both their self-interest and the consensus decision of the family, kindred elder, and the A-ETMd without any punitive measure against the patient. For example, a female family member responded that "If it is an adult, you plead with him/her to receive treatment for his/her good. S/he might accept." They noted that adult patients with mental illness (mad people) could be forced to receive medical treatment against their wishes, but with the consent of their relations. It is done in their best interest and upon the consensus decision of the family, kindred elder, as well as the A-ETMd. According to the female family members, these patients are considered incompetent to make a medical decision, that is, they are unable to comprehend and decide for themselves what is to their best interest. However, a few of the female family members added that sometimes the refusal of treatment has some repercussion on the patient. The patient has to believe in the A-ETMd and trust that the medication will cure him or her. Therefore, the patient's consent is one vital means of expressing that belief and trust.

Regarding children and minors, all the interviewees agree that parents and guardians assent for their children who are minors. Most said that children could be forced to receive medical treatment against their wishes because they do not comprehend what is at stake. They are unable to make such complex decisions. A few female family members and a female A-ETMd said that children who refuse treatment are cajoled and tricked through many ways to accept treatment. According to some, the level of intelligence and common sense, or wisdom exhibited by a child determine whether the child is considered an adult or not. The display of a certain level of wisdom depicts maturity and, therefore, one is allowed to undergo the rites of initiation into adulthood (wearing of the cloth) and permitted to marry or is admitted to the adults' kindred meeting. When one is initiated through any of the traditional means, one becomes an adult. Some of the interviewees agreed that these days, an eighteen to twenty-one years old child is considered an adult.

The interviewees offered various reasons why patients refuse traditional medical treatments or reject an A-ETMd. The reasons offered by the interviewees include uncleanliness of the doctor's practice site, the environment, and the medical facility. There is also the issue of trust. If the patient does not trust the A-ETMd or lacks faith in him/her, that patient will not receive treatment from such a doctor. Likewise, when a patient believes s/he has taken enough treatment without improvement, she/he can refuse to receive further treatment from that particular doctor.

b. Interviewees' Personal Experience of Patient Refusing Medical Treatment

The roundtable considered if they had had personal experience of someone who refused medical treatment. There was some reluctance from the A-ETM doctors in responding to the question. Most claimed to have not had. One of the doctors even emphatically stated that "there has never been a person who came to me and refused treatment/medication. No one has set foot here and after examining him or her and prescribing medication and s/he refused."

c. ***Communal Values vs. Paternalism and Vulnerability:*** In Africa (including the study area), persons are defined in relation to their community, to themselves, and to their personal creative spirit embodying their destiny (Osuji, 2014, 123ff). The African ethos presupposes an existing community into which individuals are born. The social settings and the networks of a community include varied forms and shapes such as family (both nuclear and extended), clan, village, city, ethnic group, neighborhood, as well as a nation-state. Individuals partake in these communities, and hence, participate in diverse social relationships. The community defines the persons through a system of education which includes initiation, socialization, acculturation, and experience. The community also furnishes individuals with beliefs, norms, values, and virtues which they internalize and apply as guides for conduct. In accepting these community values and norms as their own the individuals gradually become mindful of their responsibility to the community as well as the responsibilities of the community to them (Ikuenobe, 2006, p. 75). Subsequently, the socialization process "imposes some moral constraint on the actions and behavior of those individuals, even on their personal actions." (Osuji, 2014, p. 125).

d. ***Married Women and Consent/Refusal of Treatment :***The indication that a married woman would be treated differently from a man in obtaining consent resonates with other

studies. Irabor and Omonzejele noted that the methods of obtaining consent varies from a married Euro-American and a married African (Nigerian) woman. The principle of autonomy as it relates to a married Euro-American woman applies differently to a married African (Nigeria) woman (2009, p. 38). The reason behind this is that in African (Nigerian) bride price, often known as the "head money" is paid by the groom. This concedes part of the woman's autonomy to the groom and his family.

This impacts the securing of a direct first-person consent from her. Consent or refusal is given in part through the husband or the eldest male family member; in fact, "the process of obtaining consent from the husband of a female patient is perfectly in order within the local culture" (Irabor & Omonzejele, p. 38; Osuji, 2014). This can be explained as exercising autonomy in relationship (relational autonomy) and the consent or refusal in this context is referred to as Relational Autonomy in Informed Consent (RAIC) (Osuji, 2014).

e. ***Role of Trust and Faith*** From the results, the necessity and importance of the patient's trust and faith in the doctor is evident. Because trust and faith in the A-ETM doctor are considered essential for a cure, a patient can only accept treatment from a doctor that s/he has faith and confidence that his/her spirit accepts. If the patient does not like or trust the doctor, or if the patient's spirit does not accept the doctor, s/he does not consult that doctor. Eventually, the patient's relatives will not bring the patient there. This highlights the importance and the need for the patient's opinion or wishes to express consent or refusal in the practice of African traditional medicine.

f. ***Repercussions of Refusal of Treatment*** In the Western-styled medicine and hospital, when patients are discharged against medical advice, they risk reproach which may involve higher bills for treatment if they return to the same hospital or doctor. These healthcare professionals believe that such patients neglected their expertise and thus, insulted them, hence the need for reproach.

g. ***Importance of Consent in* A-ETM**: When the patient and or the relative/s first consults the A-ETM doctor, he/she takes the history and explains the diagnoses. Before any treatment, the doctor proposes a list of materials that the patient should provide for the treatment. The patient's response to the proposal is the concrete expression of consent or refusal. If the patient does not want the treatment or that particular doctor, then the patient will refuse to provide the materials. He or she will just work away never to return. But if the patient or his/her relations wish to consent to the treatment and from that doctor, then they will provide the proposed materials. Even if they cannot afford the materials or some of them, they will return to the doctor and talk it over as long as the patient is consenting to treatment.

h. ***Respect for the Wishes and Dignity of Individuals:*** The results of this study further suggest that there is a show of respect for the wishes and dignity of the individual-- contrary to the charges of paternalism often proclaimed by some scholars. A corollary to this show of respect is the consideration of the vulnerability of the sick. Patients are vulnerable in all societies and cultures. But some scholars have presupposed that patients are even more vulnerable in communal decision-making situations. The show of respect for the wishes and dignity of the patients makes it possible to refuse treatment without any punitive measure, and portrays communal solidarity with the sick, the weak, the bereaved, and the poor; it further helps to ameliorate the vulnerability of the sick.

Improving A-ETM for Public Health in Nigeria

As said earlier, public health is the science and art of protecting and improving the health of entire communities, cities, and populations rather than treating individual patients. The central concern includes *prevention* (stopping diseases, injuries, and health issues before they begin through measures like community vaccinations and health screenings); *protection* (defending populations from large-scale hazards, such as contaminated water supplies, unsafe workplaces, and infectious disease outbreaks); and *promotion* (encouraging healthy lifestyle choices, proper nutrition, and mental well-being through public education and supportive programs).

By and large, healthcare focuses on one person at a time, such as a doctor treating a sick patient in a hospital. Public health focuses on the whole group, looking at environmental, social, and systemic factors that affect millions of people at once. The Ministry of Health regulates, monitoring and collaborating with the traditional doctors in Nigeria. They should strengthen this collaboration because it has positive impacts on the practice of traditional practitioners such as improved hygiene in the preparation and storage of medicine, and in labeling and description of some medicines. We recommend more collaborations along the line of state and national meetings, seminars, and trade fairs. However, the government, through the ministry of health should encourage more collaboration between the traditional medical practice/environment and the orthodox counterparts by gradually create the atmosphere for the merging of both health care systems. There is also the need to increase the effort to check charlatans in the traditional experience.

Conclusion

Agreeably and despite short-comings associated with the Nuremberg Code, the document served as the first proof that nations could agree on common regulatory guidelines which all countries refer to as a 'research guidebook'. In addition, the Code helped to develop the Declaration of Helsinki, and the CIOMS document was meant almost an appendix to the Helsinki Declaration. This work espoused the nature of the various strands of enduring African ethical signification among traditional medical practitioners, their patients, and their communities in Afemai-Etsako of Nigeria. Hopefully, adapting those enduring values to suit modernity could enhance public health services in contemporary Nigeria.

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