

An Examination of the Moral Conundrum of Informed Consent within the Framework of African Values and Belief Systems: A Case Study

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Abstract

The notion of bio-medical ethics, which places a strong focus on individual autonomy when considering informed consent, is mostly inspired by western European medical and moral traditions, leaving African traditions and values out of the practice of medical ethics. This is due to the fact that African customs and values favour communitarianism above individualism. In African culture, your strong relationships with people in the community—which include sharing everything, including decision-making—are what define you as a human being. As a result, it is clear that when applied to the majority of Africans, the idea of individual liberty in informed consent is inapplicable. This is because African communitarian ethics focuses on the interests of the family, community and society and not the individual. Thus, there might be a conflict in the application of the western principle of medical ethics in the general population in Africa. This review paper intends to use published articles, reports, case studies, and ethical principles to explore this potential conflict.

Keywords: informed consent, African ethics, African values and norms, Ubuntu, Ukama, moral pluralism

Introduction

The notion of informed consent got its start from the idea that individual autonomy should be respected. Individual consent then became the primary goal of informed consent processes and activities. Bulger (2002) claims that after being fully informed of the processes, risks, and benefits of a research project, a patient or participant gives informed consent. Ideally, the patient or participant grants complete and conscious consent for the doctor or researcher to proceed with the procedure after thoroughly understanding the information regarding the project (Akpa-Inyang, 2017; Escobedo, Guerrero, Lujan, Ramirez, and Serrano, 2007). With the aforementioned description, it is reasonable to conclude that the principles of respect for autonomy and Western-European medical and moral traditions serve as the main sources of inspiration for the rules and norms of informed consent in bio-medical ethics.

African cultural values and traditions may be at odds with the Western-European concept of autonomy, which promotes individual respect. *Ubuntu* (isiZulu) and *Ukama* (Shona), two of the few fundamental African world views, advocate for a kind of wholeness that results from a person's connections and relationships with other members of the community.

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To be fully human is to be in close relationship with others in the community. This is due to the fact that their survival depends on yours ('you are because others are, and they are because you are'). Thus, African communitarian ethics prioritises the interests of a family or community over those of an individual, and as a result, communal decision-making replaces individual consent (Akpa-Inyang and Chima, 2021). Due to some of the traditional beliefs, customs, taboos, and practices that still influence how people act and interact with one another, it is possible for practitioners of Western biomedical ethics in Africa to run into unsolvable moral conundrums.

In light of the aforementioned argument, it has been highlighted that moral quandaries provide a challenge to the conventional Western manner of ethical thinking and may call for a number of possible solutions that may appear to be equally valid yet mutually exclusive or even unsolvable. Any ethical conflict or dispute requires the ability to recognise the issue, define it, and discuss it within a larger framework of accepted norms, guiding principles, and an ethically pertinent concern (Akpa-Inyang, 2017). Because of the disparities in cultural and moral norms and the seeming insurmountable issues with standard ethical theories, it is imperative in this study to seek for an alternative moral perspective.

Given that the communitarian system in Africa and other traditional African belief systems undoubtedly deepen one's connection to family, language, and belief in ancestral spirits/witchcraft, this paper will examine the moral conundrum of informed consent within the framework of African values and belief systems.

Defining Objectives and Setting Goals

In order to determine whether informed consent is appropriate in the context of African values and belief systems, this paper will analyse the idea of informed consent in biomedical ethics (both in research and the patient/doctor interaction). It is reasonable to assume that the concept of informed consent cannot be applied in the context of Africa because of the Western world's emphasis on individualistic lifestyles and individual autonomy; alternatively, if it can be applied, it must be done with extreme caution and with a healthy dose of cultural sensitivity and awareness. Respect for autonomy is the most widely acknowledged moral norm in the literature on informed consent, (Faden and Beauchamp, 1986; Akpa-Inyang and Chima, 2021). Informed consent, that is founded in the liberal Western culture, is envisioned as a fundamental belief in the value of individual freedom and choice for both political life and personal growth. Africa, on the other hand, is a cosmopolitan and diversified continent. Therefore, it is important to respect people's identities and the diversity of their ideals while simultaneously recognising cultural diversity. If those are

not dealt with, there is a danger of misrecognition which will be disrespectful and harmful to the research subject and patient. Hence, this review article will examine the moral conundrum of informed consent within the framework of African values and belief systems.

The Philosophical and Ethical Foundations of Informed Consent

It has been noted that informed consent is an ethical norm in contemporary biomedical ethics. Informed consent, according to Manson and O'Neil, is a key idea in modern biomedical ethics and is commonly regarded as essential to medical and scientific ethics (2007). Maclean defines consent as a freely decided, unconcerned decision by a sufficiently competent or autonomous individual to accept rather than reject some suggested course of action that will impact him or her, based on sufficient information and consideration (2009). Bulger claims that informed consent is intended to provide each participant with the freedom to accept or reject the advised medical treatment (2002). Its goal is to uphold each participant's rights as free, intelligent, and deserving being, and to ensure that they are treated as such (Escobedo, Guerrero, Lujan, Ramirez, and Serrano, 2007; Akpa-Inyang et al., 2022).

The evolution of the doctrine of informed consent can be traced back to the quiescent period in the transformation of the Hippocratic Ethic. During this period, the oath was paternalistic and authoritarian in nature. The patient had no say in clinical decisions and the doctor had all the authority in a doctor-patient relationship (Athanasiou and Bachtsetzis 2022). Over the years the Hippocratic Ethic underwent transformation. Factors such as a more educated society, distrust for authority and the spread of participatory democracy led to a demand for alternative ways of practising medical ethics. Principles suitable for medical ethics such as nonmaleficence, beneficence, autonomy and justice were adopted. The principle of autonomy became central to the doctrine of informed consent where a patient was seen to have a right to self-determination (Pugh 2020; Akpa-Inyang and Chima 2021).

The doctrine of informed consent was elucidated by Justice Cardozo in *Schloendorff vs Society of New York Hospital* when he stated in 1914 that (Bazzano et al 2021:82):

Every human being of adult years and sound mind has a right to determine what shall be done to his own body and a surgeon who performs an operation without his patients' consent commits an assault for which he is liable to damages.

This statement reinforces the fact that a human being has a right to autonomy and self-determination and cannot be compelled to accept treatment he/she does not want (Bucklin, 1975).

The first major document incorporating human rights principles that centred on the professional responsibility of the physician to the patient was the Nuremberg Code (Annas, 1999). After the Doctors' trial of 1946 - 1947, the Nuremberg Code was developed to guide biomedical research. The Judges decided that for experiments to be carried out, voluntary consent of the human subject was essential. This required that (Ghooi, 2011:74):

The person involved should have legal capacity to 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.

The doctrine of Informed Consent as spelled out in the first principle of the Nuremberg Code above comprises the elements of information, comprehension, and volition (Jones, 1996). The requirements of voluntary, competent, informed and understanding consent now generally apply not just to experimentation but treatment as well (Annas, 1999).

In 1964, The World Medical Council produced the Declaration of Helsinki, which further elaborated on the fundamental guiding principles in research involving human subjects. The Helsinki Declaration, though more paternalistic in nature, also seeks to enforce the elements of the doctrine of informed consent. The Helsinki Declaration also seeks to protect those with diminished autonomy - this includes children, prisoners, patients with mental and behavioural disorders and directs that proxy consent be obtained from a guardian or legal representative in such cases (Zimmerly, 1973).

This demonstrates the significance, sensitivity, and constant evolution of the informed consent issue. In recent years, it has been abundantly evident that informed consent is an integral component of biomedical ethics, and as the field of biomedical ethics spreads outside of its native North America and Europe, it brought with it the traditions and culture from which it originated. This is why the foundation of biomedical ethics and informed consent lies in Western-European philosophy, which has a very different idea of a human being as a rational and autonomous entity. Such views on personhood and the moral justification for informed consent are expressed in Kant's categorical imperative, which makes it clear that treating human subjects like objects is wrong (Akpa-Inyang, 2017). This simply means that people should not be viewed as tools to an end but rather as ends in and of themselves. This is due to the fact that it is morally improper and incompatible with the moral duty of a biomedical

professional to do no damage if they are not considered as ends in themselves. But thus far, it appears clear that the idea of informed consent is largely a product of Western intellectual beliefs and ideals and can potentially be damaging when extended to the African general populace. A brief explanation of African views on the existence of personhood and the ethical principles and imperatives that follow from them is necessary to assess if the existing ethical principles are directly applicable to the African biomedical environment.

African Concept of Personhood

African views assert the community's ontological independence and, as a result, its ontological dominance (Menkiti, 1984). This implies that the person's reality is secondary and derived. In Menkiti's (1984:171) view, "the reality of the communal environment takes precedence over the reality of the individual life histories, whatever these may be, as far as Africans are concerned." Menkiti draws the following conclusions from the alleged primacy of the reality of the community: firstly, that in the African view, "it is the community which defines the person as person, not some isolated static quality of rationality, will, or memory"; secondly, that the African view supports the notion of personhood as acquired through relationship; and thirdly, that "As far as African societies are concerned, personhood is something at which individuals could fail and this happens when one fails to relate or engage fully in the community".

Although there are many diverse African cultures, there are commonalities to be found among them in such areas as value systems, beliefs, and practices. These areas largely reflect the African world view which is greatly influenced by the African communitarian way of life. Particularly, Munyaka and Motlhabi (2009) contend that the guiding ideal of this worldview is referred to as Ubuntu. In order to address the ethical contradiction that results from the application of Western biomedical ethics, the paper shall examine this value along with a few others. The interaction between physicians and patients, or between researchers and study subjects, is fraught with difficulties in Africa. This problem occurs because Western European traditions place a strong focus on individual autonomy, but African notions such as Ubuntu, Ukama, and many others promote a sense of wholeness that results from relationships with and connections to other members of society. The dominant idea in Africa is communitarianism, which is founded on the idea that a person's social identity and personality are mostly shaped by ties within the society, with less emphasis on personal growth.

African Ethical Values and Imperatives

The word *Ubuntu* or other similar words are found in all African languages, although this does not make it immune to misuse and overuse. This is because it is a strong meaningful and loaded concept or value (Munyaka and Motlhabi, 2009). In most African communities, Ubuntu is considered as the most important quality of *umuntu* (a human being) (Akpa-Inyang, 2017). In this case 'Ubuntu continues to be a set of institutionalised ideals which guide and direct the patterns of life of Africans. It becomes a notion descriptive of a convergent set of desired goals which all, or at least most, Africans entertain and towards which their activities are directed' (Sogolo, 1993: 119). In addition, Broodryk (2005) argues that Ubuntu is the whole complex of traditional behaviour which has been developed by humans and is successfully learned by each generation. Ubuntu cultural norms have been orally transferred from generation to generation over a long time.

Ubuntu is commonly defined as a 'derivative of the word *muntu* meaning a person, a human being (Munyaka and Motlhabi, 2009: 64). According to Chinkanda, the word defines a positive quality supposedly possessed by a person. It is 'an internal state of being or the very essence of being human' (1990: 1). In addition, Ubuntu is not only about human acts; it is also about being, it is a disposition, and it concerns values that contribute to the well-being of others and of the community (Munyaka and Motlhabi, 2009: 65). Munyaka and Motlhabi went on to add that it is then accurate to say that Ubuntu is a person's self-realisation and manifestation as a human being. Having Ubuntu, or being human, is identified with having fully one's human nature and, by implication, in a manner that befits a human being. Thus, this makes it possible, in this sense, to denounce a person perceived to lack Ubuntu as being inhuman – literally a non-person (2009: 65). Ubuntu is a way of life which finds its humanly meaning in expressions which recur across the various African languages in Southern Africa: *Umntu ngumntu ngabany' abantu* (Xhosa) or *Motho ke motho ka batho ba babang* (Sotho) or *Umuntu ngumuntu ngabantu* (isiZulu) meaning, a person is a person through other persons (Munyaka and Motlhabi, 2009: 65). This is one of the basic and central tenets of the ethic of Ubuntu. Akpa-Inyang (2017) posit that this notion, or expression, of mutuality is in the African psyche. It is this feature or quality of Ubuntu that distinguishes a human person from other creatures. The above argument establishes that Ubuntu has also a sociological concept. Saule presented this perspective clearly when he asserted that Ubuntu represents the kind of human behaviour that is inculcated in the individual by the society through established traditional institutions over a period of time (Saule 2000; Akpa-Inyang 2017). This definition brings to awareness that Ubuntu is attained through socialisation. It is a way of life that seeks to

promote and manifest itself and is best realised or made evident in harmonious relationships within society (Akpa-Inyang, 2017).

Ukama is a Shona word that means relationship and an understanding of reality in terms of interdependence (Murove 2009: 316). Grammatically, *Ukama* is an adjective constructed U-Kama. The U- is an adjectival prefix and Kama is an adjectival stem. Kama becomes a verb meaning to milk a cow or goat. In Shona thought, the idea of milking suggests closeness and affection (Murove, 2009: 316). Those related by blood or marriage are *hama* which is a noun. In a nutshell, *Ukama* means being related or belonging to the same family (Murove 2009: 316). However, in Shona, as in many other African languages, the meaning of *Ukama* is not restricted to marital and blood ties. This is because most cultures in Africa tend to see all people as *hama* (relatives) (Murove 2009: 316). Michael Bourdillon captures the inclusiveness of the term when he asserts that, 'unrelated persons can adopt the terms *sekuru* (grandfather) and *Muzukuru* (cousin) towards one another to express a friendly relationship, reflecting the typical relationship between mother's brother and sister's son' (1976: 34). For instance, instead of an elder being addressed as a 'madam' or 'sir', such a person within the categories of *Ukama*, might be addressed as *mama* (mother) or *baba* (father) in Shona, Zulu, or Ndebele, or *ntate* in Sotho or Pedi (Murove 2009: 316). Being human entails living in relationships, seeing one another as relatives, or seeking to establish this relationship as an actuality' (Murove 2009: 316).

In addition, Murove postulates that 'among Africans, *Ukama* provides the ethical anchorage for human social, spiritual, and ecological togetherness' (2009: 317). It stands as the only enduring entity. According to Murove, 'the ethic of *Ukama* as constituting the wisdom and experiences of the community, is passed from generation to generation through these proverbs' (1999:14). For instance, instead of instructing someone that sharing food with others is a virtue, a proverb is used to convey the message, *Ukama igasva hunozadziwa nokudya* (relationship is a half-measure, it finds fulfilment in sharing). This proverb admonishes the selfish in its appeal to the *Ukama* ethic requiring one to share one's wealth with others (Murove 1999: 14). Thus, through *Ukama*, the community's moral values are conveyed to individuals from childhood into adulthood. And in social settings, individuals are frequently sensitised as well as remembered about the reality of interdependence from birth unto death (Murove, 2009: 317).

Moral Analysis of the Dilemma between Informed Consent and African Values

Top-down Approach or Bottom Up

The moral judgement and decision making can be seen in two ways. These are according to Beauchamp and Childress (2013), the 'top down' approach and the 'bottom up' approach. The top-down approach is based on the justifiability of a particular action through the application of various moral theories and principles. The 'bottom up' approach is a form of justification that begins with concrete and unmistakable instances of good and bad behaviour and proceeds to the formulation of general principles that capture and distil our fundamental moral responses to the cases. Thus, the traditional moral theory is a conceptual system that attempts to define and guide the best decisions and actions. It investigates the question of what the best way for people is to live and what actions are right or wrong in particular circumstances. Therefore, the traditional model of ethical reasoning seeks to resolve issues of human morality by putting in place concepts that will define ideologies like good and evil, right and wrong, virtue and vice, justice and crime. There are set principles and theories to be followed while making a traditional moral judgment.

The following are a few traditional moral theories:

- 'Consequentialism' argues that an act is right if and only if it produces the best consequences. Thus, right and wrong depend solely on consequences, as opposed to on intrinsic moral features such as fidelity and truthfulness.
- 'Utilitarianism' postulates that an act is right as it tends to promote pleasure and or happiness and wrong as it tends to promote the opposite of happiness. Thus, one should always act so as to promote the greatest happiness of the greatest number.
- 'Deontology' ethics by Immanuel Kant: here he argues that nothing is good or right except a good will, and a good will is one that wills to act in accordance with the moral law. Thus, an act that is done out of respect for moral law rather than out of natural inclination is a good act. He saw the natural law as a categorical imperative. This means that its content could only be established by human reason alone.

These and many other traditional moral theories are of great help when it comes to making moral judgments. But in cases of ethical dilemma, they are not sufficient. This is because each traditional moral theory looks at only one way of deciding what is right or wrong, whereas in application of ethical theories to a case-base issue, reason and happiness might conflict and then produce a dilemma. To deal with such dilemma, ethicists have come up with some alternative models of ethical reasoning.

The traditional top-down models of reasoning are monistic and reductionist, i.e. based on a belief that all moral considerations can eventually be grounded in one ultimate principle in terms of normative foundations that can provide solutions to all moral controversies. In this regard, Beauchamp and Childress (2013) argue that the traditional ethical theories are reductionist. This implies that they reduce the essence of morality to one all-embracing principle, and a single all-encompassing standard of morality of right action, not considering the fact that the moral reality is too complex in itself. The complexity of our decision making is aggravated even more by non-moral conditions. And there is no guideline on how to choose the right approach or how to determine the right moral and non-moral reasons that tend to justify our actions. The inability to give a guideline on justifying our actions establishes that the traditional moral theory is unable to resolve the question about the relationship between universal and particular. That is, it cannot state clearly how to apply the general universal principle to a specific case. This is the reason why the top-down approach fails (Beauchamp and Childress, 2013).

Beauchamp and Childress argue otherwise: traditional moral theories have internal problems and are not very helpful in the resolution of moral dilemmas and practical issues.

Considering Beauchamp and Childress' critique of the traditional top-down approach, this research study follows the bottom-up approach because the traditional moral theories as demonstrated above appeal to an abstract universal notion of personhood and could be means of intellectual and cultural imperialism. This is because biomedical ethics deals with real people in particular situations, i.e., particular persons in particular contexts or contextualised persons. Biomedical ethics is also rooted in culture. If there is no cultural practice and way of life, there will be no biomedical ethics. This is because the four assumed globally accepted biomedical ethical principles are autonomy, beneficence, nonmaleficence and justice formally established by Beauchamp and Childress (2013) to address biomedical issues in the West. This is why they are rooted in the Western-European traditions and the Western-European world is different from Africa. Constructively, biomedical ethics in the real sense cannot function without a culture because its elements and principles are based on culture and traditions (Chukwuneke, Umeora, Maduabuchi and Egbunike, 2014). Thus, the case study approach seems to be most suitable, instead of imposing some sort of priory values and principles, it allows to distil them from the particular cases that are historically, culturally, and otherwise situated. Thus, one would assume that Africa-situated cases should distil African values and principles.

Firstly, this research is opting out of monistic approach and opt for a pluralistic one because of its compatibility with the idea of multiculturalism. As argued by Wildes and Kevin (2007), culture has a deep relationship with morality. Thus, the concept of multiculturalism links directly to the reason why morality should be pluralistic while recognising diversity. He asserts that morality encompasses the moral practice which is embedded in culture which we see as a way of life. Ethics seeks to examine those practices and moral systems that are embedded in cultural practices. Thus, advocating for a multicultural society, which a lot of people do nowadays, will be synonymous to advocating for a morally pluralistic society.

Moral Pluralism

Brody's version

It is of the idea that there is an irreducible plurality of the fundamental moral principles in accounting for conflicts (Ross, 1930). For Brody, there are three angles that pluralistic theory can be defined from. These are the ontological, logical, and epistemological and they are all about using several independent moral or non-moral properties to draw conclusion to the action in question (Brody, 2003).

According to Brody, the moral world is messy because it has many different aspects which cannot be reduced or eliminated (Brody, 2003). Brody also asserts that when one examines a monistic theory, especially when it is addressing difficult cases or 'exceptions', like moral dilemmas, there are appeals to other moral properties. There is a temptation to build in other moral properties in monistic theories. Based on this examination, Brody argues that it is a fundamental mistake for moral philosophy to assume that any one aspect can capture the whole of the moral reality. With this statement, he demonstrates the understanding that the moral world is complex and cannot be reduced to a particular aspect if one is to have completeness in addressing moral issues (Brody, 2003).

Apart from Brody's defence of pluralism, he suggests a clear model of analysis of the relationship between cultural pluralism and moral pluralism. Though Brody's pluralistic theory is complex it can be very influential and useful in the aspect of cultural inclusiveness. This is because Brody is not trying to argue and simplify moral pluralism and moral differences into 'sameness', rather he is arguing for a model of pluralism rooted in the wide variety of moral appeals.

Ross' Model

The central notion of the alternative approach is *prima facie duties* – which literally means from the first sight which is different from absolute duties

that hold in all circumstances or conditional duties (Beauchamp and Childress, 2013).

Ross argues that:

Prima facie suggests in this approach that one is speaking only of appearance which a moral situation presents at first sight, and which may turn out to be illusory, whereas what he is speaking of is an objective fact involved in the nature of the situation or more strictly in an element of its nature, though not as duty proper does, arising from its whole nature (1930:20).

For example, is it your duty to keep a promise when you may be able to avert a serious accident by failing to keep it? There are two prima facie duties here: first is to keep a promise and the second, to relieve distress. The circumstances in the particular case can make the latter a greater duty, looking at the seven principles of prima facie duties which are the guidelines in decision making. These are fidelity, reparation, gratitude, justice, self-improvement, nonmaleficence, and beneficence.

- Fidelity is a duty to fulfil (explicit or implicit) promises/agreements which one has entered. This is a duty to keep one's promises and contracts and not to engage in deception.
- Reparation is a duty to make up for the injuries one has done to others.
- Gratitude is the duty to repay others for past favours done for oneself. Thus, it is a duty to be grateful for benefactions done to oneself and if possible, to show it by benefactions in return.
- Self-improvement is a duty to improve one's own condition in these respects. It is to act so as to promote one's own good in the aspect of health, security, wisdom, moral goodness and happiness.
- Nonmaleficence: these are provider-centred (like doctors) factors that advocates that no harm should be done nor allowed to happen to an individual. It also promotes protection of the interest and happiness of the other persons and of society at large.
- Beneficence: these are treatment-focused factors that focuses on the welfare of an individual, foster his or her interest and happiness.
- Justice: these are community-centred factors that request that everyone should act fairly, distribute benefits and burdens in equitable fashion and resolve dispute by means of fair procedure taking into account that this research will focus on Africa. (Ross, 1930).

The reason Ross's model is preferred in regard to this research is that the prima facie duties stem from relationships and from the analogy above, it is clear that African notion of person is relational. And although Ross's model is Western, it gives credit to relationships, obligation, and responsibility. Thus, Ross's model seems to be the most suitable model to follow.

From the above argument, there is an obvious difference between the Western and the African practice of biomedical ethics. In that case, the Western informed consent processes do not apply in African context but that do not mean that there is no way it could be amended to suit the situation in Africa and it does not also mean Africans do not need it all. Let's consider the following case in (Ten 2011:148-165; Rheeder 2016). In 1996, a meningitis epidemic erupted in the village of Kano in the predominantly Muslim North of Nigeria. Thousands of children were in danger of dying or becoming disabled. A state hospital offered free medical assistance to affected children in cooperation with Doctors without Borders. A few weeks after the eruption of the epidemic, a research team arrived from Pfizer, which is one of the largest pharmaceutical companies in the world. As a 'humanitarian gesture', the company offered a new antibiotic for the treatment of the children. Pfizer treated about 200 children. However, it was not explained to the parents or the children that the drug (Trovan) was an experimental drug and that the treatment of the children formed part of an existing scientific research study. Some children received the experimental drug and others received the approved medication. After two weeks, the research team concluded their study and they returned to the United States, although the epidemic was still in full swing. In 1996, Pfizer applied to the American FDA (Food and Drug Administration) to commercialise the drug. In 1998, the drug was approved only for use in adults in the US, while it was not approved for use in Europe at all. In the meantime, information surfaced that the treatment could have serious side effects.

Later research highlighted the following unethical actions in Kano:

- The drug had never been tested on children before the project in Kano.
- Early research on animals had indicated the possibility of liver damage.
- During the research study, half of the children received only half of the normal dosage of the approved medication; the aim was to make the experimental drug look good.
- Parents and relatives were never informed of the fact that experimental drugs were used and that they could receive free treatment with safe and effective medication from Doctors Without Borders.

- Neither the consent of parents nor the assent of the children was ever sought.
- Eleven children died over the course of the research study.
- A local medical doctor who was supposed to lead the research was the leader only in name.
- The letter of consent from the ethics committee of the local hospital was forged because no such committee existed.

Since this occurrence, clinical research has been exported to Eastern Europe, Africa, India, and China with even more frequency. From 2002 onwards, the number of new applications for research in America decreased by 5.5% due to the strict regulation of drug trials, while it increased by 15% elsewhere. From 2007 onwards, more research has been done outside America than in the country. Forty per cent of clinical experiments are performed in developing countries.

There are several reasons why research is being done in the developing world like Africa, but one reason is the conflicting situation of informed consent and autonomy. The export of clinical research to countries that do not have a strong ethical infrastructure has caused and will still cause many problems, as the above-mentioned example shows (Ten Have, 2013b:605). In court cases after the experiment in Kano, Pfizer claimed that the ethical principle of informed consent had not been necessary because there was no international norm that required it. The company asserted the norm was a typically Western norm and could not be enforced in non-western countries. Indeed, it is plausible, as argued above, that the Western notion is alien to African context. However, it does not follow that there should be no informed consent at all; just that it has to be re-interpreted within the framework of African values.

In an African context, family/community consent is important in the consent process. The process of consulting leaders and household heads about any new activity in the community, including research, follows a long-established protocol. For example, the protocol for approaching chiefs involves paying respects to the chief and the presentation of small gifts of cola nuts and a bottle of spirit. The research is explained to the chiefs, and then permission from chiefs to conduct activities in a community is given verbally. Similarly, household heads give verbal consent to approach individuals. Only after these steps have been completed may researchers approach individuals to invite them to participate in research (Tindana, Kass, Akweongo, 2006). Thus, in an African context, concept of informed consent needs to consider obligation, values, family, parent, and community leaders. When these are taken into consideration, then it can be concluded that there is a proper relationship between doctor/patient and researcher/research participant.

Summary

Many research ethics committees require written informed consent and the use of a consent form, which describes the purpose and procedures of the study and its potential risks and benefits of participation; explains that participation is voluntary and that subjects can withdraw at any time; and provides information about maintaining subject privacy and confidentiality of research data. Consent forms and other information provided to participants should be in a language understandable to the participant or to the parent or guardian if the participant is a child. Yet an individual-based consent model and the use of written consent documents may be problematic in countries where norms of decision-making do not emphasise individual autonomy and where there are nonliterate populations. Thus, several guidelines and reports on research ethics endorse the use of community approval and verbal consent for research in countries where cultural values and practices emphasise oral rather than written agreements and where community leaders, elders, and tribal chiefs play an important role in decision-making.

This brings to light the fact that Bio-Medical Ethics is on a quest for its authenticity in Africa. This is because the progress of Bio-Medical Ethics in Africa would have been easily possible if the principles of Bio-Medical Ethics were not rooted in the Western-European traditions. It will not be easy for Africans to separate themselves from their traditional African thought elements for the Western bio-medical superimposition. For instance, it is estimated by Ross (2010) that there are between 250 000 and 400 000 traditional healers in South Africa, and 28 000 medical doctors. Eight out of every 10 black South Africans are believed to rely on traditional medicine alone, or in combination with Western medicine. This is because traditional healers occupy esteemed positions within many indigenous South African cultures as they are consulted for a wide range of physical, social, and emotional problems and are often expected to assume the multiple roles of medicinal healer, physician, priest, psychiatrist, advisor, teacher, diviner and herbalist and this is what the traditional people of Africa expect when they go to the hospital.

The Western-European concept of individual respect for autonomy, which is the central tenet in bio-medical ethics looking at informed consent, conflicts with African cultural values and norms. The concepts of Ubuntu (isiZulu) and Ukama (Shona) which are among the few cores African concepts advocate for a form of wholeness that come through one's relationship and connectedness with the other people in the society.

Therefore, African communitarian ethics focusses on the interests of family/community instead of an individual; hence collective decision-making process takes precedence over individual consent. These

considerations suggest that practitioners of Western biomedical ethics in Africa may encounter intractable ethical problems (moral dilemmas) that might be generated by some of the traditional values, practices, rituals, and taboos that still govern people's behaviour and relationships.

Conclusion

Bioethics cannot be universalised or globalised because it should be aware, cognisant, sensitive, and relevant in all cultures and traditions. The existence of values and morals that vary from community to community and from different societies within communities will lead the failure of global bioethics. Thus, it will be difficult to have a global concept of bioethics without considering cultural response to ethical issues because different communities have different values and morals that guide them. The argument above has shown that the four commonly used principle of bioethics are autonomy, beneficence, nonmaleficence and justice and are based on a particular tradition and culture. Beneficence and nonmaleficence requires us to maximise possible benefits, while minimising possible harms and consequently secure the well-being of others by refraining from harming them. Justice is concerned with the fair selection and distribution of the burdens and benefits of the research among participants, while autonomy which is the central concept of informed consent, gives individuals the right to self-actualization and decision-making.

This can be very successful in the Western world that is more individualistic but fails in Africa that is more communitarian. For instance, a pregnant woman who is about to undergo an operation to facilitate the delivery of the child will require consent before the operation is carried out and the question is whose consent will be needed? In an African concept, the child is not only the woman's but also the man's (husband's family); thus, if the woman makes the decision alone it might cause a very big family conflict whereas in the Western world the woman can make an autonomous decision concerning the child and her health without really considering the individuals that will be affected by the decision. And the Western concept of individualism is what the concept of autonomy in bioethics advocates for. Thus, when it is applied in Africa it produces a conflicting situation and in some cases this conflicting situation facilitates the denial of the right for the appropriate group to consent before their children or relations are used as a research participant.

Finally, bioethics principles and framework in Africa though may take cognizance of the bioethics principles as postulated by Western philosophy but with different approaches and practices. This is because of the diversity in understanding of personhood and social interactions existing within the various communities in Africa that are different from what is seen in Western construct. Consequently, African bioethics by its application has

its own framework, based not entirely on the method of practice and application of what the western bioethics regard as global bioethics. The four bioethics principles- autonomy, justice, beneficence, and nonmaleficence - if followed and obeyed is good. Everybody will agree that autonomy is good, that justice is good, that it is good to do good, and that it is good not to inflict harm. However, what constitutes the good in various circumstances cannot be universalised because we have different cultural practices that influence deeply what we do and who we are. Thus, there is still a problem, a conflicting situation in the practice of the principle of biomedical ethics as well as informed consent in Africa. This is because all the avenues have not fully been explored because of the limited nature of the project although there are avenues for further investigation and analysis.

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