Review

Challenges to Obtaining Informed Consent for Research Participation in Nigeria: A Review of Literature

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Abstract

Background: Informed consent has its roots in the 1947 Nuremberg Code and 1964 Declaration of Helsinki. This review determined the challenges to obtaining informed consent for research participation in Nigeria.
Methodology: A review of literature was conducted using the following search engines: Google, PubMed, Google Scholar, Infolep, WHO website, Web of Science, African Journal Online, Biomed Central, and BASE Search. Ninety-four articles were retrieved and 44 articles were included in the review. The searches were done between February and March 2022 and included all articles written in English that focused on the informed consent process in Nigeria and globally.
Findings: Participants in research in developing countries are most times not informed and do not question the terms of their participation. They are often vulnerable due to lack of familiarity with medical interventions or the urgent need for healthcare and nutrition. In developed countries, informed consent for medical research has become innovative but this is not the case in developing countries. Some research participants are unaware that they are taking part in research.
Conclusion: There is the need to build capacity of researchers to understand issues related to research so they can be able to fully explain to research participants their rights. Developing culturally appropriate methods for sharing information about the research project and obtaining informed consent is essential. Effective communication between the researchers and participants during the informed consent process can build trust and enhance self-decision. Vulnerable populations should be adequately protected during their participation in research.

Key words: Informed consent, challenges, research participation, Nigeria

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Introduction

Before the Second World War, medical practice was guided by the Hippocratic Code of Conduct.[1] Thus, for about 2500 years of Western medicine, medical practice relied on the paternalistic concept that physicians should protect their patients from information about their diseases or treatment options. The Hippocratic Oath which has been used by physicians for thousands of years indicated that the physician knows 'what is best' for his or her patients. The Nuremberg Code which was introduced after the Nuremberg trials introduced the concept of voluntary consent and competence in giving consent to participate in medical research.[2] This was a reaction to the horrific and unethical experiments that were done during the Second World War. The Code emphasised the relevance of voluntary participation of human subjects in research and also the ethical responsibilities of researchers.

Suffice it to say that the rights of human subjects were persistently violated during research even after the Nuremberg Code.[3] This is because the Nuremberg Code had no standing on international law. Also, due to the fact that the Code focused on voluntary consent of individuals involved in research it failed to address the needs of children and other special populations who may not be able to provide consent.[4] Perhaps in a bid to protect study participants from undue risks associated with research, the World Medical Association in 1964 developed a guideline for physicians in biomedical research involving human subjects. This guideline which is referred to as the Declaration of Helsinki[5] has been updated several times. The need for participants to consent to take part in medical research was recognised in international human rights instruments[6] and documented in international documents related to research ethics.[7]

The Belmont Report which was initiated in 1979 stated three basic ethical principles for biomedical research. They are 'Beneficence' 'Justice' and 'Respect for Persons' which addressed the issue of informed consent.[7] The Belmont Report indicated three elements that were necessary for a consent to be valid. The elements included sufficient relevant information for decision making, comprehension and voluntariness. The implication is that for a consent to be valid, the participant should have received sufficient relevant information and adequately understood the information provided to enable the person to take a decision without an undue influence.

In 1996, the combined efforts of Japan, the European Union and the United States of America enabled the publication of the International Conference on Harmonisation of Good Clinical Practice (ICH-GCP). The ICH-GCP enumerated twenty basic elements that should form part of an informed consent form and how the informed consent should be documented. The ICH-GCP provided that the responsibility of developing an informed consent form is the responsibility of the researcher. It also stipulated that Institutional Review Board or Independent Ethics Committee has the responsibility of reviewing the contents of informed consent form and the informed consent process which are the essential steps in obtaining a valid consent.[8] In a similar vein, the Council for International Organisation of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) developed and published International Ethical Guidelines for Biomedical Research involving Human Subjects in 1998.[9]

Informed consent

From the mid twentieth century, a drift emerged towards the rights of patients and this included the right to know what the physician intends to do and why. This is the essence of informed consent.[10] Informed consent has its roots in the 1947 Nuremberg Code and the 1964 Declaration of Helsinki and is now a guiding principle for conduct of medical research.[11] Within its ethical and legal foundations, informed consent has two specific goals in clinical research, to respect and promote a participant's autonomy and to protect participants from harm.[12,13] Thus, obtaining written informed consent from participants before enrolment in research is presently an international accepted standard.[14,15] Five elements are put into consideration in establishing informed consent. They include voluntariness, capacity, disclosure, understanding and decision.[16]

Voluntariness means that an individual's decision to participate in the research is made without coercion or persuasion. Capacity relates to an individual's ability to make decisions that come from his or her ability to understand the information provided. Disclosure involves giving research participants all relevant information about the research including its nature,

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purpose, risks and potential benefits as well as the alternatives available.[17] Understanding implies that research participants are able to comprehend the information provided and appreciate its relevance to their personal situations. Decision is that position taken by the participant to participate or not in the research process.[16] It is important to emphasise that the quality of informed consent in clinical research is determined by the extent to which participants understand the process of informed consent.[18]

The concept of informed consent in research in Nigeria

In Nigeria, the concept of informed consent in research is enshrined as a fundamental right under Section 37 and 38 of the 1999 Constitution of the Federal Republic of Nigeria (as amended).[19] Expectedly, Nigeria as a member of the international community recognises the need for informed consent in research and medical practice which are parts of certain international guidelines.[20]

Relevance of obtaining Informed Consent from research participants in Nigeria

In recent times, international organisations such as the Gates Foundation, Wellcome Trust and National Institutes of Health and others are increasing research funding for diseases that affect the world's poor. This has made it possible that several research works are being conducted in Nigeria as well as other low-and middle-income countries. These research works are expected to enable the development of superior diagnostic tools, prevention strategies and interventions to reduce or eliminate the negative impact of diseases. The success in completing these research works and the adoption of the findings will depend on successful engagement with the intended beneficiaries[21] whose informed consent is a necessary condition for inclusion in the research activities. The increasing number of these research works makes it necessary that the informed consent process is strengthened in Nigeria so as to protect future research participants from undue harm.

Challenges to obtaining informed consent for research participation in Nigeria

There is evidence that most externally funded research works in developing countries pay more attention to the mechanical components of the research process than ensuring good understanding of the informed consent procedure and voluntary participation. Furthermore, the task of overseeing the informed consent process is left to the local research ethics committee which in most instances are underfunded with little or no institutional support.[22,23]

Voluntary decision making is a challenge in research settings especially in developing countries including Nigeria. Medical doctors and researchers occupy positions of authority which patients and participants may be unwilling to challenge. Based on the Hippocratic Oath, there is a belief that the medical practitioners will do 'good always' to their patients. However, the participants in research in developing countries are most times not informed, gullible and do not question the terms of their participation in research.[24,25] For instance, a study that assessed participants' understanding and voluntariness of informed consent in a clinical trial in Nigeria showed that voluntariness was influenced by access to diagnosis and treatment which were unavailable outside the research setting. Thus, the decision to participate in the research by the participants centred on the benefits accruable from participation.[26]

Furthermore, the results of a questionnaire-based study to evaluate factors associated with voluntariness and understanding of the study's genetic purpose showed that of 655 individuals who participated in the research comprising 348 from United States of America and 307 from Nigeria showed that 99% of participants from United States of America and 72% from Nigeria reported being informed of the purpose of the study. Also, 97% of the respondents from United States of America reported knowing that they could withdraw from the trial compared with 67% of the respondents from Nigeria.[27] To a large extent, it is expected that individuals involved in genetic research in industrialised countries where literacy rates were high might be expected to have greater understanding of the purpose of genetic studies than their counterparts in low-income countries especially in areas of low literacy.[28] From the results of another study among Hansen disease patients in Nigeria , majority of the patients would prefer to give consent for use of their data. However, among those not willing to give consent, intrusion into privacy and lack of trust were the major reasons.[29] This feeling of lack of trust by the participants and intrusion into privacy to an extent limit the informed consent process also.

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Also, citizens of developing countries are often vulnerable due to lack of political power, low literacy level, lack of familiarity with medical interventions, effects of war, famine or the urgent need for health care and nutrition which make them both suitable research participants and also vulnerable for exploitation.[30-32] A good example of this is in the treatment of children for meningitis during an epidemic in Kano, Nigeria in 1996. During that period, the multinational drug firm, Pfizer administered Trovafloxacin (Trovan), a quinolone antibiotic to many paediatric patients in a bid to determine the effectiveness of the experimental medicine in treating meningitis. However, the medicine had neither been tested in children, nor wee the parents of the children told that it was a clinical trial, nor approval obtained from relevant authorities for the study. All the children in the study were selected from among the long lines of people seeking care. The Pfizer team completed the trial in three weeks and returned to United States of America even while the epidemic was in progress. The Washington Post brought this research to public attention in 2000. The study has been severely criticized for falling short of ethical standards.[33] The drug Trovafloxacin, was eventually withdrawn from European markets after it was linked with liver disease. It is being recommended only for emergency use in the United States of America since 1999.[34]

In developed countries, informed consent for medical research has become innovative but this is not the case in developing countries, including Nigeria because guidelines for obtaining informed consent are difficult to implement perhaps due to low literacy levels, socio-economic and cultural factors.[35] The local research ethics committee which has the role to critically scrutinize the informed consent process is not only underfunded but has weak institutional support.[22,23] The implication is that when the western-oriented consent-seeking procedure is applied in poor resource settings as obtained in these countries, individuals may participate in a trial without the basic knowledge of what is involved. For example, a study revealed that researchers and members of Institutional Review Boards in Asia Pacific and African regions had limited knowledge of the underlying elements of required informed consent form.[36]

In some instances, research participants may not be aware that they are taking part in a research.[40] For example the result of a systematic review on ethical issues in biomedical research in Nigeria revealed that even though informed consent was the most studied of ethical issues in Nigeria, participants had poor understanding of their rights as research participants.[41] This necessitated the call to build the capacity of researchers to understand issues related to research so they can be able to fully explain to research participants their rights in the field of research. Moreover, there is evidence that despite enhanced regulatory efforts, gaps exist in the comprehension of research participants of their involvement in research alongside variations in the methods used to evaluate this understanding.[42]

In research circumstances the consent form may be inadequate in relaying the necessary information to the research participants or be complicated on its own or that the research participants may not be given enough opportunity to ask questions and have their personal worries and interests addressed.[42] Religious beliefs, and cultural hindrances could also limit the passage of adequate information to the research participants.[43] There is also the barrier of language in the understanding of informed consent. For instance, the term 'research' does not have a corresponding term in the local languages of people in all regions of Nigeria.[43]

In Nigeria, majority of clinical trials take place in public tertiary health institutions and as such research participants may find it difficult to differentiate between routine clinical care and research activities.[35] Thus, there is no major differentiation between health service delivery and research in such circumstances as the physician may also double as the researcher[25] and this could lead to therapeutic misconception.

New approaches

Based on the poor knowledge of the essential requirements of an informed consent form by researchers and members of research ethics committees in developing countries, there has been a suggestion for training of researchers and members of the research ethics committees in African region on valid informed consent. It was also specified that the training should also focus on the importance of obtaining a valid consent.[36] Similarly, a review article on informed consent practices in Nigeria concluded that the Nigerian medical community should improve on the ethical conduct of its physicians through better education of physicians and

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also additional research on the consent needs of the Nigerian public.[44] This suggestion became necessary bearing in mind that most of the physicians in Nigeria are also researchers.

Also, a study in Jos Nigeria revealed that though both dental patients and professionals agree that informed consent is important to clinical research and that they should be asked of their consent before participation in research, the respondents were ignorant on what the inform consent form should contain.[45] Based on the results of a systematic review on ethical issues in biomedical research in Nigeria, it was concluded that there is the need to build the capacity of investigators to better understand the issues in medical research and also increase their explanatory skill to help participants achieve complete understanding of their rights as research participants. This is expected to assist both the investigators and participants towards a better research approach.[38] There may also be the need to review the current guidelines and processes for obtaining informed consent in developing countries. The main aim of the review process will be to develop culturally appropriate methods for sharing information about the research project and obtaining and documenting a true informed consent.[46]

Based on the evidence that voluntariness on the part of research participants was influenced by access to diagnosis and treatment which were unavailable outside the research setting,[26] there is the need for effective communication between the researchers and participants during the informed consent process so that the participants could participate in clinical trials based on self-decision.[26] Furthermore, the results of a study that involved research participants from Nigeria and United States of America highlighted the need for more effective approaches and interventions to improve comprehension of consent for genetic research among ethnically and linguistically diverse populations in all settings.[47]

Similarly, based on the finding that voluntariness of participants was influenced by the benefits to be derived through participation, there was a call for additional protection of vulnerable populations. In effect, the need for adequate time to ensure an improvement in the understanding of participants of the consent form by use of indigenous and innovative ways of explaining complex concepts such as randomisation will be good. This will help to provide the participants the needed support to facilitate self-decision.[26] Also, relying on the evidence of lack of trust hindering the informed consent process, there is the need for caregivers and stakeholders to put in more efforts in a bid to win trust before seeking for informed consent from research participants.[29]

Positive action taken so far

Increasing attention to multinational research conducted in developing countries has prompted revisions of international ethical guidelines. There have also been efforts aimed at building capacity for scientific and ethical review of research in developing countries who do not have the required competence. The World Health Organisation and the Fogarty International Centre which is part of the National Institutes of Health have conducted trainings in research ethics for individuals in developing countries. For example, the NIH's Fogarty International Research Ethics Education and Curriculum Development Program, since the year 2000 has provided grants for the development of training programs for research ethics for professionals in LMICs.[48] This became necessary due to urgent need for competence in research ethics in these countries. These trainings were necessitated by the ethical controversies that emanated from a trial which was to evaluate the short course Zidovudine against placebo for the prevention of mother –to-child transmission of human immunodeficiency virus.[49] The researchers were accused of ethical double standards by conducting research on vulnerable populations in developing countries which otherwise could not be conducted in high income countries.[50] The overall aim of the trainings by Fogarty International Center is to prepare participants from developing countries to lead ethical review of research in their home countries and by this effort contribute to an international discussion of research ethics issues in LMICs . They are also expected to train other individuals in research ethics and develop and disseminate research ethics guidelines.[51]

Conclusion

There is the need to build capacity of researchers to understand issues related to research so they can be able to fully explain to research participants their rights. Developing culturally appropriate methods for sharing information about the research project and obtaining and documenting a true informed consent is essential.

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