



**OYO STATE COLLEGE OF AGRICULTURE AND
TECHNOLOGY, IGBOORA (OYSCATECH)**



in Collaboration with

OYSCATECH GLOBAL CONSULT

PRESENTS

2ND BIENNIAL CONFERENCE

TAGGED:

OYSCATECH

2021

E-Proceeding

Theme:

**A SYNERGY BETWEEN AGRICULTURAL PRODUCTION,
TECHNOLOGICAL INNOVATION & MANAGEMENT EFFICIENCY:
A PANACEA TO ECONOMIC STABILITY
DURING PANDEMIC**

Date: Mon. 12th - Thur. 15th July, 2021

Venue: 800-Seater, Lecture Hall, OYSCATECH, Igboora

Editors:

Dr. W. B. BELLO, Dr. M. A. MOSOBALAJE

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THE RELEVANCE OF ETHICS IN DESIGN AND IMPLEMENTATION OF PUBLIC HEALTH RESEARCH IN NIGERIA

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Abstract

Ethics is very essential to Public Health Research (PHR) and interventions which have high value to the society and contributes significantly to health discoveries and improvement to public health. All through the phases or stages of PHR design, investigators have responsibilities to ensure that good ethical conducts and principles are adhere to. The relevance of ethics to public health stemmed from history of abuse of research participants which gave birth to Nuremberg code, World Medical Association Declaration of Helsinki, Council for International Organization of Medical Sciences international guidelines. In Nigeria, National Code of Health Research Ethics which applies to public health and health research contain the ethical principles of; respect for persons; beneficence/non-maleficence; and distributive justice. Major challenges relating to PHR ethics include poor financial support for research, socio-cultural beliefs and practices relating to health, cultural perspectives on decisional authority concerning health care and poor access to ethics review committee. The relevance of ethical principles and issues is highly important in the design and implementation of PHR in Nigeria. Hence, any public health-related research without the consideration for ethical principles may constitute abuse of research participants and thus fail to contribute meaningfully to the improvement of health of people.

Introduction

In recent years, ethics has become an increasingly important topic in various areas of health research including public health research (Elsayed, 2007). It is said that ethics is the branch of philosophy which deals with the dynamics of decision making concerning what is right and wrong. Public health research activities are governed by individual, community and social values (Fouka & Mantzorou, 2011). Ethics can be "considered as dealing with the principles by reference to which any relevant particular or concrete human actions can be judged right or wrong, moral or immoral" (Valasquez, Andre, Shanks & Meyer, 2010; Beauchamp & Walters, 2003; Beauchamp & Childress, 2001).

The ethical principles in public health have emerged from professional practice in the field of clinical medicine, epidemiology, biomedical research, nursing, and the social and behavioral sciences (Elsayed, 2007). Little attention has been given to the field of public health ethics compared to bioethics that gained more prominence in the 1950s and 1960s which led to development of ethical guidelines and principles which focused on protection of individuals involved in clinical care and research (Elsayed, 2007). Public health research ethics object of concern is the whole populations, not individual human being, concerning to maximize welfare of the whole population (Khan, Tareen & Sultan, 2016). The foundation of public health research ethics is social justice contributing to the good of the society.

Promoting public health involves a high degree of commitment to the deterrence of disease focusing mainly on preventive aspect, involves diagnosing and treating illnesses, with all the attendant clinical services that those activities require (Khan, Tareen & Sultan, 2016). Public health has four characteristics that provide much of the subject matter for public health ethics as follows: (1) its promotion involves a particular focus on prevention; (2) it is a public or collective good; (3) it involves an intrinsic outcome-orientation and (4) its promotion often entails government action (Gitau-Mburu, 2008; Bhutta, 2002). Public health research has high value to the society and contributes significantly to health discoveries and remarkable improvement to health care and public health. It

can provide important information about disease trends, risk factors, outcome of treatment or interventions, health system issues, pattern of care, and health care cost and use. Public health researches address the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes. It is broader in scope than clinical research which refers to the subset of individual human subject's research that focuses on improving well-being and human health, normally by identifying better methods to treat, or prevent individuals from diseases (Khan, Tareen & Sultan, 2016). Public health researches emphasize on the prevention of diseases and promotion of overall public health. Public health researches often consider multiple approaches or strategies in developing effective interventions which interact with behavioural, social, biological, environmental and economic factors (Coughlin, 2006).

Public health research can be designed in form of exploratory, descriptive, analytical and experimental or interventional studies, focusing on health issues or concern of community or population. All through the phases or stages of public health research design (planning, implementation or execution and evaluation), public health investigators have responsibilities to practice or showcase good ethical conducts and principles in order to make their research worthwhile. This paper considered issues relating to the relevance of ethics in design and implementation of public health research in Nigeria

Historical overview- ethical codes

Abuse of research participants involved in medical and health research began even before 18th century. However, the ethical attitudes and atrocities of Nazi scientists and physicians under the guise of medical experimentation during Second World War led to global outrage and dictated the need to put forward a code of conduct for human research, namely the Nuremberg Code (Bhutta, 2002). The Nuremberg Code was the leading code for all subsequent codes made to protect human rights in health-related research. This code focuses on voluntary informed consent, liberty of withdrawal from research, protection from physical and mental harm, or suffering and death. It also emphasizes the risk- benefit balance (Burns and Grove, 2005). The only weak point of this code was the self-regulation of researchers which can be abused in some research studies (Burns and Grove, 2005).

In 1964, the World Medical Association Declaration of Helsinki took this process a step further and underscored 12 basic principles for the conduct of human biomedical research (World Medical Assembly, 2000). The declaration emphasized the protection of research participants in health research and strongly proclaimed that the well-being of individuals is more important than scientific and social interests (Burns and Grove, 2005). However, these principles were largely physician-oriented and did not directly address the issue of research in developing countries (Bhutta, 2002).

The issue of research in developing countries was eventually taken up by the Council for International Organization of Medical Sciences (CIOMS), which, in collaboration with WHO, proposed international guidelines for biomedical research involving human subjects in 1982. The guidelines were further amended in 1993 (CIOMS, 1993) and the most recent revision of the guidelines was published in 2002.

The National Health Research Ethics Committee (NHREC) which is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants in Nigeria was inaugurated in 2005. In 2007, National Code of Health Research Ethics was launched in Nigeria (NHREC, 2007). This code applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria (NHREC, 2007).

Relevant fundamental ethical principles

Guidelines for ethical conduct in scientific research throughout the world are informed by the following ethical principles: respect for persons; beneficence/non-maleficence; and distributive justice (Beauchamp & Childress, 2001).

The principle of respect for persons emphasizes the importance of individual autonomy and rights. Investigators need to honour the wishes of a competent individual regarding their desire to participate in scientific research. Requirements for the fulfillment of this principle include obtaining informed consent and ensuring confidentiality in the implementation of research. Informed consent seeks to incorporate the rights of autonomous individuals through self-determination. Research details must be provided in a clear, simple and culturally appropriate manner. If a participant lacks capacity to exercise an informed choice to participate, an appropriate person to make the choice for him or her must be identified by the investigator. A participant is free at any time to withdraw consent to further at any point or stage in research, without having to face any unfair negative consequence or disadvantage (Fouka and Mantzorou, 2011). The principle of respect for persons also suggests that researchers have an obligation to honour the concerns of communities involved in their studies (Marshall, 2007). In the design of public health research and intervention, investigators have the duty of respecting cultural and traditional beliefs and practices as well as fundamental values of the people.

Beneficence- Do not harm

The principle of beneficence refers to the obligation of researchers to ensure that researches are beneficial to individuals and/or communities (Marshall, 2007). Non-maleficence requires a high level of sensitivity from the researcher about what constitutes "harm". Harm can be physiological, emotional, social and economic in nature (Burns and Grove, 2005). Non-maleficence dictates both preventing intentional harm and minimizing potential harm. A public health researcher must consider all possible consequences of the research and balance the risks with proportionate benefit. According to NHREC (2007), all health research including public health research involve risks; to be ethical therefore, there must be valid attempts to minimize risks and maximize health related benefits (NHREC, 2007). However, Investigators have the responsibility to inform participants about the potential benefits and risks involved in their studies.

The principle of distributive justice is directly linked to issues of equality and fairness in determining who receives the benefits and who bears the burdens of biomedical and behavioural research (Marshall, 2007). Certain populations such as ethnic minorities, refugees and immigrants, children, prisoners may be vulnerable to discrimination, coercion, or other injustices in the implementation of scientific investigations. The selection, recruitment, exclusion and inclusion of research participants must be just and fair, based on sound scientific and ethical principles. No person may be inappropriately or unjustly excluded on the basis of race, age, sex, sexual orientation, disability, education or any other social characteristics.

Good ethical conducts and practices necessary in design and implementation of public health research

In addition to the basic ethical principles for scientific research, researchers in the field of public health need to observe certain ethical conducts, principles and practical benchmarks in the design and implementation of their studies.

Value and relevance of research

Researchers in the field of public health have ethical responsibility to ensure that research is relevant both to the broad health and development needs of the country and to the needs of community members under study. For public health research to have good impact the design needs to be adapted to the health economic, cultural, and technological conditions in which research is to be conducted (Keune, 2012). Public health research should be designed based on health issues that have the potentials to improve the health conditions or problems of the study population.

Scientific Integrity

In addition to fulfilling a need and being of value, the research proposed must demonstrate sound methodology and a high probability of providing answers to the research questions posed (NHREC, 2007). The research protocol must show knowledge of relevant literature. Moreover, research methods and results must be open to

peer-review and scrutiny. Also, a suitably qualified investigator should conduct the study. The investigator's competence is usually assessed in terms of research competence, knowledge and certification.

Approval of research protocol

Review of protocol for the research by ethics committee provides an objective appraisal of the effect of the proposed research as it affects the potential participants and the provisions for protection of research participants (NHREC, 2007). Hence, for public health research to be certified to be 'ethical', the protocol for the research must be reviewed by a research ethics committee granted approval by NHREC before commencement of the research.

Conflict of Interest disclosure

A researcher must disclose the sources and extent of funding to the research participants, the ethics committee and, where appropriate, to the regulatory authority (NHREC, 2007). Commercial affiliations or financial interests at the time of proposing and reporting the research must also be disclosed.

Informing research participants about research progress and outcome

Public health research **investigators** need to be mindful of the rights of research participants and ensure that participants are treated as partners in the research enterprise with every opportunity taken to inform them of the progress of the research and any new finding that may have potential impact on their health and well-being, and on their continued participation in the research (NRHEC, 2007).

Community involvement in research planning and design

The process of community engagement in public health research is important. Involvement of community members in the design of public health research ensures that research is not only well planned, but also culturally appropriate and beneficial to the community. According to NHREC (2007), engaging communities where research is being conducted in the design of research is a good ethical requirement which indicates respect both enrolled and potential participants.

Protection of vulnerable groups of people

Public health research involving vulnerable persons need to make intense plans for protecting such participants and establish procedure for acquiring consent (Coughlin, 2006). Vulnerable people are individuals with the characteristic trait of not being able to protect their own rights and welfare" who may be children, pregnant women, aged people, critically ill or dying, sedated or unconscious persons, captive populations (prisoners, institutionalised), persons with mental and physical disabilities, persons with stigmatizing diseases and conditions and extremely poor people.

Provide feedback to participants and community

An important ethical responsibility of researchers in the field of public health is to provide feedback about the results of their research to the research participants, communities as well as inform local health authorities about implications of results for further investigations, health care or prevention of disease in the community (Coughlin, 2006). Public health researchers also have the obligations to answer any questions the participants or other members of the community may have about the nature and significance of their findings. Research findings may be presented through different means including scientific publications and conferences, newspapers, bulletin, press conference, policy brief and public meeting.

Major challenges involved in the design and implementation of public health research

In Nigeria, several factors including financial support for research, disparity in the burden of disease and access to public health services and research, socio-cultural beliefs and cultural practices relating to health, cultural perspectives on decisional authority concerning health care as well as access to ERCs have serious implications for the application of ethical guidelines for public health research and interventions.



Community engagement in the design and implementation of public health research are often limited in many donor funded studies due to the fact that terms and conditions of the international donors may not properly reflect the concerns and conditions of local communities where research is to be conducted. Community members may give minimal support to a public health research or intervention which does not reflect the felt needs of the community members. This may partially explain why many donor-funded public health interventions are not of much desired impact or sustained by communities. Many public health researchers are involved in self-funded studies which are often designed as sentinel studies. Some of these studies have weak design and/or lack the capacity to fulfill some of the principles underlying guidelines and recommendations for ethical conduct of sound scientific research.

The complexity of scientific or medical concepts associated with research and the need to explain to research participants in the consent discussion may pose serious ethical burden. This can be challenging for public health researchers working with communities and individuals in rural areas and populations with a lower level of literacy (Bhutta, 2004; Sankar, 2004). For example, in many African languages, some English and medical words have no local translations (Kass & Hyder, 2001), example of such words are ‘ebola’, ‘Avian flu’ and “Covid-19”.

Cultural and religious beliefs about health problems or issues may influence community members participation in public health research and interventions. For example, suffering and illness are interpreted through a cultural lens informed by social context, emotional awareness, physical sensations and experience. Sickness or death may be attributed to witchcraft, sorcery or spiritual reasons rather than biomedical explanations.

In many Nigerian communities, the culture of male dominance and role of males as decisional authority are well entrenched. The male household-head may need to give permission to his wife for her to consent to take part in the study. The wife might be viewed as defiant if she participates when her husband had refused. Although the rights of every individual are important and need to be respected, it is also necessary to respect the cultural traditions.

Many researchers working on public health research and interventions do not submit their research protocol to ERC. In some situations, some researchers will submit their research protocol for approval even after they might have finished their filed work. Some ERCs often delay the review of research protocols for a long time which may discourage some researchers from submitting their research protocol for approval. This problem poses serious ethical challenge for the protection of research participants from undue abuse by researchers.

Conclusion

The relevance of ethical principles and issues in the design and implementation of public health research in Nigeria cannot be overemphasized. Without the consideration of these ethical principles and requirements such as scientific integrity, fair selection of participants, respect for person, favourable Risk-Benefit Ratio, confidentiality and protection of participants, and independent review of research protocol, public health research conducted in Nigeria will not only fail to contribute meaningfully to the improvement of health of people but also constitute abuse of research participants.

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