Ethics for Public Health Research in Africa

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Ethnical Issues in Scientific Research

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Introduction

Scientists use the scientific method to explain the relationship between cause and effect in nature. Such investigations could be conducted in all aspects of human life - clinical, social, and technology sciences. Scientists ask questions; construct and test hypotheses; conduct experiment; analyse data; draw conclusions; and disseminate the outcomes of their studies.

The challenges facing humankind make the need for scientific enquiry imperative. Considerable efforts are therefore made to subdue human and environmental problems which have resulted in tremendous improvement in the quality of life in various societies (Lenhard, Lawrence, and Makenna, 1995).

The process of conducting scientific research is guided by regulations (Slutsman, Buchanan, and Grady, 2007). But quite a number of studies have, by historical accounts, resulted in harm to those that are targeted. As an example, the method of recruiting those who will participate in studies including the research process could be coercive and exploitative (Barry, 1988). All of these and others have necessitated the development of the various ethical codes that guide scientific studies today.

Historical Overview

The history of research ethics could be traced to the tragic abuse by Nazi doctors during World War II. Sixteen German physicians conducted unethical medical experiments, using Jews, gypsies, and political prisoners. Out of these horrors came the Nuremberg Code and other international codes of ethics written to protect the participants in research. The Nazi doctors were convicted of crimes against humanity under this Code. The trial introduced standards, part of which underscores voluntary participation in research and the avoidance of risks (Katz, 1996).

The scandal over the 40 year Tuskegee Syphilis Study by the US Public Health Service in Macon County (Alabama) which came to light in 1932 is another milestone in the study of research ethics. The American Government promised 400 African American men free treatment for "bad blood" which had become an epidemic in the county. However, the government did not provide the standard treatment for them despite the fact that penicillin was available in the course of the study. The participants were also not fully briefed on the research design and the possible risks to them.

There is also the experiment by Milgram (1961) on the conflict between obedience to authority and one's personal conviction. The researcher examined the justification for acts of genocide by those who were accused at the post-world war II Nuremberg trials who claimed that they acted under orders from their superiors (Jones, 1981).

Thirdly, a group of children with mental retardation who lived at Willowbrook State Hospital in Staten Island in New York were made to participate in the "Willowbrook Study" between 1963 and 1966. These innocent children/subjects were fed with extracts of stools from infected individuals and later injected with more purified virus preparations. The children were deliberately infected with the hepatitis virus. However, the researchers claimed in defense of their investigation that the vast majority of them would have in any case acquired the infection while at Willowbrook, and it was better for them to be infected under carefully controlled research conditions (Rothman, 1991; Katz, 1972).

Humphreys, a sociologist, conducted a research tagged "Tearoom Sex" study in the mid-1960s. He hypothesised that the public and the law enforcement agents and agencies held stereotypical beliefs about men who committed impersonal sexual acts with one another in public restrooms. "Tearoom sex", as fellatio in public restrooms, accounted for majority of homosexual arrests in the US. Humphreys argued that it was important for society to gain a better understanding of the identity of the men as well as what motivated them to seek quick impersonal sexual gratification. He set out to answer this question by the methods of participant/observation and structured interviews. Humphreys stationed himself in "tearooms" and offered to serve as a "watchqueen". The "watchqueen" had the duty to be on the lookout for law enforcement agents or deliberately cough if strangers were approaching the area.

During the study, he observed hundreds of acts of "tea-room sex" and gained the confidence of some of the men he observed. He disclosed his role as a scientist and persuaded them to tell him about their personal lives and motives. To avoid bias, Humphreys secretly followed some men and recorded the license numbers on their vehicles. A year later, Humphreys showed up at their private homes and claimed to be a health service interviewer. He asked them questions about their marital status, race, job, and other personal questions (Seiber, 2001).

Humphreys' findings destroyed many stereotypes. He found that 54 per cent of the men were married and 38 per cent were neither bisexual nor homosexual. Most of the men were successful, well educated, economically stable, and highly praised in the community. Only 14 per cent of the men that he observed were homosexuals and part of the gay community. Humphrey's research was carried out in the mid-1960's before the existence of Institutional Review Boards (IRB).

These studies led to the creation of the Belmont Report and the Institutional Review Board (IRB) for the protection of human subjects that are targeted in research.

Ethical Issues in Scientific Research

Virtually every scandal in research involving humans has been followed by attempts to codify the rules that should govern research. Whereas human experimentations can be traced back to several centuries, organised efforts to protect human subjects who participate in experiments started only 60 years ago (Caballero, 2002).

Emanuel *et. al.*, (2000) identified the benchmarks for determining the ethical validity of research. Considerations were given to:

1. socio-cultural value;
2. contributions to science;
3. informed consent process;
4. ethical review process, and
5. risk-benefits ratio.

But Nigeria's National Code for Health Research (NCHR) offers a more practical and culturally adaptive dimension. Section F of the Code contains a detailed analysis of what clinical investigators should consider when conducting human research (Federal Ministry of Health, 2007). The guidelines are readily applicable in social science research. The document stresses that ethical research must have social or scientific value to the:

- participants;
- population they represent;
- local community, and
- host country or the world in order to justify the use of finite resources and avoid exposing the participants to harm.

Key Issues

1. Research should evaluate issues that lead to improvements in the socio-psychological and health conditions of participants and the research community. It must also contribute meaningfully to knowledge. Such knowledge should be disseminated to all the relevant stakeholders during and after research. Research that lacks the following is unethical:
   - clear scientific objective(s);
   - valid methodology;
   - equipoise (in clinical studies);
   - adequate operational plans within the context of the environment where research is to be conducted;
   - plausible data analysis plan (including a specific role for a Data and Safety Monitoring Board [DSMB] in clinical trials), and
   - unbiased measurement(s) of outcome(s).
2. There must be fairness in the selection of participants, based on the scientific objective(s) of the research while minimising risks. This requirement refers to those who are included/excluded and the strategies for recruiting participants (including the choice of research sites and communities). Regardless of this requirement, participants who are at excessively increased risk of harm should be excluded. Children, pregnant women, socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged sub-groups or those with constrained autonomy and other vulnerable subgroups in the populations should not be excluded from research without explicit reasons for doing so from studies that can advance their health and wellbeing. However, specific safeguards should be included to protect the vulnerable appropriate to degree of risks. Groups, communities, participants, and researchers who bear the burden of research should share in the benefits
3. Effort must be made to minimise risks and maximise health related benefits. Harm can be defined as both physical and psychological. There are two standards that are applied in order to protect the privacy of research participants: confidentiality and anonymity. Researchers must assure that information that identifies the subject is not made available to anyone who is not directly involved in the study. Anonymity implies that the participant will remain anonymous throughout the study in order to guarantee the privacy of participants. This is sometimes difficult to accomplish in situations where participants are seen at multiple time points (*e.g.*, a pre-post study).

4. Protocol/project must undergo independent review. A research ethics committee or independent review board is a panel of persons who reviews grant proposals with respect to ethical implications and decides whether additional actions should be taken to assure the safety and rights of the participants. By reviewing proposals for research, the committee protects the organisation and the researcher against potential legal implications of neglecting important ethical issues.
5. Informed consent which provides adequate information at an educational level that is not higher than that of individuals with at most 9 years of education is required. Essentially, this means that prospective research participants must be fully briefed about the procedures and the risks that are involved in research and must also give their consent to participate.
6. Respect for potential and enrolled participants should be guaranteed. This is related to informed consent. It requires that participants should not be coerced to participate in studies. This is especially relevant where researchers previously relied on 'captive audiences' for their subjects (*e.g.*, prisons, universities).
7. A trust relationship between investigator(s) and potential participants should be assured. This necessitates transparency in all matters relating to the research enterprise including a clear description of the goals, risks, benefits, alternatives to participation and voluntariness. This trust principle encourages the engagement of individual participants and communities, respect for local socio-cultural values, and it also encourages the provision of relevant and timely feedback to communities.
8. The interest of participants, researchers, communities, and sponsors must be accommodated. This is to ensure that the research has lasting impact; transfers technology where appropriate; contributes to capacity building; and demonstrates respect for socio-cultural and other differences. Risks, benefits, and the responsibilities of research must be shared during the development, planning, conduct, and the dissemination of results. Intellectual property, indigenous knowledge and the contributions of all parties must be taken into consideration, adequately protected, and compensated.
9. It is vital to conduct research in accordance with the principles of good clinical and laboratory practices. These are international standards for designing, conducting, and reporting clinical trials that involve human subjects. Compliance with these standards is additional assurance that the rights, safety, and well-being of participants are protected in a manner that is consistent with the highest ethical and scientific standards.

Conclusion

Research is the pivot for elucidating information otherwise not obtainable (Lefor, 2003). It is relevant because it helps to describe, explain, predict and control interventions and practices in science. Concurrent with the rapid growth of scientific research in many regions of the world, there are unending reports of lapses and challenges that are related to ethical, cultural, and social concerns as exemplified by the activities of Nazi physicians between 1935 and 1945 (Pace and Sullivan-Fowler, 1996). Studying and understanding these issues will promote the science and ethics of planning, implementing, and utilisation of scientific research. With these, the research enterprise will contribute to generalisable knowledge with which the bio-psychosocial challenges of man and his environment can be surmounted. Added to these, scientific investigations will minimise their potential adverse impacts on those who participate in them irrespective of the setting, race, or status if researchers give adequate attention to local and international ethical standards.

The nuances of researchers as well as conflicts of interest are often explicated in their dual roles as service providers and researchers (Levine, 1986). The usual power imbalance between researchers and

the resource limited members of the society that are targeted in research heightens the potential vulnerability of the latter and could compromise their autonomy in decision making.

It is vital for researchers to adhere to ethical standards in their relationship with the less advantaged members of the society. This becomes imperative due to the growing appreciation of the rights of patients and the global quest for the protection of human subjects who are included in investigative procedures. Without these, the gains that are already recorded in the growth of science would be reversed. Research activities in whichever discipline and professional practice that do not adhere to ethical standards amount to mere exploitation of the less-advantaged fellow human beings as was the case in the days of the Tuskegee syphilis study.

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