Current role of research ethics committees in health research in three geopolitical zones in Nigeria

Current role of research ethics committees in health research in three geopolitical zones in Nigeria: A qualitative study

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Background. Ethics are rules or standards governing the conduct of a person or members of a profession. Medical research must be regulated to ensure that fundamental human rights are not breached in the quest for knowledge. Nigeria had no laws or specific guidelines to regulate health research until 2007, when a national regulatory body, the National Health Research Ethics Committee (NHREC), was established. Its function is to ensure ethical conduct in research and to accredit institutional and state health research ethics committees (HRECs).
Objective. To document the current role of HRECs in the ethical practice of health research in Nigeria, 4 years after the establishment of the NHREC.
Methods. Functioning of the HRECs was evaluated via interviews of 14 members of state and institutional HRECs chosen from selected geopolitical zones of the country.
Results. The HRECs surveyed had between nine and 15 members, with more males than females. Review meetings were held only occasionally owing to the competing interests of members, who receive no incentives for participation, and poor funding. Scientific and ethical reviews are conducted together by the same committee, but few members of the HRECs are trained in research ethics. Monitoring of research after approval is poor.
Conclusion. Nigeria now has about 30 institutional HRECs, but their functioning is hampered by a shortage of both money and qualified individuals to serve on them.

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There have been several reports of non-ethical conduct of health research in developing countries. In some cases research does not conform to international standards, and researchers do not always respond to the health needs and priorities identified. Most of these cases have been in sub-Saharan Africa.[1,2] The more vulnerable groups in such populations have been most exploited. Poor sanitation, lack of adequate healthcare services and illiteracy, among other factors, mean that citizens of developing countries are often plagued with a range of diseases. These countries have therefore become a fertile ground for medical research, especially by pharmaceutical companies.

In Nigeria it is easy to find volunteers for trials because of widespread disease, poverty, and the large population. There was no means of enforcing ethical practices in health research in Nigeria until recent developments following the negative publicity that resulted from testing of the drug trovafloxacin (Trovan) by the drug company Pfizer during a bacterial (meningococcal) meningitis epidemic in Tudun Wada, Kano, Northern Nigeria, in 1996.[3] At least 11 children died during the course of the trial, and several others suffered brain damage and paralysis.

Subsequent to this incident, the National Health Research Ethics Committee (NHREC) was established in October 2005. The National Code of Health Research Ethics of August 2007,[4] produced by the NHREC, regulates all processes concerning research in Nigeria. The code also contains criteria for the registration and functioning of institutional or regional health research ethics committees (HRECs).

Objective

To document the current role of HRECs in ensuring ethical practices in health research in Nigeria, and to identify the strengths and weaknesses of their process of ethical review.

Methods

Nigeria has six geopolitical zones. The country was divided into northern and southern regions along tribal, cultural and religious lines, and further subdivision into six zones ensured that all minority and majority tribes are represented. Three HRECs from three geopolitical zones (North-Eastern (Maiduguri), South-Western (Ibadan) and South-South (Calabar)) were selected, and 14 members in total were recruited after a process of simple random sampling. Two of the HRECs were institutional and based in universities, while the third was a regional state government HREC. The study was carried out between June and August 2011.

The invitation to be interviewed was made via telephone or email. The date, time and place chosen for the interview were designed to be convenient to the participant. After written and signed consent

had been obtained, semi-structured interviews (Appendix 1) were conducted with individual participants using an interview schedule that had been validated using pre-tests. All interviews were audiotaped and then transcribed to respect the participants' speaking style, and each lasted 30 - 60 minutes. Consent was obtained before the use of the audio tape recording, and if consent to tape the interview was not given, secretarial staff recorded the response in written form.

Ethical approval was obtained from the National Health Research Ethics Committee of Nigeria (NHREC) (ref. no. NHREC/01/01/2007-04/05/2011).

Data were analysed using N6 qualitative software (QSR International). Analysis aimed to describe the functioning of the HREC, focusing on the membership of the committees, their representativeness, their independence from research sponsors, and the institutions in which they were based.

Results

A total of 14 HREC members were interviewed, only two of whom were females, giving a male:female ratio of 7:1.

The membership of the HRECs studied ranged from nine to 15. People often became members because of positions they held in the government or an institution, and membership was sometimes based on experience in ethics as a subject. Tenure of membership was therefore frequently related to tenure of the position held. However, only a few (<30%) of the HREC members had formal training in research ethics. All the HRECs had legal advisers.

All researchers who submitted proposals for ethical review paid a fee of between 2 000 and 20 000 Nigerian naira (US$1 = ~N150), the fee being higher for sponsored projects. It was the applicants' responsibility to submit enough hard copies of their proposals for all members of the HREC.

The frequency of HREC meetings to review submitted proposals ranged from fortnightly to quarterly. Scientific and ethical reviews were conducted together by the same committee. All the HRECs followed the guidelines of the NHREC, which is the national and supervising body. After approval, two of the HRECs did not monitor approved projects and the only HREC that monitored approved proposals relied solely on funding by the researcher to do so.

Two of the three HRECs relied solely on the processing fees paid by the researchers to fund the committees, while committee functioning in the third was funded by the institution in which it was based.

The HRECs ensured that participants with an excessive risk of harm were excluded from studies if possible. These included children, pregnant women, and members of socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged groups. Specific safeguards were used to protect vulnerable subjects involved, appropriate to the degree of risk.

Social and cultural factors that sometimes limited application of international ethical norms to research proposals during ethical reviews in Nigeria included the low level of education of much of the population, religious beliefs, lack of understanding of the concept of research on the part of most Nigerians, and unco-operative attitudes among some research participants, who viewed the researchers as strangers in their community.

Most HREC members understood the concepts of autonomy and consent in research. With regard to issues relating to beneficence and non-harm to participants in the review of research protocols, most committees were multidisciplinary in composition, and experts in relevant fields were frequently asked to evaluate the risks and benefits to research participants. Financial compensation to research participants was usually not made compulsory for researchers, but incentives such as transport and refreshment allowances were advised when there was no direct benefit to the research participant.

Challenges faced by the HRECs included irregular meetings due to committee members' busy schedules, haphazard selection of members, and lack of remuneration or incentives for members.

Discussion

Ethics are the rules or standards governing the conduct of a person or the members of a profession. The medical profession deals with human life, and research is an integral part of medicine. However, medical research must be regulated in order to ensure that fundamental human rights are not breached in the quest for knowledge. Before the 1960s, researchers were thought to be responsible and they were quite free to conduct 'good research'. However, from the 1960s, ethics became a concern in the world of health and biomedical research.

Researchers in developed countries have realised that using developing countries for their trials incurs lower costs compared with traditional research areas. Furthermore, less strict (or lack of) legislation means that research protocols are accepted more easily and sooner than in developed countries. If preparatory procedures are done quickly, the company will have more time to optimise profits within the patent period. Also, volunteers for trials are easy to find in developing countries because of widespread disease and abject poverty. Although various organisations have been promoting ethical health research in Africa in conformity with international ethical guidelines,[5] Nigeria, as a developing country with a large population, is prone to exploitation by researchers, a classic example of which is the Pfizer testing of trovafloxacin on children with meningitis in 1996.[3] Before 2005, only the National Agency for Food and Drug Administration and Control (NAFDAC) had jurisdiction over medical research in the country, especially research involving drug trials. However, the NAFDAC focused largely on food safety and drug control and paid little attention to ethics in medical research.

Nigeria had no laws or specific guidelines to regulate health research until the NHREC was established in 2005 by the Minister of Health as the body responsible for ensuring the protection of human research participants. The National Code of Health Research Ethics was produced by the NHREC in August 2007 and regulates all processes concerning research in Nigeria, such as granting approval for research, research supervision, and processes for suspension, revision or termination of research. International codes served as guidelines for the production of this code, with adjustments to cater for Nigeria's specific sociocultural environment. Kirigia *et al.*[6] recommended that African countries should adopt international guidelines on biomedical research, pass laws on standards and regulations to strengthen the ethical review framework, and develop governance mechanisms to make sure that their HRECs approve projects in accordance with the Council for the International Organizations of Medical Sciences (CIOMS) guidelines of 2002.[7] The national code is easily accessible by researchers, as it is available online (www.nhrec.net).

The NHREC has published a list of accredited HRECs, also known as ethics review committees or institutional review boards or committees, in various parts of Nigeria. Although the country now has about

30 institutional HRECs, our study and previous work show that their functioning is hampered by a shortage of qualified individuals to serve on them, together with an imprecise definition of mandates and a highly scientific membership.[8,9] Evaluation work done by committee members is voluntary, and ethical review is very limited. Under such circumstances, even if laws are in place it may be difficult to enforce and apply them.

We found that financial shortages faced by the HRECs mean that there is also inadequate monitoring of approved research protocols to ensure strict compliance by researchers. A study published by Kass *et al*.[10] on the organisation and functioning of 12 ethical review committees in nine African countries identified two similar main issues: lack of training of ethical review committee members, and lack of funding. These same issues were discussed by African participants, and participants from other regions of the world, during the Third International Bioethics Meeting of French-speaking Countries held in Quebec in October 2008 on the topic 'A new governance, diversity, and sharing space of Francophone countries'.

Conclusions and recommendations

In view of the scale of previous ethical breaches in some research projects in Africa, and in Nigeria specifically, compliance with national and international ethical standards is vital. Ethical issues in the Pfizer testing of trovafloxacin in 1996[3] provided the impetus for change in the conduct of health research in Nigeria. However, our study shows that the HRECs still face many challenges. Suggested recommendations for improvement are:

- Allocation of more funding to the NHREC and HRECs for better functioning.
- Provision of financial incentives to HREC members to motivate them and improve their commitment.
- Proper monitoring and supervision of projects by the HRECs to ensure that researchers comply with approved project formats.
- Training and re-training of HREC members to update them on ethical principles.
- Training of researchers and undergraduate students in the health professions on research ethics.
- An increase in research funding and promotion of autonomy of researchers from funders.
- Establishment of a forum for all HRECs in the country to meet and share knowledge and exchange ideas. This may be co-ordinated by the NHREC.
- To ensure relevance of research to the population, research findings should be submitted to the approving HREC. An agency may be set up by the government to collate all such research findings in the state or country to influence government policies.

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Appendix 1. Interview guide for Health Research Ethics Committee members

a) Functioning of the HREC

When was the committee formally established?

What are the functioning modalities and the committee membership?

What are the criteria for selecting members of the committee?

How many members of the committee have been trained in research ethics?

How frequently does the committee meet?

What are the procedures of protocol or proposal approval?

What are the normative regulations used?

What are the specific regulations used?

What are the special arrangements made for vulnerable populations such as women, elderly people, children, migrants?

Are the ethical review and the scientific review conducted together or separately?

Does the same committee conduct both the ethical and scientific review of the proposals?

How is the committee funded?

Do you have dedicated staff and office space for the committee?

What are the relationships between the various committees in the country?

What are the main challenges confronting the smooth operation of the committee?

What suggestions would you make to address these challenges?

b) Ethical principles and rules

International regulations (Council for the International Organizations of Medical Sciences, Good Clinical Practice, Declaration of Helsinki, etc.) state that research ethical principles include respect for research subjects, beneficence (and non-harming), and justice. How do you think these principles could be applied, taking into account the situation of individuals in Nigeria?

What sociocultural factors in Nigeria complicate the application of international ethics rules?

How do you understand the concept of autonomy of research participants in the Nigerian context?

How do you understand the concept of consent of research participants in the Nigerian context? What difficulties have researchers been confronted with in getting consent from research participants? How can illiterate participants be helped to truly understand the research objectives and the scientific terms?

How do you understand the concept of beneficence in the review of research projects in the Nigerian context?

How do you understand the concept of justice in the review of research projects in the Nigerian context?

How do you assess the fairness of the financial compensation proposed by researchers to research participants?

c) Ethical monitoring of the protocol

Is there any ethical monitoring of the protocol after approval by your ethical review committee?

If yes, who is in charge of the monitoring? How is the monitoring funded?

Has ethical monitoring of the protocol taken into account vulnerable populations (children, adults with disabilities, dependent populations/care) and/or the level of risks?

Does the researcher draft an annual monitoring report? Does the report include the number of subjects recruited, and the number who have withdrawn from the research?

Is there any ethical monitoring of the protocol with regard to:

- observation of the consent process?
- control of how research documents and duly signed consent forms are kept?
- notification of modifications to the protocol, the administrative modifications?
- re-submission of application to the ethical committee in case of modifications to the protocol?

d) Comments

What do you see as the key challenges confronting researchers with regard to conforming to the standards of ethics?

Do you have suggestions to improve the framework of ethical research?