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Implementing National System of Health Research Ethics Regulations: The Nigerian Experience

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Abstract

Efforts by Nigerian authorities to institutionalize health research dates back to the early 70's with the establishment of the Medical Research Council. Subsequently efforts to strengthen a national health research system in line with the concept of Essential National Health Research (ENHR) were made but albeit un-successfully. This may have been as a result of poor political support, and lack of regulations to promote health research in the country. However little is known about health research regulations and their implementation in Nigeria.

Health and health research in Nigeria is not regulated via a set of clearly defined legislation. While the country has developed a regulation document for health research ethics, compliance to this document is likely to be affected by the lack of legislation in for the health system as an entity. In this paper we narrate the developments in health, health research, and health regulations; we describe process for, and extent of implementation of the National Code of Health Research Ethics. We conclude that several factors affect the extent of implementation of the ethics code amongst which legislation is an important one.

Keywords

Ethics; Regulations; Nigeria

Health Research in Nigeria

The need to institutionalize Health Research in Nigeria dates back to the early 1970s when the Decree No 1 of 1972 for the establishment of the Medical Research Council of Nigeria (MRCN) was enacted. This decree was later subsumed under the National Science and Technology Development Agency (NSTDA) by virtue of Decree No. 5 in 1977.[1] Nigeria is one of a number of developing countries[2] to establish a mechanism for Essential National Health Research (ENHR) which is promoted by the Council on Health Research for Development and supported by the World Health Organization (WHO). Thus ENHR is a

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concept that promotes the development of locally driven research agenda which seeks to address health related issues in a given country. The establishment of the ENHR was therefore, an attempt to bridge the 10/90 gap and get developing countries to have a voice in setting the international health research agenda.[3]

The Federal Ministry of Health, with the department of health planning and research as the secretariat was responsible for implementing ENHR in Nigeria. Over the years however, while research investments were on the increase, the health research system did not keep with the pace as a result of the low priority accorded health research by the Nigerian authorities. The increases in research investments in the last decade from the WHO/TDR, and other international organisation has since helped reawaken the interest of the government in health research.

The year 2006 can perhaps be said to be one that turned around health research in Nigeria because a number of initiatives that took place that year all aimed at strengthening health research in the country. Key amongst these was the Technical Panel Meeting on ENHR that was held in February 2006[4] and the High Level Ministerial Meeting on Health Research for Development held in March and June of 2006.[5] These two initiatives have been of particular significance because they both were locally initiated by the Nigerian Federal Ministry of Health (FMoH) and born out of genuine concern to strengthen the national health research system in the country.

Without a doubt, the efforts of the Knowledge Enterprise and Health Systems Committee, the National Health Research Ethics Committee, the strengthening of the National Health Accounts, and the establishment of an online mechanism (http://www.nhrd.gov.ng/index.php) to collate data on health researchers and researches in Nigeria by the department of health planning and research were driven out of this renewed commitment to health research.

The main challenges identified by these several fora including the recent Global Forum on Health Research held in Bamako, Mali[6], included lack of funding, lack of coordination mechanism, weak ethics regulatory infrastructures, lack of training for researchers, absence of health research to policy linkages which were and are still persistent in Nigeria and indeed most of the developing countries.

Health Research Governance and Regulation in Nigeria

Health research in Nigeria is a mandate of the FMoH as clearly described in the National Health Policy of 1988, and the revised 2004 version.[7] The Federal Ministries of Education and Science and Development were included in the policy as key stakeholders in health research governance after looking at their support for significant health-related research undertaken under their supervision by universities and other research institutes,

With the department of health planning and research as secretariat, the FMoH has the mandate to develop policies, set national priorities and coordinate health research nationwide. These mandates are yet to be fully realized. Over the years however, health research has remained uncoordinated and often dictated partly by the whims of the researchers, institutions or is largely donor driven.[8]

Prior to 2004, there was no organized set of legislations governing health, health research and health care provision. The national health system functioned based, at the time, on provisions of the Constitution of the Federal Republic of Nigeria (FRN) for the right of all Nigerians to quality, affordable, and accessible health care.[9] In 2004 however, the FMoH embarked on what was arguably the first strategic reform initiative in the health sector,

called the Health Sector Reform Program (HSRP).[10] This initiative sought to revolutionize the way health governance, programming and service delivery from one that is based on ad-hoc systems to one that is based on carefully planned strategies with clear deliverables, targets, and responsibilities.

Although this reform program was initially developed as a short term sector strategy, it is now seen to serve rather as a land mark initiative in setting the stage for proper regulation for health and health research in Nigeria.

The HSRP is anchored in seven major strategic thrusts (Box 1). The need for an act of parliament that establishes a national health system which delineates responsibilities of the various governments and stakeholders in its operationalization was articulated in thrust one – 'strengthening the stewardship role of government'. The reform document recognized the "constant and never-ending need to generate new information and develop improved and more effective ways of protecting and promoting health and of reducing diseases".[11] This perhaps justified why health research was rather captured under the thrust three of the reform document – reducing the burden of diseases.

The implementation of this reform program led to the development of a draft national health bill which was ratified by the senate in 2008 [12] and is now awaiting presidential assent.

Research Ethics Governance and Regulation

Research ethics in Nigeria, like in many African countries, is only recently been given the attention it deserved. This is exemplified by the fact that most developing countries that might have had some ethics review mechanism earlier in place are only recently developing guidelines. In South Africa for example, there has been an ethics committee since 1966[13] but it was after 31 years that the government issued a guideline for their operations and functions.[14] Similarly, the oldest ethics committee in Nigeria was established in 1980[15], the National Code for Health Research Ethics was only issued in 2006, 26 years later.[16]

Ethics committees in Nigeria have been established over the years largely in university teaching hospitals and a few research institutes and most commonly in accordance with United States (US) regulations and the Common Rule. This is probably because of several mechanisms that were introduced by US authorities to ensure ethical conduct of research funded by U.S. Federal government.[17] Thus far, the Office of Human Research Protection (OHRP) of the United States records that there are 39 ethics committees in Nigeria registered with it. However local experience suggests that there indeed might be more as some of these committees have been in existence for the greater part of the last decade then without any local guidance and mechanism for coordination of their activities.

In 2006, the Nigerian Authorities provided what can now be considered a lasting formal support for a National Human Research Participant Protection system through the National Health Research Ethics Committee (NHREC) [18]. This is part of its resolve to strengthen health research and in so doing, ensure that the experience of the 1996 unethical trial[19] is avoided. The NHREC was to serve as the apex body responsible for providing guidelines and ensuring that all stakeholders in health research in Nigeria adhere to the guidelines. See box 2 for mandates of NHREC.

The National Code of Health Research Ethics

Development Process

The need for countries to develop and or adapt international ethics regulations for better local application has been highlighted severally.[20,21,22] This has the advantage of

harmonizing the workings of ethics committees and supporting a system of ethics infrastructure. The benefit of adapting international ethics regulation for better local application cannot be overemphasized as it has the advantage of harmonizing the workings of ethics committee and supporting a system of ethics infrastructure. Through its technical cooperation agreement with the United States National Institutes of Health funded West African Bioethics Training Program (WAB) at the university of Ibadan,[23] the National Health Research Ethics Committee developed the National Code of Health Research Ethics in 2006.[24] With WAB in the lead, the Nigerian Code was developed based on review of current research ethics codes especially the CFR 45 Part 46[18]; CIOMS[25]; Helsinki Declaration (revised)[26]; and the ethics guidelines from India (ICMR)[27] and South Africa[28] among others using a modified Delphi approach. The team also considered recent developments in international health research ethics, the Nigerian Constitution and the Federal structure of the country, other relevant laws, the history of research and research ethics in Nigeria.

In order to ensure its successful implementation, the need for ownership of the code by its potential users at an early stage was recognized. Thus, as soon as the first draft of the code was approved by NHREC, a National Workshop of researchers and ethics committee members in University Teaching Hospitals and Research Institutes was conducted in December 2006 [29] to discuss the provisions of the Code with potential users and obtain their inputs and ownership. Comments, suggestions and corrections received were incorporated by the NHREC into the code was and submitted to the government for adoption as the first domestic legal regulation establishing ethical review of research in Nigeria.

Governance Structure

The National Health Research Ethics Committee is largely responsible for the regulation of other institutional ethics committees in the country. Each institution in which research is being conducted is encouraged to establish its own ethics committee, or enter into an agreement with an ethics committee from another institution to serve as its ethics committee of record. Central review by the NHREC is only provided for multi-centre studies and is entirely at the discretion of the researcher. This is seen as an important initiative because it provides the researcher and or sponsor with choices, to potentially avoid the problems observed with local reviews for multi-centre studies.[30]

Enforcement of Ethics Regulations

The National Code of Health Research Ethics, which is the highest policy document on research ethics in Nigeria and it was approved by the National Council on Health in its 50th Annual Meeting in January 2007.[31] The procedure entailed that health policy be reviewed and approved by all commissioners of health for nation-wide implementation.[32] While awaiting the passage of the act of law to provide further backing for the Code, it received the Ministerial approval for implementation, as with all other health policy in the country.

The availability of the Code on NHREC's website, and the need for all researchers and members of ethics committees to abide by the code was publicized nationally in the media[33, 34] conferences[35] and the 51st National Council on Health meeting in 2008. The Code requires ethics committees to register with NHREC in line with calls for accreditation of ethics committees [36, 37] which was for quality assurance purposes.

This is seen as an important avenue to lure the committees to apply the Code in their practices. The National Agency for Food and Drugs Administration and Control (NAFDAC) is the agency, for example, responsible for regulating clinical trials for new pharmaceutical products in Nigeria amongst other mandates.[38] Concerned about the ethical aspects of

clinical trials and in the bid to fulfill this responsibility, NAFDAC welcomed the establishment of NHREC and its requirement for registration of ethics committees to be essential to ensuring the ethics of clinical trials in Nigeria. The collaboration between these two agencies has thus far, helped in fostering the application of the Code. By this partnership, NAFDAC does not approve any clinical trial that is not approved by either NHREC, or an NHREC registered ethics committee.

Taking registration of ethics Committees as a proxy to adherence to the Nigerian Code of ethics; the fact that only about 14 ethics committees are registered so far and compared to the 39 ethics committees registered with OHRP, seem to depict a relatively slow compliance rate. It can be argued however that a number of the ethics committees in the OHRP records are not functional. One reason might be that some ethics committee were only established for short term projects and thus once the project was over, had seized to function thereby affecting the overall number of functional ethics committees as recorded in the OHRP dataset. Also, a number of ethics committees might have failed to renew their registration status since its expiration. The above are not reasons enough, however, to significantly affect the total number of functional ethics committees. An argument for the slow adherence might likely be a low level of awareness about both the NHREC and the Nigerian Ethics Code since both are relatively recent developments. And perhaps more aggressive awareness of these amongst the ethics committees and researchers may result in increased adherence to the Code.

Of the few registered ethics committees, anecdotal evidence suggests that ethics committees' compliance with the Code in Nigeria differs by the characteristics of the ethics committee. Ethics Committees that have been in long existence, those in which the host institution and its researchers have more research activity including international collaborative research, and those with greater political support, appear to be more eager to register with NHREC and comply with the National Code than others.

Recognizing the benefits of abiding by the Code, it is pertinent to explore concrete reasons for the slow compliance of the ethics committees with the national code. Experiences from the UK[39] and South Africa[12] have also shown a historic slow adherence to national guidelines by local ethics committees. There is however, limited or no empirical data providing reasons for the slow adherence in these countries. This may also be an important area for further exploration.

The Challenges

Legislation—On a global level, the declarative nature of ethics guidelines such as the Nuremberg Code[40], Belmont Principles[41], Helsinki Declaration[26] and CIOMS[25] has been a major limitation for their use to enforce ethical standards through litigation. These guidelines lack the specificity required for legal action.[19] It is important therefore to build capacity of developing country professionals and support them to domesticate existing international research ethics guidelines that are supported with legislation under the coordination of a national ethics regulatory body like NHREC, if we are to advance the cause of ethical research in these countries.[16]

Researchers and ethics committees in Nigeria have considered the development of the National Code a laudable achievement in the right direction for the human research participant protection in the Country.[42] However it has been suggested that in order to ensure compliance with the code, a system to sanction non-compliance with the Code needs to be put in place [43], which is more likely by putting efforts to facilitate the speedy approval of the National Health Bill by the legislature.

Vertical Support Systems

The need to strengthen the research participant protection systems in developing countries has been long recognized.[44, 45] Responses to these calls have been generous over the years by such support for training of ethics committees provided by the NIH Fogarty International Centre[46], European and Developing Countries Training Programme (EDCTP)[47], Bill and Melinda Gates Foundation (through AMANET) [48], among others. Other support is provided by UNESCO[49], WHO[50], and EDCTP to develop and or strengthen National Bioethics Commissions. With credit to these initiatives, there are now a significant number of professionals trained in bioethics from countries with national ethics regulatory infrastructures whether referred to as National Bioethics Committees or some other term.[51] It is noteworthy however that these efforts have been undertaken outside a uniform framework that would coordinate and maximize the benefits of these initiatives. As argued by Adebamowo et al[16], training of professionals without taking into consideration their eventual working environments leads to situations where trainees are unable to put into practice their newly acquired knowledge and skills. Following this observation, a systems approach which includes closer working relationship between the organizations providing support and national authorities was advocated. This was in line with the model for a research ethics systems developed by Hyder et al[52] two years later. The model recognized the complex interplay between National and or regional Strategy, Institutional commitment, Research ethics review and Investigators' conduct that were necessary to have a functional system which ensured protection of research participants and promoted ethical conduct in research. Thus, bringing together various aspects of this model to promote an effective system is inherently a stewardship function of the health system[52] requiring the National Bioethics Committees should be seen to play leadership position in this regard.

Bringing together professionals trained in bioethics to set a national agenda can be a fairly simple task to accomplish. However, it is through the vertical support systems that a number of ‘National Bioethics Committees’ is established. Thus, reconciling these committees can be a potentially daunting task to achieve. A careful consideration, therefore, of the elements of the model proposed by Hyder et al[52] could possibly help mitigate such a development.

Conclusion/Recommendations

The Nigerian experience in implementing local regulations has shown the value of collaboration with stakeholders as described in the role that the collaboration with NHREC and NAFDAC has played in getting ethics committees to comply with the national code. The experience has also shown the need to have legislation in place and a systems approach to strengthening national ethics regulatory infrastructures.

Development of modern research programs and participating in internationally funded researchers requires developing countries to have transparent and effective research ethics regulatory infrastructures. “In its absence, attempts to ensure compliance with ethics regulations are likely to remain superficial and falter over time”.[16]

While having both National Ethics Committees and local ethics guidelines is important, ensuring adherence to such guidelines require appropriate national legislation, collaboration with researchers, ethics review committees and the international community.

Ethics development programs need to move beyond the mere training of individuals towards a systems approach that takes account of the eventual working environment of their trainees. Programs such as those by UNESCO[49] and EDCTP [47] for developing and or strengthening national ethics regulatory infrastructures should extend their activities to include a closer working relationship with national authorities in order to institutionalize the ethics review process while fully considering what already exists in these countries

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Box 1

Seven thrusts of Health Sector Reform Program

- Improve the performance of the stewardship role of the Federal Government in health
- Strengthen the national health system and its management,
- Reduce the disease bur den attributable to priority health problems;
- Improve the availability of health resources and their management;
- Improve access to quality health services;
- Promote effective public-private partnership in health;
- Increase consumers' awareness of their health rights as well as their health obligations.

Box 2

Mandate of National Health Research Ethics Committee of Nigeria

- Determine guidelines for the functioning of health research ethics committee;
- Register and audit health research ethics committees;
- Set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials;
- Adjudicate in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by a health research ethics committee;
- Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider;
- Institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act; and
- Advise the Federal Ministry of Health and State Ministries on any ethical issues concerning research.