

Health research ethics review and needs of institutional ethics committees in Tanzania

J.K.B. IKINGURA^{1*}, M. KRUGER² and W. ZELEKE²

¹National Institute for Medical Research, P.O. Box 9653, Dar es Salaam, Tanzania

²University of Pretoria, School of Health Systems and Public Health, Pretoria, South Africa

Abstract: This study was undertaken to describe the performance of health research ethics review procedures of six research centres in Tanzania. Data collection was done through a self-administered questionnaire and personal interviews. The results showed that there were on average 11 members (range= 8-14) in each Research Ethic Committee. However, female representation in the committees was low (15.2%). The largest proportion of the committee members was biomedical scientists (51.5%). Others included medical doctors (19.7%), social scientists (7.6%), laboratory technologists (10.6%), religious leaders (4.5%), statisticians (3.0%), teachers (1.5%) and lawyers (1.5). Committee members had different capacities to carry out review of research proposals (no capacity=2%; limited capacity=15%; moderate capacity=20%; good capacity=48%, excellent capacity=13%). Only half of the respondents had prior ethics review training. Although the majority deemed that ethical guidelines were very important (66%), there were challenges in the use of ethical guidelines which included lack of awareness on the national accreditation mechanisms for ethics committee (59%). Adherence to ethical principles and regulations was influenced by being a scientist (OR= 42.47), being an employee of a professional organization (OR= 15.25), and having an interests in the use of ethical guidelines (OR= 10.85). These findings indicate the need for capacity strengthening (through training and resource support), inclusion of more female representation and other mandatory professions to the research ethics committees.

Key words: health research, ethics, review, committee, Tanzania

Introduction

It is a requirement that all biomedical researches involving human subjects must be reviewed by an independent research ethic committee (REC) (WMA, 2000; WHO, 2000). Research ethics committees serve a number of important public functions, including demystification of health research and provision of a public forum for the accountability of researchers (Ashcroft & Pfeffer, 2001).

Until 1980s, there were no research ethics committee (REC) in many countries. In some countries, the main reason that led to REC establishment was the requirement of scientific journals of ethics committee approval from researchers who wanted to publish their findings (Aksoy & Aksoy, 2003). In some countries such as Japan, ethics committee were established specifically for the ethics of *in vitro* fertilization (Kimura, 1989). Since then, because of growing public concern over the complexities of new biomedical technologies and their social, ethical and legal implications, the idea that ethics committees would discuss, evaluate, and approve or disapprove a proposed medical protocol had generated a very positive public image of biomedical scientists, physicians and ethics committees (Kimura, 1989).

The establishment of REC in many countries has faced several constraints. These included uncertainties of which guidelines to follow, who to appoint as members, what procedures to follow and how to train

members. Moreover, there is lack of competence, lack of clear job description and varied interpretation and understanding of the international guidelines (McPherson, 2001). Research ethics committees are challenged by a number of problems that influence their function and their terms of reference. These problems range from lack of funds; training; competence; independence to practice; clear job description and lack of legal backing (McPherson, 2001; Aksoy & Aksoy, 2003; Kimura, 1989). A report on ethics review study in the UK, documented the immense variation in membership, workloads and working practices of research ethics committees (Nicholson, 1996).

The work of RECs in Africa has been fraught with a number of challenges. A recent case study on the ethical review processes in a number of African countries identified inadequate training, inconsistent funding, and disproportionate focus on science in the review process, constraints in budget, multiple responsibilities of REC members and the tendency of some RECs to "rubber stamp" approvals in order to secure international funding as the major challenges (Kass *et al.*, 2007).

The national research ethics committee in Tanzania was established in 2002. It was constituted and functions according to the Office of Human Research Protections guidelines (<http://www.hhs.gov/ohrp/>). The committee operates under the auspices of the Medical Research Coordinating Committee (MRCC) established in early 1980s (URT, 1979). The MRCC is an overall coordination body for health research in

*Correspondence: Joyce K. Ikingura; E-mail: jikingura@nimr.or.tz

Tanzania. It has formed the National Health Research Ethics Review Committee (NHRERC), which is charged to oversee ethical review and approval of health research to be conducted in the country. The NHRERC is hosted and operates under the National Institute for Medical Research (NIMR). In recent years, however, NIMR Centres have formed local RECs, which issue institutional ethical approvals (URT, 1997; Rugemalila, 1997), and forward research proposals, with recommendations to the national REC, for further review of ethical issues. To reduce the workload of the NHRERC, there have been some deliberate efforts to empower local RECs in the country. It was therefore, the objective of this study to evaluate the performance and ethics review procedures of the selected RECs under the National Institute for Medical Research within the national ethics review framework. This paper reports on the findings of a survey conducted to review the structure of NHRERC and its satellite RECs, identify needs and assess the perception and attitude of members towards the process of ethical review.

Materials and Methods

Study design and data collection

This cross-sectional study involved the use of both qualitative and quantitative methods. A self-administered questionnaire was developed by adopting that used by the HIV/AIDS Vaccine Ethics Group based at the School of Psychology, University of Kwa-Zulu Natal, South Africa. It was pre-tested, modified and finalised. The questionnaire enquired into basic demographic background of REC members, extent of training in ethics review, procedures and use of guidelines, extent and nature of follow-up of approved studies, financial and material resources and REC independence. Information was also collected on the composition of the REC.

The survey was conducted between July and October 2004 and involved the NHRERC in Dar es Salaam and RECs at Muhimbili, Mwanza, Amani, Tabora and Tukuyu Research Centres. The centers were conveniently chosen on account of enthusiasm to participate and considerations of the workload of research in the respective regions of the country. The principal investigator liaised with the administrators of the various RECs and arranged visits to the sites. Such visits were designed to coincide with one of the REC meetings. After a briefing on the aims and objectives of the study, questionnaires were distributed to each member of the REC to be completed either during the meeting or after and sent back to the investigators.

No identification was required of members and forms were returned direct from the member to the investigator.

Personal interviews were conducted with the chairpersons and secretaries/administrators of the RECs in Mwanza, Amani, Muhimbili, Tabora, and Tukuyu. Interviews centred on broad discussions on issues related to the work of the REC, and the relation between the respective RECs and the NHRERC. Specific issues discussed included compensation for time devoted by the secretariat, funding of the work of the REC, application of the national guidelines for health research ethics review, attitude towards conducting review at local institutional level and modalities for interaction between RECs working under NHRERC. During the interviews the respondents were also asked of the availability of REC office space specific for REC activities and access to Internet and email facilities, and if staffing for the committees work was adequate.

Data analysis

Data from the questionnaire was double-entered into computer using Excel, with reconciliation done to develop a final master data file. The data was exported to STATA 7 and analysed. Data from the conducted interviews were analysed manually using emergent themes out of the various topics covered during the interview.

Ethical consideration

Ethical clearance for the conduct of the study was granted by the Medical Research Coordinating Committee and the respective Institutional RECs. Participants were assured of confidentiality, and information collected did not include identifiers that could link forms to individual members of the RECs.

Results

There were 66 members in the six RECs surveyed. On average each REC had 11 members (range= 8-14). Of the 66 members, only 10 (15.2%) were females (5/14 in NHRERC, 3/ 9 in Muhimbili, 0/12 in Mwanza, 1/8 in Tukuyu, 0/12 in Tabora and 1/11 in Amani). The reason advanced for the low level of female membership was the restriction of REC membership to scientists and senior technicians within the institution. The largest proportion of the committee members was biomedical researchers (51.5%). Others included medical doctors (19.7%), social scientists (7.6%), laboratory technologists (10.6%), religious

leaders (4.5%), statisticians (3.0%), teachers (1.5%) and lawyers (1.5).

A total of 45 members of the REC participated in the questionnaire survey. Of these, 6 (13.3%) were females. To the question whether members felt their respective RECs had adequate capacity to conduct ethical review, 13% (50% of NHRERC respondents) of members felt their REC had excellent capacity, 48% rated capacity as good with 20% indicating capacity as moderate.

Only about half (51%) of the respondents had prior formal training in research ethics review.

Most (66%) of the respondents agreed that guidelines are important in the process of ethic review. With regards to the challenges to the use of ethics review guidelines (59%) agreed with the need for a national accreditation mechanism for ethics committees, whereas 16 (41%) members disagreed. Only twenty-four (53%) respondents were aware of the existence of national standards for the REC composition. Fifty-three percent (24/45) said that there was a lack of standard operating procedures for the committees. Eighty-four percent (38/45) of the respondents were not aware of a national audit mechanism for research ethics committees. The majority (90%) of the respondents identified lack of knowledge of international ethical guidelines. The guidelines of the Council for International Organizations of Medical Sciences and the Helsinki Declaration were the two best known (86.7%; N=39/45) to the respondents. Most respondents felt that it was very important to develop national /institutional ethical guidelines. Thirty-one (69%) members reported to have written SOPs for their committees. Ten (22%) respondents reported unavailability of SOPs for their committees.

In all Centres, there was lack of office space specific for REC activities and poor financial support was common. The committees were understaffed, as there was lack of secretaries at five sites, where members volunteered to do the secretarial work. The majority (58%) of members were remunerated for their time, but this was reported to be as a token and was not proportion to the workload. Monitoring of research undertaking was identified as a problem in all the research ethics committees. Sixty-nine percent of the committee members reported lack of mechanisms for monitoring of approved research while 33% did not know whether such mechanisms were in existence. The committee mainly relied on researchers for submission of progress reports. This

was attributed to lack of financial resources and capacity of the members.

As regards to application of ethical principles, 46.5% (20/43) of the scientists and 11 (25.6%) non-scientists applied ethical principles. Four (9.3%) scientists and 8 (19%) non-scientists did not apply ethical principles. There was no response from two members. Adherence to ethical principles and regulations was influenced by 3 factors: being a scientist (OR= 42.47), being an employee of a professional organization (OR= 15.25), and having an interest in following ethical guidelines (OR= 10.85), in a decreasing order of strength. The association between being a scientist and applying ethical principles was a statistically significant ($P=0.02$). There was a marginally significant association between the application of ethical principles and an interest in ethical principles ($P=0.05$) as determined by Fisher's exact Chi-square test of association.

The adequacy of the fitted binary logistic regression model was assessed using 2 commonly used techniques: the classification table and the magnitude of area that lies under the receiver operating characteristic curve. The percentage of overall correct classification was 81.40%, which indicate that the fitted model had a fairly high predictive capacity regardless of the small sample size of study. The sensitivity and specificity for the question with regards to the application of ethical principles were respectively 90% and 62% with a positive predictive value of 84% and a negative predictive value of 27%.

Discussion

In Tanzania, the RECs were found to exist, operating within their institutional levels, and conducting ethics reviews. In this study, similarities in the formation, membership, regulation and functioning of RECs were observed like elsewhere in the world (Aksoy & Aksoy, 2003). Lack of specific office space for the REC members prompted one to work from his/her office, which was always a limited space. Nonetheless, there were adequate resources in the form of telephones, computers and e-mail access. These findings differ from situations in other countries where the RECs have offices and designated staff (Fuchs, 2002). Many African countries lack Research Ethics Committee's expertise and this has been observed to impede research (<http://www.sahealthinfo.org/ethics/amanet.htm>).

The RECs members in Tanzania have varied backgrounds. However, the majority of the members were biomedical and medical scientists. This is likely to be to the advantage of the review expertise required by the review process. Similar findings have been reported elsewhere (Pickworth, 2000; Kirigia & Wambebe, 2006). Recently, a study by Fuchs (2002) reported that an adequate judgement, concerning the risks and burdens of the research subjects, on the one hand and the expected benefits for the individual, group of patients or society on the other hand, requires expertise from many scientific and medical disciplines. According to Fuchs (2002), the membership of medical doctors is mandatory for all ethics committee composition and in many systems are among the majority members. Our findings are similar to those observed in other countries (Fuchs, 2002). In Tanzania, other professionals such as nurses, teachers or lawyers were few or not available among the research ethics committees. Lawyers and nurses tend to be regarded as a second and third group of mandated representatives (Fuchs, 2002). Contrary to our situation in Tanzania, in Denmark, the layperson group represents significantly a large group on the REC members (Fuchs, 2003). The low representation of women in the local committee calls for efforts to have equal representation of both genders in future.

In Tanzania, the research ethics committee members rarely receive reward for the time they spend carrying out REC activities because of inadequate resources. With inadequate funding, many committees have resorted to charging for review of commercially sponsored proposals (Pickworth, 2000). Likewise, in recent years, the NHRERC in Tanzania introduced some fees for proposal review regardless whether it is a commercially sponsored proposal or not.

Reports in Africa indicated the existence of ethics review committees in some countries, with none in others. Moreover, there is limited awareness and understanding of concept of research ethics such as informed consent and confidentiality (Kilama, 2001). In recognition of such constraints, the World Health Organization initiated a plan to strengthen ethics review capacity in Africa and established ethics review guidelines. These initiatives included providing support for training of personnel in ethics review skills (WHO, 2000). Although experts as well as lay people could learn ethics review by doing as reported elsewhere, many experts emphasize the need for such training and that training for ethics committee members should be part of the entire culture of medical ethics and bioethics (Fuchs, 2003). Tanzania developed its national guidelines in 2001 (Mashalla

et al., 2001). Most health research institutions in the country use these guidelines to guide the researchers on appropriate research procedures. Moreover, the national guidelines are used by many of the RECs to develop standard operating procedures.

Like in our findings in Tanzania, many RECs in African countries lack expertise in monitoring and evaluation of various qualitative methodologies proposed in planned research, which impedes research undertaking. This lack of capacity to monitor research implementation means the committees are unlikely to detect fraudulent practices by researchers. The current monitoring process of RECs in Tanzania is largely confined to collecting progress reports and reviewing changes in protocols. This has similarly been reported in United Kingdom (Pickworth, 2000).

In conclusion the NIMR RECs are able to conduct review of health research proposals, but there is a need for ethics review training, more female representation and other mandatory professions on the committees. There is need to support RECs in term of human, financial and material resources. Moreover, the RECs in Tanzania need to have their capacity in research monitoring and evaluation strengthened.

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