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Silent Voices: Current and Future Roles of African Research Ethics Committee Administrators

key goal in establishing appropriate governance structures for research ethics review is to ensure that research ethics committees (RECs) operate within a clear mandate, have explicit authority and accountability, and have well-described roles and responsibilities for their members. REC administrators, where these have been appointed, are key actors in achieving the goals of any REC to conduct high-quality ethics review in a timely and responsive manner.

To the best of our knowledge, there have been no previous studies conducted in Africa to examine the positions and potentials of REC administrators. At the same time, programs to improve ethics review capacity of RECs in Africa¹ have mostly targeted REC chairs and members with coursework and empirical research skills to enhance their understanding of ethical theory and principles and, to a lesser extent, operational guidance for RECs. The professionals who usually manage the operations of RECs and implement review administration have not had an explicit focus, either in terms of understanding their roles and potentials or in terms of receiving tailored specific capacity-building inputs in Africa.

Over 165 RECs are currently known to be operating in 34 African countries with great variability in skills, membership, capacity, and efficiency.² Among these, 70% (115) have a chairperson and an administrator; the REC chairperson functions as chair and administrator for the remaining 30% of RECs. There is little empirical knowledge about the roles and responsibilities attached to the REC administrator position and about the professional identity and career trajectory of REC administrators in Africa. However, clues to REC administrators in Africa may be found both in literature and anecdotally, suggesting that REC administrators can be effective contributors to the ethics review process.3 The position and roles of REC administrators are well documented in some developed countries. For example, some of the principal functions performed by REC administrators in the United States include, but are not limited to, routine management of REC activities, ensuring availability of ethics guidance documents (ethics policy, research agenda, standard operating procedures, and legislation), maintaining and disseminating REC documentation, providing advice, ensuring compliance, monitoring of and arranging for training of REC members, ensuring quality improvement of reviews, handling allegations of research misconduct and unacceptable research practices, and dealing with complaints (i.e., matters related to public responsibility in medicine and research).4 In addition, REC administrators interact with researchers and REC members and are key to managing the review process and schedule.

Most African research institutions do not have—or allocate—adequate financial resources to strengthen the capacity of their own RECs.⁵ Many REC administrators may not have defined roles and responsibilities, may lack adequate training, and do not have efficient electronic information management systems to assist with their heavy and often complex workloads.⁶ Furthermore, many RECs in Africa are overwhelmed by an increase in the volume and complexity of research proposals due to a significant increase in the number of research initiatives, largely in response to the serious burden of disease, including the HIV epidemic.⁷

The guidelines of the Council for International Organizations of Medical Sciences acknowledge the vital role played by REC administrators in facilitating the ethics review process and assisting with safeguarding

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the dignity, rights, safety, and well-being of actual and potential research participants.⁸ In spite of this, capacity-building initiatives to date have mainly focused on training of REC chairs, committee members, and research applicants, using both in-house and web-based programs.9 The only known training program aimed specifically at REC administrators seems to be available to RECs in the U.S. through the organization Public Responsibility in Medicine and Research (PRIM&R). PRIM&R offers short courses and certification for REC administrators that seem to focus largely on compliance with U.S. regulations that may not be entirely relevant or affordable to African REC administrators.¹⁰ More recently, in 2011, the Southern Africa Research and Innovation Management Association and the Tshwane University of Technology held a joint workshop targeting new REC administrators from academic institutions and national science councils in the southern African region.¹¹ In the same year, the Council on Health Research for Development (COHRED) convened the first meeting of African Administrators of Research Ethics Committees (AAREC) in Botswana that brought together 40 REC administrators from 21 African countries.¹² The participants endorsed a call for more support to strengthen the capacity of REC administrators, develop a process to encourage their formal recognition by establishing an African accreditation system, and support efforts to harmonize ethics review systems in Africa.

It is nonetheless clear that the research ethics review process in some African settings may be compromised with regard to efficiency, quality, consistency, nuanced application of relevant regulations, ethics guidelines, and management of diverse aspects of the ethics review process. Most of these problems may be the result of ineffective and under-resourced REC administration.¹³ REC administrators could, therefore, be an important missing link to improving quality and efficiency of ethics review in Africa. In preparation for the first AAREC conference, participants and others were asked to participate in this study to understand better the role, responsibilities, and potential of REC administrators to improve the efficiency and effectiveness of ethics review in Africa.

Study Methods

The target population for the study was made up of the 165 REC administrators from the 165 RECs that had been mapped onto the COHRED's Health Research website.¹⁴ Sixty of the RECs that indicated that they had an REC administrator were invited to apply for sponsorship to attend the AAREC conference based on regional representation, REC workload (higher workload receiving preference), English fluency, and limited local funding. On this basis, 40 REC administrators from 21 countries were selected and sponsored to attend. A semistructured questionnaire with closed and open questions in English was emailed to these 40 REC administrators, and participants were asked to respond prior to the meeting so that an initial analysis could be made. This was also meant to serve as an icebreaker for workshop discussion on the roles, responsibilities, and potentials of REC administrators in Africa. The questionnaire used in our survey was adapted from a survey by Dunscombe¹⁵ that used constructs similar to those that we were interested in eliciting from our sample. Other constructs were derived from the literature cited above, covering demographic characteristics of REC administrators, the structure and functions of the RECs they served, their roles and responsibilities, the extent of REC administrators' involvement in ethics review processes, and their opinions about their roles and responsibilities. Returned completed questionnaires were captured and analyzed with SPSS data analysis software (version 16.0). The survey received ethics approvals from the Botswana National Research Ethics Committee (Health Research and Development Committee) and the Humanities and Social Sciences Research Ethics Committee at the University of KwaZulu-Natal, South Africa. Informed consent was requested in the introduction to the survey questionnaire. The consent preamble assured potential participants that their participation was voluntary and that their responses would be kept confidential. No names were required or recorded. Participants were also assured that if they decided not to participate in the study, it would not affect their collaboration with COHRED or affect their jobs in any way. On reflection, the only possible source of potential deductive disclosure was participants' country of origin in the event that the country in question had only one REC. Finally it was indicated that "by answering the questions, you have consented to participating in the survey."

Study Results

Twenty-seven of a total of 40 REC administrators (67.5%) who were invited to participate in this survey provided written responses to the questionnaire.

Respondents were from 14 of the 21 participating African countries (67%). Table 1 (available, along with all the tables for this article, via the *IRB: Ethics & Human Research* web page) shows that there were slightly more male than female REC administrators and that nearly three quarters of REC administrators were mid-career professionals aged 31 to 50 years (74%). All respondents held at least a bachelor's degree, while 81% had a master's or doctoral degree. Eight (32%) of these were medical doctors. Two-thirds (18/27) of REC administrators had been in their position for more than three years. As a result of our selection criteria, our sample is biased towards Anglophone countries: 22 out of 27 REC administrators (81%) came from these countries.

Table 2 shows the professional fields of training of the REC administrator. Respondents were asked to provide information about other REC administrators they knew of, and 23 out of 27 provided this information in addition to the 25 who provided their own educational backgrounds. As several REC administrators held qualifications in more than one discipline, the total is more than the total number of respondents. Health-related training dominated all training, but general science and research background and education in library or computer sciences followed as main other categories. Just over two-thirds of REC administrators (68%) indicated that they had received training in research ethics, and just over half (52%) indicated that they worked as REC administrators in their institutions.

Characteristics of the research ethics committees served by administrators. The survey showed that the great majority (23/26, or 88%) of RECs were based in urban institutions, while very few (2, or 8%) were in semiurban and rural (1, or 4%) institutions. Just over half of the RECs belonged to government institutions (14/25, or 56%), and one third were from universities (36%), with only two (8%) being privately owned. Results showed that almost an equal number of RECs received funding directly from government (9/24, or 38%) or universities (8, or 33%), while an almost similar number reported receiving funding from "other sources" (7, or 29%) without providing more detailed information. In addition, most respondents (21, or 81%) indicated that they also received funds from external grants, mostly from national and international organizations that undertake research in their countries. REC administrators also reported on the frequency of their meetings. Approximately two-thirds (14/22, or 64%) of respondents who answered this question

reported that their RECs met monthly, while only the two private RECs (9%) reported holding REC meetings every two weeks, and the remaining 3 (14%) reported holding meetings twice a year or on demand.

■ *Research ethics administrators' titles, roles, and responsibilities.* Respondents reported a variety of REC job titles. These were grouped into three broad categories: "researchers," "REC administrators," and "managers." Only 5 out of 26 (19%) of the respondents were actually referred to as "REC administrators," which indicates that for most respondents, the administration of the REC was not their primary function. Instead, they performed other primary roles, including research (10/26, or 38%), lecturing (5/26, or 19%),

None of the respondents in this study had undergone training specific to the function of their role as a research ethics committee administrator, and only two-thirds had received formal training in research ethics.

and management (6/26, or 23%). At the same time, when asked to indicate whether they thought that REC administration was a potential area of professional or career specialization, the majority (23/26, 88%) strongly agreed that it was.

Respondents were asked to select from a list of tasks those that matched their own functions and scope of work most closely. As shown in Table 3, most REC administrators had a wide range of responsibilities, many of which were more complex than simple administration. The most frequent responses included recruitment of REC members (85%) and providing research ethics training (81%). In addition, approximately three-quarters (74%) also had the dual role of REC administrator and chairperson of their REC. Over half had senior management responsibilities (56%) included as part of their work.

Table 4 shows the variety of tasks and responsibilities in which REC administrators in this study were engaged. They are grouped in three main areas of work: administration of the review process, management of the REC, and providing guidance and advice. The demands made of REC administrators were wide and varied and appear to exceed the competencies provided by their professional education shown in Table 2.

Discussion

he REC administrators in this study were mostly midcareer professionals with substantial undergraduate and postgraduate education in a wide variety of fields relevant to health research. The group was well balanced in terms of gender. Most of the participants had more than three years of work experience as an REC administrator, with the longest-serving administrator having been in place for 15 years. Although the oldest REC in Africa was established in South Africa in 1967,¹⁶ many RECs in Africa are still relatively young. There will be an increasingly experienced cadre of REC administrators on the continent as RECs around Africa mature. Collectively, the REC administrators in this study constitute a major human capital investment in health research with the potential to have impact on the efficiency and quality of ethics review in Africa. The survey findings also suggest that this wealth of training and experience could be accessed to develop a locally relevant training program for those involved in research ethics administration in sub-Saharan Africa. This could lead to professionalization and formal recognition of the REC administrator position, which is currently often lacking. For example, better-resourced institutions could offer formalized and certified courses in research ethics administration. However, additional research will be required to identify effective management tools and strategies for training programs.

Significantly, none of the respondents in this study had undergone training specific to the function of REC administrator. Only two-thirds had received formal training in research ethics, which consisted mostly of local training provided by their home institutions. Unfortunately, our questionnaire did not request details about the source, content, and duration of the training that was provided, but from responses received during the subsequent AAREC meeting,¹⁷ it appears that their training was typically informal, ad hoc, and not sponsored, recognized, or rewarded by their institutional employers.

■ *Clarifying job titles and responsibilities of research ethics committee administrators.* The work done by most respondents was more complex than mere REC administration. Almost three quarters of REC administrators were also reviewing members or chairs of their REC, a situation that creates additional duties and possible conflicts of interest.¹⁸ This dual role is potentially problematic and requires further considered discussion. Most respondents also had other primary roles and responsibilities, including research, lecturing, or managing departments or programs. This suggests that many REC administrators do not have formally protected time for REC duties and that REC work has to compete with other priorities. We strongly advocate for a system in which employees who work as REC administrators in secondary or temporary roles are formerly assigned REC responsibilities for a specified time (e.g., two days per week, depending on REC workload and REC resources) to ensure that REC matters receive regular and ongoing attention. Workloads as reported appear heavy and fragmented. This picture implies a lack of specific job descriptions for REC administrators and poor specification of the REC administrator's role in facilitating efficient and effective REC management. As in many other work situations, job titles are determinants of roles and responsibilities as well as badges of authority. Not having a job title appropriate to the position can undermine standing both inside and outside the organization and may hinder REC administrators' access to future promotion, advancement, and career opportunities.¹⁹ Some of these deficits are common and acceptable in voluntary work and tasks²⁰ but unacceptable in formal employment. Our finding of various ambiguous job titles in this study is probably generalizable to many other African REC administrators. Our data suggest that REC administrators were perceived as performing varied functions ranging from providing technical expertise in research oversight to clerical tasks restricted to receiving and dispatching correspondence and maintaining files. The majority of REC administrators in this study had multiple managerial tasks but did not have prior training tailored to this role.

Encouragingly, just over half of all REC administrators in this study (15/27, or 56%) reported that their institutions had *a very realistic* understanding of their position. The majority (23/27, or 85%) of respondents perceived REC administration as a potential formal specialization and career option. This is a clear indication of a need to formalize REC administrator positions and creates an opportunity to improve the quality and responsiveness of African research ethics review through a targeted approach.

REC administrators' work context. The contexts in which REC administrators in sub-Saharan Africa work appear to be highly varied because of the large differences in number, quality, and expertise of the RECs they manage.²¹ For example, the administrators of some RECs were experienced, while others had only minimal training and experience. There are also varied membership and specializations. This imbalance affects the efficiency of RECs in terms of volume of workload and the turnaround time with applications. With the advent of multisite studies, especially clinical trials, this variation is bound to affect negatively the effectiveness and efficiency of many REC administrators.

Most REC administrators were employed in RECs without dedicated budgets. The financial constraints under which African RECs operate have also been noted by several studies, which have shown that insufficient funding is a continuing problem for many RECs.²² However, "autonomous governance" was noted as important for RECs' ability to make decisions independently, appoint well-trained and competent REC administrators and members, set performance criteria, and have independent budgets, office space, and adequate equipment to enable sustainable and efficient service to the research community.²³ Therefore, while RECs remain underfunded or over-reliant on unpredictable external funding, it is unlikely that they can operate effectively, efficiently, and independently and avoid or manage institutional conflicts of interest. A more recent investigation into financing of RECs shows, however, that many, even those in publicly funded institutions, are charging for reviews or considering charging for them.²⁴ However, no systematic assessment of ethics review fees has been conducted in Africa to date. This potential source of income could be used to increase the material and human resources of RECs to improve efficiency and possibly effectiveness.

More than half (52%) of REC administrators reported that their RECs met monthly, and approximately one-third (30%) reviewed more than 100 applications annually. In some South African RECs this may be much higher: between 350 to 1500 applications annually.25 The workloads that come with such numbers, even in the lower ranges, can be overwhelming without adequate and digital REC information management systems for administration and tracking. For example, the Research for Health Innovation Organizer is a software system for developing countries that the COHRED developed to oversee and automate the entire lifecycle of the research process, thus allowing users to improve efficiency and effectiveness by speeding up the ethics review process.²⁶ The absence of electronic REC management systems was also noted in a followup meeting of REC administrators²⁷ as a cause of

compromised efficiency and review quality and of poor adherence to local and international ethics guidelines.

Resourcing, training, and management information systems together can only improve the performance of REC administrators and their RECs,²⁸ especially if understaffed, as most African RECs are reported to be.²⁹ Although this study had only a small sample of private RECs, these RECs reported greater efficiency and reported meeting twice monthly to minimize delays to researchers. This was also observed in a South African study that found that members and administrators at private RECs had similar or even heavier workloads than those working in government and academic RECs³⁰ but were more efficient and offered better services to researchers.³¹ Our sample was too small to confirm this, however. Future research is required to examine this apparent difference.

Results also showed relatively low levels of involvement by REC administrators in collaboration and networking activities (Table 4). Collaboration and networking between RECs and key stakeholders can occur through REC administrators' attending conferences or meetings and publishing in areas related to research governance. Such contact can stimulate cross-REC support and assistance and identification of troublesome protocols and REC shopping. No such fora exist in sub-Saharan Africa to date. Effective collaboration, networking, and visibility at conferences or meetings can improve the quality of the review process through the sharing of best practices, new ideas, data, and methods for the management of REC resources. Collaboration can also lead to recognition and career advancement. It is important for institutions to provide collaboration and networking opportunities to REC administrators in the form of continued professional training and attendance at regional conferences, workshops, and meetings. These needs were echoed in the AAREC's report³² and may assist in developing and harmonizing ethics review in Africa.

Several limitations are applicable to this study. Purposive sampling, time, and financial constraints could have made the study prone to bias, as the selected sample was limited to a potential pool of respondents from Anglophone countries and established but underresourced RECs with higher workloads and relatively more experience. This might have affected the representativeness of the sample and generalization of findings. Nevertheless, this study provides a picture of active RECs with substantial workloads. A more inclusive survey may need to be conducted in the future for a more representative view of African REC administrators. Use of closed-ended questions limited the detail that could have been obtained through open-ended questions. Future studies could use other data collection methods like in-depth interviews and focus-group discussions or an online discussion forum on the social network of the Mapping African Research Ethics Capacity project.³³

Conclusion

he REC administrators who participated in this study were in general a well-educated group, well balanced between men and women, whose members possessed long and probably substantive working knowledge of REC operations. As such, the participants represent a strong potential to improve the quality of research ethics review and administration of RECs. This potential could be maximized by defining the job description, minimum qualifications, and training needed for REC administrators. If REC administrators had clearly defined roles with distinguished primary employment positions, this would accord greater recognition of and protected time for the REC administrator role. These issues should be earmarked across Africa or subregions for harmonization through the provision of specific capacity-building for this group of professionals and through defining a formal career path and commensurate rewards to increase recruitment and retention of REC administrators. The conclusions of the first AAREC meeting remain valid: REC administrators are an overlooked resource. Many are skilled and committed people who work in a gray area between "being an administrative support person" and being "the kingpin around which an REC performs." Training in research ethics typically focuses on professionals and on the interpretation of research ethics guidelines, in contrast to many of the concerns typically faced by REC administrators, such as good REC operational procedures, clinical trials information systems and follow-up, inviting external reviewers, rapid turnover and review, and feedback for researchers and REC members.

In spite of the limitations of this study, it seems clear that the potential of REC administrators to improve the quality and efficiency of ethics review of health research in Africa is mostly unrecognized and untapped. Specific structural and capacity-enhancing programs aimed at this key category of health research workers are needed and will have a high return on investment. Exactly what changes are necessary will need to be established by further studies that overcome the limitations of this one. Studies are also needed to identify best practices for financing African RECs that are sustainable and that do not compromise the RECs' independence.

This survey of a small sample of Anglophone REC administrators suggests that a larger, more systematic survey is required of the resources, roles, and functions of Africa's REC administrators to inform a range of capacity-building initiatives, including occupation-specific training, identification of best practices, standardized job titles, remuneration scales, and possibly development of a specific vocational path with training requirements, progression levels, and performance indicators. This could enhance recognition, morale, and standards of service delivery by REC administrators. As more African countries formalize and register RECs,³⁴ such developments are likely to generate a better skilled and trained and more motivated and capable REC administrator workforce geared to assisting RECs in Africa to perform optimally. Accessibility and implementation of efficient, reliable, and affordable electronic REC management systems will complement this process to maximize protection of Africa's growing number of research participants.

Tables

All four tables for this article are available via the *IRB*: *Ethics & Human Research* web page, part of The Hastings Center website.

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