

Results of a self-assessment tool to assess the operational characteristics of research ethics committees in low- and middle-income countries

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ABSTRACT

Purpose Many research ethics committees (RECs) have been established in low- and middle-income countries (LMICs) in response to increased research in these countries. How well these RECs are functioning remains largely unknown. Our objective was to assess the usefulness of a self-assessment tool in obtaining benchmarking data on the extent to which RECs are in compliance with recognised international standards.

Methods REC chairs from several LMICs (Egypt, South Africa and India) were asked to complete an online self-assessment tool for RECs with a maximum score of 200. Individual responses were collected anonymously.

Results The aggregate mean score was 137.4±35.8 (~70% of maximum score); mean scores were significantly associated with the presence of a budget ($p<0.001$), but not with duration of existence, frequency of meetings, or the presence of national guidelines. As a group, RECs achieved more than 80% of the maximum score for the following domains: submission processes and documents received, recording of meeting minutes, criteria for ethical review and criteria for informed consent. RECs achieved less than 80% of the maximum score for the following domains: institutional commitment, policies and procedures of the REC, membership composition and training, policies and procedures for protocol review, elements of a decision letter and criteria for continuing review.

Conclusions This study highlights areas where RECs from LMICs can improve to be in compliance with recommended international standards for RECs. The self-assessment tool provides valuable benchmarking data for RECs and can serve as a quality improvement method to help RECs enhance their operations.

INTRODUCTION

Clinical research involving human participants, especially clinical trials, has increased in low- and middle-income developing countries (LMIC) over the past two decades.¹ In response, many LMICs have increased their efforts to establish and strengthen their research ethics committees (RECs) within their ministries of health, universities, research institutions and non-governmental organisations. However, the effectiveness of these RECs remains unknown. Several studies have shown that RECs face challenges that prevent their optimal functioning.^{2–8} For example, Sleem and colleagues² found that potential barriers to the effective functioning of RECs in Egypt included insufficient

training of members, lack of diverse membership, limited human and capital resources, and lack of national regulations. Studies investigating RECs in other LMICs have shown similar findings.^{3–6} Accordingly, commentators have expressed concerns about the capability of RECs in LMICs to perform quality and consistent ethical reviews.^{9–10} Therefore, there is growing interest in establishing mechanisms to assess the effectiveness of RECs.

However, evaluating the effectiveness of an REC remains challenging, particularly as there are no gold standards to measure the ethical quality of REC reviews or the impact of RECs on research practices. Assessments have included surrogate measures such as objective process indicators (eg, turn-around times for research submissions and investigator–REC communications), study-specific outcomes (eg, the number of protocols reviewed, the type of research reviewed, and the frequency of reported adverse events)^{11–12} and subjective assessments by stakeholders in the research process (eg, investigators and members of the RECs).^{13–14}

Governmental or private auditing and accreditation initiatives have been put in place recently to formally evaluate RECs. These efforts include various external review mechanisms based on standards drawn from existing regulatory requirements. Examples of such accreditation efforts include the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER),¹⁵ which endorses a two-step process for RECs in LMICs: a self-assessment performed by the REC followed by an external review by SIDCER. The Association for the Accreditation of Human Research Protection Programs (AAHRPP), a private organisation based in the USA, evaluates an institution's human research protection programme, including the institution's REC.¹⁶ AAHRPP has predominantly been focused on RECs in the USA, but has also extended its programme to RECs in LMICs. The National Research Ethics Service in the UK has developed an accreditation process that includes registration, self-assessment and regular audits.¹⁷ In South Africa, the National Health Research Ethics Council (NHREC) conducted its first audit of all 33 registered RECs in 2012.¹⁸

However, a comprehensive auditing or accreditation mechanism remains unfeasible for many LMICs due to the large investment of human and financial resources needed for such efforts. Also, many LMICs do not have a legal or regulatory framework for clinical research and, therefore, an



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external review mechanism based on national standards is problematic for these countries. However, a self-assessment process might provide an intermediate step to help RECs evaluate their performance and demonstrate their legitimacy to their stakeholders. We previously developed a self-assessment tool for RECs from LMICs based on international standards for RECs.¹⁹ The aim of this study was to have RECs from different LMICs complete this self-assessment tool so that we can determine its feasibility and collect benchmarking data against which other RECs can make comparisons. We also wanted to identify associations between the scores achieved on this tool and independent variables that might be predictive of REC effectiveness.

METHODS

Survey tool

We used the self-assessment tool previously developed by individuals from LMICs with expertise in the operations of RECs and research ethics.¹⁹ The items in the tool were based on international standards.¹⁹ The tool contains the following domains: indices of institutional commitment; policies and procedures of the REC; membership composition and training; submission processes and documents received; recording of minutes; policies and procedures for review; criteria for ethical review; criteria for informed consent; elements of a decision letter; and criteria for continuing review. The 'institutional commitment' domain consisted of the following items:

- ▶ established under a high-ranking authority;
- ▶ institution regularly evaluates the operations of the REC;
- ▶ institution requires investigators to have training in research ethics in order to submit protocols to the REC;
- ▶ institution requires a conflict of interest policy for members of the research staff;
- ▶ the REC is given its own budget;
- ▶ the REC has its own administrative staff;
- ▶ the REC has access to capital resources.

Each item was assigned one, two or five points based on its value to the optimal effectiveness of REC function. For example, five points were given to indices concerned with the educational efforts of the REC, existence of conflict of interest policies, and member composition. In contrast, one point was given to each of the review criteria. The maximum score is 200 points.

Participants

We invited REC chairs or member secretaries from three LMICs (Egypt, South Africa and India) to complete the self-assessment tool. Respondents accessed the tool via the internet and individual responses were collected anonymously.²⁰

Statistics

We used descriptive statistics to analyse the data: a one-way ANOVA to identify significant differences within groups and the Bonferroni test for multiple comparison tests to identify significant differences between groups. Data were grouped according to geographical regions which were labelled 1, 2 or 3. We arbitrarily defined the following variables as characteristics of RECs that might be predictive of effectiveness: (a) duration of existence (<2 years, 2–5 years and >5 years); (b) frequency of meetings (at least once a month or less than once a month); (c) availability of a budget (yes or no); (d) balanced gender representation (eg, women members comprising between 40% and 60% of the total membership); and (e) presence of national guidelines (yes or no). We used χ^2 analysis to determine associations between these independent variables and the mean scores

as well as with responses to individual items. A *p* value of <0.05 was considered significant.

Ethics

Ethics approval was obtained from the respective RECs of the principal investigators from each of the regions. A cover letter explaining the informed consent was given to each potential REC participant and their initiation of the survey indicated their informed consent. To enhance confidentiality, we collected the responses anonymously and have chosen not to link the aggregate regional data with the identity of the specific regions.

RESULTS

A total of 64 RECs completed the self-assessment survey; 19, 14 and 31 from regions 1, 2 and 3, respectively. The aggregate mean score was 137.4 ± 35.8 . The mean scores for the RECs in regions 1, 2 and 3 were 128.7 ± 38.7 , 157.5 ± 16.1 and 133.7 ± 37.8 , respectively ($p=0.05$). The median score was 145.

Table 1 shows the characteristics of the RECs and indicates that just over half (55.9%) had been operating for more than 5 years and approximately 15% had been established in the previous 2 years. A slight majority of the RECs reported having meetings at least once a month, less than 40% stated they had an annual budget, and in 50%, women comprised between 40% and 60% of the total membership. Two of the regions have national guidelines on research ethics and more than 70% of RECs were presumably operating under the guidance of such guidelines. This table also shows the mean scores associated with each characteristic. The mean scores for those RECs that received an annual budget was significantly higher than for RECs operating without a budget ($p<0.01$).

Table 2 shows the characteristics and associated mean of the total scores from each region. For regions 2 and 3, RECs that received an annual budget had mean scores that were significantly higher than RECs without a budget (both $p<0.05$). Associations between mean scores and other variables were not significant.

We calculated the percentage of 'yes' responses for each item on the assessment tool (see online supplementary table 1A).

Table 1 Characteristics of research ethics committees and associated mean of total scores (n=64)

Characteristic	Number (%)	Mean of total scores
Duration of existence		
≤2 years	9 (15.3)	134.2±22.9
2–5 years	17 (28.8)	126.6±40.3
≥5 years	33 (55.9)	143.2±33.9
Frequency of meetings		
At least once a month	35 (54.7)	137.7±40.7
Less than once a month	29 (45.3)	136.9±29.7
Availability of an annual budget*		
Yes	22 (37.9)	158.0±19.2
No	42 (62.1)	126.5±37.9
Balanced gender representation		
Yes	31 (50)	144.6±35.0
No	31 (50)	137.3±24.3
Presence of national guidelines		
Yes	45 (70.3)	141.0±34.3
No	19 (29.7)	128.7±38.7

* $p<0.01$.

Table 2 Characteristics of research ethics committees in individual regions and associated mean of total scores

Characteristic	Region 1 (n=19)		Region 2 (n=14)		Region 3 (n=31)	
	No. (%)	Mean of total scores	No. (%)	Mean of total scores	No. (%)	Mean of total scores
Duration of REC existence						
≤2 years	6 (33.3)	138.0±27.3	1 (8.3)	145.0± 0.0	2 (6.9)	117.5± 7.8
2–5 years	9 (50.0)	112.9±46.4	3 (25.0)	156.7± 12.7	5 (17.2)	133.2±30.7
≥5 years	3 (16.7)	149.3±26.5	8 (66.7)	156.5±18.9	22 (75.9)	137.5±35.8
Frequency of meetings						
At least once a month	15 (78.9)	131.2±39.4	10 (71.4)	158.0±18.8	10 (32.3)	127.3±53.3
Less than once a month	4 (21.1)	119.3±40.3	4 (28.6)	156.3± 8.2	21 (67.7)	136.6±29.0
Availability of an annual budget						
Yes	5 (26.3)	152.4±13.9	6 (42.9)	167.3±8.2*	11 (39.3)	155.5±24.3*
No	14 (73.7)	120.2±41.5	8 (57.1)	150.1±17.0	20 (60.7)	121.5±38.9
Balanced gender representation						
Yes	11 (61.1)	141.0±29.6	8 (57.1)	162.0±12.7	12 (40.0)	136.3±46.1
No	7 (38.9)	125.6±24.5	6 (42.9)	151.5±19.3	18 (60.0)	137.1±24.4

*p<0.05.
REC, research ethics committee.

Survey items assigned a value of 2 or 5 that were associated with a greater than 90% ‘yes’ response included: (a) presence of standard operating procedures; (b) requirement of a quorum for meetings; (c) having a member who was non-affiliated with the institution; (d) written guidelines for submission of protocols to the REC; (e) requirement that investigators use a specific application form and follow an informed consent template; (f) maintaining meeting minutes; (g) having a policy detailing how protocols will be reviewed; and (h) having a policy on how decisions will be made.

Survey items assigned a value of 2 or 5 that were associated with a less than 60% ‘yes’ response included: (a) REC established under a high-ranking authority; (b) institution regularly evaluates the REC; (c) women/total membership ratio between 0.4 and 0.6; (d) REC chair required to have formal training in research ethics; (e) REC members required to have formal training in research ethics; (f) REC conduct of continuing education for its members; (g) requirement for the research team to use an REC-approved informed consent form; and (h) presence of a budget.

Significant differences between the three regions were observed for several of the survey items and included: registration with a national authority; establishment by a high-ranking

authority; a conflict of interest policy for members of the research team; mechanism for research participants to file a complaint; requirement for the REC chair to have formal training in ethics; and REC conduct of continuing education for its members. Significant differences between the three regions were not observed for any of the other survey items.

RECs that received an annual budget compared with RECs without an annual budget were significantly more likely to: (a) have a conflict of interest policy for REC members (100.0% vs 71.4%, p<0.005); (b) conduct continuing education (68.2% vs 33.3%, p=0.019); (c) have a budget for training (54.5% vs 2.4%, p<0.0001); and (d) ask members whether they have a conflict of interest at the beginning of meetings (95.5% vs 71.4%, p=0.023).

Table 3 shows the mean scores for each of the survey domains, expressed as a percentage of the maximum achievable score for that domain. As a group, RECs achieved more than 80% of the maximum score for the following domains: submission processes and documents received, recording of meeting minutes, criteria for ethical review, and criteria for informed consent. RECs achieved less than 80% of the maximum score for the following domains: institutional commitment, policies and procedures of the REC, membership composition and training, and procedures for protocol review, elements of a

Table 3 Scores of individual domains on the self-assessment tool (% of total for each domain)

Domain	Region 1 (n=19) % Of total	Region 2 (n=14) % Of total	Region 3 (n=31) % Of total	Aggregate % Of total
Institutional commitment	36.2	44.6	34.7	37.4
Policies and procedures of REC	64.2	83.5	71.3	71.7
Membership composition and training	57.7	59.0	46.8	52.7
Submission processes and documents received*	72.8	91.7	83.6	82.2
Recording of minutes	76.9	89.6	85.9	84.0
Policies and procedures for protocol review	74.6	85.1	79.8	79.4
Criteria for ethical review*	78.5	98.4	84.7	85.9
Criteria for informed consent	76.3	92.9	85.5	84.4
Elements of a decision letter	55.8	61.4	63.9	60.9
Criteria for continuing review	48.7	72.8	57.1	58.0

*p<0.05.
REC, research ethics committee.

decision letter, and criteria for continuing review. Table 3 also shows the results categorised by the different regions. There were significant differences between the regions for the following two domains: (a) submission processes and documents; and (b) criteria for ethical review.

Regarding aspects of the survey itself, more than 85% of the RECs thought that the survey would produce useful information and more than 85% completed the survey in less than 1 h.

DISCUSSION

Our results demonstrate the extent to which RECs from LMICs are in compliance with accepted international standards (ie, policies and procedures) for RECs. Out of a maximum achievable score of 200, RECs achieved a mean aggregate score of 137.4 ± 35.8 , approximately 70% of the maximum score. While it is difficult to assign a qualitative weight to such a result (such as 'excellent', 'good', 'fair' or 'poor'), the results indicate that RECs have considerable room for improvement.

Our study also identified areas where RECs are performing well and those that should be targeted for quality improvement. For example, RECs are performing well as regards submission processes, recording of minutes, and using recommended criteria for the ethical review of protocols and informed consent documents. In contrast, aspects needing improvement include: policies and procedures of the REC, membership composition and training, policies and procedures for protocol review, elements of a decision letter, and criteria for continuing review.

Regulatory compliance—the extent to which RECs are in compliance with structures and processes—can have a significant impact on the quality of the ethics review process.²¹ For example, adherence to protocol review procedures, management of conflicts of interest, and input from members with adequate training in research ethics can help promote the consistent application of ethical principles. The availability of human and financial resources can also enhance the effectiveness of REC review, as such resources can ensure that RECs have sufficient expertise and diversity, staff support and training. Unsurprisingly, our results showed that mean scores were associated with having an annual budget. However, the mean scores were not associated with other characteristics that can influence the effectiveness of RECs, for example, balanced gender member representation and the presence of national guidelines.

Regarding the former, our results showed that only 50% of the RECs had a balanced gender member representation. Several studies have demonstrated inadequate gender representation in some European and LMIC RECs.^{5 6 22} Commentators have suggested that adequate representation of women on committees that evaluate research proposals may encourage equitable representation of men and women in research.²² The European Union directives of 2001 and 2004 do not contain provisions for gender representation on RECs nor do the national regulations of EU member states.^{22 23} Several of the international guidelines, however, recommend adequate gender representation.^{24 25} In the USA, the Code of Federal Regulations governing institutional review board (IRB) membership requires gender representation such that 'no IRB consists entirely of men or entirely of women'.²⁶ The South African national research ethics guideline for RECs requires representation of both genders, with neither exceeding 70%.²⁷ The Indian guidelines also recommend that there should be adequate representation of gender.²⁸

That balanced gender member representation and the presence of national guidelines were not associated with the mean scores could be due to the insensitivity of our small sample size

or because these characteristics influence REC effectiveness but not whether RECs are in compliance with their recommended standards, which the REC self-assessment tool, as well as auditing and accreditation programmes, measures.²¹ While quality ethics reviews must achieve regulatory compliance, there is no empirical evidence that procedural compliance guarantees that the rights and welfare of research participants are being protected.²⁹ Indeed, a process-oriented examination of REC effectiveness ensures neither quality ethics review (eg, documentation that an REC has considered risks and benefits does not guarantee that it has done a credible job of weighing these factors) nor investigator integrity (eg, whether RECs' guidance to researchers is actually being followed).^{21 29} Commentators have emphasised that compliance with guidelines and the performance of research ethics review, while necessary, are insufficient to protect human subjects involved in research.^{30 31}

To investigate the larger question of how research is actually being conducted, one must consider a systems approach to protecting human research participants^{30–32} and examine whether the organisational culture in which research is undertaken affects ethical conduct, and whether or not it is supported or valued. The institution can promote an ethical culture through (a) its embrace of a set of appropriate values and (b) the adoption of organisational structures and processes that ensure that such values are incorporated into the decisions and behaviours of the members of the organisation.³³ This theory of organisation ethics presupposes that individual ethical behaviour is highly influenced by a systems theory of causation. With systems thinking, the focus is not on individuals as objects of improvement (which is the focus of traditional training programmes) but rather on examining inter-relationships, communications, structures and ongoing processes of the organisation that promote, support and value ethical conduct.^{33 34}

Developing an ethical culture that facilitates and improves the ethical conduct of research within the organisation requires the unequivocal support and commitment of the organisation's leaders.³² Conditions that sustain the establishment of an ethical culture include^{31–33}:

- ▶ transparency (eg, conflict of interest policies, appointment policies for the chair and members, and open communication and interaction with the local community, research participants, investigators and other stakeholders);
- ▶ accountability (eg, appropriate monitoring and review by instituting a quality assurance and improvement programme and establishing a procedure for participants' complaints);
- ▶ integrity (eg, REC member diversity, requirement of ethics training for investigators and REC members, and implementation of a system of rewards and penalties);
- ▶ legitimising the authority of the RECs that promotes investigator compliance with their decisions and safeguarding the independence of RECs from institutional pressures and other biases;
- ▶ availability of an adequate budget to support the required financial and human resources;
- ▶ conformance with national laws and guidance.

The ethical conduct of organisation member is central to the development of any research ethics system, and quality ethics review and investigator behaviour are crucial indications of its effectiveness.

Several of the above items were included in the self-assessment tool, for example, establishment of the REC under a high-ranking authority, the institution's regular evaluation of the REC, the availability of a budget, the presence of conflict of interest policies, and the requirement of investigator training in

research ethics. However, the domain of institutional commitment received the lowest points from the participating RECs.

Our survey also revealed that less than 50% of the RECs required their members to have training and less than 50% conducted continuing education. Studies have demonstrated inadequate training of REC members in Iran, South Africa and Egypt.^{2 3 5 35} Inadequate training of REC members compromises the quality, efficiency and consistency of ethical reviews. Failure to provide adequate training can be due to (a) lack of capacity to teach research ethics in many LMICs; (b) absence of regulations mandating such training as a requirement; and (c) lack of organisational support.

A self-assessment tool can provide helpful information to RECs in several ways. First, it can serve as a quality improvement mechanism by identifying which standards need improvement. Second, RECs can use the mean scores obtained in this study as a benchmark for how well they are operating compared to other RECs in the developing world. Accordingly, chairs can use such data to lobby for more support in deficient areas.

There were several potential limitations to our study. First, there might have been a lack of objectivity and accuracy in completing the self-assessment tool. However, such a limitation is inherent in any attempt at obtaining data for quality improvement. Second, our sample size might have been biased, as RECs that were willing to participate in the study and complete the self-assessment tool might have represented a skewed sample of RECs. For example, it is possible that poorly functioning RECs failed to respond to our enquiries due to concerns with confidentiality, even though completion of the survey was anonymous. Additionally, RECs might have declined to participate because of a perception that the survey tool represented a 'western standard', although the tool was mainly developed by individuals from the Middle East. These potential sources of sample bias could affect the generalisability of our data and therefore, our mean scores would not represent benchmarking data. Finally, several items used to denote the characteristics of RECs (eg, budget and balanced gender representation) and accordingly, possibly association with the mean scores, were items on the assessment tool itself and hence there might have been a coupling effect, as these items also affected the total score. However, these items contributed only five points each to the total score and hence, the existence of a coupling effect was minimal at most.

Nonetheless, our results show that a self-assessment process can provide quantitative data on how well RECs are complying with recognised standards. The exercise of completing the assessment tool itself has the potential to call attention to the standards that need to be met by RECs. Also, the process of self-assessment can raise awareness of strengths and challenges at the individual REC level. Repeating the survey in a few years might show interesting trends in terms of improvement plans implemented since the original survey. Finally, results obtained from this survey might provide an impetus for top institutional and government officials to discuss possible changes that can enhance their RECs. A final caveat, however, is that results from such a tool, as well as those from auditing and accreditation mechanisms, do not necessarily reflect the ethical quality of the examined research ethics review system.

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