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Title

Strengthening ethics committees for health-related research in sub-Saharan Africa: a scoping review protocol

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ABSTRACT

Introduction

Health research in low- and middle-income countries, who face the greatest burden of disease, is a vital component of efforts to combat global health inequality. With increased research, there has also been concern about ethical and regulatory issues and the state of research ethics committees, with various attempts to strengthen them. This scoping review examines the literature on ethics committees for health-related research in sub-Saharan Africa, with a focus on regulatory governance and leadership, administrative and financial capacity, and conduct of ethical reviews.

Methods and analysis

We will use the methodological approach proposed by Arksey and O'Malley and adapted by Levac et al and the Joanna Briggs Institute. Inclusion and exclusion criteria are based on the 'Population–Concept–Context' framework. Literature (from Jan 2000 to Oct 2020) will be searched in multiple databases including EMBASE and PubMed and websites of relevant organisations. All records will be screened by applying the PRISMA extension for Scoping Review flowchart: two reviewers will independently screen titles and abstracts, and full text of included records. Using an inductive approach, we will synthesise the literature, identify best practice and gaps in evidence on strengthening research ethics committees.

Ethics and dissemination

Ethical approval is not required as the review will include only published literature. The findings will be published in a peer-reviewed journal and presented at stakeholder meetings and conferences.

ARTICLE SUMMARY

Strengths and limitations of this study

- The review focuses on ethics committees for health-related research in sub-Saharan Africa, which is largely under-studied.
- A comprehensive search strategy will be followed to identify peer-reviewed papers and grey literature.
- The review will be limited to literature published between 2000-Oct 2020 and in English, French, Portuguese, or Swahili.
- There is a possibility that we will find insufficient literature to address all the objectives of the review.

Keywords

Ethics committees, leadership, Africa, review, organization & administration

INTRODUCTION

Health research in low- and middle-income countries (LMICs), who face the greatest burden of disease, is a vital component of efforts to combat global health inequality [1]. The benefit of increased research is accompanied by major challenges for research governance [2,3]. International collaboration and external funding can skew priorities; external investigators may lack knowledge of the local context and local researchers may have had limited exposure to research methodology and ethics training [4]. Gross ethical misconduct has occurred in sub-Saharan Africa (SSA), such as the lack of obtaining informed consent of meningitis vaccine participants or the provision of placebos to HIV-infected pregnant women despite evidence of the impact of antiretroviral therapy (ART) on mother-to-child transmission [5,6]. Many less blatant challenges to ethical research exist, resulting from the fact that participants are more likely to be vulnerable and questions have been raised around the nature of 'informed consent' among such participants [7]. New and complex challenges are emerging, as seen when urgent measures such as during Ebola outbreak are implemented or resulting from research involving genetic and genomic analyses [8,9].

A key component of health research governance involving human participants includes ethical review by a Research Ethics Committee (REC) which in different settings may also be called an Institutional Review Board (IRB) or an Ethics Review Committee. Research Ethics Committees set out to protect human participants by conducting ethical reviews of health-related research. They monitor approved studies and review adverse events. The Declaration of Helsinki [10], highlights the need for ethical review by an independent and appropriately constituted REC. The committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence, and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards. The committee must have the right to monitor ongoing studies including information about any serious adverse events. At the end of the study, a final report should be submitted to the committee including the study's findings and conclusions.

While ethical and regulatory bodies in LMICs and SSA are best placed to understand their local context and advise on challenges to informed consent, vulnerable

populations, cultural beliefs and the way care is delivered, their capacity to do so may be limited by a range of factors. These include a lack of infrastructure (e.g. IT resources, meeting and storage space, transport to trial sites); limited financial and administrative support; a small pool of expert reviewers and regulators; lack of theoretical training in ethics and regulatory affairs; and a lack of comprehensive governance structures [11].

There has been ongoing concern about ethical and regulatory issues and the state of research ethics committees in SSA, with various attempts to strengthen them. In 2007, a mapping of ethical review committee activity in western and central Africa reported little available information on existing committee structures[12]. Subsequent workshops followed that led to the creation of national structures in many countries. As health research initiatives in SSA grew in scope and complexity, increased research activity resulted in the need for sound ethical review structures and functions in the form of Research Ethics Committees (RECs).

The Mapping African Research Ethics Capacity (MARC) project started in 2009; it has created an online interactive wiki-type platform and tools on the Council on Health Research for Development's (COHRED) Health Research website. The platform was to understand the capacity of the research institutions that were part of the network, to help to facilitate the flow of information between the centres and provide a public space where researchers could provide each other with technical and strategic support for health research. Tools were designed for strengthening ethical review and regulation of health research in Africa and supported the establishment of COHRED [13]. There was a need to identify existing capacity and funding and demonstrate the areas where this needed to be developed. In 2012 there was seen to be lagging in requirements; often because of poor resource availability and lack of capacity[13]. MARC went on to develop an interactive map of health research ethics review capacity and drug regulatory capacity in Africa [14]. Since then, studies focussing on different aspects of national research systems of different countries have identified weaknesses and in some counties, have recommended extensive work to strengthen the ethical and regulatory systems [9]. A 2015 systematic review, focusing on the structure, functioning and outcomes of biomedical RECs in SSA, found several factors that hinder the work of RECs

including lack of membership diversity, scarcity of resources, insufficient training of members, inadequate capacity to review and monitor studies, and lack of national ethics guidelines and accreditation [15]. Further, studies have conducted assessments of needs in different countries [16], sometimes as part of developmental programmes [17,18] while other studies have conducted only partial evaluations looking at certain aspects of research development [19]. The overall evidence on health-related RECs in SSA is growing but is largely fragmented. This review will provide a more comprehensive understanding of the health-related RECs in SSA.

A scoping review is considered to be the most suitable approach to establish the current situation, rather than a systematic review and meta-analysis [20]. A scoping review provides an overview of a broad field [21], in this case how ethics committees for health-related research operate and ways of developing them in countries in SSA, to support the wider health systems strengthening agenda, especially in the post-shock/crisis phase, wherein it is anticipated that there will be a high flux of research projects, seeking ethical approval. The evidence about research ethics committees is likely to be from disparate or heterogeneous sources which a scoping review can bring together. Scoping reviews provide a map of the existing literature, here about the capacity of ethics committees for health-related research in sub-Saharan Africa. These reviews do not normally assess the quality of evidence as the main purpose is to identify and map the evidence itself. While scoping reviews may inform future systematic reviews, they are also useful for policy-makers and practitioners [22].

The objectives of the review were formulated from the issues outlined above and the preliminary literature search. They are to identify and analyse literature on leadership and governance, strategies to develop the technical ability of ethical committees, and the administrative and financial capacity of health-related research ethics committees in sub-Saharan Africa.

METHODS AND ANALYSIS

A preliminary search for existing scoping reviews on the topic was conducted using PubMed and Global Health databases to check that a similar review had not been undertaken. A scoping review of empirical research relating to quality and

effectiveness of research ethics review published in 2015 sought to find research assessing ethics review processes but reported no work related to Africa [23]. At a similar time, Silaigwana and Wassenar [15] conducted a collective review of empirical studies examining the structure, functioning, and review outcomes of African research ethics committees. We will build on their work by examining wider issues related to research ethics committees. The protocol is registered with OSF and is funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) grant number RE16586.

This scoping review will use the six-stage methodological framework proposed by Arksey and O'Malley 2005 [20], as well as the amendments made to this framework by Levac et al 2010 [24] and by the Joanna Briggs Institute [25]. We used the PRISMA Extension for Scoping Reviews (PRISMA-ScR) to draft this protocol [26] to ensure key aspects were included.

1. Identifying the research question

Arksey and O'Malley [20] suggest a scoping review framework is not dependent on set words or study types; rather it is an iterative process, developing one or more questions to be addressed. Scoping searches were carried out at the start of the project to give an overview of the extent and types of studies on strengthening ethics committees for health-related research in sub-Saharan Africa. These indicated there was an abundance of material related to ethics, review boards and institutional reviews in sub-Saharan Africa on which we will draw.

Based on the preliminary search, we identified the following research questions for the scoping review: How can ethics committees for health-related research in sub-Saharan Africa be further strengthened?

We will examine the literature on three aspects of RECs

- Leadership and governance,
- Administrative and financial capacity
- Strategies to develop the technical ability of ethical reviewers and regulators

2. Identifying Relevant Studies

The electronic literature search strategy will follow the three-step process, identification, screening and eligibility as in PRISMA and recommended by the Joanna Briggs Institute [25]. Based on the first step, the preliminary search, a comprehensive search strategy was developed to identify relevant literature, underpinned by key inclusion and exclusion criteria (see Table 1). These are based on 'Population–Concept–Context (PCC).

Table 1. Inclusion and exclusion criteria

	Inclusion	Exclusion
P—Population	RECs for health-related research in sub-Saharan African countries	RECs not focusing on health-related research and RECs outside SSA. Papers and material focussing on the ethics of individual research studies, including consent for specific empirical studies
C—Concept	Studies exploring the leadership and governance structures of RECs, administrative and financial capacity and technical capacity of REC members to conduct the review.	Studies not focusing on the structure and capacity of RECs but focusing on the implementation of ethical practices in research such as informed consent and data storage as well as papers focussing on the ethics of individual research studies
C—Context	Studies focusing only on SSA	Studies outside SSA
Type of publication	Publications using empirical data such as peer-reviewed journals. reports, discussion, theory papers, editorials and commentaries.	Publications not using empirical data such as opinion pieces.
Language	Publications written in English, French, Portuguese or Swahili	Studies available in a language other than English, French, Portuguese or Swahili

Time Period	Published after 2000 until end of October 2020	Pre-2000

In the second step, after reviewing the titles and abstracts of pertinent papers, we identified the following search string which will be adapted for different databases: (Ethics committees OR ethics guidance OR ethics review committees OR ethics regulation OR research regulation OR institutional review boards) AND (capacity development OR capacity OR governance OR leadership) AND (health OR medical) AND (SSA OR <individual countries in SSA>) AND Language (English OR French OR Portuguese OR Swahili) AND Publication date (2000 to Oct 2020)

The following databases will be searched: BioOne, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase (via Ovid), Education Abstracts, Global Health, Google Scholar, Jstor, OpenEdition (French), Philosopher's Index, PsycINFO, PubMed, Science Citation and Expanded Index (Web of Science). In the third and final stage, reference lists of included studies will be hand-searched.

For grey literature, we will search websites of organisations which display a strong interest in National Ethical and Review Boards in sub-Saharan African countries such as Commission on Health Research for Development https://www.cohred.org/, WHO Regional Office for Africa https://aho.afro.who.int/, Pan African Bioethics Initiative (PANBIN) http://www.who.int/sidcer/fora/pabin/en/ and Mapping Africa Research Capacity https://ahrecs.com/resources/mapping-africa-research-ethics-capacity-marc/. Besides these websites, we will also search Google Scholar using terms such as 'ethics', 'ethics committees', 'Institutional review board' and 'Africa'.

As scoping reviews use an interactive process, our research objectives might be refined, or new questions added, as familiarity with the literature is developed and different issues become important.

3. Study Selection

Records identified in stage two will be exported to Excel. After removing duplicates, title and abstracts will be reviewed based on the inclusion and exclusion criteria. An iterative approach to selecting studies and extracting data will be undertaken [24] by two reviewers independently. The second part of the process will involve retrieving

the full text of all potentially eligible material. Articles selected for full-text review in which the full text is unavailable will be documented. All records will be assessed based on our inclusion and exclusion criteria. Disagreements between the two reviewers will be discussed with a third reviewer. Following best practice, a flowchart detailing the stages of the search will be documented, adapted from the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) format.

4. Charting the Data

A draft charting form (see table 2) has been developed for the collection and sorting of key pieces of information from the selected articles to facilitate the synthesis and interpretation of qualitative data by sifting, charting and sorting material according to key issues and themes [20]. The form and process will be tested in the early stages of searching and it will be refined during the full-text screening to capture detailed information on each study. Additional categories that may emerge during data extraction will be added.

Table 2. Draft data charting form

Author and year of publication
Type of publication
Study country
Title
Aims/purpose of the study
Study design
Methods and data
Findings on Leadership and governance of REC,
Findings on Strategies to develop the technical ability of REC members
Findings on Administrative and financial capacity of REC
Funding source

5. Collating, summarizing, and reporting the results

Key characteristics extracted from included publications will be used to produce an annotated summary of the literature. We will conduct the scoping review following the PRISMA-ScR Checklist [26]. This descriptive summary will outline the nature of the current literature relevant to the strengthening of ethics committees for health-related research in sub-Saharan Africa. Where possible, it will identify gaps and synthesis

evidence related to leadership and governance, technical capacity of reviewers and regulators, and the administrative and financial capacity of RECs.

6. Consultation Exercise

The final stage refers to consultation with stakeholders. This has also been shown to be a knowledge translation activity and an important step in scoping reviews [26]. The project is part of an EDCTP funded project, and throughout the process of this review, we will use a participatory approach, involve key stakeholders from SSA, namely in Sierra Leone. This will ensure that individual and institutional expertise is maximised to ensure material from the literature are context-specific and application can be sustainable in the long term.

CONCLUSIONS AND DISSEMINATION

We have described a protocol for a scoping review to examine and map evidence on ethics committees for health-related research in sub-Saharan Africa Findings will be disseminated and used to inform the consequent development of the ethics review system in Sub Saharan Africa.

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