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

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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 inequality¹. 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 training⁴. 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 participants⁷. 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 Helsinki¹⁰, 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

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3 populations, cultural beliefs and the way care is delivered, their capacity to do so
4 may be limited by a range of factors. These include a lack of infrastructure (e.g. IT
5 resources, meeting and storage space, transport to trial sites); limited financial and
6 administrative support; a small pool of expert reviewers and regulators; lack of
7 theoretical training in ethics and regulatory affairs; and a lack of comprehensive
8 governance structures ¹¹.
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14 There has been ongoing concern about ethical and regulatory issues and the state of
15 research ethics committees in SSA, with various attempts to strengthen them. In
16 2007, a mapping of ethical review committee activity in western and central Africa
17 reported little available information on existing committee structures¹². Subsequent
18 workshops followed that led to the creation of national structures in many countries.
19 As health research initiatives in SSA grew in scope and complexity, increased
20 research activity resulted in the need for sound ethical review structures and
21 functions in the form of Research Ethics Committees (RECs).
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29 The Mapping African Research Ethics Capacity (MARC) project started in 2009; it
30 has created an online interactive wiki-type platform and tools on the Council on
31 Health Research for Development's (COHRED) Health Research website. The
32 platform was to understand the capacity of the research institutions that were part of
33 the network, to help to facilitate the flow of information between the centres and
34 provide a public space where researchers could provide each other with technical
35 and strategic support for health research. Tools were designed for strengthening
36 ethical review and regulation of health research in Africa and supported the
37 establishment of COHRED ¹³. There was a need to identify existing capacity and
38 funding and demonstrate the areas where this needed to be developed. In 2012
39 there was seen to be lagging in requirements; often because of poor resource
40 availability and lack of capacity¹³. MARC went on to develop an interactive map of
41 health research ethics review capacity and drug regulatory capacity in Africa ¹⁴.
42 Since then, studies focussing on different aspects of national research systems of
43 different countries have identified weaknesses and in some counties, have
44 recommended extensive work to strengthen the ethical and regulatory systems ⁹. A
45 2015 systematic review, focusing on the structure, functioning and outcomes of
46 biomedical RECs in SSA, found several factors that hinder the work of RECs
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3 including lack of membership diversity, scarcity of resources, insufficient training of
4 members, inadequate capacity to review and monitor studies, and lack of national
5 ethics guidelines and accreditation ¹⁵. Further, studies have conducted assessments
6 of needs in different countries ¹⁶, sometimes as part of developmental programmes
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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

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3 effectiveness of research ethics review published in 2015 sought to find research
4 assessing ethics review processes but reported no work related to Africa ²³. At a
5 similar time, Silaigwana and Wassenaar ¹⁵ conducted a collective review of empirical
6 studies examining the structure, functioning, and review outcomes of African
7 research ethics committees. We will build on their work by examining wider issues
8 related to research ethics committees. The protocol is registered with OSF and is
9 funded by the European and Developing Countries Clinical Trials Partnership
10 (EDCTP) grant number RE16586.
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14 This scoping review will use the six-stage methodological framework proposed by
15 Arksey and O'Malley 2005 ²⁰, as well as the amendments made to this framework by
16 Levac et al 2010 ²⁴ and by the Joanna Briggs Institute ²⁵. We used the PRISMA
17 Extension for Scoping Reviews (PRISMA-ScR) to draft this protocol ²⁶ to ensure key
18 aspects were included.
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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 |

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| Time Period | Published after 2000 until end of October 2020 | Pre-2000 |
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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 undertaken²⁴ 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

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| 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 reviews²⁶. 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.

REFERENCES

1. Commission on Health Research for Development. *Health Research: Essential Link to Equity in Development*. Oxford University Press; 1990.
http://www.cohred.org/downloads/open_archive/ComReports_0.pdf
2. Hyder A, Dawson L, Bachani A, Lavery J. Moving from research ethics review to research ethics systems in low-income and middle-income countries. *Lancet*. 2009;373(9666):862-865.
3. Alemayehu C, Mitchell G, Nikles J. Barriers for conducting clinical trials in developing countries- a systematic review. *Int J Equity Health*. 2018;17:37.
4. Ward C, Shaw D, Sprumont D, Sankoh O, Tanner M, Elger B. Good collaborative practice: reforming capacity building governance of international health research partnerships. *Glob Health*. 2018;8(14):1.
5. Ezeome E, Simon C. Ethical problems in conducting research in acute epidemics: the Pfizer meningitis study as an illustration. *Dev World Bioeth*. 2010;10(1):1-10.
6. de Zulueta P. Randomised placebo-controlled trials and HIV-infected pregnant women in developing countries. Ethical imperialism or unethical exploitation? *Bioethics*. 2001;15(4):289-311.
7. Mbuagbaw L, Thabane L, Ongolo-Zogo P, Lang T. The challenges and opportunities of conducting a clinical trial in a low resource setting: the case of the Cameroon mobile phone SMS (CAMPS) trial, an investigator initiated trial. *Trials*. 2011;9(12):45.

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8. Raina C, MacIntyre & Joanne F. Travaglia. Heightened Vulnerability, Reduced Oversight, and Ethical Breaches on the Internet in the West African Ebola Epidemic. *The American Journal of Bioethics*, 2015;15(4): 65-68.
 9. Barchi F, Little TM. National ethics guidance in Sub-Saharan Africa on the collection and use of human biological specimens: a systematic review. *BMC Med Ethics*. 2016;17(1):64.
 10. World Medical Association. Declaration of Helsinki - Ethical principles for medical research involving human subjects. Published online 2013. <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
 11. Nyika A, Kilama W, Chilengi R, et al. Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges? *J Med Ethics*. 2008;35(3):189-193.
 12. Effa P, Massougbdgi A, Ntoumi F, et al. Ethics committees in western and central Africa: concrete foundations. *Dev World Bioeth*. 2007;3:136-142.
 13. IJsselmuiden, Marais D, Wassenaar D, Mokgatla-Moipolai B. Mapping African ethical review committee activity onto capacity needs: the MARC initiative and HRWeb's interactive database of RECs in Africa. *Dev World Bioeth*. 2012;12(2):74-86.
 14. Mapping African Research Ethics Capacity. Research Ethics Web. Accessed August 14, 2020. <http://www.researchethicsweb.org/>
 15. Silaigwana B, Wassenaar D. Biomedical Research Ethics Committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes. *J Empir Res Hum Res Ethics*. 10(2):169-184.
 16. Ateudjieu J, Williams J, Hirtle M, Baume C, Ikingura J, Spumont D. Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali and Tanzania. *Dev World Bioeth*. 2010;10(2):88-98.
 17. Ndebele P, Wassenaar D, Benatar S, et al. Research ethics capacity building in Sub-Saharan Africa: a review of NIH Fogarty-funded programs 2000–2012. *J Empir Res Hum Res Ethics*. 2014;9(2):24.
 18. Aidam J, Sombié I. The West African Health Organization's experience in improving the health research environment in the ECOWAS region. *Health Res Policy Syst*. 2016;20(14):30.
 19. Ali J, Hyder AA, Kass N. Research ethics capacity development in Africa: Exploring a model for individual success. *Dev World Bioeth*. 2012;12(2):55-62. doi:10.1111/j.1471-8847.2012.00331.x
 20. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol*. 2005;(8):19-31.
 21. Moher D, Stewart L, Shekelle P. All in the family: systematic reviews, rapid reviews, scoping reviews, realist reviews, and more. *Syst Rev*. 2015;4:183.
 22. Armstrong R, Hall B, Doyle J, Waters E. 'Scoping the scope' of a Cochrane review. *J Public Health*. 2011;33(1):147-150.
 23. Nicholls SG, Hayes TP, Brehaut JC, et al. Scoping Review of Empirical Research Relating to Quality and Effectiveness of Research Ethics Review. *PLoS One*. 2015;10(17).
 24. Levac D, Colquhoun H, O'Brien K. Scoping studies: advancing the methodology. *Implement Sci* 2010;5:69. *Implement Sci*. 2010;10(5):69.
 25. Joanna Briggs Institute. In: *JBIR Reviewers' Manual. Scoping Reviews*. JBI; 2020.

- 1
2
3 26. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR):
4 checklist and explanation. *Annals of internal medicine*, 169(7), pp.467-473. *Ann Intern Med*.
5 2018;169(7):467-473.
6
7 27. Peters MD, Godfrey CM, McInerney P, Baldini Soares C, Khalil H, Parker D. *The Joanna Briggs*
8 *Institute Reviewers' Manual 2015: Methodology for JBI Scoping Reviews.*; 2015.
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16 to the development of this protocol. AL conceived the idea for the project. AL, DP,
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18 led the writing of the manuscript. All authors provided detailed comments on earlier
19 drafts and approved the final protocol.
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29

30
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34

35
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37

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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, which 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 understudied.
- 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-Dec 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), which face the greatest burden of disease, is a vital component of efforts to combat global health inequity 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 not obtaining informed consent from meningitis vaccine participants or giving placebos to HIV-infected pregnant women despite evidence of the beneficial effect of antiretroviral therapy on mother-to-child transmission ^{5,6}. Many less blatant challenges to ethical research exist. These can be because participants in SSA are more likely to be vulnerable and questions have been raised on the nature of 'informed consent' for such participants ⁷. Further, new and complex challenges are also emerging. These are observed when urgent measures such as during the Ebola outbreak were implemented or resulting from research involving genetic and genomic analyses, and the use of artificial intelligence in healthcare ^{8,9,10}.

A key component of health research governance involving human participants includes ethical review by a Research Ethics Committee (REC). RECs may also be called an Institutional Review Board (IRB) or an Ethics Review Committee. RECs set out to protect human participants by conducting ethical reviews of health-related research. The Declaration of Helsinki ¹¹, 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

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3 populations, cultural beliefs and the way care is delivered, their capacity to do so
4 may be limited by a range of factors. These include a lack of infrastructure (e.g. IT
5 resources, meeting and storage space, transport to trial sites); limited financial and
6 administrative support; a small pool of REC members and regulators; lack of
7 theoretical training in ethics and regulatory affairs; and a lack of comprehensive
8 governance structures ¹².
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14 There has been ongoing concern about ethical and regulatory issues and the state of
15 RECs in SSA, with various attempts to strengthen them. In 2007, a mapping of
16 ethical review committee activity in western and central Africa reported little available
17 information on existing committee structures¹³. Subsequent workshops followed that
18 led to the creation of national structures in many countries. As health research
19 initiatives in SSA grew in scope and complexity, increased research activity resulted
20 in the need for sound ethical review structures and functions in the form of REC. A
21 large-scale survey of research ethics policies and practices in SSA concluded that
22 there are extensive gaps in the capacity of health research institutions in Africa to
23 undertake ethical reviews of studies.¹⁴The Mapping African Research Ethics
24 Capacity (MARC) project started in 2009. It has created an interactive wiki-type
25 platform and tools, which can be found on the Council on Health Research for
26 Development's (COHRED) Health Research website¹⁵. The platform was to
27 understand the capacity of the research institutions that were part of the network, to
28 help to facilitate the flow of information between the centres and provide a public
29 space where researchers could provide each other with technical and strategic
30 support for health research. Tools were designed for strengthening ethical review
31 and regulation of health research in Africa ^{16,17} There was a need to identify existing
32 capacity and funding and demonstrate the areas where this needed to be developed.
33 In 2012 this was seen to be lagging in requirements; often because of poor resource
34 availability and lack of capacity¹⁶. MARC went on to develop an interactive map of
35 health research ethics review capacity and drug regulatory capacity in Africa ¹⁵.
36 Since then, studies focussing on different aspects of national research systems of
37 different countries have identified weaknesses and in some counties, have
38 recommended extensive work to strengthen the ethical and regulatory systems
39 ^{10,18,19}. A 2015 systematic review, focusing on the structure, functioning and
40 outcomes of biomedical RECs in SSA, found several factors that hinder the work of
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3 RECs including lack of membership diversity, scarcity of resources, insufficient
4 training of members, inadequate capacity to review and monitor studies, and lack of
5 national ethics guidelines and accreditation ²⁰. Further, studies have conducted
6 assessments of needs in different countries ²¹, sometimes as part of developmental
7 programmes ^{22,23} while other studies have conducted only partial evaluations looking
8 at certain aspects of research development ²⁴. The overall evidence on health-
9 related RECs in SSA is growing but is largely fragmented. This review will provide a
10 more comprehensive understanding of the health-related RECs in SSA.
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18 A scoping review is considered to be the most suitable approach to establish the
19 current situation, rather than a systematic review and meta-analysis ²⁵. A scoping
20 review provides an overview of a broad field ²⁶. This review will identify and examine
21 current literature to understand how ethics committees for health-related research
22 operate and ways of developing them in SSA. . The evidence about RECs is likely to
23 be from disparate or heterogeneous sources which a scoping review can bring
24 together. Scoping reviews provide a map of the existing literature. These reviews do
25 not normally assess the quality of evidence as the main purpose is to identify and
26 map the evidence itself. While scoping reviews may inform future systematic
27 reviews, they are also useful for policy-makers and practitioners ²⁷.
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36 The objectives of the review were formulated from the issues outlined above and the
37 preliminary literature search. They are to identify and analyse literature on leadership
38 and governance, strategies to develop the technical ability of ethical committees, and
39 the administrative and financial capacity of health-related RECs in SSA.
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44 **METHODS AND ANALYSIS**

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47 A preliminary search for existing scoping reviews on the topic was conducted using
48 PubMed and Global Health databases to check that a similar review had not been
49 undertaken. A scoping review of empirical research relating to quality and
50 effectiveness of research ethics review published in 2015 sought to find research
51 assessing ethics review processes but reported no work related to Africa ²⁸. At a
52 similar time, Silaigwana and Wassenaar ²⁰ conducted a collective review of empirical
53 studies examining the structure, functioning, and review outcomes of African RECs.
54 We will build on their work by examining wider issues related to RECs. The protocol
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8 This scoping review will use the six-stage methodological framework proposed by
9 Arksey and O'Malley 2005²⁵, as well as the amendments made to this framework by
10 Levac et al 2010²⁹ and by the Joanna Briggs Institute³⁰. We used the PRISMA
11 Extension for Scoping Reviews (PRISMA-ScR) to draft this protocol³¹ to ensure key
12 aspects were included.
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16 17 *1. Identifying the research question* 18

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20 Arksey and O'Malley²⁵ suggest a scoping review framework is not dependent on set
21 words or study types; rather it is an iterative process, developing one or more
22 questions to be addressed. Scoping searches were carried out at the start of the
23 project to give an overview of the extent and types of studies on strengthening ethics
24 committees for health-related research in SSA. These indicated there was an
25 abundance of material related to ethics, review boards and institutional reviews in
26 SSA on which we will draw.
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33 Based on the preliminary search, we identified the following research questions for
34 the scoping review: How can ethics committees for health-related research in SSA
35 be further strengthened?
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39 We will examine the literature on three aspects of RECs
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- 41 • Leadership and governance,
 - 42 • Administrative and financial capacity
 - 43 • Strategies to develop the technical ability of ethical reviewers and regulators
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50 51 *2. Identifying Relevant Studies* 52

53 The electronic literature search strategy will follow the three-step process,
54 identification, screening and eligibility as in PRISMA-ScR and recommended by the
55 Joanna Briggs Institute³⁰. Based on the first step, the preliminary search, a
56 comprehensive search strategy was developed to identify relevant literature,
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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 (SSA) 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 on SSA, including studies examining international collaborations with SSA countries. Studies across multiple countries including SSA countries if the findings were relevant for SSA. | Studies outside SSA |
| Type of publication | Publications using empirical data such as peer-reviewed journals, reports, discussion, theory papers, case studies, 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 the end of December 2020 | Pre-2000 |

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3 In the second step, after reviewing the titles and abstracts of pertinent papers, we
4 identified the following search string which will be adapted for different databases:
5 (Ethics committees OR ethics guidance OR ethics review committees OR ethics
6 regulation OR research regulation OR institutional review boards) AND (capacity
7 development OR capacity OR governance OR leadership) AND (health OR medical)
8 AND (SSA OR <individual countries in SSA>) AND Language (English OR French
9 OR Portuguese OR Swahili) AND Publication date (2000 to December 2020).
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16 The following databases will be searched: BioOne, Cumulative Index to Nursing and
17 Allied Health Literature (CINAHL), Embase (via Ovid), Education Abstracts, Global
18 Health, Google Scholar, Jstor, OpenEdition (French), Philosopher's Index,
19 PsycINFO, PubMed, Science Citation and Expanded Index (Web of Science). In the
20 third and final stage, reference lists of included studies will be hand-searched.
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26 As an example, search string for PubMed: ((ethic* committee* [title/abstract]) OR
27 (ethics guidance [title/abstract]) OR (ethics review committee*[title/abstract]) OR
28 (ethics regulation [title/abstract]) OR (research regulation [title/abstract]) OR
29 (institutional review boards [title/abstract])) AND ((capacity development
30 [title/abstract]) OR (capacity [title/abstract]) OR (governance [title/abstract]) OR
31 (leadership [title/abstract])) AND (health OR medical [title/abstract]) AND (sub
32 saharan Africa [MeSH Terms]) AND ((English[Language] OR French[Language] OR
33 Portuguese[Language] OR Swahili[Language])) AND (("2000"[Date - Publication] :
34 "2020"[Date - Publication])). For grey literature, we will search websites of
35 organisations that display a strong interest in National Ethical and Review Boards in
36 SSA such as the Commission on Health Research for Development
37 <https://www.cohred.org/>, WHO Regional Office for Africa <https://www.afro.who.int/>
38 [Integrated African Health Observatory](https://www.afro.who.int/Integrated-African-Health-Observatory) <https://aho.afro.who.int/>, Pan African
39 Bioethics Initiative (PANBIN) <http://www.who.int/sidcer/fora/pabin/en/> and Mapping
40 Africa Research Capacity [https://ahrecs.com/resources/mapping-africa-research-
41 ethics-capacity-marc/](https://ahrecs.com/resources/mapping-africa-research-ethics-capacity-marc/). Besides these websites, we will also search Google Scholar
42 using terms such as 'ethics', 'ethics committees', 'Institutional review board' and
43 'Africa'.
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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 undertaken²⁹ 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) checklist.

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 themes²⁵. 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

| |
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| 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 Checklist³¹. This descriptive summary will outline the nature of the current literature relevant to the strengthening of ethics committees for health-related research in SSA. Where possible, it will identify gaps and synthesise evidence related to leadership and governance, the 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 reviews³¹. 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. We will be completing the scoping review by September 2021.

ETHICS AND DISSEMINATION

We have described a protocol for a scoping review to examine and map evidence on ethics committees for health-related research in SSA. 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.

REFERENCES

1. Commission on Health Research for Development. *Health Research: Essential Link to Equity in Development*. Oxford University Press; 1990.
http://www.cohred.org/downloads/open_archive/ComReports_0.pdf
2. Hyder A, Dawson L, Bachani A, Lavery J. Moving from research ethics review to research ethics systems in low-income and middle-income countries. *Lancet*. 2009;373(9666):862-865.

- 1
- 2
- 3 3. Alemayehu C, Mitchell G, Nikles J. Barriers for conducting clinical trials in developing countries-
4 a systematic review. *Int J Equity Health*. 2018;17:37.
- 5
- 6 4. Ward C, Shaw D, Sprumont D, Sankoh O, Tanner M, Elger B. Good collaborative practice:
7 reforming capacity building governance of international health research partnerships. *Glob*
8 *Health*. 2018;8(14):1.
- 9
- 10 5. Ezeome E, Simon C. Ethical problems in conducting research in acute epidemics: the Pfizer
11 meningitis study as an illustration. *Dev World Bioeth*. 2010;10(1):1-10.
- 12
- 13 6. de Zulueta P. Randomised placebo-controlled trials and HIV-infected pregnant women in
14 developing countries. Ethical imperialism or unethical exploitation? *Bioethics*. 2001;15(4):289-
15 311.
- 16
- 17 7. Mbuagbaw L, Thabane L, Ongolo-Zogo P, Lang T. The challenges and opportunities of
18 conducting a clinical trial in a low resource setting: the case of the Cameroon mobile phone
19 SMS (CAMPS) trial, an investigator initiated trial. *Trials*. 2011;9(12):45.
- 20
- 21 8. Wahl B, Cossy-Gantner A, Germann S, Schwalbe N. Artificial intelligence (AI) and global health:
22 how can AI contribute to health in resource-poor settings? Published online 2018.
- 23
- 24 9. Hansson M, Dillner J, Bartram C, Carlson J, Helgesson G. Should donors be allowed to give
25 broad consent to future biobank research? *Lancet Oncol*. 2006;7(3):266-269.
- 26
- 27 10. Barchi F, Little TM. National ethics guidance in Sub-Saharan Africa on the collection and use of
28 human biological specimens: a systematic review. *BMC Med Ethics*. 2016;17(1):64.
- 29
- 30 11. World Medical Association. Declaration of Helsinki - Ethical principles for medical research
31 involving human subjects. Published online 2013. [https://www.wma.net/policies-post/wma-
32 declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)
- 33
- 34 12. Nyika A, Kilama W, Chilengi R, et al. Composition, training needs and independence of ethics
35 review committees across Africa: are the gate-keepers rising to the emerging challenges? *J*
36 *Med Ethics*. 2008;35(3):189-193.
- 37
- 38 13. Effa P, Massougbdji A, Ntoumi F, et al. Ethics committees in western and central Africa:
39 concrete foundations. *Dev World Bioeth*. 2007;3:136-142.
- 40
- 41 14. Zielinski C, Kebede D, Mbondji PE, Sanou I, Kouvidila W, Lusamba-Dikassa PS. 2014
42 Research ethics policies and practices in health research institutions in sub-Saharan African
43 countries: results of a questionnaire-based survey. *J R Soc Med*. 2014;107(1S):70-76.
44 doi:10.1177/0141076813517679
- 45
- 46 15. Council for Health Research for Development. Mapping of ethics review capacity in sub-
47 Saharan Africa (MARC). Published online undated. Accessed March 30, 2021.
48 <https://www.cohred.org/marc/>
- 49
- 50 16. IJsselmuiden, Marais D, Wassenaar D, Mokgatla-Moipolai B. Mapping African ethical review
51 committee activity onto capacity needs: the MARC initiative and HRWeb's interactive database
52 of RECs in Africa. *Dev World Bioeth*. 2012;12(2):74-86.
- 53
- 54 17. Mapping African Research Ethics Capacity. Research Ethics Web. Accessed August 14, 2020.
55 <http://www.researchethicsweb.org/>
- 56
- 57 18. Sombié I, Aidam J, Konaté B, Somé TD, Kambou SS. The state of the research for health
58 environment in the ministries of health of the Economic Community of the West African States
59 (ECOWAS). *Health Res Policy Syst*. 2013;11:35.
- 60

19. Silaigwana B, Wassenaar D. Biomedical Research Ethics Committees in Sub-Saharan Africa: A Collective Review of Their Structure, Functioning, and Outcomes. *J Empir Res Hum Res Ethics*. 2015;10(2):169-184.
20. Silaigwana B, Wassenaar D. Biomedical Research Ethics Committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes. *J Empir Res Hum Res Ethics*. 10(2):169-184.
21. Ateudjieu J, Williams J, Hirtle M, Baume C, Ikingura J, Spumont D. Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali and Tanzania. *Dev World Bioeth*. 2010;10(2):88-98.
22. Ndebele P, Wassenaar D, Benatar S, et al. Research ethics capacity building in Sub-Saharan Africa: a review of NIH Fogarty-funded programs 2000–2012. *J Empir Res Hum Res Ethics*. 2014;9(2):24.
23. Aidam J, Sombié I. The West African Health Organization's experience in improving the health research environment in the ECOWAS region. *Health Res Policy Syst*. 2016;20(14):30.
24. Ali J, Hyder AA, Kass N. Research ethics capacity development in Africa: Exploring a model for individual success. *Dev World Bioeth*. 2012;12(2):55-62. doi:10.1111/j.1471-8847.2012.00331.x
25. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol*. 2005;(8):19-31.
26. Moher D, Stewart L, Shekelle P. All in the family: systematic reviews, rapid reviews, scoping reviews, realist reviews, and more. *Syst Rev*. 2015;4:183.
27. Armstrong R, Hall B, Doyle J, Waters E. 'Scoping the scope' of a Cochrane review. *J Public Health*. 2011;33(1):147-150.
28. Nicholls SG, Hayes TP, Brehaut JC, et al. Scoping Review of Empirical Research Relating to Quality and Effectiveness of Research Ethics Review. *PLoS One*. 2015;10(17).
29. Levac D, Colquhoun H, O'Brien K. Scoping studies: advancing the methodology. *Implement Sci* 2010;5:69. *Implement Sci*. 2010;10(5):69.
30. Joanna Briggs Institute. In: *JBI Reviewers' Manual. Scoping Reviews*. JBI; 2020.
31. Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of internal medicine*, 169(7), pp.467-473. *Ann Intern Med*. 2018;169(7):467-473.

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2
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5
6

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8
9

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11 and/or analysed for this study.
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14 **Patient and Public Involvement:** No patient involved.
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17 **Word count:** 2465
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Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|------|--|--------------------|
| TITLE | | | |
| Title | 1 | Identify the report as a scoping review. | Page 1 |
| ABSTRACT | | | |
| Structured summary | 2 | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives. | Page 2 |
| INTRODUCTION | | | |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach. | Pages 4-6 |
| Objectives | 4 | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives. | Pages 6-7 |
| METHODS | | | |
| Protocol and registration | 5 | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number. | Page 7 |
| Eligibility criteria | 6 | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale. | Pages 8-9 |
| Information sources* | 7 | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed. | Pages 9-10 |
| Search | 8 | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated. | Pages 9-10 |
| Selection of sources of evidence† | 9 | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review. | Pages 8-10 |
| Data charting process‡ | 10 | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | Pages 10-11 |
| Data items | 11 | List and define all variables for which data were sought and any assumptions and simplifications made. | Pages 10-11 |
| Critical appraisal of individual sources of evidence§ | 12 | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate). | NA |

| SECTION | ITEM | PRISMA-ScR CHECKLIST ITEM | REPORTED ON PAGE # |
|---|------|---|--------------------|
| Synthesis of results | 13 | Describe the methods of handling and summarizing the data that were charted. | Page 11 |
| RESULTS | | | |
| Selection of sources of evidence | 14 | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram. | NA |
| Characteristics of sources of evidence | 15 | For each source of evidence, present characteristics for which data were charted and provide the citations. | NA |
| Critical appraisal within sources of evidence | 16 | If done, present data on critical appraisal of included sources of evidence (see item 12). | NA |
| Results of individual sources of evidence | 17 | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives. | NA |
| Synthesis of results | 18 | Summarize and/or present the charting results as they relate to the review questions and objectives. | NA |
| DISCUSSION | | | |
| Summary of evidence | 19 | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | NA |
| Limitations | 20 | Discuss the limitations of the scoping review process. | Page 3 |
| Conclusions | 21 | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps. | NA |
| FUNDING | | | |
| Funding | 22 | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review. | Page 14 |

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

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