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Integration of healthcare services for HIV and non-communicable diseases in sub-Saharan Africa: protocol for a scoping review of randomised controlled trials

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ABSTRACT

Introduction Stand-alone HIV clinics in sub-Saharan Africa (SSA) have effectively expanded antiretroviral therapy since the 2000s, transforming HIV from a deadly infection into a chronic condition. However, over the past decade, there has been a significant rise in the prevalence of non-communicable diseases (NCDs) globally and in SSA. People living with HIV are at higher risk for some NCDs, including hypertension, diabetes and different cancers. The region's current healthcare infrastructure is not equipped to address this growing burden. Integrating health services for HIV and NCDs (ie, combining services for HIV with services for hypertension, diabetes, depression and mental health, substance use disorder or cancer) could be one strategy for responding to these challenges. In this scoping review, we aim to identify randomised controlled trials on HIV-NCD integration, assess implemented integration models and measured outcomes and highlight evidence gaps.

Methods and analysis This scoping review will follow the Arksey and O'Malley (2005) methodological framework. Reporting will be guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist. We will conduct a systematic search of the databases OVID Medline, Embase, Web of Science, Global, Africa Index Medicus, including terms related to HIV, NCDs and healthcare integration. Included trials must have been conducted within SSA and have been published in English or French after 1 January 2010. We will not select based on sample size or number of clusters. Both the title and abstract screening and full-text screening will be done in Covidence by at least two reviewers working independently. Data extraction will focus on key variables, including study design, geographical location, integration intervention, measured outcomes and reported findings.

Ethics and dissemination This scoping review aims to generate new insights from publicly available research. Therefore, ethical approval is not required. Study findings will be shared through discussion with policymakers, implementation science researchers and healthcare providers. The results of this study are intended to be published in a peer-reviewed journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This scoping review includes only randomised controlled trials (RCTs) and protocols for RCTs to facilitate comparison across studies evaluating an integration intervention through similar study designs.
⇒ This scoping review will be limited to studies published in English and French, which may exclude studies with research objectives and study designs relevant to this review that are published in other languages.
⇒ This review may be impacted by publication bias, reflecting the proportion of published studies with findings that are strong or directional. To account for this, we also include protocols of randomised controlled trials.
⇒ This scoping review selects only published studies, which could exclude implementation projects resulting from initiatives that have not been published in the scientific literature.

Trial registration This protocol has been registered with Center for Open Science OSF Registry (DOI: 10.17605/OSF.IO/RGQSN). The search was conducted on 25 March 2024 and updated on 21 October 2024. The review is expected to be completed by March 2025.

INTRODUCTION

The scale-up of HIV testing and treatment through stand-alone HIV clinics achieved immense success in battling the HIV pandemic in sub-Saharan Africa (SSA) since the 2000s. This healthcare model scaled the delivery of antiretroviral therapy (ART) so that today's treatment is available to approximately 75% of people living with HIV in the region and ultimately transformed HIV from a deadly infection to a manageable, chronic condition.[1] As a result, there has been a large increase in the population of ageing individuals living with

HIV.[2–4] Furthermore, there has been a significant rise in the prevalence of non-communicable diseases (NCDs) globally and among the SSA population, particularly hypertension and diabetes, driven in part by cardiovascular risk factors such as lifestyle, dietary and environmental changes.[5] Today, research suggests that 40% of adults living in SSA suffer from hypertension and 5% from diabetes.[6 7] People living with HIV face an increased risk of developing some NCDs. For instance, people living with HIV are at higher risk to be diagnosed with Kaposi sarcoma, non-Hodgkin's lymphoma, and, among women, cervical cancer.[8] ART, the standard treatment for HIV, is associated with a higher risk of diabetes and hypertension.[9 10] Concerningly, it is estimated that only 15% of individuals with hypertension and 20% of individuals with diabetes receive regular, quality treatment.[11–13] Hence, there is a critical need for scaling up health services for NCDs in SSA, with an emphasis on scaling services for people living with HIV.

HIV-NCD healthcare integration models have been identified as a promising strategy to bridge the healthcare delivery gap for NCDs. Many SSA countries have already incorporated screening and treatment guidelines and adopted recommendations for integrated services into national health policies.[14] Using the robust physical infrastructure for HIV services could present a viable pathway for the expansion of services for NCDs. An additional rationale for exploring HIV-NCD integrated service models includes the shared disease burden (notably the high disease burden of both HIV and NCDs in SSA) and compatibility of treatment protocols.[9 15] HIV-NCD integration models can address the growing burden of NCDs in the general population and they reduce the burden on existing NCD services, (eg, district hospitals) and present a feasible and scalable strategy for improving NCD diagnosis and treatment.

There are many nuanced definitions of health service integration. For the purpose of this scoping review, integration refers to the combining of two or more health services that had previously been delivered separately. We will include two models of integration: NCD services integrated into existing HIV services and HIV services integrated into existing NCD services. Studies will not be limited by facility type, as the goal is to understand the structure of implemented HIV-NCD service models evaluated in the scientific literature. Research into the impact of these models is often challenging as integration models vary significantly in structure, size and location.[16] However, a crucial first step to design and scale models for integrated healthcare delivery is defining and understanding the existing landscape.

A number of reviews on HIV-NCD integrated healthcare services in SSA currently exist, including Chireshe *et al*, McCombe *et al* and Bulstra *et al*.[16–18] These reviews report on the current state of integrated care and identify key enablers and challenges. This scoping review aims to build on existing research in two ways. First, it will be limited by study design, selecting only randomised controlled trials (RCTs), including cluster-RCTs and stepped wedge trials. The authors of existing reviews have identified the lack of high-quality research on HIV-NCD service integration in low- and middle- income countries (LMICs) as a barrier to large-scale integration and have highlighted the need for further RCT data with well-defined comparator groups and standardised measurements of HIV and NCD outcomes.[17–21] Thus, this scoping review aims to address this research gap by identifying and analysing the current state of RCT research on HIV-NCD service integration in SSA. The inclusion of RCT protocols, a further departure from existing reviews, will allow the authors to accurately represent the current state of relevant RCT research, including future and ongoing projects. Second, this scoping review will include a broader definition of NCD, including CVD, diabetes, mental health and cancer. Existing HIV-NCD integration research tends to focus on either CVD and diabetes or mental health, and few have brought these two categories together.[17 18 20–30] Overall, this scoping review will address the need for high-quality empirical data on integration in LMICs by summarising and reporting on current relevant studies. Our findings will be useful for policymakers evaluating the effectiveness and utility of HIV-NCD service integration to address the growing NCD burden.

A scoping review is an appropriate model for this study since trials that analyse HIV-NCD integrated service models are an emerging field. The main purpose of our study is to evaluate and map existing trials, including their integration models, outcomes measured and reported findings, in order to assess the extent to which different trials can be compared. Few RCTs have published their full findings at this stage, and as such, this study does not aim to solely report on measured outcomes of integration. Instead, it will provide an overview of the state of research in the field, thus, a scoping review structure was selected rather than a systematic review structure.[31]

METHODS AND ANALYSIS

Protocol design

This scoping review adheres to the Arksey and O'Malley (2005) methodological framework for conducting scoping reviews. The framework consists of five steps with an optional sixth step: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, (5) collating, summarising and reporting the results and (6) consultation exercise.[32] The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) checklist was used to guide the reporting of this scoping review protocol. Though this review will not evaluate the efficacy of included studies, it is still recommended to rely on this structure for protocol development, due to the lack of other standard guidelines in this area.[33] The PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist will be used to guide the reporting of the completed scoping review.[34]

Patient and public involvement

No patients were involved in the design of this scoping review. Public involvement in study design included discussions with healthcare professionals and researchers. These discussions influenced the structure of the research objective, inclusion and exclusion criteria, search databases and measured outcomes. Additional discussions with key stakeholders will help to guide data extraction methods and the presentation and dissemination of results to ensure that the findings of this scoping review are made accessible to a diverse readership, including healthcare professionals, policymakers and researchers globally.

Stage 1: Formulating the research question and eligibility criteria

In this scoping review, the authors will investigate trial characteristics—including study settings, intervention models and outcome measures—to offer a comprehensive summary of the current state of robust research on HIV-NCD integrated healthcare in SSA. The review will include studies on HIV-NCD integrated healthcare, specifically within SSA. The populations included in this study will be drawn from healthcare settings within SSA that offer community-based or facility-based HIV services for adults and/or adolescents (10 years and older). Paediatric populations will not be included in this scoping review. The intervention is the implementation of integrated healthcare services for testing and/or counselling, and/or treatment initiation, and/or treatment monitoring with screening, and/or diagnosis, and/or treatment of diabetes, hypertension, cardiovascular disease, cardiometabolic risk factors (eg, high blood pressure, high cholesterol, high blood sugar), cancers, mental health and/or substance use disorder. Studies for which the intervention is not integration itself, but optimisation of previously implemented health service integration, will not be included. Control groups from included studies should follow standard-of-care models, which in most settings follow a stand-alone, vertical model in which patients receive separate, non-integrated testing and counselling, treatment and care for HIV and for NCDs. In this model, patients attend separate appointments with separate providers, typically at separate facilities, for each disease or condition. The outcomes will be dependent on the studies included in the scoping review. All outcomes related to service uptake, utilisation, health outcomes and cost-effectiveness will be included.

English and French language studies published between 1 January 2010 and 21 October 2024 will be included, reflecting recent advancements in the field focusing on integrated healthcare. Only publications that are RCTs, including cluster-RCTs and stepped wedge randomised trials, and protocols for RCTs, will be considered to ensure a uniform study structure and to facilitate comparison across studies adhering to stringent research methodologies. While there is some debate surrounding the classification of stepped wedge randomised trials as RCTs, this review will follow the recommendation of the *British Medical Journal*, which recognises stepped wedge randomised trials as RCTs.[35] Secondary studies based on trial data will not be included in this study. However, the trial will be included in the mapping of previous and ongoing RCTs. If a study's eligibility is unclear based on the title and abstract screening, it will pass on to the full-text screening for further review. The inclusion criteria are summarised in table 1.

Table 1 Inclusion criteria

	Inclusion criteria
Topic	HIV-NCD integrated healthcare
Location	Sub-Saharan Africa
Language	English or French
Year	1 January 2010–21 October 2024
Study design	RCTs, for example, randomised and cluster-RCTs and stepped wedge cluster-randomised trials

NCD, non-communicable disease; RCTs, randomised controlled trials.

Stage 2: Identifying relevant studies

Search strategies were developed and executed with the support of a librarian from the Harvard Countway Library of Medicine. The search strategies were peer-reviewed by additional Countway research librarians in accordance with the Peer-Review of Electronic Search Strategies checklist.[34] The following databases will be searched to identify relevant studies: OVID Medline, Embase, Web of Science, Global, Africa Index Medicus. Search results will be exported to Covidence,[36] where duplicates were identified and removed by the Countway Library research team. The full search strings for each database are included in online supplemental appendix A. Grey literature and unpublished trials will not be sought for inclusion.

Stage 3: Study selection and screening

The outlined eligibility criteria will be used to screen studies for inclusion. Before beginning the title and abstract screening, we will conduct a preliminary review of our search results to confirm that our target studies are present and that the initial search was generally in line with expectations.

Two reviewers (LM and JTF) will independently complete the title/abstract screenings for the initial studies and indicate whether each study should be included in the review. Any disagreements during the title/abstract screening will be resolved by a third reviewer (CAB). The second round, full-text screening will, again, be performed independently by two reviewers (CAB and JTF). During this stage, each reviewer will nominate studies for inclusion that meet all aspects of the stated inclusion criteria. If consensus cannot be met, a third reviewer will be sought. The title/abstract and full text screenings will take place in Covidence.[36]

Stage 4: Data extraction

The data extraction form will be developed by a reviewer (CAB). The development of the data extraction form will be an iterative process based on feedback from additional reviewers (LM, JTF and RA) and piloting. The full texts to be piloted will be selected at random from the included studies. Following the pilot round, the reviewers will meet to discuss discrepancies, suggest improvements to the form and decide whether additional pilot rounds will be necessary. Variables for data extraction include specific information on article characteristics, study population, time and setting of study, intervention type, control group, outcomes and findings. A full table of envisioned included variables can be found in online supplemental appendix B.

The extraction will be carried out by the three reviewers (CAB, LM and JTF), with each reviewer extracting from two-thirds of the studies so that each study is extracted twice. In the case of discrepancies, the three reviewers will meet to discuss the discrepancy until a consensus is reached. Missing, incomplete or unclear information will be recorded as such in the data extraction form. If necessary, the team will attempt to contact the authors for clarification via email. In the case of friend studies, we will extract data from the most recently published study, assuming all eligibility criteria are met, and participant size is similar.

Stage 5: Summarising and reporting outcomes

The studies selected and included in this scoping review will be analysed using the methods outlined above, where key variables will be extracted and aggregated to demonstrate patterns and outline findings. We aim to first map out the different integration models by location and setting of the included trials. In addition, the results of this study will consider the outcomes measured within the included studies and identify gaps in current research for future analysis. Descriptive analysis will be used to summarise the results of this scoping review. If the number of completed trials is sufficient, we aim to review the reported results across trials.

Synthesis and presentation of results

The review process will be captured in a PRISMA flow diagram. The results will be analysed through narrative analyses. The presentation structure for each variable will be outlined specifically based on the availability of data in the included studies. Additional collaborators will be included to help inform the presentation structure and interpret the findings in this scoping review.

Limitations

This review is limited to all SSA countries and, therefore, does not include studies from countries outside of this geographical scope. This review may suffer from publication bias, which is the rationale behind choosing a scoping review approach and including grey literature to supplement the published scientific literature. The review is limited to English and French language articles, which may bias the evidence.

ETHICS AND DISSEMINATION

This scoping review aims to generate new insights from publicly available studies and, therefore, ethical approval is not required. Study findings will be shared through publication and discussion with policymakers, implementation science researchers and healthcare providers. The results of this study are intended to be published in a peer-reviewed journal.

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Contributors CAB was responsible for the idea of this scoping review. CAB and LM outlined and executed the structure of the protocol. LM completed the full protocol draft, implementing feedback throughout from CAB, JTF, RA and AF. All authors contributed to the overall structure of this project, including the research objective and methods. CAB is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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