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Rationale and design of leveraging the HIV platform for hypertension control in Africa: protocol of a cluster-randomised controlled trial in Uganda

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ABSTRACT

Introduction There is a high burden of hypertension (HTN) among HIV-infected people in Uganda. However, capacity to prevent, diagnose and treat HTN is suboptimal. This study seeks to leverage the existing HIV-related infrastructure in primary care health facilities (HFs) using the integrated HIV/HTN care model to improve health outcomes of patients with HIV and HTN.

Methods and analysis Integrated HIV/HTN study a type-1 effectiveness/implementation cluster randomised trial, will evaluate the effectiveness of a multicomponent model intervention in 13 districts randomised to the intervention arm compared with 13 districts randomised to control. Two randomly selected HFs per district and their patients will be eligible to participate. The intervention will comprise training of primary healthcare (PHC) providers followed by regular supervision, integration of HTN care into HIV clinics, improvement of the health management information system, IT-based messaging to improve communication among frontline PHCs and district-level managers. HTN care guidelines, sphygmomanometers, patient registers and a buffer stock of essential drugs will be provided to HFs in both study arms. We will perform cross-sectional surveys at baseline, 12 and 24 months, on a random sample of patients attending HFs to measure effectiveness of the integrated care model between 2021 and 2024. We will perform in-depth interviews of providers, patients and healthcare managers to assess barriers and facilitators of integrated care. We will measure the cost of the intervention through microcosting and time-and-motion studies. The outcomes will be analysed taking the clustered structure of the data set into account.

Ethics and dissemination Ethics approval has been obtained from the Research Ethics Committees at London School of Hygiene and Tropical Medicine, and Makerere University School of Medicine. All participants will provide informed consent prior to study inclusion. Strict confidentiality will be applied throughout. Findings will be disseminated to public through meetings, and publications.

Trial registration number NCT04624061

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Study will provide a large data set to arrive at robust statistical results on intervention effectiveness.
⇒ Study sites have varying geographical and culture characteristics, an opportunity to examine the hypertension (HTN) care components among patients with HIV.
⇒ The study will be implemented in 'real-life conditions' of the Ugandan healthcare system.
⇒ A combination of both quantitative and qualitative outcomes will facilitate the interpretation of main quantitative results.
⇒ Study focuses on HTN care among HIV-infected patients hence will not cover other common non-communicable diseases.

INTRODUCTION

Significant investment in HIV diagnosis and treatment infrastructure and human capacity in sub-Saharan Africa (SSA) have resulted in major gains in care and treatment for HIV infected persons leading to reduction in HIV associated morbidity and mortality.[1–3] This remarkable investment in HIV care presents a significant opportunity to improve health in HIV-infected persons for conditions other than HIV infection and potentially in the larger general population in SSA contributing to the attainment of Sustainable Development Goal 3.3.[4] Hypertension (HTN) is the leading cause of cardiovascular death in SSA, experiencing a 67% increase in prevalence since 1990, and studies showing a high incidence of HTN among HIV-infected persons initiating antiretroviral therapy (ART) have led to a call for increased attention to screening of and treatment for HTN among HIV patients.[5] Currently, there are 1.1 million HIV patients in care in Uganda and 60% of these receive care at Health Centre IVs and IIIs). However, HTN care at regional referral hospitals is fare compared with general hospitals and health centre IVs[6] making HTN diagnosis and care challenging to access. The barriers to HTN

Table 1 Showing levels of district public health services in Uganda

Health facility level	Administrative level	Target population	Main function/infrastructural requirement	Facility head
District health office	District	500 000–2 million	Resource distribution, staffing	DHO, MD or public health specialist
District hospital	District	500 000–2 million	Beds for up to 200 inpatients, operation theatre, general laboratory, often with NCD clinic	Medical director (MD or public health specialist)
Health centre IV (HC IV)	County	100 000–500 000	Beds for up to 30 inpatients, operation theatre, general laboratory, provides HIV care including ART	MD
HC III	Subcounty	30 000	Maternity unit, provides HIV care including ART, limited NCD care	Non-MD clinician or midwife
HC II	Parish	5000–10 000	First-line emergency and outpatient care	Nurse
HC I	Village	1000–5000	Outreach post, village health team	Visiting health staff

ART, antiretroviral therapy; DHO, district health officer; NCD, non-communicable disease.

care in HIV clinics can be categorised as follows: Knowledge gaps in HTN care among middle-level managers and primary healthcare (PHC) providers. Middle-level managers, also known as district health officers (DHOs), often have inadequate knowledge required for planning, implementation and reporting of integrated HIV/HTN services. PHC providers also lack basic skills in diagnosis, treatment and follow-up of HTN and HIV/HTN patients.[7] Limited capacity of the Ugandan public sector health facilities (HFs) to prevent and control non-communicable diseases (NCDs).

RATIONALE

Currently, comprehensive HTN care services are routinely offered at regional referral hospitals, however, the bulk of patients receive care at lower-level facilities,[8 9] which lack structured chronic HTN care but have functional systems for chronic HIV care (table 1). Lower-level HFs lack training and capacity to routinely screen for HTN, limited access to guidelines for HTN care, absence of sphygmomanometers and limited stock of essential medicines and supplies. Weak health management information systems (HMIS): The current national HTN HMIS only counts patient attendance at registration without tracking patient outcomes like proportions screened, treated and controlled. The inadequate data collected limits utilisation of the health information for improved care delivery, patient management and outcomes review and overall programme planning. There are no data collection tools such as NCD-specific or HTN-specific registers, individual patient cards and electronic databases. To address these barriers, there is a need for collaborative efforts between the ministry of health (MoH), academia including implementation science researchers, middle-level health district management and front-line PHC providers to scale up effective evidence-based interventions.[10]

We will conduct an implementation science study of the introduction of a multilevel strategy involving a strong collaboration between researchers and national disease control programmes to evaluate an evidence-based integrated HIV and HTN care model. The study will be conducted in randomly selected districts in southwestern Uganda, because the region has higher HIV prevalence compared with other regions in the country, in addition we are leveraging on the HIV and HTN infrastructure developed in the region by SEARCH (NCT01864603). Our intervention will be based on the empirically validated PRECEDE model,[11] which suggests that health promotion strategies are most effective when they combine: (1) predisposing factors composed of knowledge, attitudes or beliefs that affect behaviour; (2) enabling factors that facilitate change by making the behaviour easier and (3) reinforcing factors which include anticipated consequences following behaviour.

Study objectives

Objective 1

To determine the effectiveness of an integrated HIV/HTN care model on HTN and dual HIV/HTN control among adult patients in HIV clinics.

Objective 2

To assess the facilitators and barriers to the implementation of the integrated HIV/HTN care model for HIV patients at different levels including the MoH officials, DHOs, PHC providers and patients and explore the potential for expansion of the care delivery model for HTN to non-HIV patients.

Objective 3

To determine the cost and cost-effectiveness of the integrated HIV/ HTN care model intervention.

METHODS AND ANALYSIS

Study design

This is a hybrid type-1 effectiveness/implementation study[12] to evaluate a multicomponent integrated HIV/HTN care intervention through a cluster randomised controlled trial in the western parts of Uganda. The district is defined as the randomisation unit. Uganda has

135 districts and 26 districts located in western Uganda will be selected to participate in this project. District selection will be based on geographical location and availability of HIV clinic. District randomisation will be performed using stratified, blocked randomisation employing the Ralloc command in the Stata statistical analysis programme.[13] Stratified, blocked randomisation will involve two levels of stratification: (1) geographical region (four regions) and (2) total HIV patient clinic size (two strata: large, small). A block size of 2 will be selected for the randomisation within the combined strata. We will document and archive the output of the randomisation procedure results prior to communication of the district randomisation assignment to the principal study investigators. These results will be shared with the district stakeholders for their buy-in and input into the overall design. The anticipated timeframe for the study is between 2021 and 2024.

Intervention components

Facilities in intervention districts will receive the multicomponent intervention of combined HIV and HTN care which includes:

(1) Training and capacity building on the INTEGRATED HIV/HTN model and NCD care. The healthcare providers will be trained for 3 days using an MoH-approved training curriculum adapted to the project. The trainees will receive HTN treatment algorithm, body mass index chart, HW training manual and a desk guide. The trainers and project staff will conduct regular support supervision visits to observe blood pressure (BP) measurement procedures, review patient charts, provide coaching and mentorship sessions to HWs, and get feedback on implementation challenges of the intervention. (2) The Integrated HIV/HTN care delivery model by promoting HTN screening and care in HIV clinics. Patients with both HIV and HTN diagnoses will be managed at the same station, integrating the medical appointment visits, drug dispensing and patient chart/records filling systems. (3) HMIS enhancements through mentorship and coaching on use of NCD registers and NCD patient cards, and capture of HTN data in the existing Electronic Medical Records (EMR) of Uganda; The Uganda EMR is an open source application that is used to capture HIV patient data such as patient demographics, vitals measurements, opportunistic infections, ART regimens and patient adherence. (4) SMS and/or WhatsApp messages for data coordination and communication among providers, DHOs and the project staff. The WhatsApp group membership include district health teams, PHC and project staff. The messages shared on the platform include weekly reports on study implementation, logistical challenges such as drugs supply, clinical cases discussion, patient referrals and sharing new information regarding HTN and HIV.

The 13 control districts will continue implementing the current standard of care as per MoH guidelines. In both trial arms, HFs will implement national HTN care guidelines, and will receive sphygmomanometers (BP machines), MoH-approved NCD registers and NCD patient cards, and a buffer stock of essential HTN drugs.

Study setting and population

The study is being conducted in public health centre level IV clinics and high-volume health centre III clinics offering HIV care in 26 districts located in the western and south-western regions of Uganda. On average, each district contains 5–7 health centres III and IV that each serve between 500 and 2500 HIV infected adult persons in western Uganda. The current practice of managing HTN and other NCDs at health centre IIIs and IVs is based on the.[14 14] Patients presenting to the outpatient clinics are only assessed/screened for HTN if they have symptoms. Those found to have HTN are then treated based on Uganda clinical guidelines 2016[14] published by the MOH. For stage 1 HTN, clinical guidelines recommend lifestyle adjustments for 3 months and for stage 2 HTN, a patient receives two types of medicines that is a diuretic and calcium channel blocker for 2 months. If BP control not achieved, an additional type of medicine such as Angiotensin II receptor antagonist or ACE inhibitors is given.

HIV care is routinely provided at health centres that have been supported by United States Agency for International Development (USAID) funded implementing partners such as The AIDS Support Organisation, Baylor-Uganda and EGPAF - Uganda. The site selection will be based on the presence of at least two health centres IV and/or high-volume health centre IIIs that will be randomly chosen from each of the districts to participate in the study. We will select 26 public health centres from each study arm (2 per district) that: (A) are government-sponsored and supported; (B) care for an approximate total of ≥1000 people living with HIV (PLHIV) across the two clinics in the district (at least 200 per clinic) and (C) provided a letter of commitment/consent to participation from the DHO.

Precede framework

The multicomponent integrated HIV/HTN care model was designed using the PRECEDE framework for implementing and evaluating health promotion and public healthcare delivery programmes.[15 16] This model has shown that health promotion strategies are most effective when they address: (1) 'predisposing factors' comprised of knowledge, attitudes or beliefs that affect behaviour; (2) 'enabling factors' that facilitate change by making the behaviour 'easier' and (3) 'reinforcing factors' which include anticipated consequences following a behaviour (figure 1). The use of a proven implementation science framework enhances both the scientific rigour of the intervention research and the likelihood of success.

Measurement of outcomes

RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) will be used to measure the

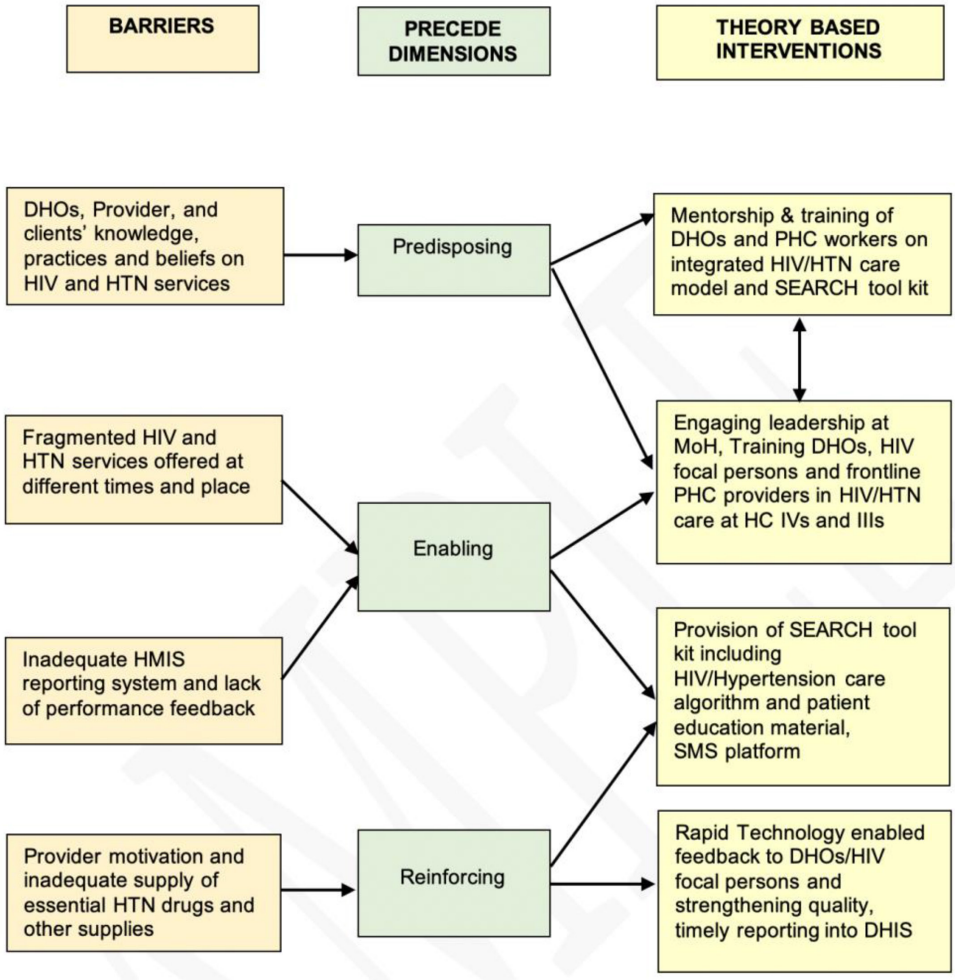

Figure 1 Precede model barriers and corresponding integrated HIV/HTN care model components. DHOs, district health officers; HC, healthcare; HMIS, health management information systems; HTN, hypertension; PHC, primary healthcare; DHIS, District Health Information Software.

impact of the intervention on the different implementation outcomes. For the evaluation at the patient level, the study will involve 50 randomly selected HIV-infected patients per health centre that will be evaluated on their screening status for HTN, and 50 randomly selected HIV/HTN patients that will be evaluated on whether the care provided has been successful ('controlled'). The primary outcome indicators of the implementation effectiveness will be measured through cross-sectional surveys at baseline and after 12 and 24 months of trial participation. These will include: (1) HTN Screened: proportion of HIV infected patients screened for HTN within last 12 months; (2) Proportion of HTN patients diagnosed and started on treatment (3) HTN Control: proportion of HIV infected patients with a documented history of elevated BP or prior HTN diagnosis who are 'controlled' (ie, systolic BP below 140 mm Hg and diastolic BP below 90 mm Hg) at the patient's last routine visit within the last 12 months; (4) HIV/HTN Dual Control: Proportion of HIV infected patients with a documented history of elevated BP or prior HTN diagnosis whose BP is 'controlled' and who has an undetectable HIV viral load (at last visit within the last 12 months). The qualitative evaluation will be conducted to identify facilitators and barriers to implementation of the integrated HIV/HTN care model in selected facilities. We will interview 40 patients; 30 healthcare providers, 14 healthcare managers at baseline, 12 months and 24 months. Purposive stratified sampling approach will used based on clinic characteristics and available data.

Secondary outcome measures

1. Knowledge of HTN management and complications among health workers (measured through conducting surveys among health workers working in the HIV clinics using a standardised knowledge test).
2. Proportion of HTN patients with successfully lowered BP (by at least 10 mm Hg systolic and/or diastolic) compared with the time at first HTN diagnosis; (data to be obtained from NCD registers and patient cards at follow-up).
3. Proportion of participating HFs per arm providing HTN care as routine practice.
4. Proportion of HC IIIs and IVs adopting the integrated HIV/HTN care model.

5. Patient satisfaction in a subsample of facilities (determined through a survey among subsample of HIV/HTN patients).
6. Adoption of the integrated HIV/HTN HMIS tools particularly NCD registers and NCD patient card approved by the MoH.
7. Proportion of HFs that demonstrate service readiness for delivering adequate HTN care for patients with and without HIV-infection (will be measured by HF inspection against a predefined set of criteria derived from the WHO SARA assessment tool)).
8. Proportion of hypertensive patients (HIV-positive and HIV-negative) registered at HFs that are being managed according to national guidelines (will be measured by applying a list of essential predefined criteria to randomly selected HTN patients who will be invited for interview and examination).
9. Incremental costs of the intervention (will be measured using microcosting through interviews with coordinators, site visits and time-and-motion studies with clinic staff).

Data management and quality assurance

All members of the study team will be been trained on the study protocol prior to the onset of the study. Study group meetings will be conducted regularly to review study progress, address difficulties and provide feedback on overall implementation of the study. The study database will be custom designed in Microsoft Access. All patient data from the registers and patient care charts will be validated before being uploaded into the database. The collected data will be transferred and merged with the main study database at monthly intervals. Detailed standard operating procedures for data management will be written for all study activities and be provided to relevant team members. The monitoring of the study to assess adherence to the protocol, respect of participant rights and data quality will be done routinely by the appointed Ethics advisor. If during the assessment surveys, the research teams come across patients who are not appropriately managed or who have a high BP that requires immediate treatment, the patients will be managed according to the existing national guidelines and if referral is needed, a study staff will arrange for accompanied referral to hospital. We will share data collected during the study by depositing these data at an open access repository such as Dryad.

Sample size considerations

Using a cluster adjusted comparison of two proportions and an intraclass correlation coefficient of 0.1 (based on available data from HIV clinics[17]), this study would have 80% or greater power to detect a significant improvement in HTN screening rates in between intervention and control districts if the observed proportion was 36% or greater in the former compared with 20% in the latter. Based on the same assumptions, the trial would have 80% or greater power to detect a significant improvement in HTN control among HIV patients from 47% or greater compared with 28%. Effectiveness of the integrated HIV/HTN care model intervention will be assessed using generalised linear models (GLM) particularly a multilevel random effects model using random intercepts by clinic site and region.

Quantitative data analysis

Effectiveness of the integrated HIV/HTN care model will be assessed following a prespecified analysis plan. Descriptive analysis of clusters and individual study participants will be conducted. For the analysis of the coprimary outcomes, an intention-to-treat analysis will be performed. We will calculate cluster-level summaries. For the primary evaluation of the trial effectiveness, we will use a two-sample proportions test for cluster randomised designs in the Stata statistical analysis package (Jeph Herrin, 2002. 'CLTEST: Stata modules for performing cluster-adjusted χ^2 and t-tests,' Statistical Software Components S424901, Boston College Department of Economics, revised 3 February 2012.), (StataCorp. 2019. Stata Statistical Software: Release 16, StataCorp). In addition, we will examine trial data for evidence of significant heterogeneity between geographical blocks and if this is found, we will use random effects modelling of binary outcomes allowing for a random intercept for each geographic region. Likewise, if significant heterogeneity in primary outcomes is found by clinic size block (small vs large), we will incorporate a clinic size block level into the random-effects model allowing a random intercept for clinic block size overall or within geographic region as appropriate. Results from both the cluster adjusted two-sample proportions test and the random-effects modelling (if found to be required) will be presented.

Implementation science study evaluation

To identify facilitators and barriers to implementation and perceived utility of the intervention from both the providers and patients, we will measure fidelity (degree of intended implementation) to each of the intervention components using different approaches. We will use the Consolidated Framework for Implementation Research (CFIR) and the RE-AIM evaluation frameworks to guide measurement of implementation process outcomes.

The Consolidated Framework for Implementation Research is a conceptual framework that was developed to guide systematic assessment of multilevel implementation contexts to identify factors that might influence intervention implementation and effectiveness.[18] Target areas for mixed-method investigation guided by the CFIR construct area will include: (1) intervention characteristics (stakeholders perceptions of intervention source, evidence strength, adaptability and costs), (2) outer setting factors external to the care organisations that may influence implementation (patient needs, community awareness of HTN issues, external NCD policies, HTN drug supply issues), (3) inner setting factors internal to the care organisations that influence implementation

(structure of HIV clinics and staffing, communications norms, clinic culture, organisational capacity for change, MoH prioritisation of NCD care, access to HTN education and available resources for implementation), (4) characteristics of Individuals (knowledge and beliefs about HTN diagnosis and care, self-efficacy for lifestyle change, readiness for change/treatment and competing needs), (5) process (level of engagement of formal and opinion leaders, integrated HIV/HTN care champions, engagement in planning and presence of external change agents, quality of evaluation and feedback processes).

In addition, the RE-AIM will be used to measure the impact of the intervention on the different implementation outcomes. RE-AIM is a planning and evaluation framework that addresses five dimensions of individual and setting-level outcomes important to impact and sustainability of the project.[19] Reach refers to the absolute number, proportion and representativeness of individuals who participate in a given intervention or programme. Effectiveness is the impact of an intervention on important outcomes and includes negative effects, quality of life and economic outcomes. Adoption is the absolute number, proportion and representativeness of settings and intervention agents who initiate a programme. Implementation refers to the intervention agents' fidelity to and adaptations of an intervention and associated implementation strategies, including consistency of delivery as intended and the time and costs. Lastly, maintenance is the extent to which a programme or policy becomes institutionalised or part of the routine organisational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level and has been defined as the long-term effects of a programme on outcomes after 6 or more months after intervention contact.[20]

We will use a mixed-methods approach combining patent-level, clinic-level and health district-level outcomes from the randomised implementation comparison data collection and analysis (aim 1) along with quantitative implementation process measures and qualitative key informant and in-depth interviews with a sample of key stakeholders including HIV and HTN patients, HIV clinic providers and leadership, DHOs, and National HIV and NCD Control Programme officials (see figure 2).

Qualitative data analysis

We will use a two-phase analysis approach:

1. Qualitative interviews: Audiorecorded interviews will be transcribed, and analysed via a directed content analysis method. Study staff will code transcripts using Dedoose software. The transcribed data will be initially coded using an inductive, exploratory approach to identify themes related to facilitators and barriers of integrated HIV/HTN model. Transcripts will be colour-coded independently by two analysts to identify codes/categories. The themes will be grouped and exemplary quotes identified and presented for each theme.
2. Mixed-methods analysis of qualitative data grouped by categories defined using effectiveness, process and fidelity measures. This will involve analysing qualitative data collected within categorised groups of stakeholders. This approach will allow us to identify emergent themes within groupings and to assess conceptual alignment or differences across stakeholders, with attention to evidence of contradictory findings and deviant cases in the data.

Cost data analysis

We will employ an activity-based costing approach. We will assess costs twice in each of the trial arms: once before and once after the adoption of the Integrated HIV/HTN model in the intervention arm, in order to compare costs of the standard of care to the intervention. Costs will be estimated as the sum of the product of resources (eg, staff minutes) times unit costs (eg, compensation levels). 'Economic' costs (the true value of resources consumed or 'opportunity costs') will be assessed by identifying the value of subsidised or donated resources with information from databases (eg, wage rates) and donors. We will use prices prevailing at the time of study onset and will convert any locally incurred costs using the Uganda Shilling/US dollar exchange rate at that time.

Health effects will be quantified in two ways. First, we will use directly measured study outcomes pertaining to health-related events such as stroke, chronic kidney disease, blindness and myocardial infarction. Second, and following best practices in cost-effectiveness analysis, we will integrate the health impact of HTN/HIV morbidity/mortality events averted, using disability-adjusted life-years (DALYs), including lost years of life and the collective disability effects of adverse events. DALY estimates will be for the short term (during the project) and the long term (5, 10 and 20 years) using clinical modelling. We will conduct extensive sensitivity analysis on our assumptions, to describe the range of probable DALYs averted.

Patient and public involvement

We involved the public during the idea conception stage, through which the district health managers and teams provided letters of support. In addition, during the national and regional stakeholders meetings we involved the patients and public by inviting a section representative such as the community advisory board, researchers, MoH staff, academia, district and health centre staffs to discuss and provide input in the overall design and implementation of the study.

Ethics and dissemination

Ethics approval has been obtained from the Research Ethics Committees at London School of Hygiene and Tropical Medicine, and Makerere University School of Medicine. All participants will provide informed consent prior to study inclusion. Reports and publications emanating from the Integrated HIV/HTN Project will not include any information that identifies the patient

RE-AIM Area	Quantitative Measures	Qualitative Question Areas and Sampling
Reach	• % HIV Patients Screened for HTN • % HIV Patients Repeat Screened for HTN • Demographics of Screened & Not-Screened • % of HIV clinic days with integrated HIV/HTN care	• Barriers and Facilitators of HTN Screening (Patients, Providers, & Clinic In-Charges) • Barriers and Facilitators of integrated HIV/HTN care • Level of Engagement of District Health Officers • Level of Engagement of Providers and In-Charges
Effectiveness	• % HTN Control (12 % 24 months) • % HIV/HTN Dual Control (12 & 24 months) • Clinic & District Level Aggregate Control Rates • Demographics of Controlled & Not-Controlled	• Perceptions of effectiveness of Integrated HIV/HTN Care system (Patients, Providers & District Health Officers) • Key stakeholder understanding and agreement of what constitutes "success" (in-Charges & District Health Officers)
Adoption	• % Routine use of HIV/HTN Patient Register • % Individual patient chart use of HTN Green Card • % HTN Green Card completeness • % with algorithm appropriate treatment plan • % SMS data upload to District Health Office	• Barriers and Facilitators of Integrated HIV/HTN Care (Patients, Providers & District Health Officers) • Barriers and Facilitators of Use of HTN Diagnosis & Treatment Algorithm (Providers & In-Charges) • CFIR-guided perceptions of HIV/HTN care model evidence strength, advantages, and adaptability (Providers, In-Charges, & District Health Officers) • Perceived utility of HTN Job Aids & Patient Lifestyle Brochures (Patients & Providers)
Implementation	• Integrated HIV/HTN Care System Fidelity • # Training and Re-Training Sessions • # SMS Communications • Training and Re-Training Costs • # required uses of medication buffer stocks	• Acceptability and perceived utility of HIV/HTN training and re-training sessions (Providers) • Feasibility and Acceptability of SMS data submission • Potential for incorporation of HTN Green Card into Uganda EMR system (District Health Officers) • CFIR-guided examination of inner setting factors (organizational) that influence implementation (In-Charges, District Officers, & Control Programs)
Maintenance	• 12- & 24-month HTN and Dual Control Outcomes • Program Sustainability Assessment Tool (PSAT) • Sustained integrated HIV/HTN Care System costs (exclusive of start-up costs)	• Barriers and facilitators of sustained behavior change (Patients, Providers, In-Charges, District Health Officers) • PSAT qualitative sustainability and future directions questions. (District Health Officers) • CFIR-guided examination of outer setting influences for maintenance of HIV/HTN care model.

Figure 2 Implementation science measures (mixed methods) by RE-AIM framework area. CFIR, Consolidated Framework for Implementation Research; EMR, electronic medical record; HTN, hypertension; RE-AIM, Reach, Effectiveness, Adoption, Implementation and Maintenance.

themselves. Participants will be identified throughout the study duration by the study number allocated to them at the time of survey. All data will be stored on a password-protected computer and handled in the strictest confidence. Findings will be disseminated to public through meetings, policy briefs, peer-reviewed journal articles and publications.

Status of the project and preparation of study sites

In the first year of the project, we (1) conducted stakeholder engagement meetings; (2) received ethical approval of the developed study protocol and tools.

DISCUSSION

The integrated HIV/HTN intervention seeks to make use of the existing well-functioning care HIV infrastructure developed in Uganda over the past decade, to tackle HTN which has emerged as a major threat to PLHIV/AIDS. The model employed in this project uses a collaborative approach to build capacity in the primary care HFs; this is critical because a large part of the population seeks care at these HFs.

SUMMARY

HTN is a growing burden among the PLHIV, hence the need to have novel strategies to tackle it. The integrated HIV/HTN project represents one such attempt to improve the patient outcomes with co-occurring HTN and HIV. In addition, the project will document the burden disease in rural communities in Uganda, and further collaborate with several NCD players and stakeholders to strengthen health systems and build capacity of NCDs care at the lower HFs.

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Contributors The authors confirm contribution to the paper as follows: MK and EO prepared the initial draft of this manuscript. MK, JK, BT, JN, GM, SBS, HG and EC reviewed and made substantive contributions to subsequent drafts. All authors have read and approved the final manuscript.

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Competing interests None declared.

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

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

1 Lunyera J, Kirenga B, Stanifer JW, *et al*. Geographic differences in the prevalence of hypertension in Uganda: results of a national epidemiological study. *PLoS One* 2018;13:e0201001.
2 Kalyesubula R, Kayongo A, Semitala FC, *et al*. Trends and level of control of hypertension among adults attending an ambulatory HIV clinic in Kampala, Uganda: a retrospective study. *BMJ Glob Health* 2016;1:e000055.
3 Kotwani P, Kwarisiima D, Clark TD, *et al*. Epidemiology and awareness of hypertension in a rural Ugandan community: a cross-sectional study. *BMC Public Health* 2013;13:1151.
4 Kayima J, Nankabirwa J, Sinabulya I, *et al*. Determinants of hypertension in a young adult Ugandan population in epidemiological transition-the MEPI-CVD survey. *BMC Public Health* 2015;15:830.
5 UNAIDS. *Ending AIDS progress towards the 90-90-90 targets*. UNAIDS, 2017. https://www.unaids.org/en/resources/documents/2017/20170720_Global_AIDS_update_2017
6 Rogers H. *Assessment of the capacity of Ugandan health facilities, personnel, and resources to prevent and control noncommunicable diseases*. Yale University, 2014.
7 Musinguzi G, Bastiaens H, Wanyenze RK, *et al*. Capacity of health facilities to manage hypertension in Mukono and Buikwe districts in Uganda: challenges and recommendations. *PLoS One* 2015;10:e0142312.
8 MoH U. *Consolidated guidelines for prevention and treatment of HIV in Uganda*, 2018.
9 MoH U. *Health sector strategic plan III*, 2010.
10 Johnson M, Wilkinson J, Gardner A, *et al*. Global partnerships to support noncommunicable disease care in low and middle-income countries: lessons from HIV/AIDS. *AIDS* 2018;32 Suppl 1:S75–82.
11 Green L, Kreuter M. The precede–proceed model.. In: *Health promotion planning: an educational approach*. 3rd ed. Mountain View, CA: Mayfield Publishing Company, 1999: 32–43.
12 Curran GM, Bauer M, Mittman B, *et al*. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217–26.
13 Ryan P. RALLOC: Stata module to design randomized controlled trials, statistical software components.. *Boston College Department of Economics* 1997.
14 Uganda MoH. *Uganda clinical guidelines 2016*, 2016.
15 Ataklte F, Erqou S, Kaptoge S, *et al*. Burden of undiagnosed hypertension in sub-Saharan Africa: a systematic review and meta-analysis. *Hypertension* 2015;65:291-8.
16 Petersen M, Balzer L, Kwarsiima D, *et al*. Association of implementation of a universal testing and treatment intervention with HIV diagnosis, receipt of antiretroviral therapy, and viral suppression in East Africa. *JAMA* 2017;317:2196–206.
17 Kwarisiima D, Atukunda M, Owaraganise A, *et al*. Hypertension control in integrated HIV and chronic disease clinics in Uganda in the search study. *BMC Public Health* 2019;19:511.
18 Damschroder LJ, Aron DC, Keith RE, *et al*. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Sci* 2009;4:50.
19 Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999;89:1322–7.
20 Harden SM, Smith ML, Ory MG, *et al*. RE-AIM in clinical, community, and corporate settings: perspectives, strategies, and recommendations to enhance public health impact. *Front Public Health* 2018;6:71.