CHAO (Comorbidities in HIV/AIDS Outpatients) study: an epidemiological research to reduce mortality of HIV patients in Kenya

I. Introduction/Background

HIV-related mortality has markedly diminished in the last two decades, thanks to progress in HIV treatment and increased access to Anti-retroviral treatment (ART)(UNAIDS, 2021). However, though the life expectancy of people living with HIV (PLHIV) continues to increase, the causes of death have shifted from AIDS to non-AIDS related causes such as tuberculosis, hypertension, diabetes, hepatitis, obesity, syphilis, dyslipidemia, and kidney diseases (Lerner et al., 2020). Compared to the general population, HIV+ people are more likely to develop comorbidities (CMs). This is because of the effects of ART, the HIV itself, and the increased risk associated with ageing. Undiagnosed, untreated, or incorrectly treated comorbidities can undermine the positive effects achieved by current HIV treatments. For these reasons, comorbidities are a major public health problem among people living with HIV (PLHIV), particularly in developing countries, where the HIV burden is the highest (Ciccacci et al., 2019; George et al., 2019; Njuguna et al., 2018).
In Kenya, there are 1 400 000 people living with HIV (UNAIDS, 2020). Nonetheless, the impact of comorbidities on these people is still not clearly defined. Although there is evidence of the correlation between HIV and co-morbidities, the paucity and unreliability of data in Sub-Saharan Africa limits the capacity to make inference on their relevance and consequences.
A more accurate analysis is crucial to treat and control comorbidities and to implement programs to mitigate their burden. For this reason, the aim of this study protocol is to understand the prevalence of CMs in PLHIV in the Meru County of Kenya and their effects of CMs on mortality and treatment outcomes.

The present document is organised as follows:

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II. Problem statement

The target of the present proposal is to assess the prevalence of comorbidities in PLHIV and their effects. This will improve Kenyan Health Ministry's capacity to promote high-quality health services that integrate HIV and CMs treatment.

In Kenya, 4.5% of adult population is affected by HIV (UNAIDS, 2020). HIV is the first cause of death in the country among people aged 15-49. The Kenya AIDS strategic framework 2 highlights the need to increase the quality of life and the survival possibilities of HIV patients. In particular, this document underlines the need to integrate HIV services with other health services designed to cure different co-morbidities. Moreover, the Kenya HIV & AIDS Research Agenda refers to the paucity of reliable epidemiological data regarding NCDs in PLHIV, which are fundamental to plan adequate health interventions.

III. Review of literature

For the purpose of this protocol, a literature review was carried out by using the following search strings: (HIV OR PLWHIV OR AIDS) AND (Afric* OR Meru OR Kenya) AND (Co-morbidit*) AND (Prevalence), (HIV OR PLWHIV OR AIDS) AND (Co-morbidit*) AND (Mortality rate OR Death rate OR Survival rate), (HIV OR PLWHIV OR AIDS) AND (Co-morbidit*) AND (Nutritional status OR BMI), and (HIV OR PLWHIV OR AIDS) AND (Co-morbidit*) AND (HIV treatment success OR HIV treatment outcome OR ART OR Viral load OR CD4).

Among the studies examined, many found a correlation between HIV and NCDs in Sub-Saharan Africa and in Kenya specifically. However, huge gaps exist in the collection of data, screening, diagnosis, treatment, and outcomes of comorbidities and HIV within this context.

A review conducted by Gonah et al. in 2020 found slightly higher NCD prevalence rates in PLHIV compared with HIV-negative people, even if the NCDs prevalence rates from studies conducted outside Africa was consistently higher (Gonah et al., 2020). Indeed, studies from Sub-Saharan Africa are fewer and report inconsistent NCD prevalence rates. This is also due to the predominance of cross-sectional studies, which have many intrinsic limitations and do not take into account effects of NCDs on treatment outcomes (Achwoka et al., 2020a).

In the same year, Achwoka et al. published a study on the prevalence of NCDs among key population enrolled at a large HIV prevention and treatment program in Nairobi (Achwoka et al., 2020b). As in the study before, they observed high prevalence of NCD diagnosis among people living with HIV and on ART. Nonetheless, they focused only on key population living in Nairobi, an urban setting. This may limit the scalability of the analysis and lead to biased interpretations being Kenyan population is mainly rural countryside based.

Another research conducted in Kenya in 2020 by Chepkondol et al. confirmed the same trend: there is a prevalence of opportunistic infections (OIs) in PLHIV. Moreover, they discovered that the years of living with HIV are a predictor of TB infections, because of the close relation between the CD4 count and TB (Chepkondol et al., 2020). Even if this analysis adds relevant findings to the existing literature, it also presents important limitations, as it narrows focus on TB and on the city of Nairobi. In general, the limited data collection and analysis capacity of Sub-Saharan African countries strongly limits the possibility to find consistent information and make inference regarding this topic.

Already the Kenya AIDS Strategic Framework 1 (KASF 1 - 2014/2015-2019/2020) identified important gaps regarding the integration of screening, prophylaxis and management of co-infections and co-morbidities whose level was defined as sub-optimal. Therefore, among the areas of focus identified, one related specifically to the ability to provide targeted and integrated HIV testing and counselling, and it was recommended to provide integrated packages to include tuberculosis screening, family planning services, cervical cancer screening, and other health checks

such as, blood pressure/glycemia, weight, and include other risk reduction services. In parallel, it is also recommended to increase prevention interventions for tuberculosis, infectious diseases and other co-morbidities, water and sanitation-related diseases, and vaccination for preventable diseases (cervical cancer, hepatitis, pneumococcal disease), identifying Government and non-state actors, the National AIDS Control Council (NACC) and National AIDS and STI Control Program (NASCOP) to lead in implementing these recommendations (National AIDS Control Council, 2013a).
The new document KASF 2 2020/2021-2024/2025, recalls and integrates what was indicated in KASF 1, identifying in thematic area 1 the need to provide universal, comprehensive and quality access to HIV and other sexually transmitted diseases (STIs) prevention services, and, in thematic area 2, the need to strengthen screening and management of co-morbidities in PLHIV, including NCDs such as diabetes, hypertension and cancer (National AIDS Control Council, 2019).
In addition, the document Costing the Implementation of the 2016 HIV Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya identifies diagnosis of co-morbidities as one of the main gaps in terms of financial coverage (Ministry of Health, 2017). This issue was also captured by Module 3 ("Integrated Service Delivery and quality improvement") of the 2017 HIV/TB Funding Request for the Global Fund (The Global Fund, 2021).
Moreover, the Kenya HIV & Aids research agenda (2014/2015-2018/2019), reports a major gap in terms of availability of data on the prevalence of the impact of co-infections and co-morbidities for HIV patients and identifies, among the research priorities, that of improving epidemiological data in this regard (Key research priority 2) (National AIDS Control Council, 2013b).
At a more detailed analysis, going to identify the situations of greatest vulnerability, the National AIDS Control Council reports that at the end of 2017 in Meru County there were no active international partners with operational research projects, an element that would instead need support and funding for a more effective development of interventions adapted to the needs (Meru County Report on the HIV implementing partners online reporting system (HIPORS) for the financial year 2016/2017). In addition, the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 (NASCOP and Ministry of Health data) reports that Meru County is among those with the lowest rates of treatment success of HIV infection programs (National AIDS and STI Control Programme, 2018).

Several factors could be implicated in the increased prevalence of co-morbidities in patients with HIV. A paper published in the Journal of the International AIDS Society, presents a correlation model between data from the Kenya Statistical Abstract, Food and Agriculture Organization (FAOSTAT), and the World Bank's online database on dietary habits, employment, urbanization, and gross domestic product (GDP) (Kasaie et al., 2020). One of the most relevant data according to the model, is that providing treatment for any co-morbidities to 50% of HIV patients from 2019 to 2023, and keeping them on treatment, could prevent 116,000 cardiovascular events and 43,600 deaths in Kenya over the next 15 years. According to the model, the central region of Meru would experience the highest impact with a reduction of 22,200 cardiovascular events. The integrated HIV/NCD intervention could prevent 7.76 million disability-adjusted-life-years (DALYs) over 15 years at an estimated cost of $6.68 billion ($445.27 million per year). Therefore, integrated HIV and NCD screening and treatment are recommended as an effective and cost-effective approach.

CHAO aims at providing epidemiological and operational tools to address the HIV/co-morbidities phenomenon acting at local level of the Meru county, where, according to the Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 (NASCOP and Ministry of Health data) the lowest rates of treatment success of HIV infection programs occur.

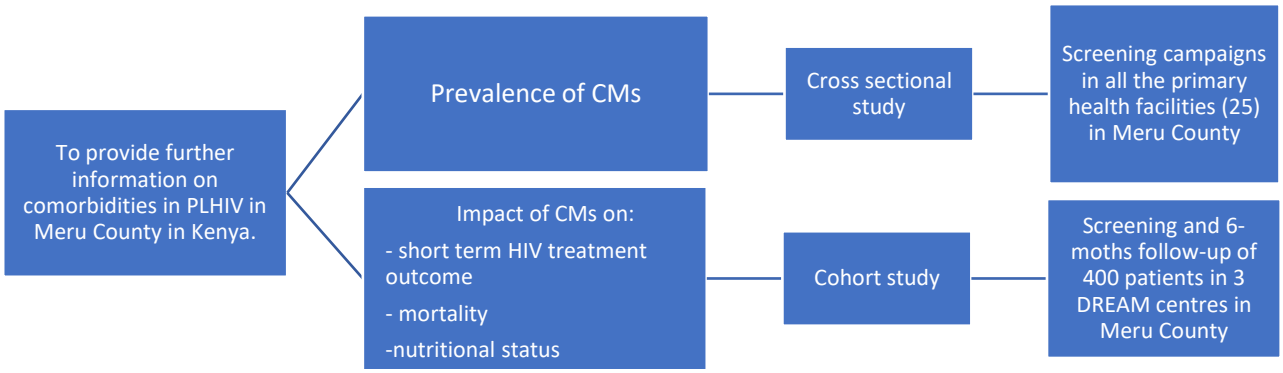
Considering all the limitations of the studies mentioned above, the present study will be based on data collected through systematic screening in primary healthcare facilities that offer HIV services in the Meru County of Kenya. The systematic screening and the rural setting should foster the reliability and scalability of data. In addition, the analysis will consider many different non-communicable diseases, namely tuberculosis, hypertension, diabetes, hepatitis, obesity, syphilis, dyslipidaemia, hypercholesterolemia, hypertriglyceridemia, kidney diseases, and cardiovascular diseases. The focus will be not only on the prevalence of these co-morbidities but also on their effects on the HIV treatment outcome, mortality, and nutritional status. By doing so, the investigation will not be limited to a cross-sectional study, as many other studies reviewed. Instead, a longitudinal and operational study will be executed to inform about the consequences of opportunistic infections in HIV patients.

IV. Research objectives

The general objective of the present study is to provide further information on comorbidities on PLHIV in Meru County in Kenya.
The specific objectives are:

- To understand the prevalence of CMs in PLHIV in the Meru County of Kenya
- To understand the effects of CMs on short-term HIV treatment outcome, mortality and nutritional status of PLHIV

V. Conceptual framework and operationalization



VI. Hypotheses/research question

The research questions of this study are the following:

- What is the prevalence of comorbidities associated with HIV, namely: tuberculosis, hypertension, diabetes, hepatitis, obesity, syphilis, dyslipidaemia, hypercholesterolemia, hypertriglyceridemia, kidney diseases, and cardiovascular diseases, in HIV+ adults treated in basic health facilities in Meru County?

- What is the impact of comorbidities associated with HIV, namely tuberculosis, hypertension, diabetes, hepatitis, obesity, syphilis, dyslipidaemia, hypercholesterolemia, hypertriglyceridemia, kidney diseases, and cardiovascular diseases, on the mortality rate, nutritional status, and short-term HIV treatment success of HIV+ adults treated in HIV clinics in Meru County?

VII. Study Design and Sampling Strategy

The study will be conducted on HIV-positive adults (from 18 years of age onward) assisted in health facilities in the County of Meru in Kenya.
As shown at point V, a cross-sectional study will be carried out to assess the prevalence of CMs in the selected population. In addition, a cohort study will be conducted to make inference on the impact of co-morbidities on short-term HIV-treatment outcome, mortality and nutritional status of PLHIV.
The sites taken into consideration for the cross-sectional study are all (25) basic health facilities in the County of Meru, precisely:

- HWWK Maua Dice (MFL Code 24622)
- Mutiokiama Health Centre (MFL Code 17379)
- Cottolengo Mission Hospital (MFL Code 11977)
- Nyambene District Hospital (MFL Code 12684)
- Consolata Hospital Gitoro (MFL Code 12044)
- Consolata Mission Hospital (MFL Code 11976)
- Gatimbi Health Centre (MFL Code 12031)
- Githongo District Hospital (MFL Code 12041)
- Kanyakine District Hospital (MFL Code 12181)
- Kaongo Health Centre (MFL Code 12192)
- Kiarago Health Centre (MFL Code 12283)9i
- Kibirichia Sub-District Hospital (MFL Code 12282)
- Mikumbune Sub-District Hospital (MFL Code 12526)
- Kinoro Sub-District Hospital (MFL Code 12325)
- Laare Health Centre (MFL Code 12422)
- Maua Methodist Hospital (MFL Code 12492)
- Mutuati Sub-District Hospital (MFL Code 12605)
- Ruiri Catholic Health Centre (MFL Code 12716)
- St Ann Hospital (MFL Code 12743)
- Timau Sub-District Hospital (MFL Code 12802)
- Uruku Health Centre (MFL Code 12831)
- Miathene District Hospital (MFL Code 16234)
- Theere Health Centre (MFL Code 16555)
- St Theresa Kiirua Hospital (Kiirua) (MFL Code 12303)
- Mbeu Sub-District Hospital (MFL Code 12500)
- Meru Teaching and Referral Hospital (MFL Code 125160

Instead, the sites taken into consideration for the cohort study are three DREAM centres in Meru county, eastern province, precisely:

- Cottolengo Mission Hospital, Chaaria (MFL Code 11977)
- Consolata Hospital Nkubu (MFL Code 11976)
- Aina dispensary, Meru (MFL code 20030)

The study focuses on basic health facilities because these are at the same time the most widespread and the least equipped in the county. Being these sites the first entry points of Kenyan patients, people treated in there can be considered as the best representation of the whole Kenyan population.

Criteria for inclusion of subjects: HIV+ patients, age >18,
Criteria for exclusion of subjects: pregnant or lactating women, children

Sampling and data storage: All the patients meeting the inclusion criteria and accepting to be included are going to be enrolled in study.
In each site involved, when patients meet the inclusion criteria, they will be asked to join the study and, if they agree, they will be entered in the datasheet (demographic, anthropometric and clinical data) and samples will be collected in the same day.

EXPLAIN ABOUT SAMPLE PROCESSING

1000 patients participating in cross sectional study will be screened for comorbidities as per National guidelines on enrolment in the study with a confirmed HIV positive test. The tests to be performed for screening include Full blood count, SGOT/SGPT, Creatinine, Lipid profile, Hepatitis B, Hepatitis C, Random blood sugar, CD4 and VDRL. Serum crag as a reflex test for patients with CD4 less than 200 cells/mm.
These samples will be processed in Aina dispensary laboratory, Cottolengo Mission Hospital Laboratory and Consolata Hospital laboratory and results entered on the spreadsheet or database of the study.For patients with symptoms of TB, Gene Xpert will also be performed in regional laboratories with Gene Xpert machine. Viral load and CD4 count will be done as per national guidelines. Viral load samples will be collected at 6 months after initiation of ART and send to KEMRI. CD4 incase indicated as per national guidelines will be collected and send to regional laboratories for processing. All the results will be updated in the study database and or spreadsheet.

400 patients participating in the cohort study will also undergo screening as per national guidelines with the following tests performed upon enrolment in the study; Full blood count, SGOT/SGPT, Creatinine, Lipid profile, Hepatitis B, Hepatitis C , Random blood suger,CD4 and VDRL. Serum crag as a reflex test for patients with CD4 less than 200 cells/mm.These samples will be processed in Aina dispensary laboratory, Cottolengo Mission Hospital Laboratory and Consolata Hospital laboratory and results entered on the spreadsheet or database of the study.Similarly, patients with symptoms of TB, gene xpert will also be performed in regional laboratories with Gene xpert machine. Viral load and CD4 count will be done as per national guidelines. Viral load samples will be collected at 6 months after initiation of ART and send to KEMRI.CD4 incase indicated as per national guidelines will be collected and send to regional laboratories for processing.
This group will also be monitored through the laboratory tests at 3 months and 6 months respectively.

VIII. Data collection

All data will be collected in a specific datasheet elaborated by the partners (DREAM program and Università di Roma Torvergata). It will be excel based and it will be storage in selected and password-protected computers. All data collected on the datasheet will be anonymous.
In each site of the research, some meetings will be held at the beginning of the study to train personnel in charge for the data entry in the datasheet.
A weekly connection of the laboratories with the coordinator of the study will ensure the proper collection of data. Each month a researcher affiliated with the partner university (Università di Roma Torvergata) will control the up to date datasheet and will review data and possibly ask for correction.

All patients enrolled in the study will be HIV+ patients in care in the sites of the study. The HIV and co-morbidities services in the facilities involved in the research are served with protocols and algorithms in accordance with the Kenyan MoH policies and recommendations. Each patient meeting the inclusion criteria will be asked to join the study. They will receive detailed information. In case of acceptance, the patient will undergo further tests for comorbidities, specifically tuberculosis, hypertension, diabetes, hepatitis, obesity, syphilis, dyslipidaemia, hypercholesterolemia, hypertriglyceridemia, kidney diseases, and cardiovascular diseases.
All data will be collected ensuring anonymity and privacy. Each study participant will be properly informed, and a content form will be signed.

IX. Data Processing and Analysis

Each patient in the study will have a unique code that will be associated with the clinical and laboratorial data in order to ensure anonymity and privacy.
The following variables will be collected:

- Demographic variables:
  - Age
  - Gender
- Anthropometric variables:
  - Weight
  - Height
  - BMI
  - BMI for age

The variables will be analysed with the following statistical tools: chi-square test and Fisher exact test for categorical qualitative variables, Student T-test for quantitative variables. Logistic regression model will be used to identify which tests are predictable for TB. SPSS (IBM Corp., NY, USA) will be used for the analysis, with a 0.05 significance level.

X. Plan for Communicating Findings of the Study

Findings will be published on national and international journals and presentations on national and international conferences will be done to disseminate data.
Throughout the study period specific events will be held to meet local stakeholders and communicate preliminary results and research progresses.
An event at the end of the project will be organised to share the results and lessons learnt from the research.
The results of the research could have implication on health policies and give contribution to new TB diagnostic recommendations in the country.

XI. Study Limitations and Risks

A limit of the study is that it will be conducted in a sample of HIV+ patients assisted in regional health facilities, therefore the results could not be applicable to all HIV+ people. That could be a limit but it is also an advantage as the results could provide useful information for policy making and management in these centres.

Another limitation of the study is that the selection of patients could be not exactly random, thus resulting in a sampling bias. This is because the longitudinal study considers only 400 patients in the centres, who probably are the first comers or those who live closer. This undermines the scalability of the analysis to the whole population.

XII. Management and Organization of the Study

Team members, their roles, and management procedures in the study:

First Name	Last Name	Work Position	Organisation	Responsibilities
Stefano	Orlando	Researcher	University of Rome Tor Vergata	• Principal Investigator • Coordinator and Researcher
Fausto	Ciccacci	Researcher	Community of Sant'Egidio DREAM Program	• Study design and overview • Study design,data control and analysis
Giovanni	Guidotti	Director,DREAM Kenya Trust	Community of Sant'Egidio DREAM Program	• International coordinator • Data Overview,Interpretation of results
Giuseppe	Liotta	Associate Professor	University of Rome Tor Vergata	• Study Overview • Data analysis and Interpretation
Mariachiara	Carestia	Researcher	University of Rome Tor Vergata	• Monitoring and Evaluation of Progress • Liason officer between Community of Sant Egidio DREAM Program,University of Rome Tor Vergata and DREAM Kenya Trust
Benjamin Welu	Kithinzi	Clinical Coordinator- Eastern Region	Community of Sant' Egidio, DREAM Kenya Trust	• Local Study coordinator • Investigator • Study design and data control • Data Analysis
Harrison Ndoi	Musyimi	Clinic coordinator-Aina Dispensary	Community of Sant' Egidio, DREAM Kenya Trust	• Investigator • Data collection coordination in Tigania Sub counties • Data control
Irene Karea	Kiogora	Clinic coordinator-Cottolengo Mission Hospital	Community of Sant' Egidio, DREAM Kenya Trust	• Investigator • Data collection coordination in Imenti subcounties • Data control
Regina	Kawira	Nursing Officer-Aina Dispensary	Community of Sant' Egidio, DREAM Kenya Trust	• Health education • Investigator • Data entry

Humphrey Meeta	Kirimi	Health Records and Information officer-Aina Dispensary	Community of Sant' Egidio, DREAM Kenya Trust	• Investigator • Data control • Data aggragation • Data analysis
Eric Mumba	Muthuka	Medical Laboratory Officer-Aina Dispensary	Community of Sant Egidio, DREAM Kenya Trust	• Investigator • Sample processing • Data entry
Kenneth Kirema	Munene	Medical Biotechnologist-Cottolengo Mission Hospital	Community of Sant Egidio, DREAM Kenya Trust	• Investigator • Sample processing • Data entry
Abel Ogwoka	Nyabuto	Nursing officer-Cottolengo Mission Hospital	Community of Sant Egidio, DREAM Kenya Trust	• Health education • Investigator • Data entry
Edward	Karithi	Health Records and information officer-Cottolengo Mission Hospital	Community of Sant Egidio, DREAM Kenya Trust	• Investigator • Data control • Data aggregation • Data analysis
Joseph Murungi	M'ikilanya	County AIDS and STI Coordinator-Meru County	County Government of Meru	• Liason Officer with County team and administration • Data control • Quality Assurance
Albina	Kainda	Clinical officer-Consolata Hospital Nkubu	Consolata Hospital Nkubu	• Health education • Investigator • Data entry
Hellen	Kiende	CCC coordinator-Consolata Hospital Nkubu	Consolata Hospital Nkubu	• Health education • Investigator • Data entry
George Kiriinya	Murithi	Medical Laboratory technologist-Consolata Hospital Nkubu	Consolata Hospital Nkubu	• Investigator • Sample processing • Data entry

Timetable

TIMETABLE																								
Expected duration of the initiative (in months)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Step 1.1 - Preparation of operational research (approval of the ethics committee, (approvazione comitato etico,staff training, procurement of the equippement)																								
1.2 - Realisation of "Health Days" in any dispensary/basic health centre of the County of Meru.																								
1.3 - Active screening for all new HIV patients in 3 DREAM centres and 6 months follow-up.																								
1.4 - Publication and communication of results																								

Budget (Attached as Appendix)

Appendices and References

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