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Cutting down unneeded antibiotics for HIV patients in Mozambique

Submission date
07/05/2024

Recruitment status
No longer recruiting

Registration date
16/05/2024

Overall study status
Ongoing

Last Edited
10/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Antibiotics are globally overprescribed for the treatment of upper respiratory tract infections (URTI), especially in persons living with HIV. However, most URTIs are caused by viruses, and antibiotics are not indicated. De-implementation is perceived as an important area of research that can reduce unnecessary, wasteful, or harmful practices, such as excessive or inappropriate antibiotic use for URTI, through evidence-based interventions to reduce these practices. Research into strategies that lead to successful de-implementation within the primary healthcare setting is limited in Mozambique. This study proposes a protocol to evaluate the use of a clinical decision support algorithm (CDSA) for promoting the de-implementation of unnecessary antibiotic prescriptions for URTI among ambulatory HIV-infected adult patients in primary healthcare settings. This research will provide evidence on the effectiveness of the use of the CDSA in promoting the de-implementation of unnecessary antibiotic prescribing in treating acute URTI, among ambulatory HIV-infected patients. Findings will bring evidence for the need to scale up strategies for the de-implementation practices in additional healthcare sites within the country.

Who can participate?
HIV-infected patients aged between 18 and 99 years old with URTI symptoms in six primary healthcare facilities in Maputo and Matola municipalities in Mozambique

What does the study involve?
This study involves multiple centres across multiple locations and is guided by an implementation science framework, the Dynamic Adaption Process. Two groups (or arms) of patients will be randomly assigned to the intervention or control arms. For intervention sites, the CDSAs will be posted on either the exam room wall or the clinician's exam room desk for ease of reference during clinical visits. The sample size is powered to detect a reduction in antibiotic use by 15%. The study will evaluate the effectiveness and implementation outcomes and examine the effect of multi-level (sites and patients) factors in promoting the de-implementation of unnecessary antibiotic prescriptions. The effectiveness and implementation of the antibiotic de-implementation strategy are the primary outcomes, whereas the clinical endpoints are the secondary outcomes.

What are the possible benefits and risks of participating?
Possible benefits of participating include the enhanced quality of care by reducing unnecessary antibiotic prescriptions and the number of medications that HIV-infected patients are exposed to.

Possible risks of participating include the non-improvement of upper respiratory tract infection symptoms after 5 or 7 days of medication and the onset of complications due to not having received an antibiotic prescription.

Where is the study run from?
University Eduardo Mondlane (Mozambique)

When is the study starting and how long is it expected to run for?
December 2022 to June 2026

Who is funding the study?
Fogarty International Center (USA)

Who is the main contact?
Candido Faiela, candido.faiela@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

Study information

Scientific Title
De-implementation strategy to reduce unnecessary antibiotic prescriptions for ambulatory HIV-infected patients with upper respiratory tract infections in Mozambique: a study protocol of a cluster randomized controlled trial

Study objectives
The de-implementation of antibiotics for the treatment of upper respiratory tract infection in ambulatory HIV-infected adults is possible with the introduction of an appropriate clinical decision support algorithm

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/08/2023, National Bioethics Committee for Health of Mozambique (Ministry of Health, 2nd Floor, Avenue Eduardo Mondlane, Salvadore Allende, Maputo, 00000, Mozambique; +258 824066350; cnbsmocambique@gmail.com), ref: 451/CNBS/23

Study design
Multicenter two-arm cluster randomized controlled implementation science trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
De-implementation of antibiotic use among ambulatory HIV-infected adults with upper respiratory tract infection

Interventions
A multicenter two-arm cluster randomized controlled implementation science trial will be undertaken employing a mixed-methods approach. This study will be guided by two conceptual frameworks, the Dynamic Adaptation Process (DAP) and the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework, and will be carried out in three phases.

Randomization and allocation will be performed before the initiation of the pre-implementation phase in 2 stages. A simple method of randomization using a computer program (Microsoft Excel) will generate a sequence of random numbers corresponding to 6 primary clusters (administrative units). Then for each primary cluster, only one primary healthcare facility (secondary cluster) will be randomly selected to participate in the study using the same program. Assignment and allocation will be at the level of primary cluster randomization to avoid contamination within the participating healthcare facilities (secondary clusters). All participants in the same facility will be assigned to the same treatment, either experiment or control intervention.

Experiment arm: a multifaceted de-implementation strategy that includes health worker education, organizational adjustments, audit and feedback, and roll-out of the Clinical Decision Support Algorithm. Patients will be monitored 5, 10, or 15 days after the initial medical visit to see improvement of symptoms through a phone call, and if necessary, will be asked to visit the healthcare facility for a follow-up clinical examination in person.

Control arm: routine treatment (the clinicians will decide to prescribe medication during each medical visit as they are used to do). No specific intervention will be assigned to the control arm except for follow-up. Patients will be monitored 5, 10, or 15 days after the initial medical visit to see improvement of symptoms through a phone call, and if necessary, will be asked to visit the healthcare facility for a follow-up clinical examination in person.

Intervention Type
Behavioural

Primary outcome(s)
Appropriate non-prescription of antibiotics for upper respiratory tract infection measured using study data collected on a registration form on the day of a medical visit and 5 or 10 days after the initial visit if not recovered

Key secondary outcome(s))
1. The proportion of clinicians who adopted the de-implementation strategy measured using study data collected on the registration form on the day of a medical visit and 5 or 10 days after the initial visit if not recovered
2. Clinician satisfaction with the use of the clinical decision support algorithm measured using an in-depth interview record and a 5-point Likert scale at 6 months of the intervention period (the end of the intervention phase)
3. Fidelity to the de-implementation strategy measured using study data collected on the registration form at the end of the intervention phase
4. Feasibility of use of the clinical decision support algorithm measured using study data collected on the registration form and in-depth interview records at the end of the intervention phase

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adult HIV-infected patients with URTI symptoms
2. Frontline healthcare workers in selected primary healthcare clinics providing HIV care and treatment services

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
379

Key exclusion criteria
1. Adult HIV-infected patients without URTI symptoms
2. Fever ≥39°C
3. Severe mental illness
4. Advanced HIV status

Date of first enrolment
01/06/2024

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Mozambique

Study participating centre
Health Center Matola 2
Matola
Mozambique
0000

Study participating centre
Health Center Bagamoyo
Maputo
Mozambique
0000

Study participating centre

Health Center 1st of May
Maputo
Mozambique
0000

Study participating centre
Health Center Ndlavela
Matola
Mozambique
0000

Study participating centre
Health Center Alto Mae
Maputo
Mozambique
0000

Study participating centre
Health Center Hulene
Maputo
Mozambique
0000

Sponsor information

Organisation
Tulane University

ROR
https://ror.org/04vmvtb21

Funder(s)

Funder type
Research organisation

Funder Name
Fogarty International Center

Alternative Name(s)
Fogarty, Fogarty at NIH, John E. Fogarty International Center, John Edward Fogarty International Center, NIH John F. Fogarty International Center, NIH's Fogarty International Center, NIH Fogarty International Center, Fogarty International Center at NIH, Fogarty International Center, U.S. National Institutes of Health (NIH), Fogarty International Center AT THE NATIONAL INSTITUTES OF HEALTH, FIC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analyzed during the current study will be stored in a publicly available repository at https://osf.io./r2kw4. Consent from participants was required and will be obtained. An original consent form is attached to this registration. Participants will be de-identified through codes. All identifying information will be kept locked in a file at the Faculty of Medicine of Eduardo Mondlane University in Maputo.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/07/2025	10/07/2025	Yes	No
Protocol article		16/07/2024	17/07/2024	Yes	No
Participant information sheet	Portuguese version 4.0	01/08/2023	10/05/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	Portuguese version 4.0	01/07/2023	10/05/2024	No	No