

# Cutting down unneeded antibiotics for HIV patients in Mozambique

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| <b>Submission date</b><br>07/05/2024   | <b>Recruitment status</b><br>No longer recruiting        | <input checked="" type="checkbox"/> Prospectively registered |
|  |  | <input checked="" type="checkbox"/> Protocol                 |
| <b>Registration date</b><br>16/05/2024 | <b>Overall study status</b><br>Ongoing                   | <input type="checkbox"/> Statistical analysis plan           |
|  |  | <input checked="" type="checkbox"/> Results                  |
| <b>Last Edited</b><br>10/07/2025       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> 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 URIs 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

### Contact name

Mr Candido Faiela

### ORCID ID

<https://orcid.org/0000-0002-6746-9343>

### Contact details

University Eduardo Mondlane

Avenida Salvador Allende

Maputo

Mozambique

0000

+258 847145631

candido.faiela@gmail.com

## 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  $\geq 39^{\circ}\text{C}$
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

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**Study participating centre**

**Health Center Bagamoyo**

Maputo

Mozambique

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**Study participating centre**

**Health Center 1st of May**

Maputo  
Mozambique  
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**Study participating centre****Health Center Ndlavela**

Matola  
Mozambique  
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**Study participating centre****Health Center Alto Mae**

Maputo  
Mozambique  
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**Study participating centre****Health Center Hulene**

Maputo  
Mozambique  
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**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? |
|---|------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |                        | 02/07/2025   | 10/07/2025 | Yes            | No              |
| <a href="#">Protocol article</a>              |                        | 16/07/2024   | 17/07/2024 | Yes            | No              |
| <a href="#">Participant information sheet</a> | Portuguese version 4.0 | 01/08/2023   | 10/05/2024 | No             | Yes             |
| <a href="#">Protocol file</a>                 | Portuguese version 4.0 | 01/07/2023   | 10/05/2024 | No             | No              |