



MWOTAJI

Making **W**omen's **O**ptions for HIV Prevention
in **T**anzania **A**ccessible and **J**oining in **I**mplementation
Science Capacity Building

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MWOTAJI Objectives

The goal of the Mwotaji (“Dreamer”) PATC³H-IN Clinical Research Center is for adolescent girls and young women (AGYW) in Tanzania to dream of a future where they can reliably and safely access HIV prevention and reproductive health services through public-private partnerships.

To achieve this, we will identify the strongest and most sustainable version of a pharmacy-based PrEP implementation strategy (Malkia Klabu) for AGYW. We will also launch an implementation science training program to enable locally-led scaling and adoption.



AIM 1: Adapt the Malkia Klabu implementation strategy for pharmacy-based PrEP distribution for AGYW and evaluate four models on pharmacy adoption and implementation, and after addition of user cost-sharing, maintenance.



AIM 2: Evaluate Malkia Klabu implementation strategies for pharmacy-based PrEP distribution for AGYW on effective use of PrEP, reach, and maintenance.



AIM 3: Create an Implementation Science Certificate program at Mzumbe University to build Tanzania’s capacity to lead policy-relevant implementation science research to benefit AGYW and beyond.

MWOTAJI

Overview & Setting

Overview

- **Design:** Type 3 Hybrid Effectiveness-Implementation study
- **Objective:** Expand access to youth-friendly HIV prevention services for AGYW through pharmacies

Setting

- **3 regions** in the Lake Zone of Tanzania
 - Geita
 - Kagera
 - Shinyanga
- **5 Clinical Research Performance Sites (CRPS)**





Malkia Klabu (The Queen Club)





Malkia Klabu (Queen Club)

Using human-centered design and behavioral economics, we developed a multifaceted, girl-friendly **loyalty program** intervention through which AGYW can:

- ✓ Interact with a **hands-on display** of SRH products, including long-acting contraceptives for which they can receive **tailored referrals**
- ✓ Earn punches on a loyalty card with any pharmacy purchase that can be redeemed for **prizes of increasing value** (e.g., lotion, pads) at future visits

Loyalty Card (Front)



Attachable MK sticker

Example prizes: Lotions and nail polish



Loyalty Card (Back)



SRH Product Display:
to be adapted with MK
colors



Study Design





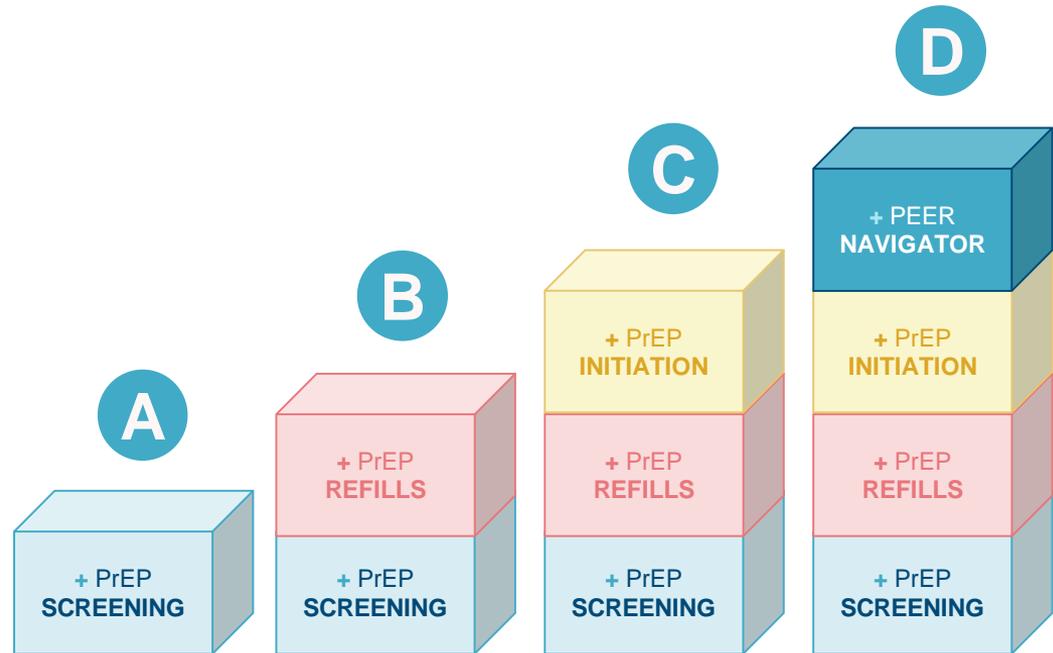
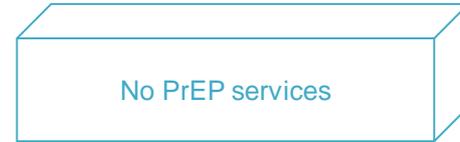
Two-Phase Implementation Study

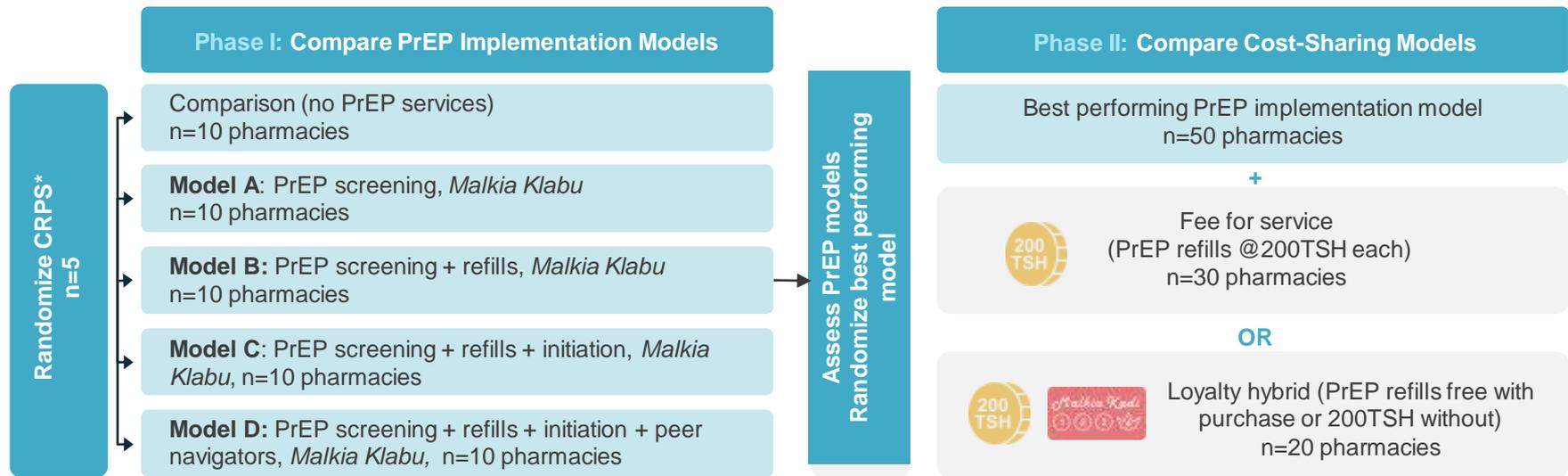
Phase I (months 0-12), four pharmacy-based PrEP models with Malkia Klabu loyalty program, each with increasing levels of PrEP integration, and compared to standard pharmacy services

Phase II (months 12-24): Pharmacies will converge to the best performing implementation model and will be randomly assigned to one of two cost-sharing structures for PrEP refills



Comparison Model:





AGYW Cohort Study (n=1,000)



Sub-studies: Household Survey, Pharmacy Staff, Health Facility Staff/Stakeholders



*CPRS: Clinical research performance site

Eligibility Criteria

Pharmacies

- 
- Geographically located within one of five CRPS in Shinyanga, Geita or Kagera regions of Tanzania;
 - Located within 4 km of at least 1 health facility that provides PrEP services and whose lab conducts creatinine and hepatitis B testing;
 - Pharmacy has a private space in which to conduct HIV testing; and
 - No planned extended closures over the next 24 months.

Cohort Study with AGYW

- 
- Female sex;
 - Age 15-24 at the baseline visit;
 - Living in a CRPS with no known plans to move;
 - Interested in starting PrEP;
 - Access to a mobile phone (either own phone or borrowed phone); and
 - Eligible for PrEP based on Tanzania National PrEP Guidelines¹

Pharmacy Staff

- 
- Pharmacy owners and staff affiliated with study pharmacies; and
 - ≥18 years of age

Household

- 
- Female sex;
 - Age 15-24; and
 - Living in a CRPS

Stakeholders

- 
- Staff employed at referral health facilities within one of five CRPS in Shinyanga, Geita or Kagera regions of Tanzania or local, regional, or national government officials;
 - ≥18 years of age

Procedures

Activity	Content	Timeline	
	<p>Cohort surveys</p>	<p>60-minute survey on pharmacy-based PrEP/Malkia Klabu, PrEP knowledge/attitudes/self-efficacy, discontinuation (if applicable)</p>	<p>Baseline, 1, 3, 6, 12, 24 months</p>
	<p>Phone check-ins</p>	<p>10-minute phone “wellness” check-ins to keep AGYW engaged with the study between surveys, abbreviated PrEP eligibility screening</p>	<p>All months with no cohort survey</p>
<p>MM</p>	<p>Maisha Meds</p>	<p>PrEP eligibility screening, refill tracking, inventory management</p>	<p>Baseline – 24 months</p>
	<p>Health facility data abstraction</p>	<p>Aggregate data abstracted in referral health facilities</p>	<p>Every 6 months</p>
	<p>Pharmacy staff surveys</p>	<p>60-minute survey on PrEP knowledge/attitudes, experience providing PrEP services and Malkia Klabu</p>	<p>Baseline, 12, 24 months</p>
	<p>Household survey</p>	<p>60-minute survey on pharmacy-based PrEP exposure, Malkia Klabu exposure, knowledge and use of PrEP</p>	<p>12 months</p>
	<p>Stakeholder surveys</p>	<p>60-minute survey on PrEP knowledge/attitudes, PrEP services 60-minute survey on acceptability and sustainability of PrEP models</p>	<p>Baseline, 12, 24 months (facility staff) 12 months (government stakeholders)</p>

Primary outcomes: phase I

Outcome	Definition	Level / Population	Data Sources	Time Points
Effective use of PrEP	Received a PrEP refill for all months during which an AGYW reports being at risk for HIV and PrEP eligible over the 12-month study period	Individual / AGYW	Maisha meds, cohort survey, phone check-in   	12 months
Persistent use of PrEP	Picked up all scheduled PrEP refills without a delay of >28 days over the 12-month study period	Individual / AGYW	Maisha meds, cohort survey, phone check-in   	12 months
Reach of pharmacy-based PrEP models	Heard of pharmacy-based PrEP services (including screening, referrals, refills, or initiation)	Individual / AGYW	Household survey 	12 months

*Effective and persistent use of PrEP will be evaluated only among AGYW who enroll in the cohort study *and initiate PrEP*.

Cost-sharing outcomes: phase II

Outcome	Definition	Level / Population	Data Sources	Time Points
Maintenance	Picked up PrEP refill during cost-sharing portion of study (phase II)	AGYW	Cohort survey 	24 months
PrEP refill revenue	Cumulative revenue derived from PrEP refill visits in the cost sharing phase over 12 months	Pharmacy	Maisha Meds 	12 months
Cost per high-risk AGYW per year	Cost of all PrEP services provided to AGYW through pharmacies	Pharmacy	Maisha Meds 	12 months 24 months

MWOTAJI CAPACITY BUILDING

An **Implementation Science Certificate** program at Mzumbe University (MU) will build Tanzania's capacity to lead policy-relevant implementation science research to benefit AGYW and beyond



Core Components:

- 1 Building on a long history of co-developing bespoke training programs to capacitate local governments, we will **co-create curricula for an IS certificate program** to supplement existing courses offered at MU
- 2 **Twin UCSF and UCB faculty** with MU faculty and Tanzanian policy makers to **enhance capacity for IS training in Tanzania**
- 3 Develop the first of its kind **Certificate in Implementation Science focusing on vulnerable populations** grounded in defined IS competencies
- 4 Implement and evaluate the program in **four trainee cohorts**
- 5 Provide opportunities for real-world application through an **experiential practicum** and opportunity for **seed grants to conduct implementation research** related to Malkia Klabu
- 6 Create a **community of practice** comprised of Certificate alumni and faculty to benefit current and future student cohorts and implementation research for AGYW



MWOTAJI SUSTAINABILITY



COST SHARING STUDY

To ensure that Malkia Klabu can continue after the research study, we will conduct a user cost-sharing study in months 13-24 to compare a loyalty hybrid model vs. fee for service



MEASUREMENT OF REACH

A household survey in Year 3 will measure exposure to Malkia Klabu in each CRPS among 750 AGYW; information that can be used to guide future program implementation

IMPLEMENTATION SCIENCE CERTIFICATE

An implementation science training program at Mzumbe University will enable locally-led scaling and adaption of Malkia Klabu and other initiatives to benefit AGYW in the future



PrEP EFFECTIVE USE

We will complement our knowledge about how Malkia Klabu increases AGYW access to SRH products (e.g., HIVST, PrEP) with data on effective use from a prospective cohort study





Thank you
Asante sana



Extra slides