

JULY  
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# OPTIONS

## Optimizing Prevention Technology Introduction On Schedule

### PrEP Modeling Gap Analysis

*OPTIONS is one of five cooperative agreements awarded by USAID with PEPFAR funding through Round Three of the Annual Program Statement (APS) for Microbicide Research, Development, and Introduction. The five cooperative agreements are also known collectively as the Microbicide Product Introduction Initiative (MPii). These five-year awards continue and expand USAID's support, in partnership with PEPFAR, for microbicide introduction and access with advances in biomedical technologies and new approaches for HIV prevention.*



**Where We Work**



**Objective**

*Provide targeted support to help expedite and sustain access to new ARV-based HIV prevention products in countries and among populations where most needed.*

**Consortium Partners**



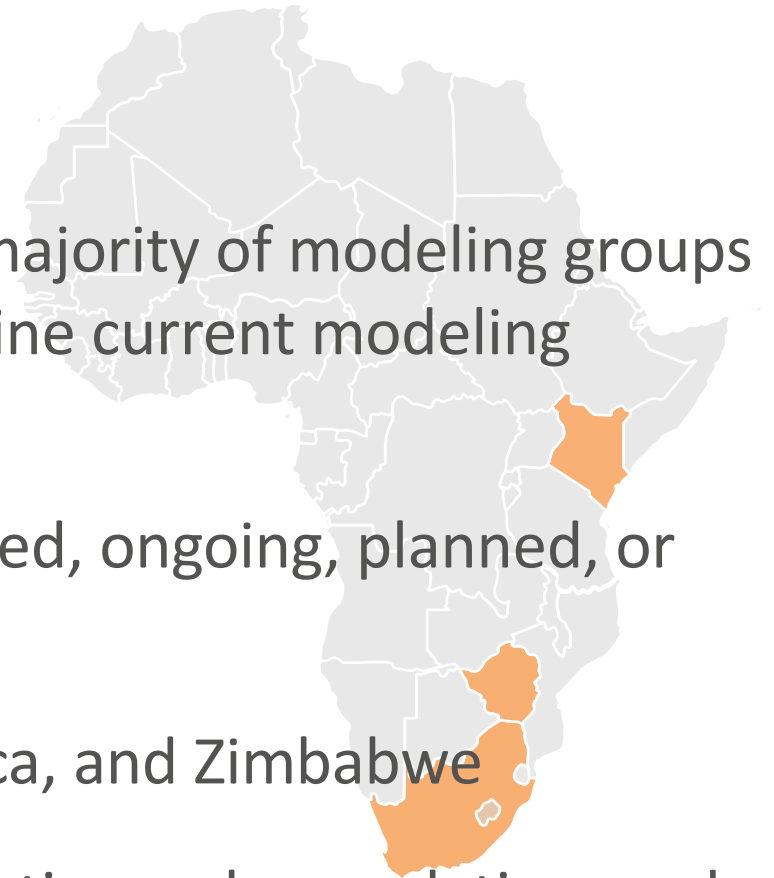
# How we work



- Our support is flexible and is designed to be **responsive to global regional and national country priorities and plans**
- We have **strong in-country partners**, e.g. Wits RHI, Pangaea and LVCT Health, with significant experience working on HIV prevention in the South Africa, Zimbabwe, and Kenya contexts
- In addition to local partners, our consortium is able to bring **multi-disciplinary expertise** to the effort to introduce female-controlled HIV prevention products in sub-Saharan Africa
- We are taking significant steps to ensure we do not replicate existing or ongoing work – our mission is to **fill gaps and help answer key questions** as outlined by global stakeholders, national governments, USAID missions, and other key local stakeholders
- OPTIONS is not a service delivery project; we apply **systems thinking to support and accelerate** product introduction

# Gap Analysis Methodology

- Literature review
- Phone/email interviews with the majority of modeling groups working in the HIV field to determine current modeling activities
- Analysis includes recently completed, ongoing, planned, or proposed PrEP modeling
- Country focus is Kenya, South Africa, and Zimbabwe
- Studies organized by research question, sub-population, and country



# Modeling Literature Review Methodology

*Aim: To identify the scope of the completed PrEP and microbicide modeling as part of an assessment to identify current modeling needs. This literature review did not attempt to assess the quality of the work but rather to identify the work and obtain a broad overview of the findings.*

- OPTIONS collected a total of 64 modeling studies, reviews and analyses focused on the impact, cost, cost-effectiveness, drug resistance and other parameters of both PrEP and microbicides. Study publication dates range from 2003 to 2016. Study types included modeling on public health impact and cost- effectiveness as well as reviews of existing modeling work.
- Of these studies, 46 looked at PrEP, 16 at microbicides and one at both PrEP and microbicides. Of these, eight studies are meta-analyses or reviews focused on PrEP and look at impact, cost- effectiveness and drug resistance.
- The literature review was conducted through peer reviewed journal and abstract searches using key terms, the snowball method, and mining of study collections from internal partners.

# Modeling Literature Review Overview

*Studies and reviews looked at the following parameters:*

<i>Measures/includes</i>	<i>Total</i>	<i>PrEP</i>	<i>Microbicide</i>	<i>Both</i>
<b>Impact</b>	37	<b>25</b>	11	1
<b>Cost/cost-effectiveness</b>	27	<b>23</b>	3	1
<b>Drug resistance</b>	15	<b>14</b>	1	0

*Studies and reviews specifically identified the following populations:*

<i>Population</i>	<i>Total</i>	<i>PrEP</i>	<i>Microbicide</i>	<i>Both</i>
<b>Heterosexual serodiscordant couples</b>	3	<b>3</b>	0	0
<b>Female sex workers (FSW)</b>	8	<b>5</b>	3	0
<b>Young women</b>	4	<b>3</b>	1	
<b>Men who have sex with men (MSM)</b>	15	<b>12</b>	3	0
<b>Young MSM</b>	2	<b>2</b>	0	0

*Studies and reviews focused on the following geographic areas:*

<i>Region</i>	<i>Total</i>	<i>PrEP</i>	<i>Microbicide</i>	<i>Both</i>
<b>East, South and South-East Asia</b>	6	<b>2</b>	4	0
<b>North America</b>	8	<b>7</b>	1	0
<b>South America and Caribbean</b>	3	<b>2</b>	1	0
<b>Sub-Saharan Africa</b>	37	<b>29</b>	7	1
<b>Eastern Europe and Central Asia</b>	2	<b>1</b>	1	0

# Modeling Literature Review Overview

- *PrEP has been extensively modelled*
- Majority of studies focus on South Africa, with fewer focusing on Kenya, and a small number focusing on Zimbabwe
- Health impact and cost-effectiveness two most common research questions addressed
- Female sex workers (FSW), adolescent girls and young women (AGYW) and unspecified populations most common populations studied
- Most studies looking at cost/cost-effectiveness concluded while PrEP can confer significant benefit it requires substantial expenditure

# Modeling Literature Review Summary

- Most modeling studies looking at cost and cost-effectiveness concluded that while PrEP can confer significant benefit, it requires substantial expenditure
- Several studies found that maximal cost-effectiveness is achieved by providing treatment to a greater number of infected individuals earlier rather than providing PrEP to uninfected individuals.
- Some modeling predicted that for PrEP to be most cost-effective it should be used before treatment reaches a saturation level while noting that early treatment alone cannot reduce HIV incidence enough (Cremin, 2013; Pretorius, 2010; Supervie, 2011)

1. Cremin, I., et al., *The new role of antiretrovirals in combination HIV prevention: a mathematical modelling analysis*. AIDS, 2013. **27**(3): p. 447-58.
2. Pretorius, C., et al., *Evaluating the cost-effectiveness of pre-exposure prophylaxis (PrEP) and its impact on HIV-1 transmission in South Africa*. PLoS One, 2010. **5**(11): p. e13646.
3. Supervie, V., et al., *Modeling dynamic interactions between pre-exposure prophylaxis interventions & treatment programs: predicting HIV transmission & resistance*. Sci Rep, 2011. **1**: p. 185.



# Modeling Questions

- What is the **total estimated demand for PrEP** within each key population (e.g., AGYW, MSM, FSW)?
- What is the **projected health impact** (e.g., HIV incidence and prevalence reductions) of adding PrEP to the mix of current HIV prevention and treatment interventions? Is it possible for national HIV prevalence and incidence reduction targets to be reached without investing in PrEP?
- What is the **incremental unit cost** of delivering PrEP through existing or new channels to reach key populations?
- What is the projected **incremental cost-effectiveness ratio (ICER)** of adding PrEP for a specified population to the mix of current HIV prevention and treatment interventions? Is PrEP for a given population cost-effective relative to international standards?
- What are the **potential cost savings** of delivering PrEP in terms of lower ART costs?

# Gaps in modeling data: Demand

Question	Population	published (L), conducted (C), ongoing (O), planned (P), or proposed (M) work; numbers refer to row number of relevant worksheet			
		Kenya	South Africa	Zimbabwe	other sub-Saharan Africa
What is the <b>total estimated demand</b> for PrEP within each key population (e.g., AGYW, MSM, FSW)?	AGYW		O12 <i>(uptake predictions from DCE)</i>		
	FSW		O12 <i>(uptake predictions from DCE)</i>		
	Sero-discordant couples				
	MSM				
	IDU				

# Gaps in modeling data: Impact

Question	Population	published (L), conducted (C), ongoing (O), planned (P), or proposed (M) work; numbers refer to row number of relevant worksheet			
		Kenya	South Africa	Zimbabwe	other sub-Saharan Africa
What is the projected <b>health impact</b> (e.g., HIV incidence and prevalence reductions) of adding PrEP to the mix of current HIV prevention and treatment interventions? Is it possible for <b>national HIV prevalence and incidence reduction targets</b> to be reached without investing in PrEP?	AGYW	M3, M5	O12, C13, O14, O15, M19, O21, L44	O21, O24, L51	
	FSW	C2, M3, M5, L18, L53	O11, O12, C13, O14, M19	O22	
	sero-discordant couples	O3	L11, L39		O3 (Uganda)
	MSM	M3, C2	P14, O16, M14		
	IDU				
	unspecified	P8, L16 (PrEP within combo prevention), L53	P8, P8 (cabotegravir), P20, L13, L15, L22, L23, L25, L29, L31, L33 (women), L35, L44	P20, P23, O24	O27, O28, L17 (global), L27 (Zambia), L30 (SSA), L31 (Zambia), L38 (Botswana), L57 (SSA)

# Gaps in modeling data: Cost-effectiveness

Question	Population	published (L), conducted (C), ongoing (O), planned (P), or proposed (M) work; numbers refer to row number of relevant worksheet			
		Kenya	South Africa	Zimbabwe	other sub-Saharan Africa
What is the incremental <b>unit cost</b> of delivering PrEP through <b>existing or new channels</b> to reach key populations?	AGYW	C6, O7	BMGF		
	FSW	L20, L21, C6, O7	O9	O22	
	sero-discordant couples				
	MSM	C6, O7			
	IDU				
What is the projected <b>incremental cost-effectiveness ratio (ICER)</b> of adding PrEP for a specified population to the mix of current HIV prevention and treatment interventions? Is PrEP for a given population cost-effective relative to international standards?	AGYW	M5	C13, O14, M19, L7, L44		
	FSW	C2, M5, L18	O9, C13, O14, M19	O22	
	sero-discordant couples		L11, L39	L2	L2 (Uganda), L10 (Mozambique)
	MSM	C2	P14		
	IDU				
What are the potential <b>cost savings</b> of delivering PrEP in terms of <b>lower ART costs</b> ?	AGYW	M5	C13, O14, M19		
	FSW	C2, M5	C13, O14, M19	O22	
	sero-discordant couples				
	MSM	C2	P14		
	IDU				
	unspecified	P8	P8	P23	O27
	unspecified	P8	P8 (cabotegravir), L15, L22, L29, L33 (women), L44	P23	O27, L27 (Zambia), L30 (SSA)
	unspecified	P8	P8	P23	O27

# Gaps: OPTIONS modeling questions

What is missing from the PrEP modeling studies conducted to date are answers to the following questions, of particular relevance to *policymakers*:

1. **Are there specific subpopulations\* in [country of interest] for which providing PrEP may:**
  - a) Provide a large additional epidemiological impact, in addition to the existing suite of prevention interventions and scale-up of ART?
  - b) Be cost-effective?
2. **How does differential uptake by different subpopulations modify the impact projections?**
  - a) Which new ARV-based prevention options best satisfy adolescent girls' and young women's own needs (preferences)?
  - b) What are the risk profiles and sociodemographic characteristics of women who prefer PrEP?
3. **Does it cost more to reach higher risk subgroups of women?**
  - a) How does this affect the cost-effectiveness projections?

Once the populations for PrEP provision have been decided upon through discussions with policymakers, donors, and program planners, based on the modeling and other considerations, the following modeling questions will need to be addressed for *program planning*:

4. **How many people will require PrEP in [country of interest] in [time frame defined by policymakers]?**
  - a) National demand projections will be disaggregated by district/county/province, risk group, and service delivery model
5. **How much will it cost?**
6. **What will be the projected impact?**

*\*Subpopulations may be defined by risk group, age, sex, geography, access to other healthcare services, and other factors.*

# What's needed to answer questions for policymakers?

- **Country-specific primary data** are needed; in the case of risk group population size, epidemiology, and behavior, the data may already be available through existing sources
- However, for PrEP-specific questions about uptake, adherence, cost of different service delivery models and reaching different subpopulations, **the data will likely come from the demonstration projects and other primary data collection**; the availability of these data may be a limiting factor for the modeling
- In addition to the data, a **detailed age-structured model** is needed to assess the potential additional epidemiological impact of providing specific subpopulations of AGYW with PrEP in the context of scale-up of antiretroviral treatment and voluntary medical male circumcision

# What's needed to answer questions for program planning?

- To estimate questions of demand, health systems resource utilization and total program cost, additional information is needed regarding the **cost of PrEP through different delivery channels for different subpopulations in each country**
  - Most of these cost data have not yet been collected, given that implementation is still in the early stages, and implementation strategies are still being worked out in the context of the demonstration studies
- In addition, information needs to be collected about the **size of specific subpopulations** (e.g., highest risk adolescent girls and young women, sex workers with different behavioral and risk characteristics) and about **existing and possible expansion capacity of the delivery systems** that would be utilized for PrEP
- If these data are available or become available, additional modeling can be conducted to assist with quantifying demand and projecting total cost and impact of a given PrEP targeting strategy

# Thank you

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