3

Oral PrEP Introduction Planning Toolkit

STEP 3: ROLLOUT SCENARIOS

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OPTIMIZING PREVENTION TECHNOLOGY INTRODUCTION ON SCHEDULE

About this toolkit

WHAT IS THE PURPOSE AND CONTENTS OF THIS TOOLKIT?

- This toolkit was developed and used by the OPTIONS Consortium to support planning for the introduction of oral PrEP for HIV prevention in Kenya, Zimbabwe and South Africa.
- This toolkit is designed to help users in other countries plan for the introduction and rollout of oral PrEP

WHO SHOULD USE THIS TOOLKIT?

This toolkit will be most relevant for:

National governments and ministries of health/HIV agencies to inform national and regional oral PrEP rollout and provide high-level guidance to counties/districts on what factors should be considered to ensure they are prepared to rollout oral PrEP

Implementing organizations (e.g., NGOs) to understand national and regional needs related to oral PrEP delivery and to support effective resource allocation

Donors (e.g., USAID) to initially scope country-specific needs and resource requirements

HOW COULD THE TOOLKIT BE MORE USEFUL?

If you have thoughts, feedback, questions, requests for additional information or other resources that you would like to add to this toolkit, please contact Neeraja Bhavaraju at FSG (an OPTIONS consortium member) at neeraja.bhavaraju@fsg.org.

Please acknowledge USAID/OPTIONS with use of this toolkit.

Value Chain for oral PrEP Introduction

The templates, frameworks and tools included in this toolkit are organized along a simplified oral PrEP "value chain" that charts what is needed for national and subnational introduction of oral PrEP through five major stages, from initial planning through to uptake and ongoing monitoring.

While this toolkit is intended to support users primarily with the first stage of the value chain: planning, it is important to analyze assets and gaps at each stage to inform a comprehensive and robust planning process. This framework can also be adapted for other HIV prevention products

Value Chain for oral PrEP

PLANNING AND BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
Plan developed to implement WHO oral PrEP guidelines for end user populations	Oral PrEP produced, purchased, and distributed in sufficient quantity to meet projected demand	Oral PrEP services delivered through appropriate channels with access to end user populations	End user populations seek and are able to access oral PrEP and begin use	End users adhere to PrEP in recommended frequency and time period; use is effectively monitored

This is the third tool in a series of six

1	2	3	4	5	6
SITUATION ANALYSIS	**PROJECT LANDSCAPE**	**ROLLOUT SCENARIOS**	**DISTRICT READINESS ASSESSMENT**	**FACILITY READINESS ASSESSMENT**	**PRIVATE SECTOR ASSESSMENT**
Understand current context for oral PrEP - Identify existing assets, gaps, challenges, and key questions for PrEP rollout - Develop a landscape of key stakeholders and ongoing efforts	**Assess findings & gaps in projects** - Survey current and planned studies and implementation projects - Identify key questions to inform implementation and assess gaps	**Inform where and how to rollout PrEP** - Define rollout scenarios that differ by counties/ districts or population groups - Highlight considerations and trade-offs between different scenarios	**Assess district readiness for oral PrEP** - Assess district/ county readiness to introduce and scale oral PrEP - Support sub-national planning for oral PrEP rollout and scale-up	**Assess facility readiness for oral PrEP** - Assess the readiness of healthcare facilities to deliver oral PrEP - Identify areas that require additional investment	**Identify opportunities for oral PrEP in the private sector** - Understand if private sector channels could expand PrEP access - Compare across channels for ability to effectively deliver PrEP

ROLLOUT SCENARIOS
Overview of contents

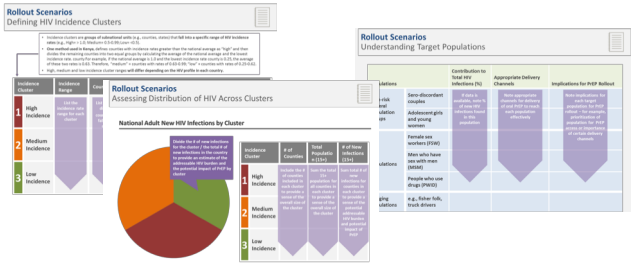
This tool provides a structured analysis that will help frame decisions about where and to whom to rollout oral PrEP within a country. While this does not replace more rigorous cost-effectiveness modeling, it does provide general estimates that can be produced quickly with existing data.

DATA COLLECTION

Guide data collection on HIV incidence and target populations for oral PrEP across districts / counties to inform analysis

SLIDES 7 - 10

Data collection templates

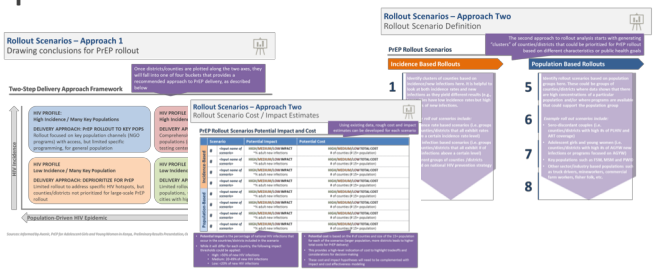


ANALYSIS & SYNTHESIS

Assess **need** for oral PrEP and **develop scenarios for oral PrEP delivery** to support decision-making and implementation plan development

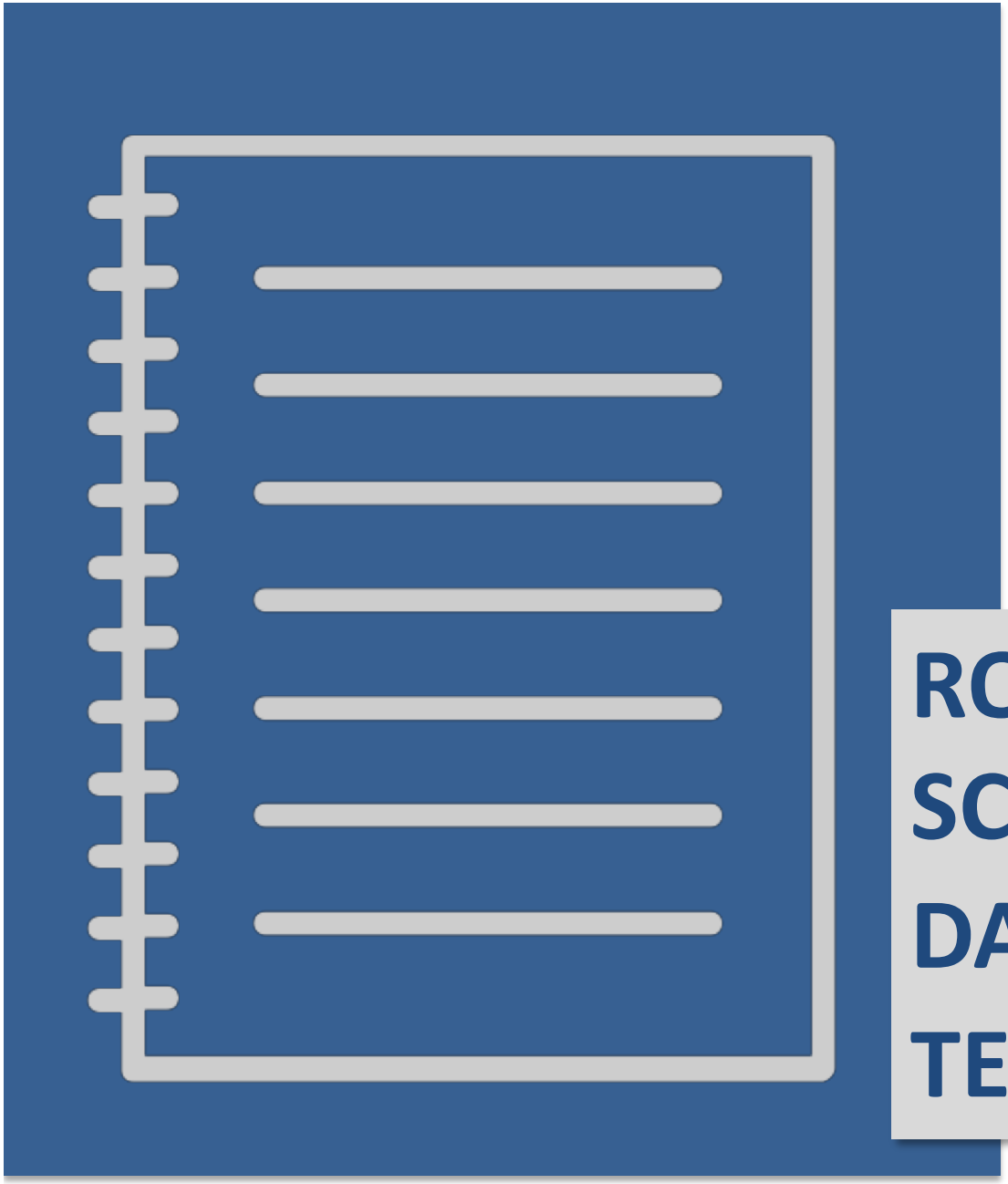
SLIDES 12 - 22

Templates to synthesize and present collected data



Completed Rollout Scenarios to Reference

Kenya | Zimbabwe



ROLLOUT SCENARIOS DATA COLLECTION TEMPLATES

Rollout Scenarios
Data Collection in Excel

Collecting data in an Excel file enables easy analysis across counties/districts.

A sample Excel template can be found here.

ORAL PrEP INTRODUCTION PLANNING TOOLKIT
STEP THREE - ROLLOUT SCENARIOS
Note: This includes a basic list of data, but additional data can be included as available

	Population				HIV Incidence				
Indicator	Total Population 15+	Population Women 15+	Population Men 15+	Population Age 15 - 24	Adult HIV Incidence (%)	Adult HIV New Infections	Adult Female New Infections	Adult Male New Infections	New Infections Age 15 - 24
Data Source									
National Average									
County / District									
County / District A	#	#	#	#	%	#	#	#	#
County / District B	#	#	#	#	%	#	#	#	#
County / District C	#	#	#	#	%	#	#	#	#
County / District D	#	#	#	#	%	#	#	#	#

Rollout Scenarios
Defining HIV Incidence Clusters

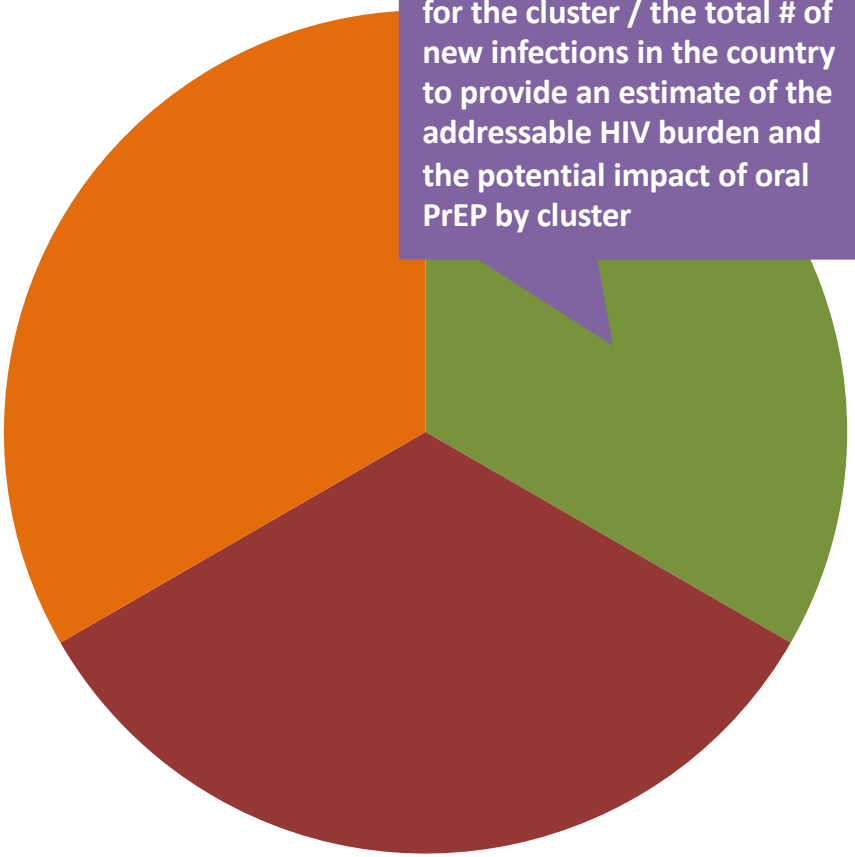
- Incidence clusters are **groups of subnational units** (e.g., counties, states) that **fall into a specific range of HIV incidence rates** (e.g., High= >0.99; Medium= 0.5-0.99; Low= <0.5).
- **One method used in Kenya**, defines counties with incidence rates greater than the national average as "high" and then divides the remaining counties into two equal groups by calculating the average of the national average and the lowest incidence rate county. For example, if the national average is 1.0 and the lowest incidence rate county is 0.25, the average of these two rates is 0.63. Therefore, "medium" = counties with rates of 0.63-0.99; "low" = counties with rates of 0.25-0.62.
- High, medium and low incidence cluster ranges **will differ depending on the HIV profile in each country.**

Incidence Cluster		Incidence Range	Counties/Districts Included
1	High Incidence	List the incidence rate range for each cluster	List names of districts/ counties that fall in each cluster
2	Medium Incidence		
3	Low Incidence		

Rollout Scenarios

Assessing Distribution of HIV Across Clusters

National Adult New HIV Infections by Cluster

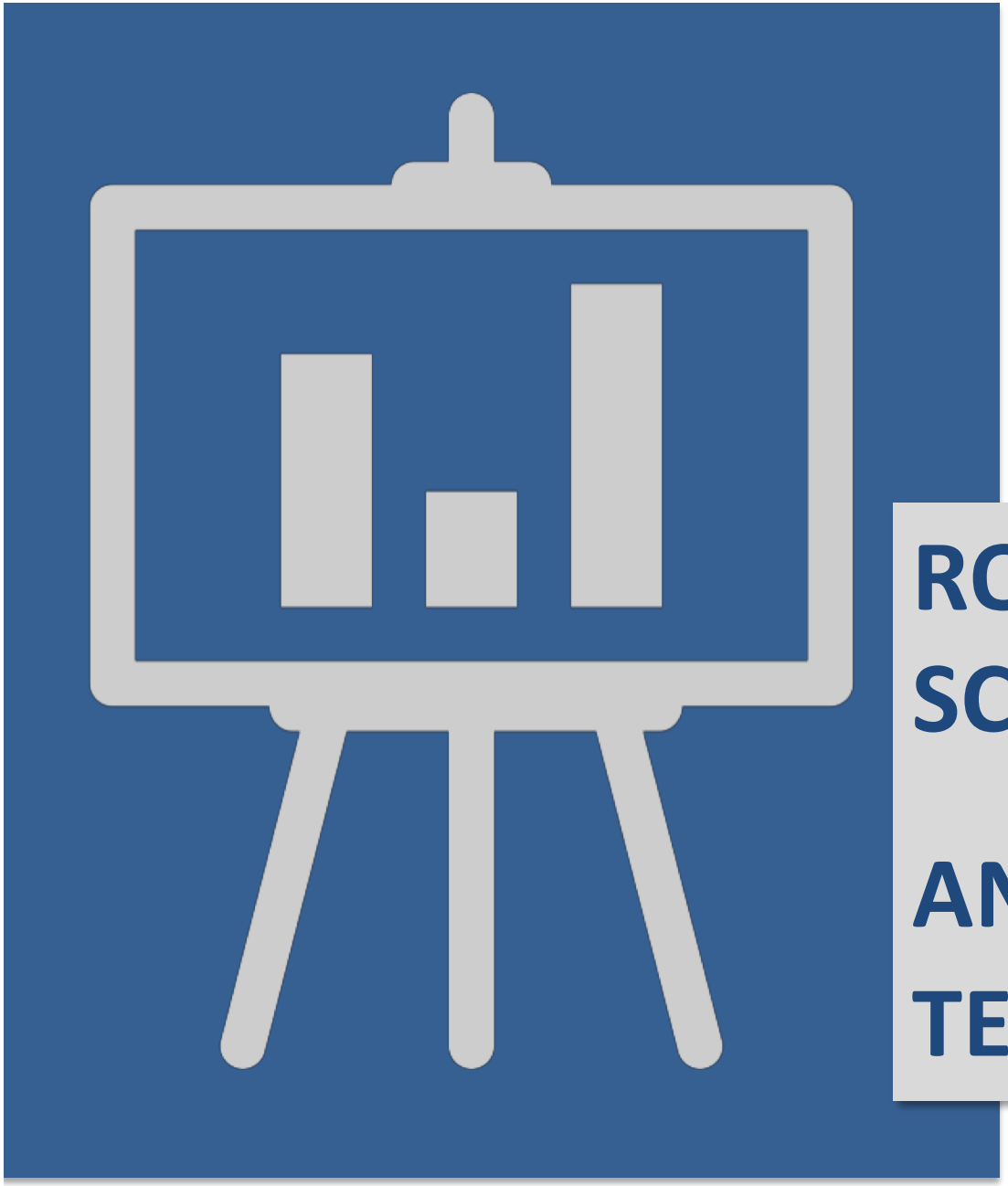


Divide the # of new infections for the cluster / the total # of new infections in the country to provide an estimate of the addressable HIV burden and the potential impact of oral PrEP by cluster

Incidence Cluster	# of Counties	Total Population (15+)	# of New Infections (15+)
1 High Incidence	Include the # of counties included in each cluster to provide a sense of the overall size of the cluster	Sum the total 15+ population for all counties in each cluster to provide a sense of the overall size of the cluster	Sum total # of new infections for counties in each cluster to provide a sense of the potential addressable HIV burden and potential impact of oral PrEP
2 Medium Incidence			
3 Low Incidence			

Rollout Scenarios
Understanding Target Populations

Populations		Contribution to Total HIV Infections (%)	Appropriate Delivery Channels	Implications for Oral PrEP Rollout
High-risk general population groups	Sero-discordant couples	If data is available, note % of new HIV infections found in this population	Note appropriate channels for delivery of oral PrEP to reach each population effectively	Note implications for oral PrEP rollout, for example: - Is population high-priority for PrEP access? - Will the population be easy to reach through existing delivery channels?
	Adolescent girls and young women			
Key populations	Female sex workers (FSW)			
	Men who have sex with men (MSM)			
	People who use drugs (PWID)			
Bridging populations	e.g., fisher folk, truck drivers			



ROLLOUT SCENARIOS

ANALYSIS TEMPLATES

Rollout Scenarios
Instructions

Analysis of collected data yields potential scenarios for oral PrEP rollout that have different implications for potential impact and potential cost.

The following slides provide two approaches to this analysis:

APPROACH 1: COUNTY/DISTRICT LEVEL ANALYSIS

Analysis includes all counties/districts in the country and results in recommendations for PrEP rollout for all counties/districts

Slides 13 - 15

APPROACH 2: ROLLOUT SCENARIOS

Analysis results in scenarios that include rollout to multiple counties based on different criteria (e.g., highest rates of HIV incidence, highest number of new infections, largest presence of key populations)

Slides 17 – 19

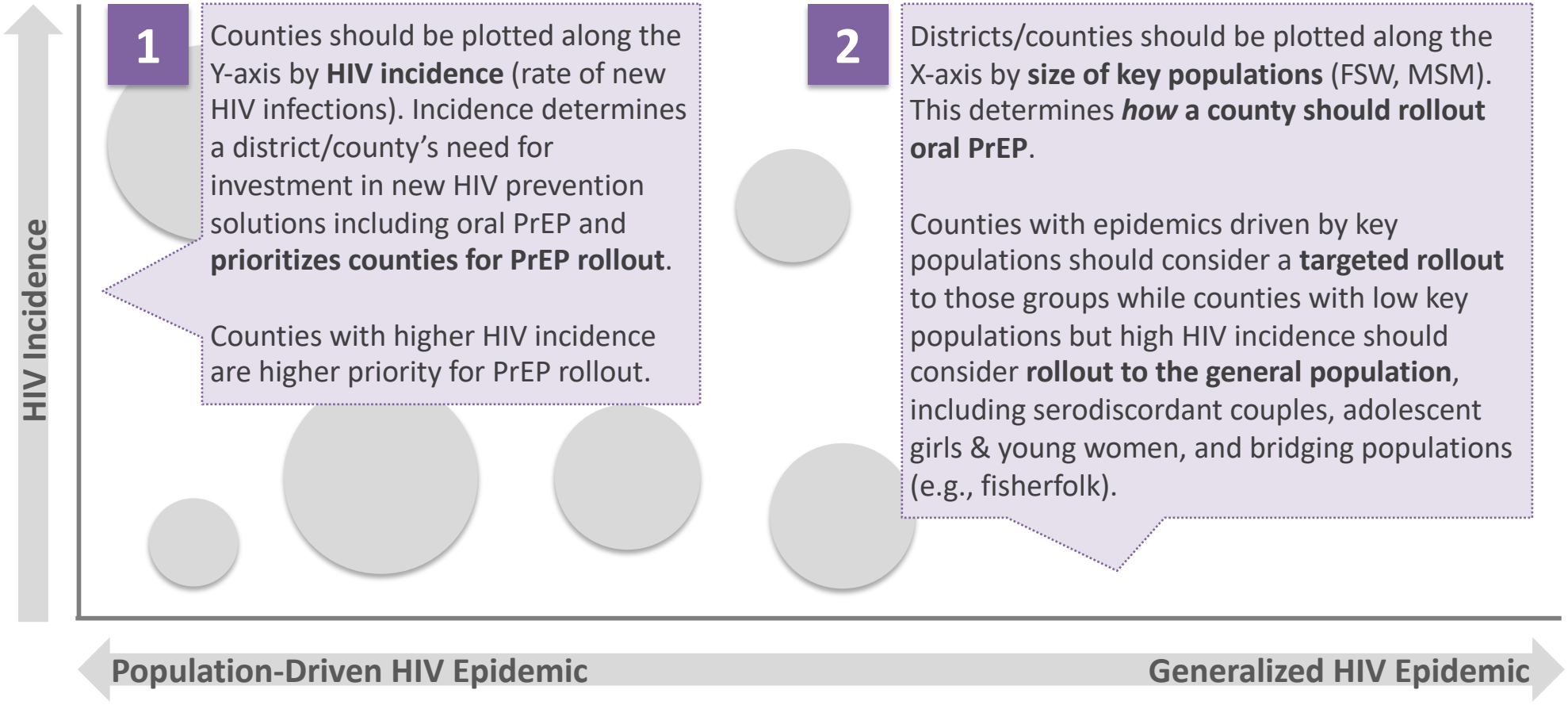
Both approaches are useful and can be used together.

Rollout Scenarios – Approach 1
Plotting districts / counties

Plot counties / districts along two axes: HIV incidence and size of key populations as described below.

Circle size can illustrate absolute numbers of new infections.

Two-Step Delivery Approach Framework



Sources: Informed by Avenir, PrEP for Adolescent Girls and Young Women in Kenya, Preliminary Results Presentation, October 2016

Rollout Scenarios – Approach 1

Drawing conclusions for oral PrEP rollout

Once districts/counties are plotted along the two axes, they will fall into one of four buckets that provides a recommended approach to oral PrEP delivery, as described below

Two-Step Delivery Approach Framework

HIV PROFILE:
High Incidence / Many Key Populations

DELIVERY APPROACH: PrEP ROLLOUT TO KEY POPS
Rollout focused on key population channels (NGO programs) with access, but limited specific programming, for general population

HIV PROFILE
High Incidence / Few Key Populations

DELIVERY APPROACH: GENERAL PrEP ROLLOUT
Comprehensive generalized rollout to reach all populations (e.g., public health facilities, HIV testing centers, family planning clinics)

HIV PROFILE
Low Incidence / Many Key Population

DELIVERY APPROACH: TARGETED PrEP DELIVERY
Limited rollout to address hotspots or reach key populations, with a particular focus on larger cities with high numbers of new HIV infections

HIV PROFILE
Low Incidence / Few Key Populations

DELIVERY APPROACH: DEPRIORITIZE FOR PrEP
With low-risk of HIV transmission and few identifiable target populations, PrEP should not be prioritized in HIV prevention plan

HIV Incidence

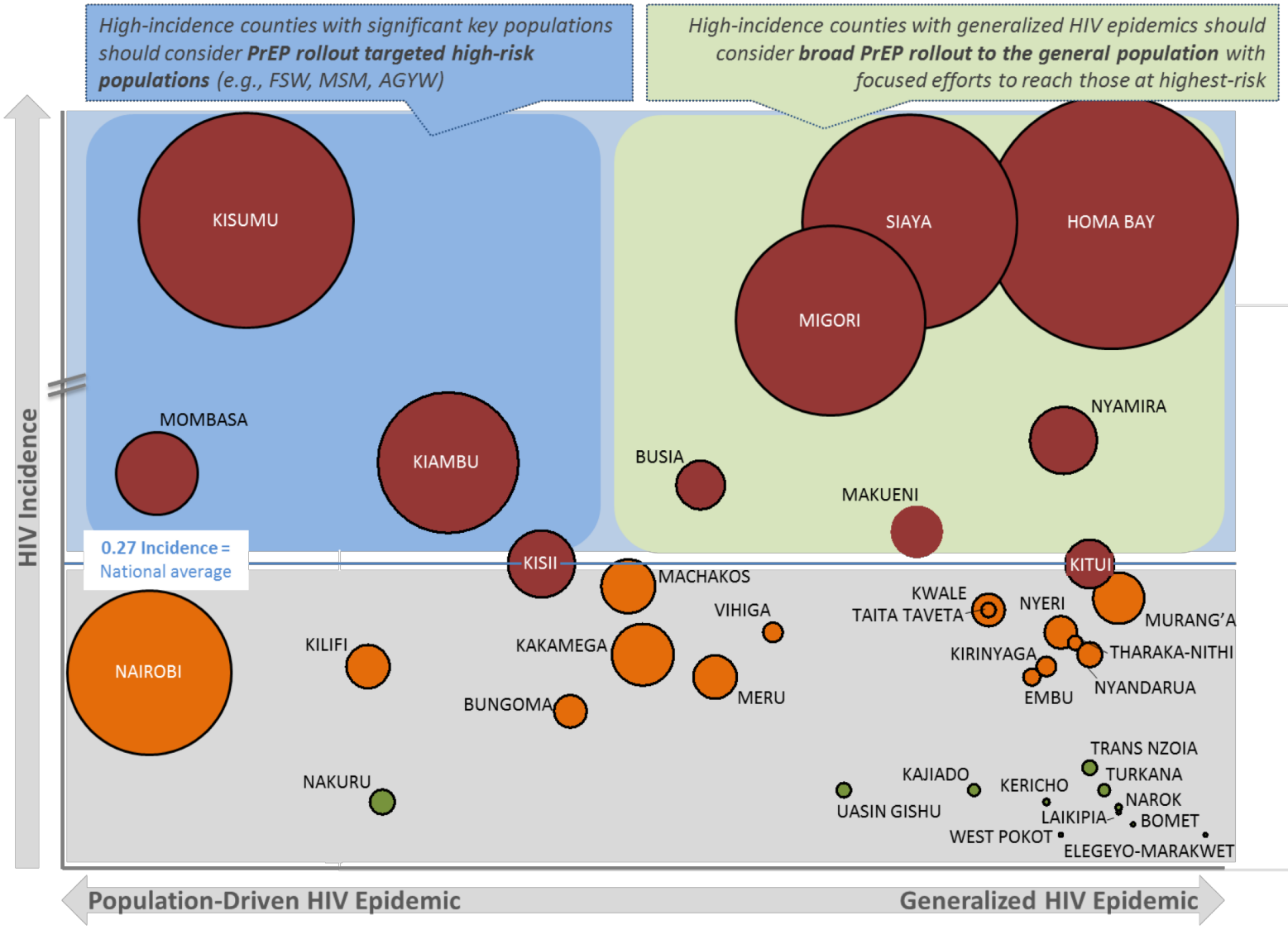
Population-Driven HIV Epidemic — Generalized HIV Epidemic

Sources: Informed by Avenir, PrEP for Adolescent Girls and Young Women in Kenya, Preliminary Results Presentation, October 2016

Rollout Scenarios – Approach 1
Completed Example of Kenya

Counties mapped by incidence and presence of key populations, 2015

Circle size represents number of 2015 adult new infections



Completed example from Kenya

Counties for "general population" rollout

- Homa Bay, Siaya, and Migori have few key populations but high rates of HIV incidence amongst ***sero discordant couples, AGYW, and bridging populations***
- Nyamira, Makueni, Busia, and Kitui have similar profiles but comprise far fewer new infections

Counties for "targeted population" rollout

- Kisumu is a significant contributor of new infections driven by ***key populations (MSM, FSW) and bridging populations (e.g., fisherfolk)***
- Mombasa, Kiambu, and Kisii have similar profiles but comprise far fewer new infections
- Nairobi has a moderate rate of incidence, but contributes significantly to new infections and may also be prioritized for targeted oral PrEP rollout

Rollout Scenarios – Approach Two
Rollout Scenario Definition

The second approach to rollout analysis starts with generating "clusters" of counties/districts that could be prioritized for oral PrEP rollout based on different characteristics or public health goals

Oral PrEP Rollout Scenarios

Incidence Based Rollouts

1. Identify clusters of counties based on incidence/new infections here. It is helpful to look at both incidence rates and new infections as they yield different results (e.g., large cities have low incidence rates but high numbers of new infections.

2. *Example rollout scenarios include:*
   - Incidence rate based scenarios (i.e. groups of counties/districts that all exhibit rates above a certain incidence rate level)

3. - New infection based scenarios (i.e. groups of counties/districts that all exhibit # of new infections above a certain level)
   - Different groups of counties /districts based on national HIV prevention strategy

4.

Population Based Rollouts

5. Identify rollout scenarios based on population groups here. These could be groups of counties/districts where data shows that there are high concentrations of a particular population and/or where programs are available that could support the population group

6. *Example rollout scenarios include:*
   - Sero-discordant couples (i.e. counties/districts with high #s of PLHIV and ART coverage)

7. - Adolescent girls and young women (i.e. counties/districts with high #s of AGYW new infections or programs focused on AGYW)
   - Key populations such as FSW, MSM and PWID
   - Other sector/industry based populations such as truck drivers, mineworkers, commercial farm workers, fisher folk, etc.

8.

Rollout Scenarios – Approach Two

Rollout Scenario Description (1/2)

For each scenario, note the key qualitative and quantitative data points below.

Incidence Based Rollouts

1 *<Input name of scenario>*	2 *<Input name of scenario>*	3 *<Input name of scenario>*	4 *<Input name of scenario>*
Incidence: *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population
Opportunity: *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*
Delivery Approach • *Define delivery approach (e.g., delivery channels)*	**Delivery Approach** • *Define delivery approach*	**Delivery Approach** • *Define delivery approach*	**Delivery Approach** • *Define delivery approach*
Target counties/districts • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*

Rollout Scenarios – Approach Two

Rollout Scenario Description (2/2)

Population Based Rollouts

For each scenario, note the key qualitative and quantitative data points below.

1 *<Input name of scenario>*	2 *<Input name of scenario>*	3 *<Input name of scenario>*	4 *<Input name of scenario>*
Incidence: *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population	**Incidence:** *x%-x%* **Annual new infections:** *~% of adult new infections* **Districts and Population:** # of districts, # of 15 + population
Opportunity: *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*	**Opportunity:** *What are the strengths of this scenario?* *What are the limitations of this scenario?*
Delivery Approach • *Define delivery approach (e.g., delivery channels)*	**Delivery Approach** • *Define delivery approach*	**Delivery Approach** • *Define delivery approach*	**Delivery Approach** • *Define delivery approach*
Target counties/districts • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*	**Target counties/districts** • *List counties and districts for each scenario*

Rollout Scenarios – Approach Two

Rollout Scenario Cost / Impact Estimates

Using existing data, rough cost and impact estimates can be developed for each scenario

Oral PrEP Rollout Scenarios Potential Impact and Cost

	Scenario		Potential Impact	Potential Cost
Incidence-Based	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
Population-Based	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~% adult new infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)
	#	*<Input name of scenario>*	**HIGH/MEDIUM/LOW IMPACT** ~%[illegible] infections	**HIGH/MEDIUM/LOW TOTAL COST** # of counties (# 15+ population)

- **Potential impact** is the percent of national HIV infections that occur in the counties/districts included in the scenario (e.g., new infections in scenario counties / total national new infections)
- While it will differ for each country, the following impact thresholds could be applied:
  - High: >49% of new HIV infections
  - Medium: 20-49% of new HIV infections
  - Low: <20% of new HIV infections

- **Potential cost** is based on the # of counties and size of the 15+ population for each of the scenarios (larger population, more districts leads to higher total costs for oral PrEP delivery)
- This provides a high-level indication of cost to highlight tradeoffs and considerations for decision-making
- These cost and impact hypotheses will need to be complemented with impact and cost effectiveness modeling

Rollout Scenarios – Approach Two
Completed Example of Zimbabwe

Note: *Delivery approach, potential cost and impact are directional and will need to be refined with additional research, analysis and impact/cost-effectiveness modelling*

Oral PrEP Rollout Scenarios

District Rollouts		Population Rollouts	
1	Highest incidence districts	5	Serodiscordant couples
2	ZNASP hotspot districts	6	Adolescent girls and young women
3	Districts with >1,000 annual new HIV infections	7	Miners and commercial farmworkers
4	Districts with >500 annual new HIV infections	8	FSW, MSM and truck drivers

Rollout Scenarios – Approach Two
Completed Example of Zimbabwe

1 Highest Incidence Districts

Incidence: 1.2% - 1.9%

Annual new infections: ~40% adult new infections

Districts and Population: 13 districts, 1.6M 15+ population

Opportunity: Provides significant impact with less expansive and expensive rollout in circumstances with limited resources; all districts are ZNASP hotspots

Delivery Approach:
Comprehensive generalized rollout

Target counties/districts
- All districts of Matabeleland South, Manicaland and Bulawayo

Comprehensive generalized rollouts to all high-risk populations via public health facilities, rural health centers, family planning and SRH clinics

More limited tailored rollouts based on localized drivers of HIV in each district

2 ZNASP Hotspot Districts

Incidence: 0.4% - 1.9%

Annual new infections: ~55% adult new infections

Districts and Population: 26 districts, 3.0M 15+ population

Opportunity: Captures over 50% of new infections, but likely requires ~2x resources than Scenario #1; all districts are ZNASP hotspots

Delivery Approach:
Comprehensive rollout to high-incidence districts; more limited rollout to medium and low incidence districts

Target counties/districts
- **High:** Mat S. Manicaland, Bulawayo, as well as Mazowe (Mash C.), Marondera (Mash E), and Bubi (Mat N.)
- **Medium:** Mat. North and Mashonaland districts, including Nkayi, Centenary, Bindura, Shamva, Mount Darwin and Makonde
- **Low:** Chegutu, Hurungwe and Kadoma

3 Districts with >1,000 Annual New Infections

Incidence: 0.5% - 1.7%

Annual new infections: ~55% adult new infections

Districts and Population: 15 districts, 3.6M 15+ population

Opportunity: Captures same number of new infections as Scenario #2 but less resource intensive given rollout to fewer districts; over 50% of districts are ZNASP hotspots

Delivery Approach
- Comprehensive rollout to More limited rollout in

Target counties/districts
- **High**: Kwekwe, Gweru, Mutare, Marondera, Mazowe, Murehwa, Gwanda and Bulawayo
- **Medium** Masvingo and Mashonaland East districts, including medium incidence Masvingo and Goromonzi
- **Low:** Harare

4 Districts with >500 Annual New Infections

Incidence: 0.4% - 1.9%

Annual new infections: ~85% adult new infections

Districts and Population: 38 districts, 6.0M 15+ population

Opportunity: Covers districts with majority of new HIV infections but requires the greatest resource allocation of any scenario; over 50% of districts are ZNASP hotspots

Delivery Approach
Comprehensive rollout to high-incidence districts; more limited rollout to medium and low incidence districts

Target counties/districts
- **High**: See alternative sheet
- **Medium** See alternative sheet
- **Low:** See alternative sheet

Rollout Scenarios – Approach Two
Completed Example of Zimbabwe

Impact and Cost Estimates for Oral PrEP Rollout Scenarios

	Scenario		Potential Impact	Potential Cost
County Rollout	4	High + medium new infections	HIGHER IMPACT ~90% adult new infections	HIGHER TOTAL COST 19 counties (16M 15+ population) | some demo project coverage
	5	Extending DREAMS and B2S to full county	HIGHER IMPACT ~70% adult new infections	HIGHER TOTAL COST 12 counties (10M 15+ population) | good demo project coverage
	2	High incidence cluster	HIGHER IMPACT ~65% adult new infections	MODERATE TOTAL COST 11 counties (7M 15+ population) | good demo project coverage
	3	High new infections	HIGHER IMPACT ~60% adult new infections	MODERATE TOTAL COST 7 counties (7M 15+ population) | good demo project coverage
	1	Highest incidence cluster	MODERATE IMPACT ~45% adult new infections	LOWER TOTAL COST 4 counties (2M 15+ population) | good demo project coverage
Population Rollout	6	High PLHIV to reach discordant couples	MODERATE IMPACT ~30% adult new infections (based on SDC proportion)	LOWER TOTAL COST 12 counties | 946K PLHIV (15+) | good demo project coverage
	8	High + medium key populations	LOWER IMPACT ~20% adult new infections (based on key pop. proportion)	LOWER TOTAL COST 16 counties |101K key populations | some demo project coverage
	7	High key populations	LOWER IMPACT ~10% adult new infections (based on key pop. proportion)	LOWER TOTAL COST 6 counties | 66K key populations | good demo project coverage