

OPTIONS Optimizing Prevention Technology Introduction On Schedule

Introduction to the Plan 4 PrEP Toolkit

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PLAN 4 PREP TOOLKIT INTRODUCTION



Tools Overview

1

SITUATION ANALYSIS

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

2

PROJECT LANDSCAPE

Assess findings & gaps in projects

- Survey current and planned studies and implementation projects
- Identify key questions to inform implementation and assess gaps

3

ROLLOUT SCENARIOS

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

4

DISTRICT READINESS ASSESSMENT

Assess district readiness for oral PrEP

- Assess district/ county readiness to introduce and scale oral PrEP
- Support subnational planning for oral PrEP roll out and scale-up

5

FACILITY READINESS ASSESSMENT

Assess facility readiness for oral PrEP

- Assess the readiness of healthcare facilities to deliver oral PrEP
- Identify areas that require additional investment

6

PRIVATE SECTOR ASSESSMENT

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

INTRODUCTION TO SITUATION ANALYSIS



Oral PrEP Introduction Framework

- Distills the complex system for oral PrEP introduction into a simple framework
- Developed and refined based on oral PrEP rollout in South Africa, Kenya and Zimbabwe
- Forms the basis of the Plan 4 PrEP toolkit

Introduction Framework for Oral PrEP











PLANNING AND BUDGETING

Plan developed to implement WHO oral PrEP guidelines for end user populations

SUPPLY CHAIN MANAGEMENT

Oral PrEP produced,
purchased, and
distributed in sufficient
quantity to
meet projected demand

PREP DELIVERY PLATFORMS

Oral PrEP services
delivered
through appropriate
channels with access to
end user populations

INDIVIDUAL UPTAKE

End user populations seek and are able to access oral PrEP and begin use EFFECTIVE USE & MONITORING

in recommended frequency and time period; use is effectively monitored



Summary Analyses

Expected Strengths

- New plan calls for HIV investment in children, adolescents, young people, women, girls, key populations
- Innovative domestic financing mechanism
- Well-coordinated procurement and distribution system that serves public and
- Variety of HIV service channels with strong coverage (e.g., ART sites, CBHC, HTC
- Good HTC coverage
- Recent positive legal change relevant to **FSWs**
- Single harmonized monitoring and evaluation system New plan (ZNASP III)

INDIVIDUAL

EFFECTIVE USE & MONITORING

PLANNING & BUDGETING

SUPPLY CHAIN MANAGEMENT PREP DELIVERY **PLATFORMS**

MOHCC develops national strategic plan, identifies drug needs, does forecasts, specifies delivery timelines, creates treatment guidelines. M&E plans

UPTAKE

National stakeholder

Local Implem

PLANNING & BUDGETING

- Not all key populations fully represented in new plan
- No clear funding sources for PrEP beyond DREAMS

Emerging Key Consid

NAC provides logis and technical assis during plan prepar

Technical working focused on key the are involved in pla









PLANNING & BUDGETING

SUPPLY CHAIN MANAGEMENT PREP DELIVERY **PLATFORMS**

INDIVIDUAL UPTAKE

EFFECTIVE USE & MONITORING

Civil society group access, and demar

Pangaea can help

Key populations a

CESHHAR conduct PrEP impact study Zimbabwe (among

International bilat

Multilateral dono

- What are the incremental benefits and costs of PrEP for target populations?
- When will PrEP be meaningfully included in national plan?
- What populations and sub-segments, and where, will receive PrEP beyond demo projects and DREAMS?
- How will PrEP be funded beyond current levels?

- · When will Truvada, or alternatives, be approved for prevention?
- What is the total forecasted need for PrEP, and how will effective forecasts be developed given data limitations?
- How will the supply chain be managed to avoid stock-outs or perceived competition with treatment?

- Which delivery channels will be used to deliver PrEP to key populations, in what sequence?
- How can non-public facilities (e.g. NGO, private) be leveraged for PrEP?
- How and when will health care worker engagement for PrEP be delivered? What are expected opportunities or challenges?
- To what extent, how, and with what funding will the challenges of stigma, access, and demand generation be addressed? Who will address these?
- Who will coordinate the communications campaign for PrEP and when? What are the most effective messages to reach populations at risk, including those in cities, commercial farming, mining, borders, etc.?
- What investment and/or capacitybuilding needs to be done to mitigate strain on the system from ongoing testing (HIV and creatinine levels) of PrEP users?
- Will users adhere to effective use of PrEP? How can adherence/ effective use be encouraged and supported?
- How will services be linked across facilities when not available on-site?



Defining steps for oral PrEP introduction

Zimbabwe example

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING	
Impact, cost and cost- effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio	Regulatory approval of form(s) of oral PrEP by authorities	Issuance of standard clinical guidelines for prescription and use of PrEP	Clear and informative communications on PrEP for general public audiences	Established plans to support effective use and regular HIV, creatinine testing that reflect the unique	
Identification and quantification of target populations for PrEP	Effective demand and supply forecasting mechanisms for PrEP	Sufficient infrastructure and human resources to conduct initial HIV	Development of demand generation strategies targeted to unique needs of different populations	needs of target populations Capacity to provide	
Inclusion of PrEP and female-controlled methods in current or upcoming national HIV	Manufacturer identification and contract negotiation to purchase PrEP	tests and prescribe PrEP in priority channels	Linkages between HTC, PrEP prescription, and PrEP access to enable PrEP uptake	ongoing HIV and creatinine level testing for PrEP users accessible to target populations	
Timeline and plan for PrEP introduction and scale-up	Product and packaging design to meet target population needs and	Plan to engage health care workers on PrEP and delivery to target populations (including mitigating stigma)	Information for clients on how to effectively use PrEP for all target populations	Monitoring system to support data collection for ongoing learning	
A budget for PrEP roll-out to target	Development of distribution plan for PrEP to reach target	Tools to help potential clients and HCW understand who should use PrEP	Sufficient resources to roll-out plans for demand generation	(e.g., rate of patients returning for 2nd visit, non-HIV STI rates)	
populations	populations		COLOR KEY		
Sufficient funding to achieve targets	Effective distribution mechanisms to avoid PrEP stock-outs in priority facilities	Sufficient resources to roll-out plans for healthcare worker engagement	Significant prog	ress and/or momentum	



Data Collection Example: Planning

Readiness for PrEP Introduction					
Readiness Factor	Progress				
Impact, cost and cost- effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio	 CESSHAR, IMPACCT, HTPN082 demo projects underway; potential for additional studies BMGF compiling cost data from PrEP demo projects to create standardized costing model 				
Identification and quantification of target populations for PrEP	 Priorities include comprehensive prevention programs for SW, adolescent and young people, people in stable unions, and discordant couples, with a focus on geographic hotspots. Target populations for PrEP specifically have not been identified 				
Inclusion of PrEP and female-controlled methods in current or upcoming national HIV prevention plans	PrEP has been incorporated into the Zimbabwe National Strategic Plan				
Timeline and plan for PrEP introduction and scale-up	 A TWG on WHO Test and Start Guidelines, as well as a sub-committee on PrEP, developed oral PrEP guidelines. Implementation planning is set to begin in 2017 ZIMPHIA study results shared in December 2016. Insights from data set to inform PrEP rollout 				
A budget for PrEP roll-out to target populations	 A costed implementation plan, to be developed in 2017, will be used as a resource mobilization tool. No budget has been created as of yet 				
Sufficient funding to achieve targets	 Available funding limited to DREAMS and CeSHHAR 				

Key Stakeholders

- MOHCC is responsible for developing national strategic plan as well as convening a the guideline adaptation TWG for WHO guidelines on UTT and PrEP, and the PrEP sub-committee
- · Country Coordinating Mechanism oversees GF proposals and grants
- Technical working groups focused on key themes are involved in planning
- **Key populations** are included in these groups, but more efforts are needed to ensure meaningful representation
- NAC provides logistical and technical assistance in the preparation of plan
- Advocacy groups for key populations (e.g., GALZ, ZNNP+, WASN, etc.)
- PrEP implementing partners- DREAMS (CeSHHAR, PSI) & HPTN (UZ-UCSF)

Key Strengths and Opportunities

- ZNASP III identifies key populations as , adolescents, AGYW, key FSW, MSM, and people in stable unions and sero-discordant couples
- ZNASP III calls for prioritization of specific **geographic hotspots**
- Technical working groups include some key populations in planning
- National AIDS Levy draws 3% of private income (totaling ~\$19M), of which 10% goes to HIV prevention
- HIV policy environment appears to be well developed, supported by strong technical expertise, and responsive to WHO guidelines

Key Emerging Considerations

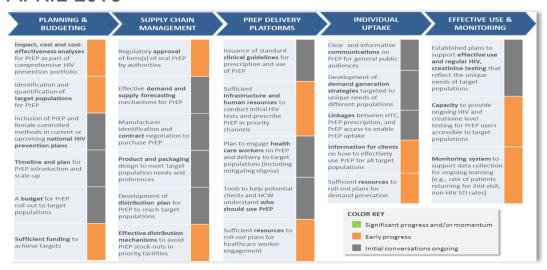
- Not all key populations meaningfully represented in working groups or national plan (e.g., plan states that not enough data exists on MSM, but it's unclear if MSM have input or if they are deemed "priority")
- Concern that PrEP will be focused primarily on FSW, which could stigmatize the use of PrEP for other populations (e.g., AGYW)
- PrEP not meaningfully included in ZNASP III
- Recent successes with VMMC have made it a key prevention strategy, but government's investment in scaling it up may prevent additional focus on PrEP scale-up
- National leaders remain concerned about ARV resistance resulting from PrEP



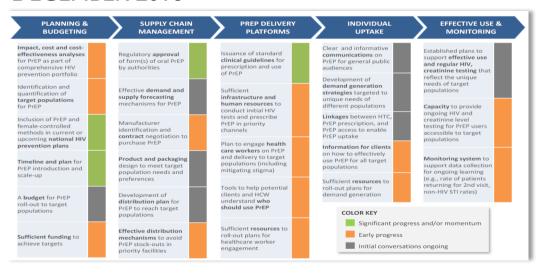
Analysis - State of Progress for PrEP

- A summary of assessments from data collection slides on current progress (via color coding) for each components of the introduction framework
- Useful for technical working groups to develop a common understanding of what was needed to rollout oral PrEP and ongoing progress
- Updated as progress was made over time

APRIL 2016



DECEMBER 2016



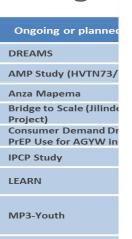
INTRODUCTION TO PROJECT LANDSCAPE



Analysis – Summary of Key Dimensions

14 ongoing or planned projects on PrEP





Partners

POWER

PrIYA

REACH

SEARCH

GEMS

IPCP Study

MP3-Youth*

POWER

REACH

SEARCH***

DREAMS AMP Study (HVTN73

Anza Mapema

Bridge to Scale (Jiline Consumer Demand I Use for AGYW in Ker

LEARN

Partners

PrIYA**

GEMS***

* Reached 100 youth (age 1 ** Will reach women age 1! *** General population age

PrEP projects by target population

These projects are concentrated around Nairobi,

Kisumu a

PrEP Projects in

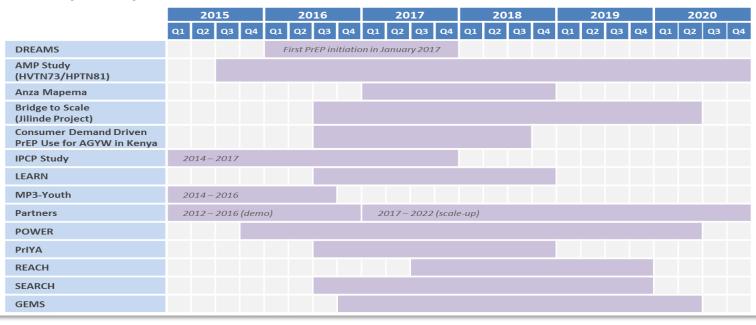
_	
_	Siaya DREAMS Partners
_	Kisumu AMP Anza Mapema DREAMS IPCP PrIYA
_	<i>Homa Bay</i> DREAMS IPCP MP3- REACH Partners SEA
_	Kisii Bridge to Scale
_	Migori Bridge to Scale Partner
	Nyeri Partners
	<i>Kiambu</i> Bridge to Scale Partner
_	Nairobi Bridge to Scale DREAM Partners
	Machakos Bridge to Scale

* GEMS will work in all countie

These projects will yield insights over the next several years on effective PrEP strategies



Timeline of PrEP Projects





Defining Key Questions

Key questions for AGYW demo projects









PLANNING FOR PREP ROLLOUT TO AGYW PREP DELIVERY CHANNELS AND HEALTHCARE WORKERS

INDIVIDUAL UPTAKE AMONGST AGYW EFFECTIVE USE & MONITORING

Q1

How can PrEP be effectively targeted to higher-risk AGYW?

- What practical tools / mechanisms are being used to assess risk and / or suitability for PrEP among AGYW? (both for HCW and self-assessment)
- To what extent are those AGYW that self-select those that are at highest need of PrEP?

Q2

What are the major barriers to PrEP uptake for AGYW and how can they be addressed?

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What legal or ethical considerations are relevant for PrEP provision to AGYW?

 If provided to persons under 18, what parental consent is required?

Q_4

What are the best channels to deliver HIV prevention to AGYW, including those who regularly access health services (e.g. SRH) and those who don't currently access health or other public services (e.g., education)?

- How effective is delivery through channels such as youth, school, and mobile clinics, facilities linked to youth clubs, and NGOs working with AGYW?
- What do AGYW need in delivery channels (e.g., hours that fit their schedules, friendly staff)?

Q5

What types of investments (e.g., expanded lab capacity) are required in various types of facilities to effectively deliver PrEP? What would it cost?

 How will facilities link AGYW to services that are not available on-site, such as lab

Q6

How can negative health care worker attitudes be effectively mitigated?

 What training, communication, messaging or other strategies (e.g., public health campaigns) could be used to generate HCW support for PrEP rollout?

Q

What are the most effective IEC messages and strategies to build awareness, understanding, and / or generate demand for PrEP amongst AGYW and their communities?

 How can these messages and strategies proactively address myths and misconceptions about PrEP?

08

How are AGYW communicating about PrEP to partners or family members and/or involving them in decisions?

 What, if any, unintended social harms (e.g., intimate partner violence) result from PrEP use?

Q_9

How are "periods of risk" defined? What strategies / tools (e.g., additional counselling and adherence support) are effective to support AGYW decision-making around on / off decisions for PrEP?

Q10

To what extent are AGYW adhering to PrEP? What strategies effectively support AGYW daily adherence to PrEP?

 What characteristics could best predict likelihood of effective use among AGYW?

Q1

To what extent are AGYW getting regular HIV and STI testing? What strategies effectively support retention in regular testing?

What roles can schools, NGOs, or others working with AGYW play in facilitating adherence and regular HIV + creatinine testing (e.g. counseling, creating peer support groups, expanding / initiating HIV + STI testing services)?

Q12

What information do health care facilities need to collect and report to NDoH? What data are demonstration projects collecting?

- South Africa realized its biggest need was to better understand and organize the evidence for oral PrEP for AGYW
- They decided to focus the analysis on AGYW projects, and defined a series of 12 questions specific to AGYW
- Topics included delivery channels, demand generation, adherence support, cost implications



Analysis – Key questions and gaps

How can PrEP be effectively targeted to higher-risk AGYW?



TARGETING		
Study	Timeline	Characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 Currently enrolling, Provisional results mid-2017	Primary objective is to identify risk factors for HIV acquisition in sexually active women (3x in past 3 months) aged 18 – 30; Recording HIV risk perception and behavioural assessment through study
EMPOWER	Ongoing July 2015 - December 2017	AGYW at risk for violence; investigating integrated Gender-based violence and stigma reduction through combination HIV prevention methods
HPTN 082	Ongoing June 2016 - August 2018 Provisional results mid-2017	Includes risk perception scoring, recoding of sexual and substance abuse behaviour; targeting AGYW sexually active in past month
MSF	Under Ethics Review Expected start April 2017	Up to 200 sexually active, HIV-uninfected females ages of 18 - 25
MTN034	Planned Expected start early-2017	 Behavioural questionnaire No planned req. for sexual activity for participation in study Developing a risk assessment tool
Plus Pills	Completed end 2016	15-19 years old Sexually active in past 12 months Using effective contraception method > 148 ppts enrolled
POWER	Ongoing Formative research completed. Recruitment ongoing. Completion expected 2020	Sexually active AGYW

Insights expected from demo projects

- ✓ CAPRISA, HPTN, and MTN studies will all record behavioral characteristics of study participants to inform identification of risk factors for AGYW
- ✓ CAPRISA and HPTN will yield insights on risk perception scoring for AGYW
- ✓ CAPRISA, HPTN, and MTN studies use different sexual activity thresholds (3x in 3 months vs. any activity in past month vs. no requirement) – a comparison across them could yield insights on the use of sexual activity as a risk factor

Remaining questions about demo projects

- ? How will DREAMS and related studies define criteria for AGYW participation?
- ? How comprehensive are the behavioural assessments and risk perception scoring? What can be learned from the tools used in the CAPRISA, HTPN, and MTN projects?
- ? What insights can Pills Plus yield on risk characteristics differences between girls and boys?

- For each question, we created a slide to summarize how each project would inform the question
- For example, to understand how the projects could inform identification of high-risk AGYW, we compared participant criteria and risk scoring methods



Status of research agenda on effective practices to target and deliver PrEP to AGYW Significant coverage in studies Some studies address topic

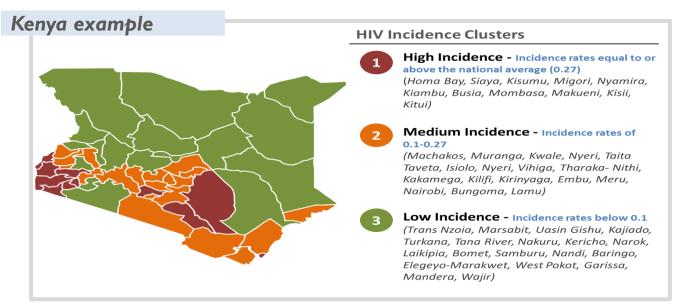
	anger and deliver file to	, , ,	No studies address topic
	Question	Status	Notes
Q1	How can PrEP be effectively targeted to higher-risk AGYW?		Studies use differing "risk factors" to identify study participants; a comparison across them will be informative
Q2	What are the major barriers to PrEP uptake for AGYW and how can they be addressed?		Several studies (HPTN 082, POWER) collect data on barriers and AGYW who decline PrEP; others will study product acceptability
23	What legal or ethical considerations are relevant for PrEP provision to AGYW?		Collection of data on parental consent, but no other specific legal/ethical considerations noted
24	What service delivery and civil society channels will most effectively reach AGYW?		Coverage across different types of delivery channels (e.g., mobile, primary care clinics, FP clinics)
(5	What types of investments are required to effectively deliver PrEP through these channels?		Only one study (POWER) explicitly includes costing component
(6	How can negative health care worker attitudes be effectively mitigated?		POWER formative research and OPTIONS Provider KAP Survey
17	What are the most effective strategies to build awareness and generate demand for PrEP amongst AGYW?		Significant focus on demand through various recruitment and communications strategies across demo projects
8	How are AGYW communicating about PrEP to partners or family members and/or involving them in decisions?		No awareness of current plans to study this aspect
(9	How are "periods of risk" defined? What strategies / tools support AGYW decision-making around on/off decisions?		CAPRISA and HPTN 082 studies explicitly discuss and track "PrEP cycling," but little focus on this (and strategies for communications) in other studies
LO	To what extent are AGYW adhering to PrEP? What messages and strategies effectively support adherence?		Significant focus on adherence and strategies for encouraging adherence across studies
11	Are AGYW getting regular HIV/STI testing? What strategies effectively support retention in regular testing?		Each study has a different testing protocol; comparisons across them may be useful
12	What information do health care facilities need to collect and report to NDoH? What data are demonstration projects collecting?		Subcommittee of AGYW TWG meeting to determine how and what data to report to NDOH

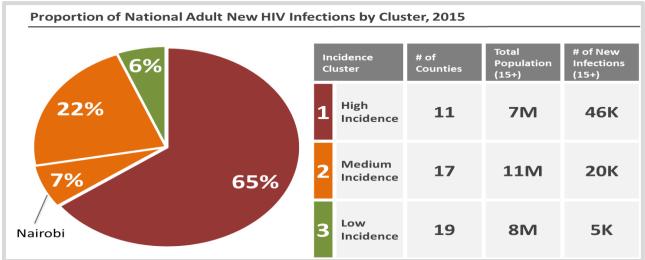
- We then created a one page summary to assess how much information would be available for each question
- This highlighted several issues, for example:
- Targeting high-risk AGYW is a topic in many projects (Q1)
- Costing was included in only 1 project (Q5)
- There is a gap on how interactions between AGYW, family members and partners impact ability to take / adhere to oral PrEP (Q8)

INTRODUCTION TO ROLLOUT SCENARIOS



Analysis - Summary





- Use the collected data on HIV (e.g., prevalence, incidence and new infections) and other demographic data (e.g., population numbers) to develop summary analyses
- The purpose of these analyses is to clarify how HIV incidence is distributed across geography within a country
- There are PPT templates in the Plan 4 PrEP Toolkit to guide development of these analyses



Analysis – Geographic Analysis

Kenya example

We also looked at the counties / districts along three dimensions (using the framework below) to better differentiate what model of PrEP rollout would be most appropriate:

- HIV incidence
- 2. Size of key populations
- Absolute numbers of new HIV infections

Two-Step Delivery Approach Framework

HIV Incidence

HIV incidence (rate and absolute number of new HIV infections) determines a county's need for investment in new HIV prevention solutions including oral PrEP and prioritizes counties for PrEP rollout.

Counties with higher HIV incidence are higher priority for PrEP rollout.

Source: 2015 NACC HIV data

2

Size of key populations (FSW, MSM) determines **how a county should rollout PrEP**.

Counties with epidemics driven by key populations should consider a **targeted rollout** to those groups while counties with low key populations but high HIV incidence should consider **rollout to the general population**, including sero-discordant couples, adolescent girls & young women, and bridging populations (e.g., fisherfolk).

Source: FSW, MSM, PWID estimates, MARPS, 2012

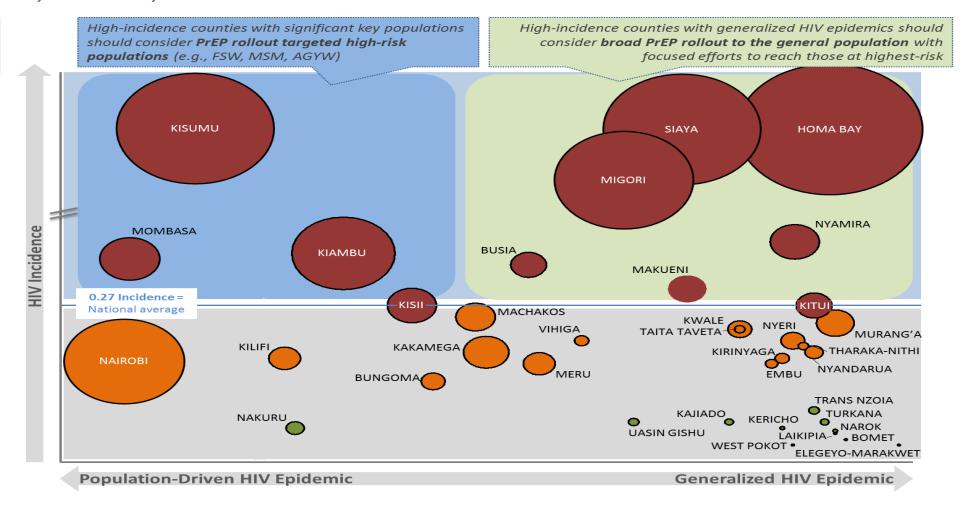


Analysis – County Assessment

Counties mapped by incidence and presence of key populations, 2015

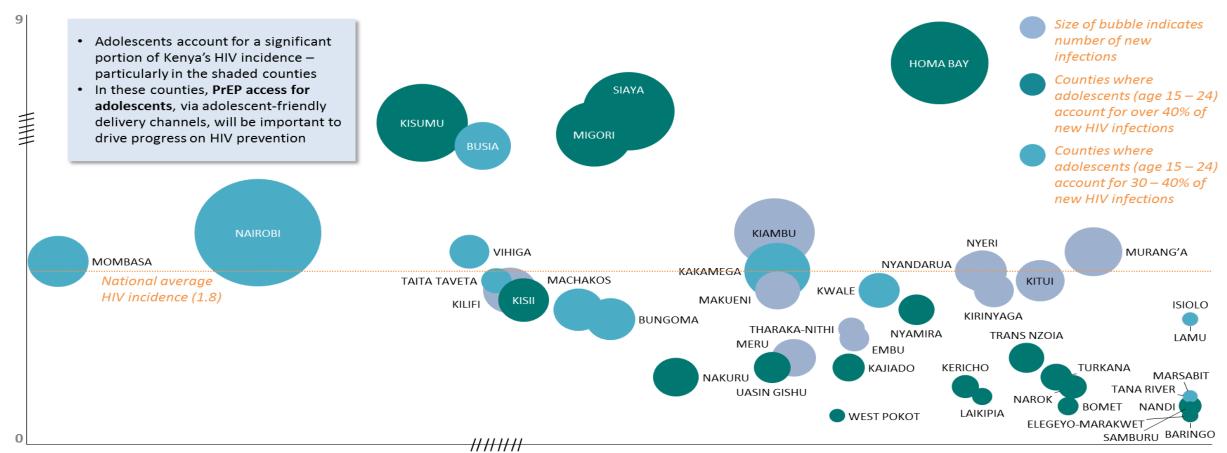
Circle size represents number of 2015 adult new infections

Kenya example





County PrEP Rollout Analysis | Adolescents





Analysis - Scenarios

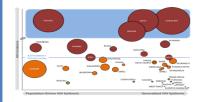
- Based on this analysis, we defined several scenarios for possible PrEP rollout three defined by geography and two defined by populations
- We worked with the Kenya TWG to define which scenarios were most relevant for their decision-making

Kenya example

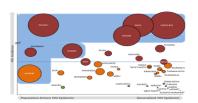
PrEP Rollout Scenarios

County Rollout

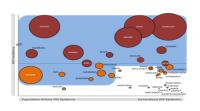
Highest incidence cluster



High new

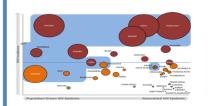


High + medium new HIV infections

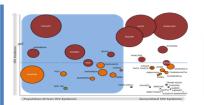


Population Rollout

High PLHIV to reach discordant couples



High and medium key populations



Note: This is not an exhaustive list of possible scenarios. These scenarios have been selected to highlight likely options for PrEP rollout and to illustrate the trade-offs between potential cost and impact across different options



Analysis – Cost / Impact Comparisons

- Based on the population, # of counties, and # of new infections that would be "covered" in each scenario, we compared scenarios across potential impact and cost
- This is something that actual modeling would be able to do in more detail and with more potential accuracy, but this approach can provide directional estimates

Kenya example

	Scenario		Potential Impact	Potential Cost	
nt	1	Highest incidence cluster	MODERATE IMPACT Covers ~45% adult new infections	LOWER TOTAL COST 4 counties (2M 15+ population) good demo project coverage	
County Rollout	2	High new infections	MODERATE IMPACT Covers ~60% adult new infections	MODERATE TOTAL COST 7 counties (7M 15+ population) good demo project coverage	
3	High + medium new Infections		HIGHER IMPACT Covers ~90% adult new infections	HIGHER TOTAL COST 19 counties (16M 15+ population) some demo project coverage	
Oppulation Rollout	4	High PLHIV to reach discordant couples	LOWER IMPACT Covers ~30% adult new infections (based on SDC proportion)	LOWER TOTAL COST 12 counties 946K PLHIV (15+) good demo project coverage	
Populatio	5	High + medium key populations	LOWER IMPACT Covers ~20% adult new infections (based on key pop. proportion)	MODERATE TOTAL COST 16 counties 101K key populations some demo project coverage	

Providing PrEP beyond key populations will require larger-scale rollout, however, it is necessary to address the majority of new infections.

Scenarios 1 and 2 offer the best balance of impact and cost.

INTRODUCTION TO READINESS ASSESSMENT



Oral PrEP Introduction Framework

The PrEP Introduction Framework provides the organizing structure for the Readiness Assessment.

Introduction Framework for Oral PrEP











PLANNING AND BUDGETING

Plan developed to implement WHO oral PrEP guidelines for end user populations

SUPPLY CHAIN MANAGEMENT

Oral PrEP produced,
purchased, and
distributed in sufficient
quantity to
meet projected demand

PREP DELIVERY PLATFORMS

Oral PrEP services
delivered
through appropriate
channels with access to
end user populations

INDIVIDUAL UPTAKE

End user populations seek and are able to access oral PrEP and begin use

EFFECTIVE USE & MONITORING

in recommended frequency and time period; use is effectively monitored



Data Collection







PLATFORMS



INDIVIDUAL

UPTAKE



PLANNING AND BUDGETING

SUPPLY CHAIN MANAGEMENT PREP DELIVERY

EFFECTIVE USE & MONITORING

- · County political will to introduce PrEP
- County engagement in the oral PrEP planning process
- · Funding for HIV prevention and treatment
- **HIV** prevention commodity management (stockouts)
- Plan for integrat oral PrEP into th local supply chai

Bold indicators represent key indicators to assess cou PrEP delivery readiness

Italicized indicators represent additional indicators to county level PrEP planning

- Experience with oral PrEP delivery (# of users involved in studies/ implementation projects)
- Likely oral PrEP demand (Uptake of HIV testing)
- Likely oral PrEP demand (Untake of
- Likely PrEP adherence (Viral load suppression)
- Environment conducive to effective

County Readiness Self-Assessment Tool for PrEP

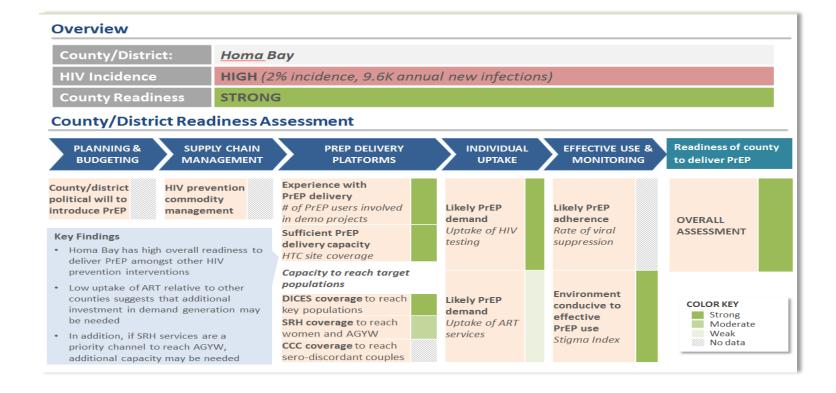
County:	Date of assessment:	
Please indicate Yes or No	Where appropriate please indicate on a scale of 0-5 0 = weak/low/insufficient 5 = strong/high/sufficient	Comments

LEADERSHIP, GOVERNANCE & FINANCING						
Is PrEP included in your County's AIDS Strategic plan?						
Are there resources available for roll-out of PrEP e.g. existing in county budgets, ongoing implementing partner projects, and on-going private sector activities? Please indicate the level of resource sufficiency.						
Are there resources available to support additional laboratory testing for PrEP patients e.g. Serum Creatinine? Please indicate the level of resource sufficiency						
Is there a technical working group that can include HIV care and treatment including PrEP?						

- The toolkit includes example indicators along the value chain and Excel and PPT templates to collect data and complete the analysis
- In Kenya, these indicators were shared with the TWG and the TWG adapted them for the Kenyan context
- The indicators were turned into a selfassesment tool included in the national plan
- In Kenya, county health officials completed the tool themselves, however this can also be completed through data analysis and interviews



Analysis – District Assessment



- Provides a summary of the readiness of each county
- Includes a summary of key indicators across the value chain, including:
- Capacity of health system to deliver PrEP and reach target populations
- Rate of viral suppression as an indicator of likelihood of PrEP uptake and adherence



Analysis – Multiple District Assessment

KEY TAKEAWAYS

- Homa Bay has the most favorable characteristics among the three counties, although relatively low ART uptake may signal need for strong demand
 generation to accompany oral PrEP introduction and investment in SRH services may be needed if oral PrEP is to be added to that delivery channel
- Nairobi largely scores moderate across indicators although the low # of DICEs may be a challenge given the likely focus on key populations
- · Nakuru has the lowest scores across indicators and may require greater investment in delivery capacity

Readiness indicators for select counties

	Plan/ Budget	Supply Chain	Delivery Platforms (Coverage of potential oral <u>PrEP</u> delivery sites)			Individual Uptake (Uptake of HIV services)		Effective Use (ART adherence + stigma)		Overall Score		
	Progress on plan	Stockout freq.	Demo project reach (#)	15+ pop. per HTC site	Key pop. per DICE	15+ pop. per SRH site	15+ pop. per CCC	HIV testing uptake	ART uptake	Viral suppression rate	Stigma Index rating	
HOMA BAY			3,499	8,399	701	2,473		64.9%	63.0%		34.5%	16
NAIROBI			2,410	15,105	1,705	3,101		59.2%	79.0%		39.5%	13
NAKURU			0	15,416	2,805	3,005		49.6%	76.0%		45.6%	8

COLOR KEY

Strong
Moderate
Weak
No data

Note: Thresholds were defined by segmenting data on each indicator into quartiles across all counties. 1^{st} quartiles strong (3 points); 2^{nd} quartile = moderate (2 points); 3^{rd} quartile = weak (1 point); 4^{th} quartile = weak (0 points).

- Similar to district assessment, but includes comparison across districts for key indicators
- Can include qualitative assessment (color coding) or a quantitative assessment (e.g., by attaching a number score to a strong – moderate – weak rating)
- This more readily allows for comparisons across districts for a small set of key readiness indicators

INTRODUCTION TO FACILITY READINESS ASSESSMENT



Facility readiness assessment overview

Purpose

A tool to assess healthcare facilities for readiness to deliver oral PrEP

Method to develop tool

- Collect existing facility readiness assessment tools from countries where tools are already in use (see list at right)
- Interview implementing partners to identify strengths and challenges of tools in practice
- Develop a tool for use by other countries based on existing examples

Countries included

- Kenya
- South Africa
- Zambia
- Zimbabwe



Some criteria were consistent across facility readiness assessments

The following criteria are evaluated across all facility readiness tools:

2	
44	

Human Resources + Personnel

- Presence of healthcare workers with training on oral PrEP or experience delivering ART
- Presence of **implementing staff** (e.g., peer educators, counselors, community outreach staff)



Service Delivery

Connection to a lab for lab-based services



Communications

• Use of information, education and communication (IEC) materials to support client education and increasing awareness of HIV prevention options and oral PrEP



Commodity **Management**

- Track record of storing and distributing ARVs
- **Procurement** systems



Monitoring + Evaluation

- Procedures and systems for tracking and reporting oral PrEP delivery
- Connection to national reporting structure



Additional criteria were used in some facility readiness assessments

These additional criteria may be included depending on the specific areas of focus and desired level of depth within the facility readiness assessment:

	Human Resources + Personnel	 Number of clinical, outreach and administrative staff Staff qualifications in terms of training/certification 	Focal staff person to integrate oral PrEP into existing services Training and mentorship capacity for staff Trained data management personnel
	Service Delivery	 Outreach model with person-centered delivery Tracing and referral processes Focus on specific key populations (KPs) Availability of tools or job aids for staff Link to adherence support programming Fee structure (prices of services) 	Private room for individual counseling and risk assessment Space in facility for additional drug storage Availability of prevention and testing services Availability of other prevention services (STI and TB screening, HIV testing, condoms) Integrated prevention approach with partners
	Communications	Presence of PrEP champions	
*	Commodity Management	 Frequency and reason for stock-outs Security and compliance of stock room Commodity requirements for oral PrEP 	Site mapped to ordering points Information about suppliers
	Monitoring + Evaluation	 Presence of electronic patient monitoring systems Client identification, confidentiality and consent processes 	
\$	Finance & Regulations	 Signed MOU with the Department of Health Copy of integrated ART guidelines Sufficient resources to support oral PrEP rollout including ad 	Iditional lab testing and training

Current funding gaps, duration and future plans



Criteria to assess youth friendliness can also be integrated into a readiness assessment

While few existing facility readiness assessments explicitly include youth-focused criteria, they can be included for facilities serving AGYW or other youth audiences.

Suggested criteria include:

- Does the facility have a policy or guidelines on youth-friendly provision of services?
- Does the facility have **staff with necessary competencies** and training to provide equitable, non-judgmental services to young people?
- Does the facility have a process for integrating the voices of young people in designing and planning efforts?
- Has the facility identified a focal person for youth-friendly services?
- Is there space to provide services to young people?
- Does the facility have a process for identifying and reviewing outreach hot spots to reach young people?

Additional dimensions of quality care for adolescents developed by the World Health organization (WHO) be found in appendix or on the WHO website



OPTIONS facility readiness tool

The accompanying Excel tool was developed based on existing tools used by countries today. The tool includes two options:

A "simple" assessment with a short list of core criteria that are essential to oral PrEP rollout

PLAN 4 PREP TOOLKIT **FACILITY READINESS ASSESSMENT TOOL - BASIC VERSION** This tool was adapted from several existing facility readiness assessment tools from South Africa, Kenya, Zimbaba acknowledge and thank all of the contributing countries for their thought partnership and for making their tools ac shared with other countries implementing oral PrEP. Date of assessment clarification and information Does the facility have clinical staff to support oral PrEP Does the facility have outreach staff or partner organization to support oral PrEP rollout (e.g., peer educators)? Service Delivery Does the facility offer prevention services such as HIV testing, PEP, oral PrEP, family planning, STI screening or other SRH services? If yes, list services in comment box. prevention and oral PrEP available? Is there a private screening room for clients? Is there a referral system or connection to labs for

A "comprehensive" assessment that includes a longer list of criteria that can be customized to each country's needs and preferences

PLAN 4 PREP TOOLKIT FACILITY READINESS ASSESSMENT TOOL - COMPREHENSIVE VERSION							
	pted from several existing facility reading tries for their thought partnership and fo						
Facility		Date of assessment					
Size of clinic (# of clients served per day)		Opening schedule					
		Select Yes, No, or Some	Where appropriate please indicate on a scale of 0-5 (0 – weak/low/insufficient 5 – strong/high/sufficient)	Comments for additional internal clarification and information			
Human Resource	s and Personnel						
	ve clinical staff to support oral PrEP delivery? al staff in the comment box, specify number with tifications						
	e outreach staff or partner organizations to llout (e.g., peer educators)? Indicate the # of comment box						
mentorship and capa	an in-place that includes continuous acity building of healthcare workers on oral acludes addressing attitudes on oral PrEP)?						
	e time to add oral PrEP? Please specify how oral e integrated into the facility management plan						
	k with implementing partners to support HIV additional context on partners in the comment						
Has the facility ident	ified a focal person or team to facilitate and						



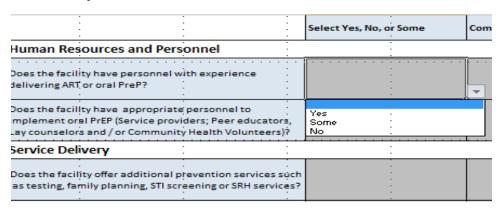
The assessment tools provide a simple rating system to highlight areas of focus/investment

The facility readiness assessment tool contains:

 A list of questions/ criteria that facilities preparing for oral PrEP delivery can answer based on current capabilities

2) Based on the answers to each question, the tools will indicate areas where the facility may be strong and other areas where the facility may need to build additional capacity, capabilities or invest to introduce oral PrEP

Screenshot of criteria in "Basic Assessment" tool



Screenshot of criteria and rating scale in "Basic Assessment" tool

	Select Yes, No, or Some	Implications	
Human Resources and Personnel			
Does the facility have personnel with experience delivering ART or oral PreP?	No	Little additional investment needed Moderate effort/investment	
Does the facility have appropriate personnel to implement oral PrEP (Service providers; Peer educators, Lay counselors and / or Community Health Volunteers)?	Yes		
Service Delivery	required		
Does the facility offer additional prevention services such as testing, family planning, STI screening or SRH services?	Some	Significant investment required	

INTRODUCTION TO PRIVATE SECTOR ASSESSMENT



Private sector assessment tool overview

Purpose

A tool to assess and compare opportunities to deliver oral PrEP through private sector healthcare channels to reach individuals at high-risk for HIV

About the tool

- This tool was developed based on consultations in the three OPTIONS countries (South Africa, Kenya and Zimbabwe)
- The tool is designed to provide answers to two key questions that were raised by policymakers and implementers in those countries:



To what extent does private sector healthcare reach individuals at high risk for HIV, especially women and adolescent girls?



What can be done to leverage the opportunity to deliver oral PrEP through the private sector?



Private sector healthcare includes diverse channels that could deliver PrEP

While different channels will be relevant in each country, the following healthcare channels are broadly relevant across many countries:

Commercial healthcare facilities

Private, for-profit hospitals and clinics

Faith-based organizations (FBOs)

Private facilities affiliated with religious institutions, including church-related networks and individual mission hospitals

Private doctors

For-profit doctors who either work in small private clinics or manage their own independent practice

Pharmacies

Private facilities in which individuals can purchase medicine, some of which are managed by trained health care workers or pharmacists

NGO clinics / Social franchises

Private, not-for-profit facilities funded by donors and for- or not-for-profit clinics participating in social franchise networks

Higher education institutions or workplaces

Health facilities and services at universities, technical schools, and places of employment



Assessing each channel against six criteria

The following six criteria were identified as critical to assess for private sector channels to understand to what extent they could improve access to oral PrEP for high-risk populations.



Can individuals at high-risk for HIV access this channel?

Factor	Definition			
1 Acceptability	Individuals at risk for HIV are comfortable with accessing family planning and other sexual and reproductive health services through this channel			
2 Affordability	Services are affordable for individuals at risk for HIV with a range of income levels			
3 Proximity	Sufficient number of facilities located in regions with high HIV incidence			



Factor	Definition
4 HIV counseling and testing services (HCT)	Channel currently offers HIV counseling and testing services
5 Healthcare workers (HCW)	Channel has healthcare workers on staff who can prescribe and support adherence to oral PrEP
6 Ability to provide follow-up	Channel enables oral PrEP users to easily follow-up for prescription pick-up and ongoing testing



Example: South Africa

Delivery channel	Can women at high-risk for HIV access this channel?		Does this channel have the capacity to deliver oral PrEP?			Opportunity to deliver PrEP	
channel	Acceptability	Affordability	Proximity	НСТ	HCW	Follow-up	
Commercial facilities							 LOW OPPORTUNITY Unaffordable prices and urban concentration limit accessibility beyond wealthy populations Strong capacity to deliver oral PrEP
NGO clinics/ social franchises							 MEDIUM OPPORTUNITY Social franchises effectively deliver affordable, integrated HIV and SRH services without stigma Small number restricts delivery of PrEP at scale
Private doctors							 HIGH OPPORTUNITY Highly accessible, as the most common private sector entry point nationwide Limited capacity for ongoing testing and follow-up
Pharmacies							 MEDIUM OPPORTUNITY Highly accessible due to privacy and proximity Most will not be able to prescribe oral PrEP, but could be an information dissemination point
Higher education institutions							 HIGH OPPORTUNITY On site health centers deliver HCT to at-risk AGYW and have high referral rates Important avenue to deliver information on PrEP in conjunction with HCT





Thank you

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OPTIONS Consortium Partners























