

# OPTIONS *Optimizing Prevention Technology Introduction On Schedule*

## OPTIONS COUNTRY SITUATION ANALYSIS SOUTH AFRICA DECEMBER 2018

*FSG in partnership with Wits RHI*



# Snapshot of oral PrEP rollout in South Africa

As of **October 2018\***, PrEP rollout in South Africa achieved the following reach:



Clients initiating oral PrEP: **9,162**



Provinces with oral PrEP Access: **8 out of 9**



Facilities Distributing oral PrEP: **65**

\* Date of latest data



# Strengths and challenges for oral PrEP rollout

- **Expanded PrEP rollout** from rollout only focused on sex workers to include MSM and AGYW

- Mylan **generic** has been approved and provides lower cost alternative *(Note: additional generics have been approved as well)*
- PrEP currently delivered through **implementing partners, campus clinics and primary healthcare facilities**

- **PrEP embedded in SRH services** for AGYW in primary healthcare
- National PrEP **training improved** (e.g., side effects counseling, AGYW)
- Facilities providing PrEP to AGYW must adopt **Youth Zone standards**

- Training and IEC materials developed based on evidence from ACCESS study (motivators / challenges for uptake)
- UNITAID Project PrEP will launch in 2018 and provide PrEP to AGYW in **comprehensive package**

- Inclusion of PrEP in **national reporting system (TIER.NET)** – preliminary module has been built and **training plan under development**



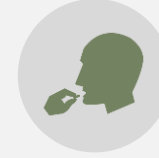
## PLANNING & BUDGETING



## SUPPLY CHAIN MANAGEMENT



## PREP DELIVERY PLATFORMS



## INDIVIDUAL UPTAKE



## EFFECTIVE USE & MONITORING

- Current considerations around where to **focus resources** based on current monitoring and modeling data
- Ongoing **operations assessment research** to inform AGYW rollout

- There have been **delivery delays** with Mylan generic
- Potential **price fluctuations** due to changing drug regimens (e.g., transition to dolutegravir)

- There is a need to determine the most effective delivery models for PrEP within **the public health system at primary health care level**
- HCW **perceptions remain challenge to providing PrEP to AGYW** *(research ongoing with KAP study)*

- Need to **scale up demand creation activities**, especially community engagement and effective communications
- **Stigma** related to ARV and preliminary rollout to KPs
- AGYW **continuation remains a concern**

- Due to TIER limitations, **tracking PrEP users who are mobile and may access PrEP services at multiple locations will be difficult at a national level** (though is being piloted in Project PrEP)

### Current Challenges



# South Africa oral PrEP rollout progress

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

**COLOR KEY**

- Significant progress and/or momentum
- Early progress
- Initial conversations ongoing



# Planning & budgeting

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Readiness factor	April 2016	December 2016	May 2018	December 2018	Progress notes
Impact, cost and cost-effectiveness analyses for oral PrEP as part of comprehensive HIV prevention portfolio					<ul style="list-style-type: none"> <li>HE2RO has conducted extensive modeling to determine impact and cost effectiveness of oral PrEP to key populations based on current uptake data – this analysis is guiding decisions on where and how to focus resources</li> </ul>
Identification and quantification of <b>target populations</b> for oral PrEP					<ul style="list-style-type: none"> <li>Key populations have been identified as target populations, starting with female sex workers (FSW) and then followed by men who have sex with men (MSM) in 2017 and adolescent girls and young women (AGYW) in 2018</li> </ul>
Inclusion of oral PrEP and female-controlled methods in current or upcoming <b>national HIV prevention plans</b>					<ul style="list-style-type: none"> <li>Oral PrEP has been included in the South African National Strategic Plans for HIV, TB and STIs 2017-2022</li> </ul>
<b>Timeline and plan</b> for oral PrEP introduction and scale-up					<ul style="list-style-type: none"> <li>There has been continuous expansion of sites providing oral PrEP to key populations, with 66 sites currently providing oral PrEP and 19 in the pipeline</li> </ul>
A <b>budget</b> for oral PrEP rollout to target populations					<ul style="list-style-type: none"> <li>With assistance from the Global Fund, oral PrEP is being effectively rolled out to target populations, with some pieces of comprehensive prevention package (STI and pregnancy screening) covered by NDOH/NHLS</li> </ul>
<b>Sufficient funding</b> to achieve targets					<ul style="list-style-type: none"> <li>More recently funding has been secured through UNITAID (WHO) for oral PrEP provision to AGYW</li> </ul>



# Supply chain management

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Readiness factor	April 2016	December 2016	May 2018	December 2018	Progress notes
Regulatory <b>approval</b> of form(s) of oral PrEP by authorities					<ul style="list-style-type: none"> <li>Gilead's TDF/FTC combination pill, Truvada®, was approved for use as oral PrEP by the Medicine Control Council (MCC) in December 2015</li> <li>Four additional TDF/FTC products have received approval for use as PrEP in South Africa as of July 2016: Aspen (Truvada and Tencitab), Cipla (Didivir), and Mylan (Tenemine)</li> </ul>
Effective <b>demand and supply forecasting</b> mechanisms for oral PrEP					<ul style="list-style-type: none"> <li>Sites submit stock figures and routine data monthly; inputs are fed into a stock tracking tool that identifies sites that require additional stock</li> </ul>
Manufacturer identification and <b>contract</b> negotiation to purchase oral PrEP					<ul style="list-style-type: none"> <li>While Mylan continues to be primary source for oral PrEP, other options (including Truvada) are being explored due to Mylan's delayed delivery</li> <li>Price of Mylan option may fluctuate with regimen changes in South Africa</li> </ul>
<b>Product and packaging</b> design to meet target population needs and preferences					<ul style="list-style-type: none"> <li><i>No further progress at present</i></li> </ul>
Development of <b>distribution plan</b> for oral PrEP to reach target populations					<ul style="list-style-type: none"> <li>Oral PrEP is distributed through implementing partners and primary health care facilities</li> </ul>
<b>Effective distribution mechanisms</b> to avoid oral PrEP stock-outs in priority facilities					<ul style="list-style-type: none"> <li>Due to delayed deliveries some stock has to be moved around – existing stock management tools have helped with dynamic management</li> </ul>



# PrEP delivery platforms

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Readiness factor	April 2016	December 2016	May 2018	December 2018	Progress notes
Issuance of standard <b>clinical guidelines</b> for prescription and use of oral PrEP	Early progress	Significant progress and/or momentum	Significant progress and/or momentum	Significant progress and/or momentum	<ul style="list-style-type: none"> <li>No further progress at present</li> </ul>
Sufficient <b>infrastructure and human resources</b> to conduct initial HIV tests and prescribe oral PrEP in priority channels	Early progress	Early progress	Significant progress and/or momentum	Significant progress and/or momentum	<ul style="list-style-type: none"> <li>Primary healthcare facilities in <i>She Conquers</i> priority districts have recently started delivering oral PrEP - these clinics have the capacity to conduct HIV tests and prescribe oral PrEP through NIMART trained nurses</li> </ul>
Plan to engage <b>health care workers</b> on oral PrEP and delivery to target populations (including mitigating stigma)	Early progress	Early progress	Significant progress and/or momentum	Significant progress and/or momentum	<ul style="list-style-type: none"> <li>Healthcare provider attitudes remain a challenge, especially when providing oral PrEP to AGYW</li> <li>OPTIONS conducted a study assessing knowledge, attitude, and practiced behaviors (KAP) of PrEP experienced (FSW and MSM) and PrEP naïve providers (campus clinics, <i>She Conquers</i> sites); results were shared with the NDOH and will inform future healthcare worker training</li> <li>OPTIONS created training tools for providers integrating provision of oral PrEP and AGYW SRH needs</li> <li>The WHO is conducting qualitative operational assessments of sites in KwaZulu-Natal serving AGYW</li> </ul>
Tools to help potential clients and HCW understand <b>who should use oral PrEP</b> have been created	Early progress	Significant progress and/or momentum	Significant progress and/or momentum	Significant progress and/or momentum	<ul style="list-style-type: none"> <li>PrEP implementation pack contains provider resources to provide oral PrEP – available to new sites and on PrEPWatch</li> </ul>
Sufficient <b>resources</b> to rollout plans for healthcare worker engagement	Initial conversations ongoing	Initial conversations ongoing	Early progress	Early progress	<ul style="list-style-type: none"> <li>No further progress at present</li> </ul>



# Individual uptake

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- Significant progress and/or momentum
- Early progress
- Initial conversations ongoing

Readiness factor	April 2016	December 2016	May 2018	December 2018	Progress notes
Clear and informative <b>communications</b> on oral PrEP for general public audiences					<ul style="list-style-type: none"> <li>A PrEP website called myPrEP.co.za launched in September 2018; reporting and metrics are in progress</li> </ul>
Development of <b>demand generation strategies</b> targeted to unique needs of different populations					<ul style="list-style-type: none"> <li>Demand creation materials used for the initial rollout have been adapted to reflect the needs and preferences of different target populations through a consultative process with end users; this process is currently being expanded with OPTIONS research to include AGYW</li> </ul>
<b>Linkages</b> between HTC, oral PrEP prescription, and oral PrEP access to enable uptake					<ul style="list-style-type: none"> <li>Oral PrEP is now available at primary healthcare facilities (through implementing partners) and will soon be launched through additional primary healthcare facilities through Project PrEP (launch December 2018)</li> <li>Linkages are facilitated through a comprehensive package of SRH services, both at fixed and mobile facilities</li> </ul>
<b>Information for clients</b> on how to effectively use oral PrEP for all end user populations					<ul style="list-style-type: none"> <li>IEC materials created to increase oral PrEP knowledge with input from potential end-users and translated to local languages</li> <li>Additional information is available on myPrEP website for PrEP users and general population</li> <li>OPTIONS is conducting research with AGYW to inform further adaptations of IEC materials</li> </ul>
Sufficient <b>resources</b> to rollout plans for demand generation					<ul style="list-style-type: none"> <li>Project PrEP is launching in December 2018 with dedicated resources for scale-up</li> <li>There are ongoing conversations with TWG on scale-up of demand creation</li> </ul>





# Effective use & monitoring

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Readiness factor	April 2016	December 2016	May 2018	December 2018	Progress notes
Established plans to support <b>effective use and regular HIV, creatinine testing</b> that reflect the unique needs of target populations					<ul style="list-style-type: none"> <li>Facilities have the capacity to provide regular HIV testing - this service is provided when someone enrolls for oral PrEP at the facility</li> </ul>
<b>Capacity</b> to provide ongoing HIV and creatinine level testing for oral PrEP users accessible to target populations					<ul style="list-style-type: none"> <li>Public facilities rolling out oral PrEP have the capacity to provide ongoing HIV and creatinine level testing</li> </ul>
<b>Monitoring system</b> to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)					<ul style="list-style-type: none"> <li>There are plans to move the monitoring system onto National TIER.Net system - this process is ongoing with the preliminary module built and training plans under development</li> </ul>