Accelerating the Curve

HSR 2016
About OPTIONS

Goal: To accelerate introduction and access to advances in biomedical technologies and new approaches for HIV prevention.

While drugs, diagnostics, and vaccines typically scale within the first two years of launch in developed countries, they often take decades to scale in lower- and middle-income countries.

Source: Bill & Melinda Gates Foundation
Adolescent girls and young women need access to new HIV prevention methods

Adolescent girls and young women account for 70-80% of new HIV infections in Sub-Saharan Africa
Ensuring access to PrEP products will require overcoming numerous challenges

Supply Side
- Effective, affordable products
- Regulatory approval
- Government plans & budget
- Knowledgeable, supportive healthcare providers

Demand Side
- Accessible facilities
- Information & communications
- Physical access to facilities
- Partner, family & community support
- Stigma, rumors & misinformation
- Adherence
A simple but comprehensive value chain introduction framework can support planning.

Value chain for PrEP products

- Effective products that meet user preferences are developed, researched, and approved
- National gov’ts develop a plan & budget to implement WHO PrEP guidelines for targeted populations
- PrEP is produced, procured, and distributed in sufficient quantity to meet demand
- PrEP services delivered by supportive HCW through channels that reach target populations
- Target populations are able to seek, access, and adhere to PrEP regimens during high-risk periods
- PrEP use, impact on HIV prevention, and potential resistance is monitored and evaluated
Our partners in South Africa, Zimbabwe and Kenya used this framework in 3 ways

1. Planning for PrEP introduction at the national level
2. Understanding the landscape of PrEP demo projects and related insights
3. Assessing readiness to deliver PrEP in high-need districts
Planning for PrEP introduction in Zimbabwe

**Expected Strengths**

- New plan (ZNASP III) 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 NGO channels
- Coordination challenges in ARV scale-up resolved
- Variety of HIV service channels with strong coverage (e.g., ART sites, CBHC, HTC centres, civil society, mobile clinics)
- Wide dissemination of treatment guidelines
- Good HTC coverage
- Recent positive legal change relevant to FSWs
- PITC is being pushed
- Civil society presence advocating for key pops (e.g., FSW, MSM)
- Single harmonized monitoring and evaluation system
- New plan (ZNASP III) mentions M&E plan to be developed and upholds importance of monitoring

**POLICIES, PLANS & BUDGETS**

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

**SUPPLY CHAIN MANAGEMENT**

- Truvada registered as treatment but not prevention
- Demand forecast will involve populations for which little data exists

**PREP DELIVERY PLATFORMS**

- Access to HTC
- Negative / stigmatizing health care worker attitudes
- Capacity limitations in some HIV channels

**END USER UPTAKE & ADHERENCE**

- Low (but rising) rates of HTC usage
- Demand generation plans early-stage
- Stigma and laws inhibit access to HIV services

**MONITORING & EVALUATION**

- Little is known about PrEP adherence
- Ongoing testing of PrEP users could place strain on the existing HIV testing capacity

**Emerging Key Considerations**
# Planning for PrEP Introduction

## Planning & Budgeting
- Impact, cost and cost-effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio
- Identification and quantification of target populations for PrEP
- Inclusion of PrEP and female-controlled methods in current or upcoming national HIV prevention plans
- Timeline and plan for PrEP introduction and scale-up
- A budget for PrEP roll-out to target populations
- Sufficient funding to achieve targets

## Supply Chain Management
- Regulatory approval of form(s) of oral PrEP by authorities
- Effective demand and supply forecasting mechanisms for PrEP
- Manufacturer identification and contract negotiation to purchase PrEP
- Product and packaging design to meet target population needs and preferences
- Development of distribution plan for PrEP to reach target populations
- Effective distribution mechanisms to avoid PrEP stock-outs in priority facilities

## PREP Delivery Platforms
- Issuance of standard clinical guidelines for prescription and use of PrEP
- Sufficient infrastructure and human resources to conduct initial HIV tests and prescribe PrEP in priority channels
- Plan to engage healthcare workers on PrEP and delivery to target populations (including mitigating stigma)
- Tools to help potential clients and HCW understand who should use PrEP
- Sufficient resources to rollout plans for healthcare worker engagement

## Individual Uptake
- Clear and informative communications on PrEP for general public audiences
- Development of demand generation strategies targeted to unique needs of different populations
- Information for clients on how to effectively use PrEP for all target populations
- Sufficient resources to rollout plans for demand generation

## Effective Use & Monitoring
- Established plans to support effective use and regular HIV, creatinine testing that reflect the unique needs of target populations
- Capacity to provide ongoing HIV and creatinine level testing for PrEP users accessible to target populations
- Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)

### COLOR KEY
- Significant progress and/or momentum
- Early progress
- Initial conversations ongoing
Analyzing demonstration projects in South Africa

Q1 | What are the most effective practices to target and deliver PrEP to AGYW

<table>
<thead>
<tr>
<th>Study</th>
<th>Timeline</th>
<th>Tag</th>
<th>Question</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPRISA 082</td>
<td>Ongoing March 2016-April 2021 Prov. results mid-2017</td>
<td>R n</td>
<td>What are the characteristics of high-risk AGYW and how can they be effectively targeted?</td>
<td></td>
<td>Studies using differing “risk factors” to identify study participants; a comparison across them will be informative</td>
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<tr>
<td>EMPOWER</td>
<td>Planned 6/16 – 8/18 Provisional results mid-2017</td>
<td>R ca U</td>
<td>What are the major barriers to PrEP uptake for AGYW and how can they be addressed?</td>
<td></td>
<td>Several studies (HPTN 082, POWER) collect data on barriers and AGYW who decline PrEP; others will study product acceptability</td>
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<tr>
<td>HPTN 082</td>
<td>Planned Expected start early 2017</td>
<td>R ca Cc</td>
<td>What legal or ethical considerations are relevant for PrEP provision to AGYW?</td>
<td></td>
<td>Collection of data on parental consent, but no other specific legal/ethical considerations noted</td>
</tr>
<tr>
<td>MSF</td>
<td>Ongoing Plus: expected in 10/16</td>
<td>R A</td>
<td>What service delivery and civil society channels will most effectively reach AGYW?</td>
<td></td>
<td>Coverage across different types of delivery channels (e.g., mobile, primary care clinics, FP clinics)</td>
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<tr>
<td>MTN034</td>
<td>Ongoing Recruitment mid-2016 Completion 2020</td>
<td>R</td>
<td>What types of investments are required to effectively deliver PrEP through these channels?</td>
<td></td>
<td>Only one study (POWER) explicitly includes costing component</td>
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<tr>
<td>Pills Plus</td>
<td>Planned Expected start early 2017</td>
<td>R a Ap</td>
<td>How can negative health care worker attitudes be effectively mitigated?</td>
<td></td>
<td>No awareness of current plans to study this aspect</td>
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<tr>
<td>POWER</td>
<td></td>
<td></td>
<td>What are the most effective strategies to build awareness and generate demand for PrEP amongst AGYW?</td>
<td></td>
<td>Significant focus on demand through various recruitment and communications strategies across demo projects</td>
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<td></td>
<td>How are AGYW communicating about PrEP to partners or family members and/or involving them in decisions?</td>
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<td>No awareness of current plans to study this aspect</td>
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<td>How are “periods of risk” defined? What strategies / tools support AGYW decision-making around on/off decisions?</td>
<td></td>
<td>CAPRISA and HPTN 082 studies explicitly discuss and track “PrEP cycling,” but little focus on this (and strategies for communications) in other studies</td>
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<td></td>
<td>To what extent are AGYW adhering to PrEP? What messages and strategies effectively support adherence?</td>
<td></td>
<td>Significant focus on adherence and strategies for encouraging adherence across studies</td>
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<td></td>
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<td>Are AGYW getting regular HIV/STI testing? What strategies effectively support retention in regular testing?</td>
<td></td>
<td>Each study has a different testing protocol; comparisons across them may be useful</td>
</tr>
</tbody>
</table>

Input is needed on: Q4 | What services should be effectively linked to youth clinics and how can they be addressed?
Q5 | What type of support is required to PrEP through? What are they?
Assessing county readiness to deliver PrEP in Kenya

Geographic Rollout Scenarios for PrEP in Kenya

1. Hyper Epidemic Lake Region (Kisumu, Migori, Homa Bay, Siaya)
   - Total Population: ~4M
   - get Populations: CSW (#), MSM (#), high-risk AGYW (#)
   - Total Prevalence: 14.7% (Migori) – 25.7% (Homa Bay)
   - Total Incidence Rate: 1.56% (Migori) - 2.98% (Homa Bay)
   - Total New Infections: ~39K total new infections in 2014

2. Other High Incidence Lake Region (Kisii, Nyamira, Bomet)
   - Regions and New Infections (2014)
   - 44%

3. Urban Centers (Nairobi, Mombasa, Nakuru, Kiambu)
   - 13%

4. Turkana
   - 3%

5. High Female Prevalence Areas (Bungoma, Kakamega, Busia, T Nzoia, T Taveta, Kwale, Makueni, Muranga)
   - 7%

Total % of new infections: 80%
What’s next?

• South Africa has introduced oral PrEP for sex workers in a pilot project

• Kenya and Zimbabwe are planning to finalize implementation plans for oral PrEP in early 2017

• Details and lessons can be found at PrEPWatch.org