OPTIONS
Country Situation Analysis Interim Findings: South Africa

FSG in partnership with Wits RHI
OPTIONS Introduction

One of five cooperative agreements awarded by USAID with PEPFAR funding through Round Three of the Annual Program Statement (APS) for Microbicide Research, Development, and Introduction.

The OPTIONS Consortium objective is to provide targeted support to help expedite and sustain access to new ARV-based HIV prevention products in countries and among populations where most needed.

OPTIONS Consortium Members
# OPTIONS Consortium Aims

OPTIONS can provide targeted support across its four project aims:

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<tr>
<th>AIM 1</th>
<th>AIM 2</th>
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<tr>
<td>Develop evidence-based <em>business cases and a coordinated investment strategy</em> for ARV-based prevention product introduction to ensure timely global, national and private sector action on priority areas</td>
<td>Support <em>country level</em> regulatory approval, policy development, program planning, marketing and implementation strategies for ARV-based prevention product introduction</td>
<td>Facilitate and conduct <em>implementation science</em> (IS) to advance the introduction of and access to microbicides and ARV-based prevention technologies</td>
<td>Provide <em>technical assistance and support for health systems strengthening (HSS)</em> with rapid use of data to identify and address implementation bottlenecks throughout the value chain</td>
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• OPTIONS is not a service delivery project; we apply systems thinking to support and accelerate product introduction

• Our support is flexible and is designed to be responsive to national country priorities and plans and will be guided by national leadership

• In addition to Wits RHI, our consortium is able to bring multi-disciplinary expertise to the effort to introduce female-controlled HIV prevention products in South Africa

• We are taking significant steps to ensure we do not replicate existing or ongoing work – our mission is to fill gaps and help answer key questions as outlined by the national government, the USAID country mission, and other key local stakeholders
About the Situation Analysis

• This document includes **interim findings** from the OPTIONS situation analysis for South Africa, completed by FSG with significant input and consultation from Wits RHI

• The situation analysis aims to take a **comprehensive and robust approach** to assessing the “state of the field” for PrEP in South Africa, including opportunities and resources as well as gaps and expected challenges

• The situation analysis serves **multiple purposes**: it provides a basis for country consultations and stakeholder engagement, it serves as a tool to clarify the roles, activities and investments needed for the successful roll-out of PrEP, and it will inform the development of the OPTIONS investment cases for PrEP

• This document reflects findings primarily from secondary **research**, with input from country consultations conducted by Wits RHI – additional consultations are forthcoming and will contribute additional detail and nuance to this analysis

• This is designed as a **“living document,”** to serve as a repository for information regarding the situation of PrEP in South Africa to be updated on an ongoing basis as additional information becomes available and progress is made towards the roll-out of PrEP

• If you have any **updates, additional information, or follow-up questions** regarding this content here, please email Neeraja Bhavaraju at neeraja.bhavaraju@fsg.org
Executive Summary

• South Africa’s regulatory and healthcare delivery bodies are in progress on the roll-out of oral PrEP to priority populations. However, a number of outstanding questions remain.

• The National Department of Health (NDoH) has voiced support for PrEP as part of the country’s comprehensive prevention package. The NDoH is developing treatment and implementation guidelines following the registration of Truvada as PrEP by the Medicines Control Council (MCC).

• The National Test and Treat (T&T) and PrEP TWG developed the Policy and Guidelines for the introduction of oral PrEP and immediate test and treat. The initial guidelines were specific for the limited rollout through sex worker programs, but they are now being updated to include all key populations, with a phased approach to rollout.

• The strongest existing channels for HIV care delivery to target populations are currently those for sex workers (SW) and for men who have sex with men (MSM), the two populations identified as the first to receive PrEP.
  - The NDoH National Sex Worker HIV Plan for 2016-2019 provides for immediate ART to all HIV-positive SW and offer of PrEP to all HIV-negative SW. An initial rollout to 11 existing donor-funded demonstration project sites began on 1 June 2016.
  - New sites for PrEP delivery will be trained in January 2017. These will expand PrEP to a limited number of MSM program sites.
  - The adolescent girls and young women (AGYW) PrEP TWG has been formed to discuss rollout considerations for this population. Since the first meeting in March 2016 there have been three phone conferences and an additional full day workshop in June 2016. The next meeting will occur in Q1 of 2017.

• Remaining questions for exploration include:
  - How to effectively identify those at significant risk, and what are the most effective and efficient service delivery channels to reach them? What are the most effective messages and strategies for demand creation for PrEP?
  - What are the barriers to, facilitators of, and strategies for oral PrEP uptake, adherence, and retention? What are the providers’ knowledge, attitudes, practices, and behaviors with regards to oral PrEP delivery?

• A number of ongoing demonstration projects, studies, and other programs in South Africa will inform these questions, including 14 demonstration and pilot projects focused on AGYW. The AGYW TWG conducted an in-depth landscape analysis of program research agendas and evidence collection, with the aim to determine remaining gaps.
Current State of HIV in South Africa

Context
- 7 million people estimated to be living with HIV\(^1\), making South Africa the country with the highest HIV burden in the world
- Prevalence rate in adults is 15-49 19.2\(^2\); 3.4 million people receive ART\(^3\)
- The number of annual new infections is estimated at 380,000.\(^2\) While new infections have been reduced by about a third since 2004, incidence is rising in certain populations, particularly among adolescent girls and young women (AGYW)
- New infections for those age 15–49 years is 1.7 times higher in women than in men; among youth 15-24 it is over 4 times higher\(^4\)

Trend
The overall trend of HIV incidence is positive, however it masks differences amongst demographic groups.

Demographics
AGYW are disproportionately affected by HIV: they comprise ~25% of new infections and are more than twice as likely to be HIV positive as male peers\(^4\)

Geography
- Prevalence varies sizably between provinces, from 40% in KwaZulu-Natal to 18% in Western Cape\(^4\)
- Prevalence is highest in medium and large urban areas, although data for rural settings is poor/incomplete

Sources:
HIV Prevention & Treatment

Context

• Despite a delayed response to the HIV epidemic in South Africa, strong commitments and programming in treatment and prevention in the past decade have made significant strides. Notably, HIV counselling and testing (HCT), ART coverage expansion, and medical male circumcision (MMC) efforts have reached and in some cases exceeded national targets.

• The focus of HIV response has been on scaling up ART. Access to ART has more than doubled since 2008, which is now available to nearly 3.4 million people living with HIV (PLHIV).1 Recent model estimates ART coverage will reach 80% of PLHIV by 2022.2

• However, prevention lags far behind treatment efforts, and a renewed focus on prevention is needed.

Current Efforts

• Largest ART program in the world with nearly 3.4 million people1 on treatment provided by 3,600 facilities3
  - ~ 600,000 people are initiated on ART each year. However loss to follow-up rate is high at ~30-40%4

• HIV Counseling and Testing (HCT) campaign launched in 2010 has improved screening rates; Universal Test & Treat (UTT) guidelines adopted in September 20165

• While focus has been on rapid scaling of ART coverage, significant prevention efforts exist:6
  • Condom distribution: 712 million male and ~21 million female condoms distributed in 2014/15
  • Medical Male Circumcisions: 508,000 circumcisions performed in 2014/15

• The National Sex Worker HIV Plan for 2016-2019 calls for UTT for all HIV-positive SW and PrEP for HIV-negative SW

Remaining Challenges

• Complex social dynamics limit reach to high-risk populations, including entrenched stigma against MSM and FSW and gender inequality and gender-based violence for AGYW

• Reaching the highest-risk populations is a challenge to meeting UTT and overall HIV prevention and treatment goals

• High rate of new infections in the AGYW population with no existing robust delivery channels (including HIV testing) for population-appropriate combination prevention package

• Limited health system capacity has resulted in task-shifting for ART delivery, further straining the system’s capacity to comprehensively deliver both treatment and prevention given the systemic prioritization of time and resources to treatment over prevention

• Robust creatinine testing capacity to support PrEP regimen

**Key Considerations for PrEP**

### Why PrEP is under consideration in South Africa

- **Achieving HIV prevention targets:** PrEP could help South Africa achieve its commitments to global and national goals: UNAIDS’ three zeros vision and 90-90-90 goals, National Strategic Plan, and the vision of an “AIDS-Free Generation.” In particular, PrEP is seen as a HIV prevention method with high potential to reach **women and adolescent girls**, who are experiencing disproportionate and growing HIV rates.

- **Implementing combination prevention:** As South Africa refocuses and reinvests in HIV prevention, PrEP can provide additional choice and empowerment to those target populations who do not use other prevention methods as part of a combination prevention package.

- **Promoting equity for AGYW, MSM and SW:** South Africa has a clear commitment to improving the health and livelihoods of adolescent girls and young women, sex workers and men having sex with men, as outlined in various policy documents including the National Strategic Plan (NSP) on HIV, STDs and TB (2012-2016). The NSP states: “the NSP must be rooted firmly in the protection and promotion of human and legal rights, including prioritizing gender equality and gender rights”.

- **Building on existing and future health care investments:** PrEP delivery can build on other investments to improve health system capacity and coordination. Several analyses suggest **PrEP may be cost effective** when delivered to the appropriate sub-segments of target populations by making incremental investments in existing delivery channels. PrEP will also lay the groundwork for future female-controlled HIV prevention methods.

### Current PrEP context

- **While PrEP is a beneficial addition to the comprehensive prevention package,** **significant questions remain** for key decision-makers around cost-effectiveness for specific populations (e.g., AGYW) and effective delivery channels and demand generation strategies

- **A National PrEP Technical Working Group** has been established, and sub-groups focusing on AGYW, MSM and SW have been created to consider these major questions.

- Truvada, Tancitab, Tenemine, Emtevir, and Dividir have been **approved** as oral PrEP by Medicines Control Council (MCC) for use by non-pregnant adults 18+

- **Draft implementation guidelines** drafted by TWG are currently under review. The Southern African HIV Clinicians Society published PrEP **clinical guidelines** in early 2016

- PrEP has been rolled out to **SW population, with MSM to follow**; expectations to deliver PrEP to AGYW, but questions remain about what sub-sections of the population to target.

- **DREAMS** will deliver PrEP for young FSW as part of AGYW prevention strategies delivered in pilot districts throughout the country.
## Key Populations for PrEP

<table>
<thead>
<tr>
<th>Adolescent girls and young women (AGYW)</th>
<th>Men who have sex with men (MSM)</th>
<th>Sex workers (SW)</th>
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<tr>
<td><strong>Key Indicators</strong></td>
<td><strong>Prevalence:</strong> 13-49%&lt;sup&gt;a&lt;/sup&gt;</td>
<td><strong>Size:</strong> ~153,000 <strong>Prevalence:</strong> ~66.1%&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td></td>
<td><strong>Incidence:</strong> 9.5%&lt;sup&gt;a&lt;/sup&gt;</td>
<td><strong>Incidence:</strong> Unknown</td>
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<td></td>
<td>Highest prevalence found in KwaZulu-Natal, Mpumalanga, Gauteng and Western Cape</td>
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<td>Urban MSM at highest risk</td>
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<td>Over 90% have tested at least once, ~50% in the last month</td>
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<td>HIV programming for MSM as well as high-risk behavior have increased in recent years</td>
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<td></td>
<td><strong>Experience high frequency of participation in transactional sex, high rates of age-disparate relationships</strong></td>
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<td><strong>Incidence</strong>&lt;sup&gt;c&lt;/sup&gt;</td>
<td><strong>PrEP perceived to be cost-effective</strong> for MSM</td>
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<td>- Age 15-24: 2.54%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>MSM will be the second population to receive PrEP (after SW), as early as Q12017</td>
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<td>- Age 20-34 Black African: 4.54%&lt;sup&gt;e&lt;/sup&gt;</td>
<td><strong>SANAC released the National Sex Worker HIV Plan for 2016–2019, providing ART to all HIV+ SW and offers PrEP to HIV- SW. Rollout began in June 2016 at 11 pilot sites. New sites will be added in Q12017.</strong></td>
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<td><strong>Prioritization</strong></td>
<td><strong>How can South Africa effectively activate channels already reaching MSM to deliver PrEP?</strong></td>
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<td><strong>What service delivery platforms are most effective in providing PrEP to the SW population?</strong></td>
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<td><strong>What sub-segments of the AGYW are at highest-risk of HIV / highest priority for PrEP?</strong></td>
<td><strong>How will civil society and health providers address structural stigma to ensure reliable and effective access to PrEP for these populations?</strong></td>
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<td><strong>What new channels could be activated to reach AGYW (e.g., SRH, schools)?</strong></td>
<td><strong>Will initial launch of PrEP in these populations stigmatize use of PrEP for other populations?</strong></td>
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<tr>
<td><strong>Questions</strong></td>
<td><strong>What service delivery platforms are most effective in providing PrEP to the SW population?</strong></td>
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<tr>
<td><strong>Not currently being considered for oral PrEP by NDoH</strong></td>
<td><strong>How can South Africa effectively activate channels already reaching MSM to deliver PrEP?</strong></td>
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<td><strong>She Conquers campaign and other initiatives currently focusing on HIV prevention among AGYW</strong></td>
<td><strong>What sub-segments of the AGYW are at highest-risk of HIV / highest priority for PrEP?</strong></td>
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<td><strong>A PrEP TWG focused on AGYW is in place</strong></td>
<td><strong>How will civil society and health providers address structural stigma to ensure reliable and effective access to PrEP for these populations?</strong></td>
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### Sources:
3. MSM estimates: NDoH, SANAC and UCSF, [http://globalhealthsciences.ucsf.edu/sites/default/files/content/gsi/msm-triangulation-south-africa.pdf](http://globalhealthsciences.ucsf.edu/sites/default/files/content/gsi/msm-triangulation-south-africa.pdf);
OPTIONS aims to take a robust and comprehensive approach to analyzing the situation around PrEP. The goal of this exercise is to **identify key bottlenecks and opportunities to introduce and scale PrEP effectively** in each OPTIONS country. This information will eventually feed into the investment cases and will be used to inform and capture country progress.

To identify what’s needed for PrEP introduction, we have organized the rest of the situation analysis along the **PrEP value chain**, introduced below.

### Value Chain for PrEP

#### PLANNING & BUDGETING
- Plan developed to implement WHO PrEP guidelines for targeted populations

#### SUPPLY CHAIN MANAGEMENT
- PrEP produced, purchased, and distributed in sufficient quantity to meet projected demand

#### PREP DELIVERY PLATFORMS
- PrEP services delivered by appropriate channels with access to target populations

#### INDIVIDUAL UPTAKE
- Target populations seek and are able to access PrEP and begin use

#### EFFECTIVE USE & MONITORING
- Target population adheres to PrEP at recommended frequency and for ideal time period
Value Chain Analyses

The following slides hold three analyses along the value chain:

- **Resources** that exist in-country to support and accelerate PrEP introduction
- **Gaps** in resources that could act as barriers to effective PrEP introduction
- **Key considerations** to inform comprehensive in-country planning for PrEP introduction

- **A list of specific factors** that need to be in-place to effectively introduce PrEP for each component of the value chain along with progress to-date for each factor
- **Details on current situation, key actors, responsibilities, timelines** and progress towards each activity are included in the appendix

- **Remaining questions to inform in-country discussions** and planning
- **Remaining questions to inform ongoing modelling, research and analysis efforts**
- **Opportunities for other partners** to support acceleration of PrEP introduction
Resources and Gaps for PrEP

**Expected Strengths**

- PrEP rollout initiated as part of SW HIV plan
- PrEP introduction plans underway by PrEP TWG for MSM
- NDoH supportive of PrEP as part of combination prevention
- UTT adoption in Sep ‘16

- Truvada and several generic options have been approved for prevention by MCC
- Established ARV procurement system
- Infrastructure for domestic manufacturing

- Clinical guidelines developed; training curriculum underway
- NDoH implementing new distribution models
- Strong existing channels for MSM and SW
- Demo projects can inform plan for AGYW

- Upcoming UTT investments could also enable PrEP roll-out
- Strong uptake expected in MSM and SW
- Current communication materials for SW rollout are well-received and continuously updated

- Call for harmonized, effective M&E in ‘12-‘16 National Strategic Plan could be prioritized in next iteration of plan
- Lessons from demo projects can inform strategies for effective use in key populations

**Emerging Key Considerations**

- There is need for more evidence before providing PrEP to AGYW, but campaigns (e.g., She Conquers) are laying the groundwork
- Participation of end-users and civil society groups in planning activities could expand

- Truvada not approved for ages <18 or pregnant women
- Potential for stock-outs, based on ARV experience, though no stock-outs in SW rollout

- New channels may be needed for AGYW
- Generating critical HCW buy-in for oral PrEP
- Increased burden on healthcare system as uptake increases; could strain limited delivery capacity

- Early demo projects suggest low AGYW uptake related to low sense of risk, GBV, and competing priorities
- Stigma associated with HIV and HIV medication
- User preference for injectable products

- Inconsistent adherence/ effective use amongst key populations
- No patient single identifier system
- M&E infrastructure improvements needed
- System capacity for initial and ongoing HIV and other testing
Key Questions for PrEP Roll-out

- For which segments of the AGYW population will it be cost-effective and/or most impactful to deliver PrEP?
- What are the incremental costs of PrEP delivery?
- What sources of funding will be available for PrEP? How will the scale-up for FSW, MSM, and a potential introduction to AGYW after DREAMS be funded?
- Will generic oral PrEP options be branded and packaged substantially differently from treatment medications (e.g., to be smaller, come in more discrete packaging)?
- To what extent and when can oral PrEP approval for the population under 18?
- How will PrEP be integrated into existing procurement and distribution mechanisms?
- To what extent do existing channels reach target populations? How might these channels need to be modified? What new channels will be needed (e.g., for AGYW)?
- What can be learned from the SW rollout to inform broader healthcare worker engagement?
- How will oral PrEP fit into current plans for She Conquers or other AGYW efforts?
- How will NDoH effectively identify those at significant risk?
- How might initial rollout plans (e.g., to sex workers, MSM) stigmatize PrEP for other populations?
- How will stigma and community buy-in be addressed for PrEP?
- What are the most effective demand generation strategies to reach target populations?
- Is there enough laboratory capacity to support effective PrEP initiation?
- What are the barriers to, facilitators of, and strategies for oral PrEP adherence and retention?
- To what extent will ongoing testing needs for PrEP users further strain health care capacity?
- How will ongoing monitoring be managed across delivery channels?
Key questions for rollout to AGYW

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 at highest need of PrEP?

Q2 What legal or ethical considerations are relevant for PrEP provision to AGYW?
- If provided to persons <18, what parental consent is required?

Q3 What do AGYW need in delivery channels (e.g., hours that fit their schedules, friendly staff)?

Q4 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?

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 work?

Q6 How can negative healthcare 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?

Q7 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?

Q8 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?

Q9 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?

Q11 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?

These questions are currently guiding the government’s collection of data from demo projects. Additional details in the appendix.
## South Africa Progress on PrEP Roll-out

### 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 **health care workers** on PrEP and delivery to target populations (including mitigating stigma)
- Tools to help potential clients and HCW understand **who should use PrEP** have been created
- **Sufficient resources** to roll-out 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
- **Linkages** between HTC, PrEP prescription, and PrEP access to enable PrEP uptake
- **Information for clients** on how to effectively use PrEP
- **Sufficient resources** to roll-out 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**
# Key Stakeholders for PrEP

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<td>guides national plans/priorities, oversees policy and guidelines, coordinates technical HIV programming, manages supply chains and capacity-building, guides and oversees health care worker training and M&amp;E</td>
<td>provides leadership and strategic guidance in the creation of clinical and implementation guidelines for PrEP, coordinates stakeholders, leverages resources to ensure timely and efficient roll-out of PrEP to target populations</td>
<td>develops National Strategic Plan</td>
<td>gives licensure to health providers, and monitors ethical practice of health workers</td>
<td>houses central procurement unit for ARVs, responsible for tendering</td>
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<tr>
<th>National government</th>
<th>National stakeholders</th>
<th>Local implementers</th>
<th>Others</th>
</tr>
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<tbody>
<tr>
<td>Coordinates multi-sector demand generation support</td>
<td>Drug manufacturers: Gilead (Truvada), Aspen Pharmacare (Tancitab), Mylan (Tenemine), Adcock (Emtevir), Cipla (Dividir)</td>
<td>Provincial Governments and Departments of Health - responsible for the implementation of the National Strategic Plan, receive and distributes ARVs to care centers/ARV outlets, coordinates and funds delivery of HIV services to PLHIV, coordinates and delivers HCW training, M&amp;E</td>
<td>Donors (USG PEPFAR, The Global Fund, German Government, UKAID, UNITAID, Gates (e.g., DREAMS, Bridge to Scale), Gilead)</td>
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<tr>
<td>National government - Coordinates multi-sector demand generation support</td>
<td>Medicines Control Council approves all new medications</td>
<td>Specific organizations will be determined upon national level implementation plans</td>
<td>International organizations (WHO, UNAIDS, CHAI)</td>
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<tr>
<td>Professional associations - (Health Professions Council of South Africa, Nursing Council) - gives licensure to health providers, and monitors ethical practice of health workers</td>
<td>Professional associations - (Health Professions Council of South Africa, Nursing Council) - gives licensure to health providers, and monitors ethical practice of health workers</td>
<td>Health care facilities (public and private) - provide core HIV/AIDS and health services</td>
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<tr>
<td>Essential Drugs Program houses central procurement unit for ARVs, responsible for tendering</td>
<td>Essential Drugs Program houses central procurement unit for ARVs, responsible for tendering</td>
<td>Community-based clinics (maternal and child health, SRH clinics, comprehensive care, HTC, SW and MSM clinics) - ARV channels that could deliver PrEP to target populations</td>
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<td>SA Clinicians Society leading development of core curriculum for PrEP service providers</td>
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<td>Civil Society/Community based organizations (non-profit, faith-based, advocacy groups) - trusted organizations that can reach target populations with PrEP and generate demand</td>
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**Note:** Specific organizations will be determined upon national level implementation plans.
APPENDIX

A. Value Chain Detail
B. Expected PrEP Activities
C. References
Appendix A: Value Chain Detail

The following slides provide additional detail on each section of the PrEP value chain in South Africa.
Planning & Budgeting

### Key Strengths and Opportunities
- The *South African Investment Case for AIDS and TB* analysis suggests PrEP is not cost-effective relative to other prevention methods.
- Upcoming modeling will use updated data and assumptions from demo/research projects.
- Priority populations have been identified as: SW, MSM, AGYW, and sero-discordant couples.
- SW and MSM identified for initial rollout; questions remain on how to reach others.
- Questions around product/use preferences for target populations are part of ongoing research.
- National Strategic Plan (NSP) on HIV, STDs and TB (2012-2016) outlines key prevention strategies, target populations and includes a call to prepare for the potential implementation of PrEP. The 2017-2022 NSP (expected in late 2016) likely to include PrEP use among some target populations.

### Key Challenges
- Number of issues for resolution by working groups, including identification of target populations and monitoring regime.
- Need additional data to make informed implementation decisions, particularly with AGYW (safety and prioritization).
- Limited participation from civil society groups in planning could prevent participatory demand generation and relevance to target populations.
- Need for greater understanding of what it will cost to deliver PrEP to develop budgets.

### Key Stakeholders
- **SA National PrEP TWG** is tasked with developing PrEP clinical and implementation guidelines. Sub-groups focused on MSM, SW and AGYW. Includes: NDoH, WHO, USAID, BMGF, UNICEF, UNAIDS, Wits RHI, ANOVA, Boston University, Right to Care, AVAC, UKZN, HE²RO, PEPFAR, CHAI.
- **Southern African HIV Clinicians Society** develops clinical guidelines, adapted by NDoH for national guidance.
- **South Africa National AIDS Council** coordinates development of the National Strategic Plan.
- **Provincial and District AIDS councils** implement NSP.

### Readiness for PrEP Introduction

<table>
<thead>
<tr>
<th>Readiness Factor</th>
<th>Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Impact, cost and cost-effectiveness analyses for PrEP</strong></td>
<td>• The <em>South African Investment Case for AIDS and TB</em> analysis suggests PrEP is not cost-effective relative to other prevention methods.</td>
</tr>
<tr>
<td><strong>Identification and quantification of target populations for PrEP</strong></td>
<td>• Priority populations have been identified as: SW, MSM, AGYW, and sero-discordant couples.</td>
</tr>
<tr>
<td><strong>Inclusion of PrEP and female-controlled methods in current or upcoming national HIV prevention plans</strong></td>
<td>• National Strategic Plan (NSP) on HIV, STDs and TB (2012-2016) outlines key prevention strategies, target populations and includes a call to prepare for the potential implementation of PrEP. The 2017-2022 NSP (expected in late 2016) likely to include PrEP use among some target populations.</td>
</tr>
<tr>
<td><strong>Timeline and plan for PrEP introduction and scale-up</strong></td>
<td>• Introduction for SW began June 2016 in 11 pilots.</td>
</tr>
<tr>
<td><strong>A budget for PrEP roll-out to target populations</strong></td>
<td>• A timeline for roll-out beyond SW is under development as part of the Policy and Guidelines process through the PrEP TWG.</td>
</tr>
<tr>
<td><strong>Sufficient funding to achieve targets</strong></td>
<td>• There will be individual budgets by individual service providers. There will be a government contribution but levels not confirmed yet. There will be no stand alone budget for PrEP.</td>
</tr>
<tr>
<td>• Funding in-place for specific programs, like DREAMS and SW rollout, but no national budget yet allocated specifically for PrEP.</td>
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</tbody>
</table>
Supply Chain Management

**Key Stakeholders**
- **Medicines Control Council** is responsible for approving new drugs
- **NDOH** is responsible for creating forecasting and delivery guidance, as well as responding to stock-outs
- **Essential Drugs Program** houses South Africa’s central procurement unit for ARVs responsible for tendering
- **Gilead / Aspen Pharmacare** is the in-country Truvada license-holder (as for ARVs)
- **Generic manufacturers** will enter market with alternatives to Truvada
- **UNAIDS** to advocate for affordable PrEP and generic manufacturing
- **Provincial medicines depots** distribute ARVs to health facilities
- **CHAI** developing demand estimates for key populations, expected 2016

**Key Strengths and Opportunities**
- **NDOH** is implementing innovative new tools like the Pipeline Analysis Tool (PAT) and the Stock Visibility System to improve forecasting and delivery
- Domestic manufacturing of Truvada could mean stronger distribution capacity and drug safety monitoring
- In 2010 the NDOH was successful in negotiating a **53% average reduction in ARV prices**. Similar negotiations might be possible for PrEP products
- **Use generic versions of Truvada or alternative formulations** (e.g., TDF alone or TAF) can provide cost savings. Truvada is R550.30, Mylan Generic is R77.05. The NDOH is using Mylan generic in the SW rollout.

**Emerging Considerations**
- **ARV forecasting and distribution systems** have not reliably supplied needed ARVs, resulting in numerous stock-outs. Forecasting and distribution to health providers will need to be strengthened to provide a reliable stream of needed ARVs for both treatment and PrEP
- **Need for demand estimates for key populations** for accurate forecasting
- **PrEP packaging format** frequently cited as concern among potential users

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**Readiness for PrEP Introduction**

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<tr>
<th>Readiness Factor</th>
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<tr>
<td><strong>Regulatory approval of form(s) of oral PrEP by authorities</strong></td>
<td>Truvada approved for prevention by MCC for adults 18+; use by pregnant women to be determined</td>
</tr>
<tr>
<td><strong>Effective demand and supply forecasting mechanisms for PrEP</strong></td>
<td>CHAI is developing demand estimates for PrEP among target populations</td>
</tr>
<tr>
<td><strong>Manufacturer identification and contract negotiation to purchase PrEP</strong></td>
<td>NDoH is procuring Mylan generic with funds from The Global Fund</td>
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<tr>
<td><strong>Product and packaging design to meet target population needs and preferences</strong></td>
<td>Currently a plastic pill bottle, to be refilled monthly; format will be consistent for other forms of oral PrEP</td>
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<tr>
<td><strong>Development of distribution plan for PrEP to reach target populations</strong></td>
<td>Mylan exploring packaging options</td>
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<tr>
<td><strong>Effective distribution mechanisms to avoid PrEP stock-outs in priority facilities</strong></td>
<td>Pilot delivery to SW underway, MSM upcoming</td>
</tr>
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**Sources:**
### PrEP Delivery Platforms

#### Readiness for PrEP Introduction

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<thead>
<tr>
<th>Readiness Factor</th>
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| **Issuance of standard clinical guidelines for prescription and use of PrEP** | • Guidelines developed by Southern African HIV Clinicians Society  
• The South African Department of Health (NDoH) PrEP guidelines were expedited for initial approval in June 2016  
• Working groups are developing plans for AGYW, MSM, and others |
| **Sufficient infrastructure and human resources to conduct initial HIV tests and prescribe PrEP in priority channels** | • HTC infrastructure is growing, but gaps remain. HIV testing rates are 37.5% for men and 52.6% for women with significant variation across districts |
| **Plan to engage healthcare workers on PrEP and delivery to target populations (including mitigating stigma)** | • Southern African HIV Clinicians Society lead the development of a national core curriculum for service providers (clinicians, counsellors)  
• Ongoing negotiations with ASPEN and NDoH to integrate this training as the primary curriculum for private and public sector providers |
| **Tools to help potential clients and HCW understand who should use PrEP have been created** | • Tools for clients are available in the context of demonstration projects  
• The South African have been working on their rollout information, education, and communication (IEC) materials being used are working well |
| **Sufficient resources for healthcare worker engagement** | • Gilead is expected to provide support for healthcare worker engagement. Details still forthcoming |

#### Key Stakeholders
- **NDoH** likely to provide framework and tools for HCW training, and support effective PrEP delivery on site
- **Southern African HIV Clinicians Society (SACS)** is creating HCW training
- **Gilead** is funding SACS efforts to train healthcare workers
- **Province Departments of Health** likely to organize/deliver HCW training for PrEP and support PrEP delivery on site
- **HIV and health service providers**, such as HIV/ARV clinics, community-based health centers, hospitals, mobile clinics, community and youth centers as potential delivery and education sites
- **Target population service providers**, such as SWEAT, Sisonke, TB/HIV Care Association, and others likely to be first to deliver PrEP to FSW, MSM

#### Key Strengths and Opportunities
- **Nurse-led, doctor-supported ART**: number of nurses certified to initiate ART from 250 in 2010 to 10,000 in 2012. This increases healthcare capacity to deliver ARVs and likely PrEP
- **Successful task-shifting** for HCW to provide ART through the Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) program could be modelled to include PrEP
- Opportunity to utilize existing SRH clinics as delivery channels for target populations, particularly AGYW and serodiscordant couples

#### Key Challenges
- **HCW stigma** against MSM, SW, and sexually active young women might result in high-risk individuals not being offered PrEP
- **Mainstreaming PrEP** outside of special programs to avoid stigma and reach broader populations
- **SA has yet to create effective and position-specific PrEP training programs** for HCW so they are able to appropriately prescribe, deliver and monitor PrEP to the right patients
- PrEP could be seen as an **additional health system burden**, particularly on HCWs already strapped for time and resources

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Sources:  
2. (2) ART trained nurses figure: Antiviral Therapy, [http://www.intmedpress.com/journals/avt/article.cfm?id=2905&pid=88&sType=AVT](http://www.intmedpress.com/journals/avt/article.cfm?id=2905&pid=88&sType=AVT)
An initial oral PrEP rollout to sex workers has delivered PrEP in 11 sites

### Sex Worker PrEP Program

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<th><strong>Background</strong></th>
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<tr>
<td>• On June 1 2016, South Africa’s NDOH rolled out oral PrEP for sex workers (SWs) at 11 sites as part of The National Sex Worker HIV Plan for 2016 – 2019.</td>
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<tr>
<td>• WHO, in coordination with the NDOH, conducted a rapid review of the sites during August 2016, final report is pending.</td>
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<tr>
<td>• In January 2017, a new site and “refresher” training will take place in existing and new PrEP delivery sites, which will include sites providing services to the MSM population.</td>
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<tr>
<th><strong>Key Strengths</strong></th>
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<tr>
<td>• Existing HTS in SW programs has the capacity to link patients to treatment and prevention, such as PrEP, through a trusted and safe (more likely to be de-stigmatized) channel</td>
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<tr>
<td>• The Information, education, and communication (IEC) materials that have been developed for the rollout have been well received and have been through one round of updating to simplify the key messages. The IEC materials have been translated into Zulu, and discussions are underway about translating into additional local dialects.</td>
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<tr>
<th><strong>Key Challenges</strong></th>
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<tr>
<td>• Some of the SW have difficulty traveling to some facility clinics, due to reasons like border disruptions, weather, lack of transportation.</td>
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<td>• Some sites have reported a delay in receiving creatinine test results required for oral PrEP initiation. This has prompted the NDoH to recommend that PrEP be initiated on the screening visit and the client be contacted if the creatinine results are abnormal.</td>
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<td>• Need to strengthen counseling, particularly surrounding adherence.</td>
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Several demo projects are providing PrEP to AGYW

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<thead>
<tr>
<th>Ongoing or planned PrEP demo projects focusing on AGYW</th>
<th>Location</th>
<th>Timeline</th>
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<tbody>
<tr>
<td><strong>3Ps</strong></td>
<td>Assessing uptake to oral PrEP and effect of conditional incentives on adherence. PrEP demand creation campaign is being developed with McCann South Africa</td>
<td>Masiphumulele</td>
</tr>
<tr>
<td><strong>CAPRISA 082</strong></td>
<td>Prospective Study of HIV Risk Factors and Prevention Choices in Young Women in KwaZulu-Natal, South Africa to identify risk factors for HIV acquisition in healthy young women</td>
<td>Umgungdlovu District, eThekwini District</td>
</tr>
<tr>
<td><strong>CHARISMA</strong></td>
<td>Pilot project with OLE to increase women’s agency to consistently and safely use microbicides while mitigating social harms, in particular IPV</td>
<td>Umzinyathi District</td>
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<tr>
<td><strong>Church of Scotland Hospital</strong></td>
<td>Planned project to recruit pregnant teenagers at their first ANC visit and enroll into a comprehensive support program with aim of improving outcomes for mothers and babies. Central focus is assisting mothers return to school, prevent acquisition of HIV and postpone further pregnancies</td>
<td>eThekwini, Ekurhuleni uMgungundlovu, uMkhanyakude, Johannesburg</td>
</tr>
<tr>
<td><strong>DREAMS</strong></td>
<td>Partnership to reduce HIV infections among AGYW; extends beyond health sector to address poverty, gender inequality, sexual violence, lack of education; PrEP implementation component included</td>
<td>eThekwini, Ekurhuleni uMgungundlovu, uMkhanyakude, Johannesburg</td>
</tr>
<tr>
<td><strong>EMPOWER</strong></td>
<td>Project on integrated GBV and stigma reduction through combination HIV prevention methods, including service delivery platforms, barriers to use</td>
<td>Hillbrow</td>
</tr>
<tr>
<td><strong>HPTN 082</strong></td>
<td>Study to assess proportion and characteristics of young HIV-uninfected women who accept versus decline PrEP and to assess PrEP adherence using drug level feedback</td>
<td>Hillbrow, Cape Town</td>
</tr>
<tr>
<td><strong>IMPAACT 2009</strong></td>
<td>Parallel, observational cohort study of HIV-uninfected pregnant adolescents and young women (aged 16-24) who initiate PrEP during pregnancy</td>
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<tr>
<td><strong>MSF</strong></td>
<td>Provision of PrEP through public facility SRH club, looking at uptake, adherence, retention, adverse events, reasons for taking or discontinuing, feasibility of service delivery model</td>
<td>Khayelitsha</td>
</tr>
<tr>
<td><strong>MTN034</strong></td>
<td>Phase 2A Crossover Trial Evaluating the Safety of and Adherence to a Vaginal Matrix Ring Containing Dapivirine and Oral PrEP in an Adolescent Female Population</td>
<td>Verulam CRS, eThekwini District</td>
</tr>
<tr>
<td><strong>Pills Plus</strong></td>
<td>PrEP component to examine feasibility/acceptability in adolescent girls and boys</td>
<td>Soweto, Masiphumelele</td>
</tr>
<tr>
<td><strong>POWER</strong></td>
<td>Project to develop cost-effective and scalable models for implementation of ARV-based prevention products for women, includes scalable microbicide and PrEP adherence support and delivery strategies</td>
<td>Hillbrow (WRHI), Khayelitsha, Cape Town</td>
</tr>
<tr>
<td><strong>Right to Care</strong></td>
<td>Planned PrEP demo project for AGYW in Johannesburg and Mpumalanga under DREAMS</td>
<td>Johannesburg, Mpumalanga</td>
</tr>
<tr>
<td><strong>UNICEF</strong></td>
<td>Project on combination HIV prevention interventions including oral PrEP</td>
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</tbody>
</table>
Other demo projects are also providing PrEP to MSM, SW, and other study participants

<table>
<thead>
<tr>
<th>Ongoing or planned PrEP demo projects focusing on target populations</th>
<th>Location</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health4Men initiative</strong></td>
<td>Implement and review a limited rollout of PrEP among MSM in Cape Town, in partnership with the Desmond Tutu HIV Foundation. PrEP offered to 150 MSM in Cape Town, and another 150 in Gauteng</td>
<td>Cape Town, Gauteng</td>
</tr>
<tr>
<td><strong>Sibanye Health Project</strong></td>
<td>To develop and evaluate a combination package of biomedical, behavioral, and community-level HIV prevention interventions and services for MSM</td>
<td>Cape Town, Port Elizabeth</td>
</tr>
<tr>
<td><strong>TAPS Demonstration Project</strong></td>
<td>Evaluates whether oral PrEP and immediate treatment can be rolled out within a combination prevention and care approach tailored to needs of 400 HIV-negative and 300 HIV-positive female sex workers.</td>
<td>Hillbrow, Pretoria</td>
</tr>
</tbody>
</table>
### Potential PrEP Delivery Channels

<table>
<thead>
<tr>
<th>Comprehensive Care Centers &amp; other ART sites</th>
<th>Sexual and Reproductive Health (SRH) care providers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public (Gov’t)</strong></td>
<td>• A range of SRH care including family planning, post-abortion care clinics, pre-natal care, post-violence care (i.e., Thuthuzela Care Centers) &amp; other SRH providers</td>
</tr>
<tr>
<td>• Public hospitals, clinics, and other health care centers (e.g., VMMC clinics, ART sites)</td>
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</tr>
<tr>
<td><strong>NGO</strong></td>
<td>• Provide greater access to sero-discordant women and AGYW in female-friendly and trusted settings</td>
</tr>
<tr>
<td>• NGO-run clinics, care centers, other HIV service programs such as key population clinics (e.g., SW clinics, NGO-run mobile clinics)</td>
<td>• Staff have lower levels of stigma against AGYW who seek family planning and HTC services</td>
</tr>
<tr>
<td><strong>Private</strong></td>
<td>• Post-abortion care clinics have the potential to reach women with very high risk of HIV infection</td>
</tr>
<tr>
<td>• Private fee-for-service providers and those privately insured</td>
<td>• Low cost of demand generation since women are already visiting SRH services</td>
</tr>
<tr>
<td><strong>Key Strengths</strong></td>
<td>• Potentially limited experience and training in HTC linkages</td>
</tr>
<tr>
<td>• Most visible to general population</td>
<td>• Limited/no laboratory capacity for necessary PrEP follow-up/monitoring</td>
</tr>
<tr>
<td>• Systems guided by and linked with county and national standards/agendas</td>
<td>• AGYW may have trouble accessing these channels due to logistical obstacles and community stigma</td>
</tr>
<tr>
<td>• Can provide greater access to key populations (FSW, MSM, PWID)</td>
<td>• Often have HTC-trained staff on site</td>
</tr>
<tr>
<td>• Effectively reach high-risk individuals with low/no stigma present in centers or among staff</td>
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<tr>
<td>• Frequent use of peer-educator programs, which might be critical to effective use and increased demand generation</td>
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</tr>
<tr>
<td><strong>Key Challenges</strong></td>
<td>• Private sector provides health care to 20% of the population but it may not capture those at highest risk of contracting HIV</td>
</tr>
<tr>
<td>• HCW stigma against target populations deter many from accessing care</td>
<td>• No single outlet effectively reaches all target populations</td>
</tr>
<tr>
<td>• Staff and resources stretched thin, suboptimal care</td>
<td>• Limited funding sources for NGO initiatives are constant challenge</td>
</tr>
<tr>
<td></td>
<td>• Integration with testing services needed for PrEP follow-up/monitoring (HIV, kidney, liver)</td>
</tr>
</tbody>
</table>

**Sources:** (1) Industry Report, Healthcare: South Africa, The Economist Intelligence Unit, April 2014
Individual Uptake

Readiness for PrEP Introduction

<table>
<thead>
<tr>
<th>Readiness Factor</th>
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<tbody>
<tr>
<td>Clear and informative communications on PrEP for general public audiences</td>
<td>Information is being shared through media channels and by word of mouth, not through a coordinated, comprehensive campaign</td>
</tr>
<tr>
<td>Development of demand generation strategies targeted to unique needs of different populations</td>
<td>Conversations are ongoing but there is little progress to date. Demand generation has been limited due to the small size of initial rollout to sex workers</td>
</tr>
<tr>
<td>Linkages between HTC, PrEP prescription, and PrEP access to enable PrEP uptake</td>
<td>The HIV Testing Services Policy of 2016 calls for the integration of oral PrEP across various entry points. Actual linkages will need to be established as PrEP is rolled out to various populations throughout the country. Current rollout is only taking place in facilities that have linkages to all necessary services</td>
</tr>
<tr>
<td>Information for clients on how to effectively use PrEP for all target populations</td>
<td>Information exists for those participating in demo projects. General information for all target populations including AGYW will need to be developed</td>
</tr>
<tr>
<td>Sufficient resources to roll-out plans for demand generation</td>
<td>Little progress to-date</td>
</tr>
</tbody>
</table>

Key Stakeholders
- Service providers such as SWEAT, Sisonke, TB/HIV Care Association, LoveLife, TAC, youth community health centers and other domestic entities creating awareness and demand among HCW and those at risk
- AVAC and other national advocacy organizations educating populations on benefits of PrEP
- SANAC calls for multi-sector participation in demand generation to reach uptake goals outlined in NSP
- UNAIDS has prioritized its role in increasing public demand for PrEP and states it will engage civil society

Key Strengths and Opportunities
- Prioritization of key populations with strong delivery channels, such as SW and MSM specific clinics, will encourage rapid uptake among SW and MSM
- NSP identifies as a sub objective “Implementing a comprehensive national social and behavioural change communication strategy with a focus on key populations” which could provide a platform for PrEP demand generation strategies

Emerging Considerations
- Failure of existing HCT efforts to reach the true high risk populations is likely to be among the biggest challenges of both UTT and PrEP efforts
- Entrenched stigma against FSW and MSM could stigmatize PrEP if perceived to be for marginalized populations only
- Community perceptions of sexually-active young women might create disapproval of PrEP use in AGYW
- Patient concerns of PrEP side effects, such as developing ARV resistance, liver, kidney, and bone density complications
### Effective Use & Monitoring

#### Key Stakeholders
- **NDOH** will oversee the monitoring of PrEP rollout
- **SANAC** is responsible for developing M&E framework for NSP, the **M&E Unit** is responsible for coordinating the tracking of NSP goals
- **Provincial and District AIDS councils** are responsible for M&E at the provincial and district levels, respectively
- **National Health Laboratory Service (NHLS)** services 80% of the population
- **Healthcare providers** administering PrEP responsible for tracking HIV status and routine lab work
- **CDC** frequent funder of lab work in SA, but NDoH is funding all screening and testing related to PrEP rollout.
- **BMGF’s Prevention Market Manager (PMM) and CHAI** are providing technical support to NDOH on early implementation M&E
- **OGAC/PEPFAR** is establishing MER indicators for oral PrEP rollout under DREAMS/PEPFAR

#### Key Strengths and Opportunities
- **UTT efforts will enable a stronger testing system critical to PrEP uptake**, effective use, and HIV status monitoring
- The NSP states that “SANAC will develop a detailed M&E framework for the NSP. The framework will take into account existing M&E systems being implemented by different stakeholders”
- **Electronic Medical Records (EMR)** will be used at all SW rollout implementation sites, with technical support from CHAI/PMM

#### Key Challenges
- Necessary **strengthening of the country’s laboratory capacity** to support initial testing and routine monitoring necessary for PrEP
- Necessary improvement to **PrEP client tracking and recordkeeping systems** to monitor PrEP use and adherence and to forecast the need for PrEP products
- The **younger women in demonstration projects have not consistently adhered to PrEP**, raising concerns about **effective use** in AGYW populations

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### Readiness for PrEP Introduction

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<tr>
<th>Readiness Factor</th>
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<tr>
<td>Established plans to support effective use and regular HIV, creatinine testing that reflect the unique needs of target populations</td>
<td>• PrEP is being included as an additional option to a “menu” of HTS services through existing programs. Medical professionals are available in these programs and have been trained on PrEP provision protocol</td>
</tr>
<tr>
<td>Capacity to provide ongoing HIV and creatinine level testing for PrEP users accessible to target populations</td>
<td>• Some capacity exists within the system; The NDoH is covering all costs associated with screening and testing</td>
</tr>
<tr>
<td>Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)</td>
<td>• UTT investments may strengthen monitoring system for PrEP users • A single patient identifier system was proposed in the 2010-2016 NSP, however one does not exist yet. This has made tracking of patients on ARVs difficult within and across provinces • At the request of the NDOH, OPTIONS will work with CHAI to adapt the SW PrEP rollout M&amp;E tools into a simplified version for PrEP implementation projects to use for reporting key data into NDOH for monitoring purposes</td>
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# Appendix B: Expected PrEP Activities

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<td>CAPRISA 082</td>
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<td>Church of Scotland Hospital</td>
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* Expected provisional results at IAS in July 2016
** Provisional/ baseline results expected
Appendix C: Key References

- **ARV Market Report**, Clinton Health Access Initiative, 2015
- **Geographic Distribution of Human Immunodeficiency Virus in South Africa**, The American Journal of Tropical Medicine and Hygiene, 2007
- **Challenges in Oral PrEP Rollout in South Africa**, James McIntyre- ANOVA Health Institute, 2015
- **Provision of antiretroviral therapy in South Africa: the nuts and bolts**, Antiviral Therapy, 2014
- South African Investment Case for HIV and TB, SAAIDS Presentation by the Investment Case Task Team and Steering Committee (2015) and Reference Report for Phase One (March 2016)
- Stabilizing HIV prevalence masks high HIV incidence rates amongst rural and urban women in KwaZulu-Natal, South Africa, International Journal of Epidemiology, 2010