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2016

OPTIONS
Country Situation Analysis Interim Findings: Zimbabwe

FSG in partnership with Pangaea Global

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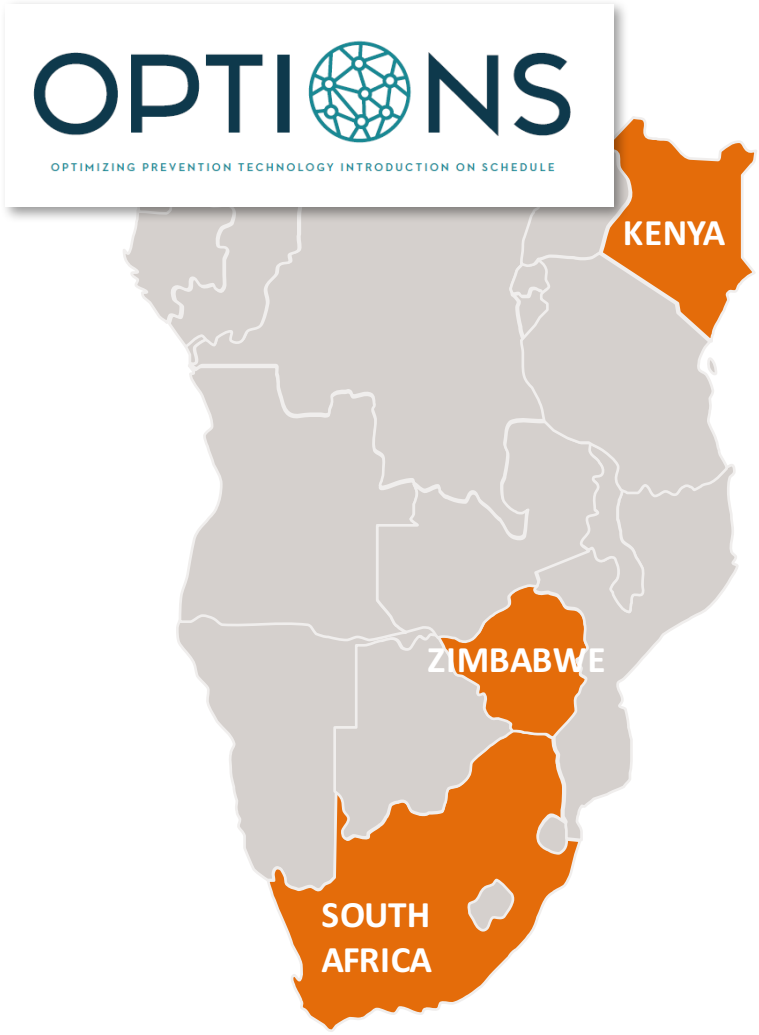
OPTIONS
OPTIMIZING PREVENTION TECHNOLOGY INTRODUCTION ON SCHEDULE

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.

OPTIONS Objective

Develop a streamlined, adaptable product delivery platform for current and future microbicide and ARV-based HIV prevention options.

OPTIONS Consortium Members

fhi360 THE SCIENCE OF IMPROVING LIVES
AVAC Global Advocacy for HIV Prevention
RHI WITS REPRODUCTIVE HEALTH & HIV INSTITUTE
FSG REIMAGINING SOCIAL CHANGE
Avenir Health
McCANN GLOBAL HEALTH
lvct health healthy societies
LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE
Pangaea

OPTIONS Consortium Aims

OPTIONS has four major goals over the next five years:

AIM 1

Develop evidence-based ***business cases and a coordinated investment strategy*** for ARV-based prevention product introduction to ensure timely global, national and private sector action on priority areas

AIM 2

Support ***country level*** regulatory approval, policy development, program planning, marketing and implementation strategies for ARV-based prevention product introduction

AIM 3

Facilitate and conduct ***implementation science*** (IS) to advance the introduction of and access to microbicides and ARV-based prevention technologies

AIM 4

Provide ***technical assistance and support for health systems strengthening (HSS)*** with rapid use of data to identify and address implementation bottlenecks throughout the value chain

OPTIONS How We Work

- 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**
- In addition to Pangaea, who has significant experience working on HIV prevention and treatment in Zimbabwe, our consortium brings **multi-disciplinary expertise** to the effort to introduce female-controlled HIV prevention products in Zimbabwe
- 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 a summary of **preliminary findings** from the OPTIONS situation analysis for oral PrEP in Zimbabwe, completed by FSG with significant input and consultation from Pangaea Global AIDS
- The situation analysis aims to take a **comprehensive and robust approach** to assessing the "state of the field" for oral PrEP in Zimbabwe, including opportunities and resources as well as gaps and expected challenges
- This document reflects findings from secondary **research** and in-country consultations with key stakeholders
- This is designed as **a "living document,"** to be updated on an ongoing basis with additional information and stakeholder feedback to inform ongoing planning and decision-making around oral PrEP
- If you have any **updates, additional information, or follow-up questions** regarding this situation analysis, please email Neeraja Bhavaraju at neeraja.bhavaraju@fsg.org

Executive Summary

- Zimbabwe is **early-stage** in creating the conditions, policies, and practices needed to successfully roll-out and scale-up PrEP. The country's HIV response has historically been on the **leading edge** among peers and generally **responsive to global guidelines**.

- In March 2016, the Ministry of Health and Child Care (MOHCC) convened a **national working group** to adapt the WHO "test and start" guidelines issued in November 2015. As part of that effort, a sub-committee on planning for oral PrEP has been established. This sub-committee will meet to develop national guidelines on PrEP and plan for roll-out in the coming months, with an expected timeline of June 2016.

- The key challenges for PrEP in Zimbabwe are ensuring timely **approval of Truvada for prevention**, identifying and agreeing on **target populations**, deploying an **effective communications strategy**, and navigating the **health system capacity limitations** inherent in closing Zimbabwe's existing treatment gap while investing in "new" prevention methods.
  - Zimbabwe will soon release an updated HIV strategic plan that focuses on **key populations** and **combination prevention** packages, but **omits PrEP.** While some have a sense that not enough is known yet to invest in PrEP, this may be changing. In early 2015, MOHCC officials expressed **interest in introducing PrEP** for a broad range of high-risk populations, including adolescent girls and young women (AGYW).
  - There are significant **legal and cultural barriers** to quantifying and reaching the key groups for whom PrEP would be well-suited, particularly female sex workers (FSW) and men who have sex with men (MSM), whose practices are illegal, and AGYW, who face stigma and opposing cultural norms related to HIV prevention.
  - Zimbabwe has made solid progress in **expanding coverage** of ART and HTC sites, but **treatment gaps** remain; in addition, health care worker knowledge and attitudes and end user awareness and demand have continued to be critical factors determining the success of HIV prevention and treatment interventions.

- Despite these challenges, PrEP rollout in Zimbabwe will be facilitated by the country's many strengths, including increasingly harmonized **procurement, distribution, and M&E systems**, an active **civil society**, the presence of **the DREAMS initiative**, and a nearly complete PrEP **demonstration project** (SAPPH-IRe).

- In the near-term, **decisions on PrEP** in Zimbabwe revolve around the question: "How much should be invested in PrEP, for whom, how, and in which areas?"

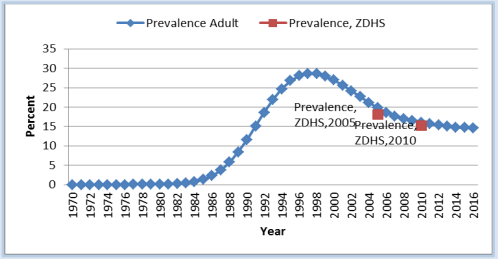
Current State of HIV in Zimbabwe

Context

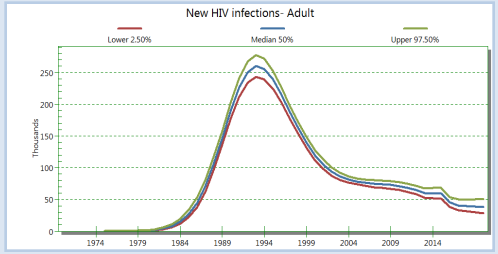
- Zimbabwe has one of the **largest HIV burdens** in Southern Africa, with **1.2M people living with HIV** (PLHIV)
- The **HIV epidemic exhibits growing rates among women** – HIV prevalence is now 1.5x higher among women than men
- **Key drivers** of the epidemic include multiple and concurrent partnerships, inter-generational sex, discordant couples and low (but rising) circumcision rates; several **key geographies and populations** listed below remain disproportionately affected by the epidemic
- Despite high absolute HIV burden and economic challenges, **rates have declined substantially in recent years** (prevalence reduced from 25% to 15%, adult incidence reduced by half to 0.98%, and 75% fewer children born from HIV+ mothers in the last decade)

Trends

- Prevalence has been **decreasing in recent years:**

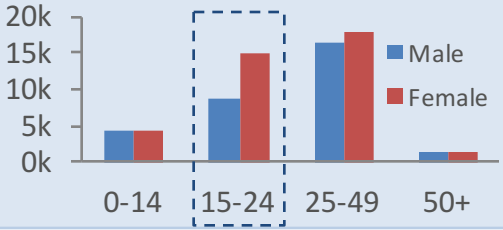


- Incidence has been **decreasing in recent years:**



Demographics

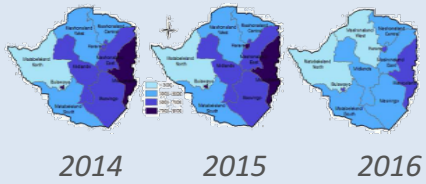
- **Source of new infections** (not mutually exclusive):
  - 55% among people in stable unions
  - 36% among young people
  - 12% among sex workers and clients
  - 4-7% among MSM and partners
- **Prevalence** (not mutually exclusive):
  - 17% among women in general
  - 12% among men in general
  - 5-6% among women 15-24 years
  - 50-70% among FSW
  - 14% in prisons
- **Incidence by age and gender (2013):**



Geography

- **Geographic hotspots:**
  – Three provinces: Matabeleland North, Bulawayo, Matabeleland South
  – 14 additional districts recently named as hotpots
- **HIV prevalence by province:**
  % of people 15-49 years old

- **HIV incidence by province:**
  New infections, people 15-49 years



***Sources*: (1)** Zimbabwe National HIV and AIDS Estimates: 2013. Ministry of Health and Child Care. 2013; (2) Zimbabwe National HIV and AIDS Strategic Plan 2011-2015 (ZNASP II). Ministry of Health and Child Care and National AIDS Council. March 2015; (3) Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) *[Not officially launched]*. Ministry of Health and Child Care and National AIDS Council. March 2015.

HIV Prevention and Treatment

Context

- Improvements in prevalence and incidence rates primarily due to **successful prevention efforts** and **reduction in personal risk-taking behavior,** while HIV-related deaths have been reduced by over 60% due to Zimbabwe's **treatment and support program**
- For prevention, the government has prioritized **social and behavior change** interventions, **condom** promotion and distribution (coupled with intensified **awareness** on correct and consistent use of condoms), and **voluntary medical male circumcision**
- For treatment, **HIV testing and counselling (HTC)** has been identified as a key entry point for **ART**, and **provider-initiated HTC** (which comprises 80% of all current testing in Zimbabwe) is being scaled up
- National HIV response is soon beginning its **third and most advanced stage** (ZNASP III), focused on **key populations and geographies**

Current Efforts

- Sustaining current **treatment and care** investment
- Rapidly scaling up **VMMC** to 80% by 2018 using WHO guidelines/standards
- **Comprehensive prevention programs** for sex workers, adolescent and young people, discordant couples
- Scaling up **innovative community HIV testing initiatives, including self-testing kits** via a PSI pilot funded by UNITAID
- Rolling out **PITC** to 94% of health facilities
- Integrating **social norm and behavior change interventions** into delivery of social and HIV-related services
- Community **system strengthening**
- Preventing **secondary increases in the epidemic** due to lower levels of funding
- Zimbabwe has allowed the existence of **informal lobby groups for FSW, prisoners, and MSM**

Remaining Needs

- **Coverage gaps:** Zimbabwe is behind by 55% in providing treatment for HIV+ children; most commitments for ART end in 2016, which will create additional gaps for HTC
- **Data gaps:** data gaps exist generally and particularly for key populations
- **Key populations**: Current strategies are inequitable to key populations (e.g., need for more female-controlled options, as 27% of Zimbabwe's women have experienced sexual violence in their lifetime; irregular condom use among MSM) and legal codes and stigma pose challenges for key populations
- **Health system:** Zimbabwe's health system has been weakened by economic crisis and is often seen as not "friendly" to women and adolescents; **community organizations** have often lacked definition, cohesion, prioritization, and funding

Sources: (1) Zimbabwe National HIV and AIDS Estimates: 2013. Ministry of Health and Child Care. 2013; (2) Zimbabwe National HIV and AIDS Strategic Plan 2011-2015 (ZNASP II). Ministry of Health and Child Care and National AIDS Council. March 2015; (3) Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) *[Not officially launched]*. Ministry of Health and Child Care and National AIDS Council. March 2015.

Key Considerations for PrEP

Why PrEP is under consideration in Zimbabwe

- **Achieving national targets:** Zimbabwe has demonstrated strong political will by adopting the global 90-90-90 goals and committing to reducing new infections by 75%. However, this target may be difficult to meet without reducing infection among high-incidence populations (e.g., sero-discordant couples, AGYW, FSW, and MSM) through prevention methods appropriate for these populations. As one MOHCC representative noted, "*There is no way to move towards zero new infections unless we have PrEP as part of the interventions package*."
- **Protecting human rights and upholding zero discrimination:** Several of the high-risk populations for whom PrEP is most appropriate are also the populations most discriminated against by Zimbabwean society and legal frameworks (e.g., FSW, MSM). Excluding PrEP from the prevention strategy runs contrary to Zimbabwe's vision for "zero discrimination."
- **Promoting equity:** Zimbabwe promises to "uphold equity-oriented interventions that promote allocation of resources preferentially to the needy so as to address challenges related to unfair differences" in outcomes. PrEP is appropriate for those most left behind by the country's HIV response.
- **Enabling a gender-sensitive response:** Zimbabwe's strategic plan commits to "promoting and implementing a gender responsive national AIDs response in the next five years," but the dominant HIV prevention strategies recommended and prioritized are male-controlled (e.g., condoms, VMMC)
- **Ensuring truly "comprehensive" prevention:** Zimbabwe's plan calls for a "comprehensive prevention program for sex workers and adolescent girls." The current package for FSW includes HIV testing and treatment, condom promotion, solidarity programs, violence and abuse support, and protective policing, but excludes health education, skills training, PrEP, and others.

Current PrEP Context

- Zimbabwe has convened a **national working group** to adapt the WHO "test and start" guidelines in March 2016, including a sub-committee on PrEP
- **Truvada** has been registered for prevention, but is currently approved only for treatment; no generics or other alternative forms of oral PrEP are approved for prevention
- PrEP **demonstration project** led by CESSHAR is ending in 2016; DREAMS program focused on AGYW is launching in 2016 with a PrEP component
- New **HIV strategic plan** being launched in early 2016 includes comprehensive prevention but excludes PrEP; potential to push for PrEP inclusion during mid-term review in late 2016 or early 2017
- While **FSW and AGYW** are prioritized for HIV prevention, not all key populations are meaningfully included (e.g., MSM) and none are prioritized for PrEP specifically
- Significant legal and cultural factors continue to marginalize **MSM and FSW** and obscure ability to quantify the size and HIV rates of these populations.

Sources: (1) Achieving an AIDS-Free Generation for Gay Men and Other MSM in Southern Africa. amfAR, The Foundation for AIDS Research and Johns Hopkins Bloomberg School of Public Health. May 2013; (2) FSG interview with Pangaea Global. December 16, 2015; (3) Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) *[Not officially launched]*. MOHCC and National AIDS Council. March 2015.

What's Needed to Introduce PrEP

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**, particularly for women and girls, 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.

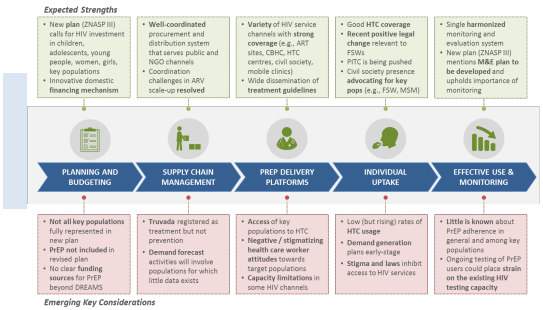
Value Chain for PrEP

PLANNING AND BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
Plan developed to implement WHO PrEP guidelines for targeted populations	PrEP produced, purchased, and distributed in sufficient quantity to meet projected demand	PrEP services delivered by appropriate channels with access to target populations	Target populations seek and are able to access PrEP and begin use	Target population adheres to PrEP at recommended frequency and for ideal time period

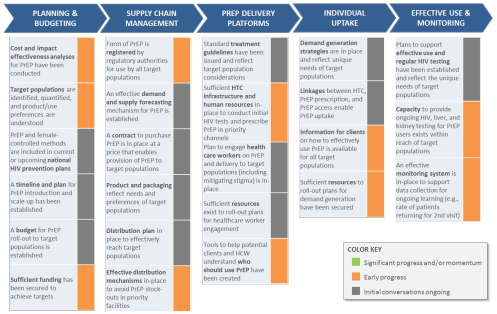
Value Chain Analyses

The following slides hold three analyses along the value chain

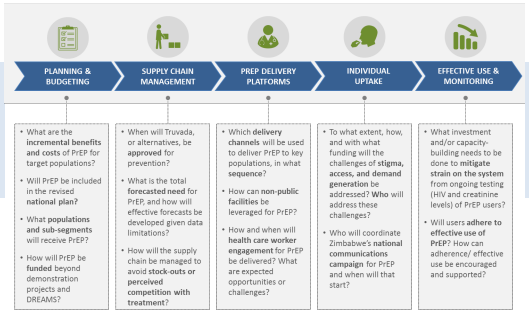
Resources and Gaps for PrEP in Zimbabwe



Towards Introduction of PrEP in Zimbabwe



Key Questions for PrEP in Zimbabwe



- **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 in Zimbabwe

Expected Strengths

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
• 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

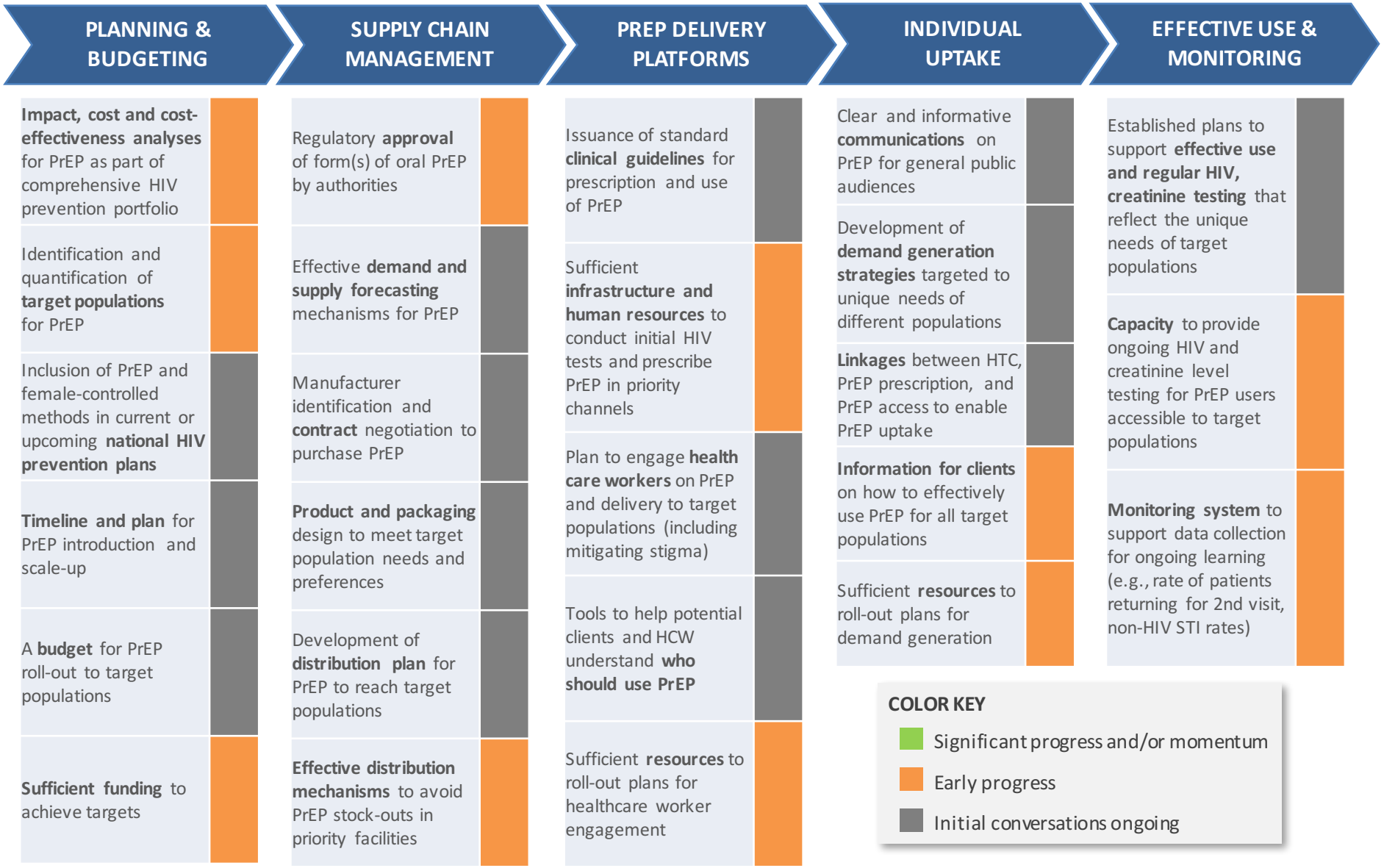




• **Not all key populations** fully represented in new plan • **PrEP not included** in revised plan • No clear **funding sources** for PrEP beyond DREAMS	• **Truvada** registered as treatment but not prevention • **Demand forecast** activities will involve populations for which little data exists	• **Access** of key populations to HTC • **Negative / stigmatizing health care worker attitudes** towards target populations • **Capacity limitations** in some HIV channels	• Low (but rising) rates of **HTC usage** • **Demand generation** plans early-stage • **Stigma and laws** inhibit access to HIV services	• **Little is known** about PrEP adherence in general and among key populations • Ongoing testing of PrEP users could place **strain on the existing HIV testing capacity**

Emerging Key Considerations

Towards Introduction of PrEP in Zimbabwe



Key Questions for PrEP in Zimbabwe

PLANNING & BUDGETING

- What are the **incremental benefits and costs** of PrEP for target populations?
- Will PrEP be included in the revised **national plan?**
- What **populations and sub-segments** will receive PrEP?
- How will PrEP be **funded** beyond demonstration projects and DREAMS?

SUPPLY CHAIN MANAGEMENT

- 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**?

PREP DELIVERY PLATFORMS

- Which **delivery channels** will be used to deliver PrEP to key populations, in what **sequence**?
- How can **non-public facilities** be leveraged for PrEP?
- How and when will **health care worker engagement** for PrEP be delivered? What are expected opportunities or challenges?

INDIVIDUAL UPTAKE

- To what extent, how, and with what funding will the challenges of **stigma, access, and demand generation** be addressed? **Who** will address these challenges?
- Who will coordinate Zimbabwe's **national communications campaign** for PrEP and when will that start?

EFFECTIVE USE & MONITORING

- What investment and/or capacity-building 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?

Key Stakeholders for PrEP

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING

National stakeholders

MOHCC develops national strategic plan, identifies drug needs, does forecasts, specifies delivery timelines, creates treatment guidelines

NAC provides logistical and technical assistance during plan preparation...

Technical working groups focused on key themes are involved in planning

NatPharm quantifies drug needs and oversees storage

MCAZ performs quality assurance and registration

SPB regulates and manages public procurement

CCM oversees Global Fund proposals and grants

UNAIDS supports civil society coordination

...and NAC is responsible for overseeing monitoring & evaluation

Local Implementers

Civil society groups (e.g., CeSSHAR, Katswe Sisterhood, GALZ, ZNNP+, ZAN, WAG, WASN) advocate for key population inclusion in plan, equitable access, and demand generation

Pangaea can help ensure inclusion of key populations in its secretariat role

Key populations are included in technical working groups but more efforts are needed to ensure meaningful representation

CESHHAR conducting only PrEP impact study in Zimbabwe (among FSW)

Local manufacturers have had some involvement in ARV production in the past

Specific organizations will be determined upon national level implementation plans

Health care facilities already delivering ART likely to be the first to deliver PrEP

Other public HIV service channels could potentially deliver PrEP (e.g., CBHCs, HTC centers, ART sites, mobile clinics)

General HTC and HIV prevention partners may play a role in PrEP delivery pending national implementation plans (e.g., FHI,PSI, OPHID, ZAPSO, ZACH, ZNFPC, PSZ clinics)

Other stakeholders (e.g., youth centers, sex worker clinics, and civil society organizations) may play a role in ensuring PrEP access among key populations

Donors

International bilateral funders and domestic public funding sources (e.g., PEPFAR, DFID, CIFF, CIDA, Zimbabwe National AIDS Trust Fund)

Multilateral donors (e.g., Global Fund, WHO, UNITAID)

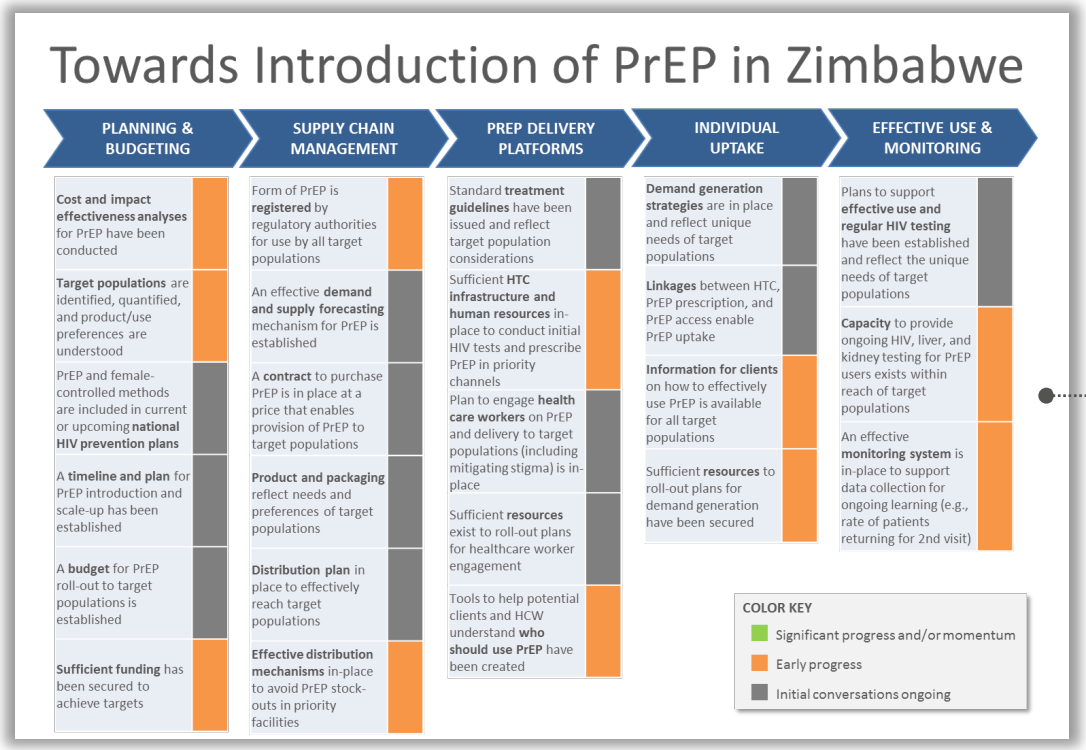
APPENDIX

A. Value Chain Detail

B. Timeline of Major Research and Activities

C. References

Appendix A: Value Chain Detail



The following slides provide additional detail on each section of the PrEP value chain in Zimbabwe

Planning for PrEP

Readiness for PrEP Introduction	
Readiness Factor	**Progress**
Impact, cost and cost-effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio	• CESSHAR demo project underway; potential for additional studies (e.g., PSI study on willingness to pay, funded by UNITAID) • 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 not yet been included in National Strategic Plans , but the process to do so is beginning and there is movement to include it.
Timeline and plan for PrEP introduction and scale-up	• A TWG has been convened to adapt WHO Test and Start Guidelines for Zimbabwe as well as a sub-committee on PrEP. There is a timeline for completing guidelines, these guidelines will guide implementation.
A **budget** for PrEP roll-out to target populations	• Very early budget considerations and thinking happening as part of broader PrEP planning.
Sufficient funding to achieve targets	• Early conversations have taken place, yet little clarity exists. Some small initial funding expected for PrEP from DREAMS and likely from UNITAID

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 (CeSShAR, 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 included** in revised national strategic plan (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 **resistance resulting from PrEP**

Key Populations for PrEP

	Adolescent girls and young women (AGYW)	Sero-discordant couples	Men who have sex with men (MSM)	Women engaged in sex work (FSW)
Key Indicators	• **~1.7M** total adolescent girls (ages 10-19), of which 61,000 living with HIV and ~1.6M without HIV • **4-6%** prevalence (ages 15-19) • **4,700** newly infected adolescent girls (ages 15-19) each year, compared to 2,100 boys • **18%** of adolescent girls (ages 15-19) have experienced sexual violence • **45%** have tested for HIV	• Heterosexual people in stable unions or people engaging in low risk heterosexual sex account for around **54.8%** of all new HIV infections • **11.3%** of married/cohabiting couples are sero-discordant • In **6.7%** of couples the man is the HIV positive and in **4.5%** the woman is HIV-positive	• **Unknown** number of total MSM • **~24%** prevalence among MSM (based on research including Zimbabwe and other countries) • **4%** of total new infections and **7%** including their partners are among MSM	• **52,214** total FSW in Zimbabwe • **20%** prevalence overall based on CESSHAR estimate, but **50-70%** in smaller studies • **12%** of Zimbabwe's total incidence is among sex workers and their clients
Prioritization	• In new national plan, AGYW are included as a priority population for comprehensive prevention but not PrEP • AGYW will be the focus of the DREAMS initiative in six districts throughout Zimbabwe	• In new national plan, people in stable unions and sero-discordant couples are acknowledged to be among key populations • One of the Priority Areas of Focus is to reduce acquisition from or to long-term sexual partners	• MSM indirectly listed as key population in national plan (e.g., "more data needed") • MSM included in Global Fund's KP-REACH initiative ($11M for HIV response across multiple sub-Saharan African countries) • Strong civil society advocates (e.g., GALZ)	• In new national plan, FSW included as a priority for comprehensive prevention but not PrEP • Zimbabwe's only ongoing PrEP impact study (SAPPH-IRe) seeks to demonstrate acceptability and feasibility of PrEP and maximize adherence among a subset of 28,000 highway-based FSW
Questions	• Which channels would be most appropriate for delivering PrEP to AGYW? • Will there be funding specifically for PrEP for AGYW?	• Which channels would be most appropriate for delivering PrEP to people in stable unions and sero-discordant couples ?	• What is the size and HIV prevalence of the population? • Which channels would be most appropriate for delivering PrEP to MSM?	• What will be the results of SAPPH-IRe study, and their impact on PrEP policy?

Sources: Adolescent Girls – (1) HIV and AIDS in Zimbabwe. AVERT. May 1, 2015; (2) Rethinking HIV Prevention to Prepare for Oral PrEP Implementation for Young African Women. Celum, et al; Journal of the International AIDS Society. 2015; (3) Sexual and Reproductive Health Needs Of Adolescents in Zimbabwe. Guttmacher Institute. 2014; (4) Zimbabwe National HIV and AIDS Estimates: 2013. Ministry of Health and Child Care. 2013.Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) *[Not officially launched]*. Ministry of Health and Child Care and National AIDS Council. March 2015. MSM – (1) Fostering evidence-based HIV programming for men who have sex with men (MSM) in sub-Saharan Africa. The Global Fund, WHO, and ANOVA Institute. April 24, 2013: (2) PSAf Study to Characterize Sexual Minorities in Zambia *[Part of research that includes Zimbabwe]*. The Communication Initiative Network: (3) Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) *[Not officially launched]*. Ministry of Health and Child Care and National AIDS Council. March 2015. FSW – (1) Engagement with HIV Prevention Treatment and Care among Female Sex Workers in Zimbabwe: a Respondent Driven Sampling Survey. Cowan, et al; PLOS One. October 2013; (2) Truvada as PrEP: A New HIV Prevention Option on the Table for Zimbabwe? ICASA YouthFront. October 19, 2015; (3) "You are wasting our drugs:" Health Service Barriers to HIV Treatment for Sex Workers in Zimbabwe. Mtetwa, et al, of BMC Public Health. 2013.

Budgeting for PrEP

$525M total HIV costs

$183M of which is prevention

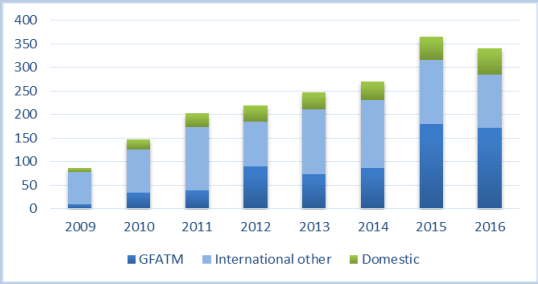
$0 of which is committed to PrEP

Summary:

- **Strong growth in funding** over past 5 years due to **PEPFAR funds doubling** to $95M and new funding model **increasing average GF annual grants** from $67M to $145M
- Zimbabwe's HIV funding needs are projected to grow to ~$600M by 2018 and ~$700M by 2023, but current annual funding commitments are <$400M
- **HIV treatment taking larger share of resources** as more people are put on ART

Current Funding for HIV

- 85% is from **international** sources
- 15% is from **domestic** resources, largely the National AIDS Trust Fund levy (thus linked to economic growth)
- Levy has drawn **~$20-50M**, of which 50% goes to ART program, 23% to program logistics, 10% to prevention, 6% to M&E, 5% to enabling environment, and 4% to assets
- **Funding for HIV in Zimbabwe** (public domestic and international, '09-'16):



Remaining Gaps and Challenges

- Of funding from National AIDS Levy, **only 10% is allocated to prevention**
- On a per-PLHIV basis, Zimbabwe receives one of the **lowest per capita allocations globally from combined funding of** Global Fund and PEPFAR
- World Bank 2011 expenditure review showed per capita development assistance for health in Zimbabwe to be **well below neighboring countries**
- HIV costs, commitments, and gap:

Year	Total Cost	Available	Gap
2013	$330M	$223M	32%
2014	$401M	$279M	30%
2015	$466M	$304M	35%
2016	$525M	$264M	50%
2017	$567M	$238M	58%
2018	$591M	$238M	60%

Potential New Funding

- PEPFAR, Global Fund, and Zimbabwe government recently joint funded the new **$3M ZIMPHIA study**
- Global Fund giving **$11M to KP-REACH** (Key Populations: Representation, Evidence, and Attitude Change) effort
- Zimbabwe submitted a **$40.2M request for incentive funding on May 18th, 2015, from the Global Fund** (on top of its ~$145 average annual committed allocation through 2016):

Incentive Funding Area	Requested
Laboratory and Pharmaceuticals	$19.5M
Youth and Adolescents	$10.0M
Community and Key Populations	$2.9M
Monitoring and Evaluation	$4.2M
Grant Management	$3.6M
TOTAL	$40.2M

Sources: (1) 126 Million Additional Funding Announced to Fight HIV in Zimbabwe. United Nations Development Program. January 20, 2015; (2) Global AIDS Response Report: Zimbabwe Country Report. UNAIDS. December 2014: (3) Global Fund approves $17 million for new HIV programmes in Africa. International HIV/AIDS Alliance. July 6, 2015; (4) Global Fund Country Allocations: 2014-2016. The Global Fund to Fight AIDS, Tuberculosis, and Malaria. March 12, 2014; (5) National AIDS Council: Funding. National AIDS Council of Zimbabwe. 2011; (6) Zimbabwe: Ministry of Health and Child Care to Launch New Health Survey – Zimbabwe Population-Based HIV Impact Assessment. AllAfrica. September 17, 2015.; (7) Zimbabwe National HIV and AIDS Strategic Plan 2011-2015 (ZNASP II). Ministry of Health and Child Care and National AIDS Council. March 2015: (8) Zimbabwe National HIV and AIDS Strategic Plan 2015-2018 (ZNASP III) [Not officially launched]. MOHCC and National AIDS Council. March 2015; (9) Zimbabwe Planned Funding. PEPFAR. 2014.

Supply Chain Management

Readiness for PrEP Introduction

Readiness Factor	Progress
Regulatory **approval** of form(s) of oral PrEP by authorities	• PrEP (Truvada) is not registered for prevention, only treatment. Plans are to secure approval for Truvada to be used as PrEP by July 2016
Effective **demand and supply forecasting** mechanisms for PrEP	• Strong supply chain in place for ARVs, which will likely translate to PrEP readiness – but no PrEP specific planning conducted to-date
Manufacturer identification and **contract** negotiation to purchase PrEP	• Very early stage. WHO meeting in March 2016 to discuss alternatives to Truvada for oral PrEP may influence what forms of PrEP Zimbabwe purchases
Product and packaging design to meet target population needs and preferences	• Unclear to date and likely to depend on chosen PrEP manufacturer
Development of **distribution plan** for PrEP to reach target populations	• No distribution plan is yet in place but will be developed in 2016/2017
Effective distribution mechanisms to avoid PrEP stock-outs in priority facilities	• Zimbabwe has a robust drug procurement and distribution mechanism that is centrally coordinated for public and NGO sites; ARV stock-outs are rare. • NatPharm does not anticipate major obstacles in adding PrEP to current distribution

Key Stakeholders

- **MOHCC** identifies drug needs, specifies delivery timelines, oversees development of treatment guidelines
- **Gilead** files for prevention indication of Truvada in Zimbabwe to MCAZ
- **NatPharm** conducts quantifications to forecast demand based on program needs, runs central medical store, public warehouses, and local branches
- **MCAZ** performs quality assurance and product registration for all drugs
- **State Procurement Board** regulates and manages all public procurement

Key Strengths and Opportunities

- Zimbabwe has **well-coordinated** procurement and distribution system to which PrEP can be added; coordination system is flexible to deliver PrEP to specified geographies and channels (NGO or public)
- Zimbabwe is one of **Africa's pioneer procurement reform countries**, with World Bank supporting SPB training, assessment, and capacity-building
- **Wide dissemination of treatment guidelines** among public health facilities bodes well for potential PrEP-related guidance
- Potential for **PrEP to be donated by Gilead** (although this could be both an opportunity and a challenge)

Key Emerging Considerations

- Truvada is currently **registered as treatment but not prevention.** Registration by MCAZ seen to be one of the most urgent priorities to move forward in Zimbabwe.
- For ARV scale-up, there were some **coordination challenges**, as procurement happened individually by donor agencies and wasn't always harmonized, though some of this has been resolved/streamlined
- Quantification process informing NatPharm procurement relies solely on program targets. Process may not be adequate for PrEP forecasting

PrEP Delivery Platforms

Readiness for PrEP Introduction	
Readiness Factor	**Progress**
Issuance of standard **clinical guidelines** for prescription and use of PrEP	• Treatment guidelines are not yet under development.
Sufficient **infrastructure and human resources** to conduct initial HIV tests and prescribe PrEP in priority channels	• Network of 1,460 HTC centers identified as key channel for ARVs and HIV prevention. These are likely to serve as key infrastructure for PrEP roll-out, but outreach will be needed. Human resources need to be determined by roll-out plan.
Plan to engage **health care workers** on PrEP and delivery to target populations (including mitigating stigma)	• No plan in place, but considerations are beginning to emerge • GALZ conducting health care worker training project – demonstrating results of reduced stigma
Tools to help potential clients and HCW understand **who should use PrEP** have been created	• No screening tool for PrEP has been developed/agreed upon, but HPTN 082 will be testing a tool that could potentially be used for scale up.
Sufficient **resources** to roll-out plans for healthcare worker engagement	• Resources not yet secured. Needed resources will be determined along with health care worker engagement plans and identification of PrEP delivery channels.

Key Stakeholders

- **General HIV service channels:** community-and-home-based care providers (CHBC), HTC centers, ART sites (including central, district, local, and mission hospitals), mobile clinics
- **General HIV prevention partners:** ZNFPC, PSI, PSZ clinics
- **General HTC implementing partners:** PSI, OPHID, ZAPSO, ZACH, WHO
- **Youth/AGYW:** youth centers, health facility youth-friendly corners; **FSW:** network of sex work clinics; **MSM:** civil society and advocacy organizations (e.g., GALZ)

Key Strengths and Opportunities

- Despite some capacity issues during ARV scale-up, **there appears to be capacity for PrEP delivery** as long as policy clarifies target populations
- **CHBCs have significant reach** (e.g., they reached 700k people in 2011)
- **1,460 HTC centers** identified as key channel for ARVs and HIV prevention
- **ART sites tripled** from '10 to '14, and >85% live within 3km in most districts
- Strong NGO programs and political will to **support FSW**
- GALZ has HCW contacts across the country; **could provide PrEP to MSM**
- Early successes in **addressing nurses' negative FSW attitudes** with training

Key Emerging Considerations

- CHBCs have **limited skills** and experience, **lower quality** assurance, and **weaker referral systems**
- Community-based HTC is not robust, and HTC is particularly lagging for target populations including AGYW
- Civil society orgs accessible in urban areas but **not peri-urban or rural**
- Official **clinical training on PrEP** needed from MOHCC. Trainings often reach staff at provincial hospitals, but not local level facilities where populations with high HIV risk are likely to go
- **Training needed** from groups who understand and represent key populations (GALZ, CESHAAR, AFRICAID) on how to deliver PrEP to key populations (GALZ trained 500 HCWs in 2015 in MSM sensitization)

Current PrEP Delivery Channels

	Demo projects and Open Label Extensions	DREAMS
Background	• The SAPPH-Ire Demonstration Project in Zimbabwe has been implemented at 14 outreach sites that offer HIV services to female sex workers . The study began in July 2014 with enrollment of 2,800 women. • HPTN to initiate three studies in 2016, including HPTN 082 and IMPACT.	• The DREAMS initiative (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women) will provide PrEP to young women in six districts (Bulawayo, Gweru, Mazowe, Makoni, Mutare, Chipinge) beginning in 2016/2017, but is currently waiting for MCAZ registration of Truvada for prevention. It is likely that oral PrEP in the form of Truvada will be donated by Gilead for use by DREAMS.
Key Strengths	• Demo project reaching target populations at high risk of HIV transmission • Existing access to PrEP and associated testing, monitoring, and counselling services • Experienced staff highly knowledgeable about PrEP • A PrEP demo project/research task force will be convened to share valuable insights from recruitment and retention efforts thus far, including demand creation and messaging, and models of service delivery • Low levels of stigma among staff working with PrEP users	• Targeted program reaching high-risk (as identified by community-led criteria) adolescent girls to start 2016/17 • PrEP delivery coupled with HTC, behavior change activities, extensive counseling, community mobilization, and initiatives to strengthen families • Potential to expand PrEP district-wide given other investments to make PrEP available to DREAMS participants, including logistics, procurement, demand generation, and community buy-in efforts
Key Challenges	• Perception of PrEP as part of an “experiment” deters potential users fearing poor safety and efficacy of drug • Higher costs of delivery in demonstration project context	• DREAMS PrEP to reach adolescent girls only in communities where many other populations could benefit from PrEP • Reach limited to 1451 young women in DREAMS districts (53,654 young women will be targeted with HTC)

Potential PrEP Delivery Channels

This is a continued area of focus. Additional details expected by the end of 2016.

	Comprehensive Care Centers & other ART sites			Sexual and Reproductive Health (SRH) care providers
	Public (Gov't)	**NGO**	**Private**	
Background	• Public hospitals, clinics, and other health care centers (e.g., VMMC clinics)	• NGO-run clinics, care centers, other HIV service programs such as PSI New Start Centers, FHI's new programs, and key population clinics (Sisters Clinic)	• Private fee-for-service providers	• A range of SRH care including family planning, post-abortion care clinics, pre-natal care & other SRH providers
Key Strengths	• Most visible to general populations • Systems guided and linked with county and national standards/ agendas	• Can provide greater access to key populations (FSW, MSM, PWID) • Effectively reach high-risk individuals with low/no stigma present in centers or among staff • Frequent use of peer-educator programs, which might be critical to effective use and increased demand generation	• Opportunities to deliver through private channels accessing key populations such • Discrete access to PrEP without stigma for those who can afford it • Not dependent on aid	• Provide greater access to sero-discordant women and AGYW in female-friendly and trusted settings • Staff have lower levels of stigma against AGYW who seek family planning and HTC services • Post-abortion care clinics have the potential to reach women with very high risk of HIV infection • Low cost of demand generation since women are already visiting SRH services
	• ~1500 ART sites throughout Zimbabwe • Well-integrated procurement and delivery systems • Laboratory capacity for necessary PrEP monitoring in place • HTC-trained staff			
Key Challenges	• HCW stigma against target populations, if present, can deter many from accessing care through these sites • Staff and resources perceived to be stretched thin, resulting in suboptimal care • No single outlet effectively reaches all target populations			• Potentially limited experience and training in HTC linkages • Limited/no laboratory capacity for necessary PrEP monitoring • AGYW may have trouble accessing

Individual Uptake

Readiness for PrEP Introduction	
Readiness Factor	**Progress**
Clear and informative **communications** on PrEP for general public audiences	• No communications strategy or planning for one has been initiated do date.
Development of **demand generation strategies** targeted to unique needs of different populations	• Demand generation activities are not in place beyond those attached to specific demo projects, but these haven't been researched or vetted.
Linkages between HTC, PrEP prescription, and PrEP access to enable PrEP uptake	• Necessary linkages will be unknown until PrEP guidelines outlining channels, populations, and prescription details are completed. If PrEP is delivered through ARV channels, the linkages are likely to enable PrEP uptake at least in those populations already accessing such channels.
Information for clients on how to effectively use PrEP for all target populations	• Information exists for those participating in demo projects. General information for all target populations including AGYW will need to be developed.
Sufficient **resources** to roll-out plans for demand generation	• Resources not yet secured. Needed resources will be determined and ultimately secured once Zimbabwe determines demand generation needs and plans.

Key Stakeholders:

- **NGO groups, including CHAI,** are in early stages of demand generation research and promotion
- **Networks** (ZNPP+, ZAN) may help with demand generation activities
- **FHI360** is coming in as a new partner under PEPFAR on HTC and may introduce new plans for mobilizing testing and care linkages that could be leveraged for PrEP delivery
- **PEPFAR and Global Fund** may be key funders of demand generation
- **PSI** deploying 354K self-testing kits, which might be critical in providing HTC to high risk populations not already accessing testing services

Key Strengths and Opportunities:

- Good HTC coverage, **but actual HTC usage is less favorable**: 91% of women and 88% of men know where to access HTC, but 57% of women (45% of young women) and 36% of men (24% of young men) have ever been tested and received results
- **PITC is being pushed** by MOHCC and scaled up to 94% of health facilities
- Track record of **success with VMMC,** as well as recognition that **gaps in consistent condom use persist, particularly among key populations**
- GALZ, CESHAAR, SAFAIDS, and others are working to **advocate for legal reform** for FSW and MSM
- Recent **positive legal change around** "loitering laws" show that things may be moving positively for FSW

Key Emerging Considerations

- **FSW:** sex work illegal, high rates of abuse/violence, high opportunity and transportation costs keep FSW from choosing to access HIV services
- **MSM:** practices are illegal (unlikely to change), facilities refuse treatment
- **AGYW:** uptake challenges with other products (e.g., for cultural reasons, only 1/4 of adolescent girls use the pill, which accounts for majority of their modern contraceptive use), low HTC uptake
- **General:** direct advertising of Rx medicines to the public is prohibited, concerns about PrEP's unintended consequences (e.g., resistance, undetected HIV infections, riskier behavior, increased abuse/violence)

Key End-user Themes for PrEP

	Key Considerations
Stigma	• **Early stigma lingers:** making PrEP widely available beyond key populations would help mitigate preconceptions of PrEP as an option only for FSW and MSM. This is important because only demo project to date in Zimbabwe is working with FSW. Any PrEP communications campaign will need to directly address the stigma associated with this population • **Among health workers**: the challenges are twofold- healthcare workers have their own biases about who should be accessing birth control options and HIV prevention services, and they often lack the appropriate information and training to effectively provide a range of options for individuals to make informed decisions • **Youth and female-friendly spaces are critical and needed**: centers that are stigma-free, youth and female-friendly will facilitate uptake, but changes to facilities have been slow and insufficient
Drug Preconceptions	• There are fears about developing **resistance** to ARVs while on PrEP, and developing physical side effects associated with ARVs • People recognize Truvada as an **ARV** and do not want to be seen taking it if they are HIV negative
Messengers	• Messages around PrEP need to be **proactive, consistent, and come from multiple directions.** Important messengers include: national and county governments, ministries, CBOs, celebrities, religious leaders, healthcare workers, peers and various forms of media (e.g. print, radio, online)
Messages	• **PrEP as power:** PrEP could be framed as an option to protect oneself and the community. Also as something that is empowering and positive as opposed to shameful and incriminating. Ideas for messaging included statements such as : "Our own choice, our own power" • **Risk in relationships**: potential to appeal to likely PrEP users by highlighting the risk associated by their own conduct and also that of their partners who may have multiple sexual partners • **Risk perception**: young women in Kenya generally do not see themselves at high risk for HIV transmission. They are more focused on economic opportunity and education • **PrEP for all:** ideas for inclusive messaging included statements such as "PrEP is for you, PrEP is for me" and "PrEP is for all of us"

Effective Use & Monitoring

Readiness for PrEP Introduction	
Readiness Factor	**Progress**
Established plans to support **effective use and regular HIV, creatinine testing** that reflect the unique needs of target populations	• While early considerations for encouraging and supporting effective use and adherence to regular testing are being discussed, specific strategies for target populations are not yet being created.
Capacity to provide ongoing HIV and creatinine level testing for PrEP users accessible to target populations	• While there is increasingly sufficient HTC capacity for current efforts, gaps remain and resources may continue to be a challenge. Additionally, exact testing needs for PrEP are yet to be determined. Country treatment guidelines should outline these specific needs.
Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)	• M&E for PrEP likely to be integrated with existing ARV M&E system. PrEP guidelines will need to dictate monitoring and training needs.

Key Stakeholders:

- **NAC** is responsible for overseeing the national M&E plan
- **NGOs** have been particularly important in providing post-test support services for HIV-negative and HIV-positive people that address risk reduction, disclosure, and treatment adherence

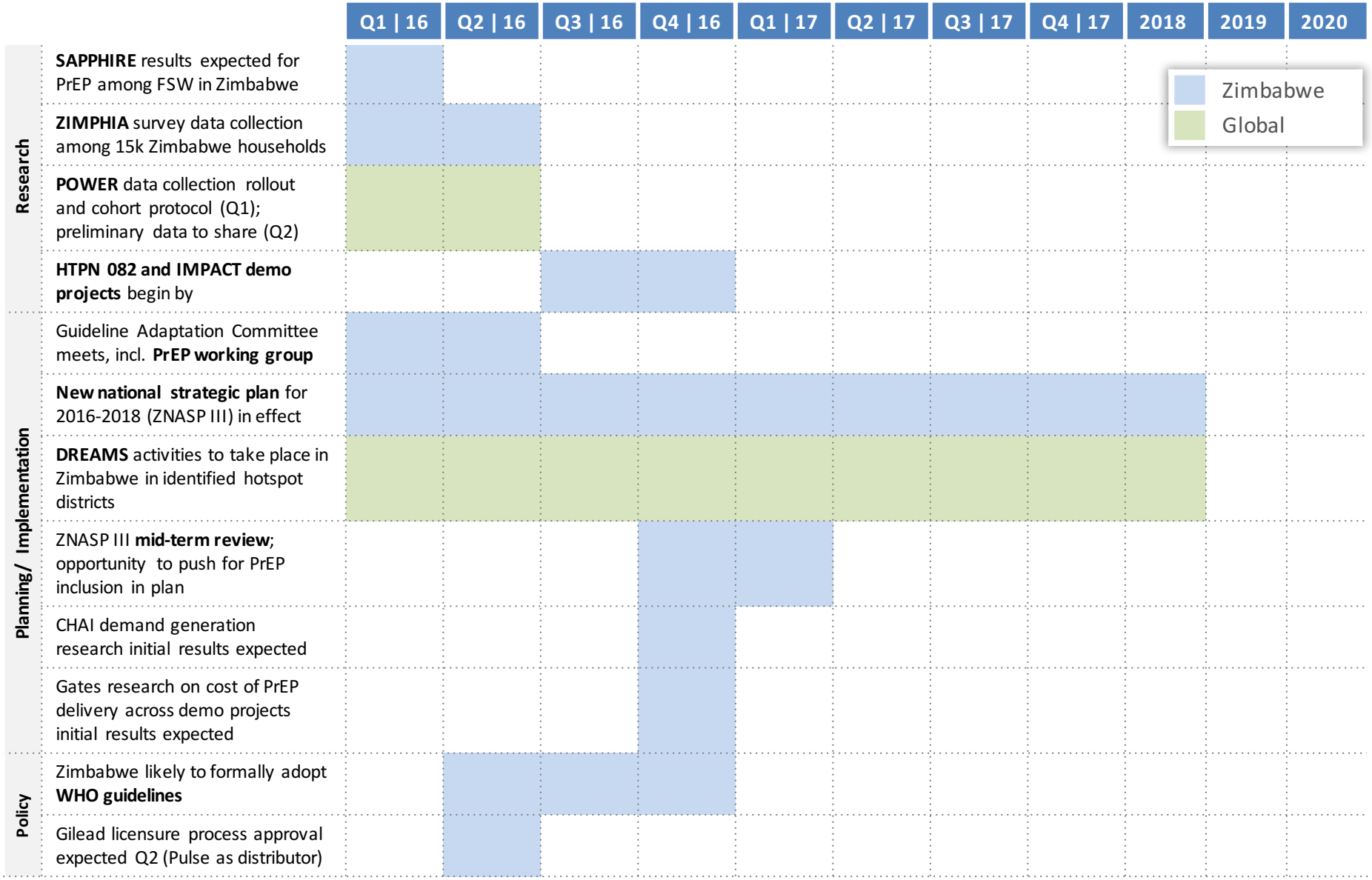
Key Strengths and Opportunities:

- Zimbabwe has a **single monitoring and evaluation system.** This system is linked to individual project/program M&E systems being used by HIV/AIDS service organizations; this system appears to be in the process of becoming **more integrated and harmonized**
- M&E for PrEP likely to be **integrated with existing ARV M&E system**
- ZNASP III states that "a contextual **National M&E Plan will be developed** to guide the implementation of the strategic plan and its partner systems"

Key Emerging Considerations

- While a data system (DHIS2) exists, only **some of facility/patient data is pulled into DHIS. Additionally,** facility registers and reporting tools do not (yet) reflect needs to track the roll-out of PrEP. Therefore, M&E tools will need to be revised to be able to report on PrEP rollout
- **Little is known about PrEP adherence in general**, and even less on how it may differ among **target populations** in Zimbabwe
- While it seems like there is sufficient capacity for HIV testing, ongoing testing of PrEP users **could place strain on the existing system**

Appendix B: Expected PrEP Activities



Appendix C: References

- 126 Million Additional Funding Announced to Fight HIV in Zimbabwe. United Nations Development Program. January 20, 2015.
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