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OPTIONS

Country Situation Analysis Interim Findings: Kenya

FSG in partnership with LVCT Health



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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.

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:

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** and will be **guided by national leadership** through NASCOP
- We have a **strong local partner**, LVCT Health, with significant experience working on HIV prevention in the Kenya context
- In addition to LVCT, our consortium is able to bring **multi-disciplinary expertise** to the effort to introduce female-controlled HIV prevention products in Kenya
- 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 Kenya, completed by FSG with significant input and consultation from LVCT Health
 - The situation analysis aims to take a **comprehensive and robust approach** to assessing the “state of the field” for PrEP in Kenya, 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 from secondary **research** and in-country consultations with key stakeholders
 - This is designed as a **“living document,”** to serve as a repository for information regarding the situation of PrEP in Kenya 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 situation analysis, please email Neeraja Bhavaraju at Neeraja.Bhavaraju@fsg.org

Executive Summary

- Kenya has made significant strides toward creating **positive initial conditions** for the roll-out of PrEP:
 - PrEP is included in Kenya’s most recent Kenya AIDS Strategic Framework (KASF), the Prevention Revolution Roadmap, and Kenya’s Fast-track Plan to end HIV and AIDS among Adolescents and Young People
 - The Pharmacy and Poisons Board has **registered Truvada (oral PrEP) for HIV prevention**, and PrEP is included in the **National ARV Guidelines**
 - Government entities such as NASCOP and NACC are taking a **proactive role** in generating local-level buy-in for PrEP, engaging diverse sectors in PrEP planning, and cooperating with key stakeholders in the development of policies and practices for PrEP. A national **TWG for PrEP and various PrEP sub-committees** are in place
 - **Potential target populations** have been initially defined: female sex workers (FSW), men having sex with men (MSM), sero-discordant couples, adolescent girls and young women (AGYW), among others. However, Kenya is motivated to provide PrEP to all those as substantial ongoing risk and has developed a risk assessment framework to define such risk
 - Beginning January 2017, PrEP will be delivered through Bridge to Scale and DREAMS. The **national PrEP program will launch officially** in March 2017
- Kenya, through NASCOP leadership, developed test and treat guidelines in 2016 that include PrEP. **Implementation guidelines** are under development and expected to be completed by March 2017 and involve multi-sector participation
- The current state of the PrEP discussion revolves around implementation considerations:
 - Designing and providing **healthcare worker training** to support PrEP delivery, monitoring, and adherence
 - Finding **key delivery channels** for reaching target populations with PrEP (e.g., comprehensive care centers and other ART sites, DREAMS districts, sexual and reproductive health (SHR) sites)
 - **Increasing uptake** will necessitate understanding target population **user preferences** and PrEP **access needs**, and deploying a successful **national communications campaign** for PrEP
 - Determining the **cost and impact** of adding PrEP to prevention strategies for target populations
 - Assessing **capacity-building needs** for the integration of PrEP into health services and other channels
 - **Monitoring and evaluation of PrEP** program and defining **commodity security systems** to ensure uninterrupted supply
- The most significant current **concerns about PrEP** include:
 - How to address **stigma** through policies, communications, and scale-up procedures
 - Obtaining **donor commitment** to sustainably fund scale-up of PrEP

HIV in Kenya

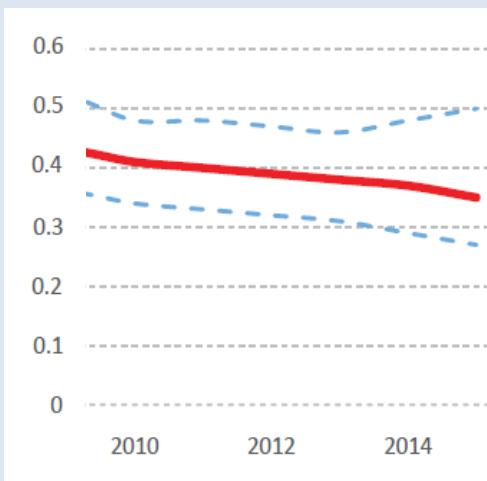
Context

- Kenya has the world's **fourth largest HIV burden**, with an estimated **1.5 million** people living with HIV (prevalence of 5.9%)¹
- ~900,000 people on antiretroviral therapy (ART) by the end of 2015², a 40% increase from 2013¹
- New HIV infections in Kenya were reduced by 19% between 2013 and 2015. **77,647 new infections** occurred in 2015
- Highly **geographically concentrated HIV burden**, thus Government and PEPFAR's response to HIV is focused at the county level

Trends

HIV incidence has **steadily been decreasing at a low rate**

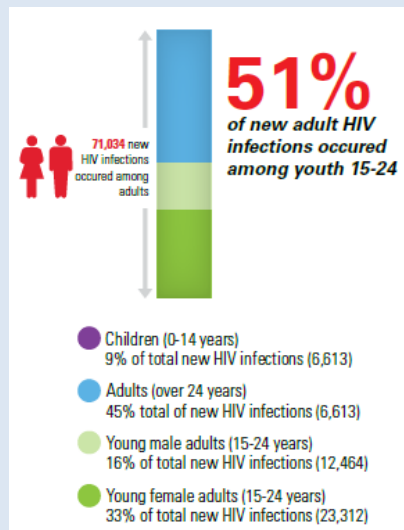
Adult HIV incidence rate over time³



Demographics

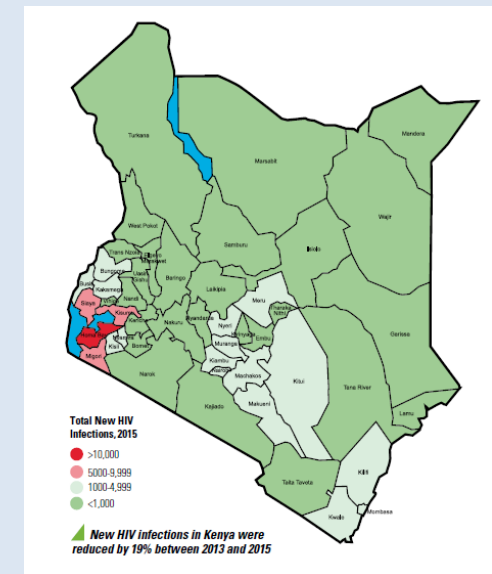
Kenya's HIV incidence is driven by a **broad set of populations**, including significant contributions from sero-discordant couples and adolescent girls and young women (AGYW):

New HIV infections, 2015¹



Geography

Highly concentrated epidemic- 65% of new infections occurring in 9 out of the 47 counties¹:



HIV Prevention & Treatment in Kenya

Context

- Through a **heightened level of investment** and a focus on **combination prevention**, the government has made significant progress in reducing the number of new infections: **49% decrease among children; 19% among adults** between 2013 and 2015¹. Infections among young people are increasing- 51% of adult infections occurring among those 15-24 compared to 29% in 2013¹
- Given the **smaller reduction in adult infections**, Kenya's most current strategy has shifted towards focusing on **priority geographies** with high-incidence, and **integrating those who are disproportionately affected by the epidemic**: girls, women and key populations such as FSW, MSM, people who inject drugs (PWID), sero-discordant couples, and people in prison²

Current Efforts

- **High HIV/AIDS treatment coverage² in ~2000 ART sites:**
 - Mother to child (78%)
 - Men (80%)
 - Women (77%)
 - Infants/children (42%)
- **High reach of HIV testing and counselling for high-risk populations, with lower rates for general public² through ~5000 testing sites:**
 - FSW (68%)
 - MSM (74%)
 - PWID (60%)
 - Women- general (47.3%)
 - Men- general (35.8%)
- **Similar percent of key populations not receiving targeted interventions¹:**
 - FSW (33%)
 - MSM (31%)
 - PWID (26%)

Remaining Challenges

- Despite growing investment, Kenya is **struggling with financial sustainability** for HIV treatment and prevention, and has begun to develop additional domestic funding sources in light of substantial **funding gaps** in recent years
- The current **health service system** faces challenges in **planning, coordination, and inadequate infrastructure investment**, leading to capacity constraints in HIV-AIDS clinics such as a shortages of staffing, insufficient space/facility infrastructure, and shortages in testing kits
- **PLHIV** continue to face **high levels of stigma** throughout the country. This indicator has not improved since 2003
- Current messaging and distribution channels are **insufficient** for reaching key populations; the GoK will need to continue to **adjust current strategies** in order to serve at-risk populations, and **invest in youth-friendly services/facilities**
- **Risk perception is low** among certain target populations, which makes prevention uptake a constant challenge

Key Considerations for PrEP

Why PrEP is under consideration in Kenya

- **Achieving national targets:** Kenya has committed to addressing the HIV/AIDS epidemic by setting a high goal for prevention: a **75% reduction in new infections by 2020**.¹ However, the rate of reduction for adult HIV transmission is slow, **seeing only a 7% decrease from 2007-2013**.¹ At this rate, **Kenya will not meet its goals**. The number of new infections will not decrease unless Kenya targets at-risk populations who are most severely affected: **FSW, MSM, sero-discordant couples, PWID, AGYW, people in prison, and other marginalized populations**.² PrEP could provide an effective method for these populations who do not use other prevention options.
- **Combination prevention:** Impact models suggest that **PrEP use by key populations** in combination with the currently available set of interventions (behaviour change, early ART, male circumcision) would **avert the highest number of infections**.²
- **Equity and human rights:** Kenya's national plan states that "the success of the HIV response is dependent on protecting and **promoting the rights** of those who are socially excluded, marginalised and vulnerable."¹ Several of the high-risk populations for whom PrEP is most appropriate are also most discriminated against by Kenyan society. Currently, demonstration projects have shown promising results for the demand for PrEP among these populations, **particularly among MSM and FSW**.³
- **PrEP offers a gender-sensitive option for prevention:** Women continue to be **disproportionately affected by HIV/AIDS**, in particular AGYW ages 15-24. If implemented effectively, PrEP could give women the choice to protect themselves against infection, regardless of their partner's preference for sexual activity.

Context and questions around PrEP

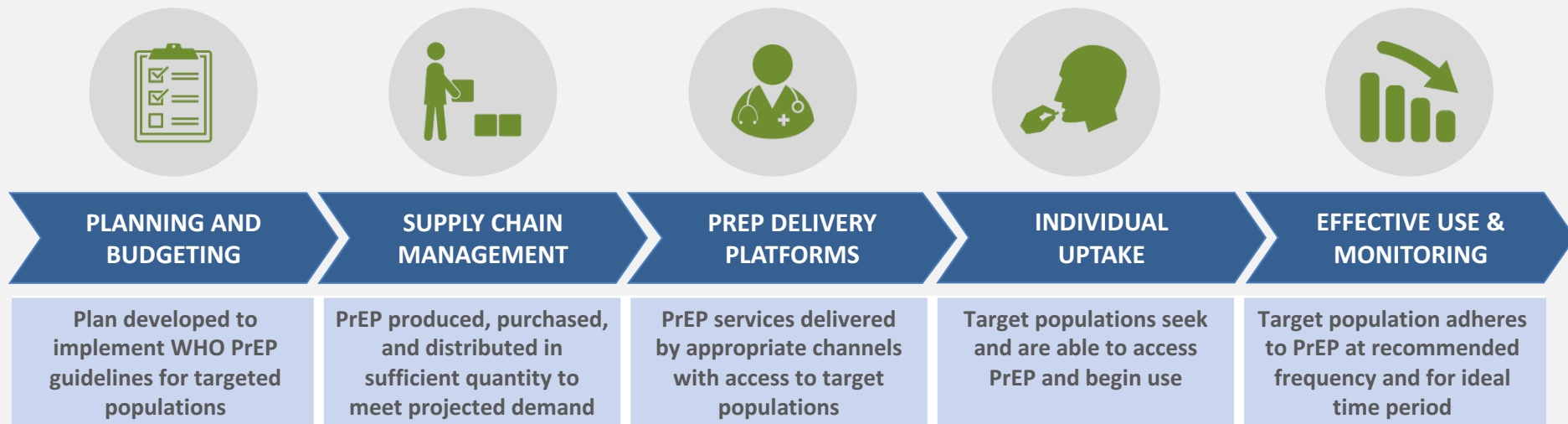
- Kenya's national plans (KASF, Revolution Roadmap, and Fast-track plans) include provision of PrEP to high-risk populations
- The Pharmacy and Poisons Board approved PrEP in December 2015, national treatment guidelines are in place, and implementation guidelines expected in March 2017
- Although national plans and policies include provisions for PrEP, questions remain on concrete plans to deliver PrEP to target populations, plans to encourage and support uptake, and funding for PrEP, especially at the county level
- Remaining questions about the most effective delivery channels for PrEP, as well as the health care system capacity to reach key populations and provide additional PrEP-related services
- Funding for PrEP is still unclear, yet donors such as Gates and PEPFAR have shown initial commitments to fund PrEP introduction in Kenya
- Planning for PrEP will be initially focused on counties with current and planned PrEP demonstration projects

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** 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.

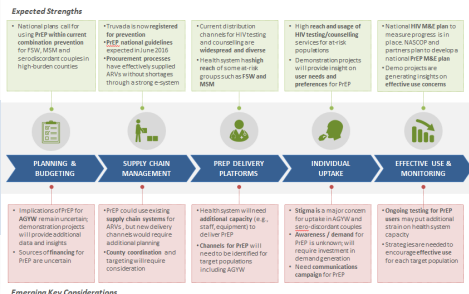
Value Chain for PrEP



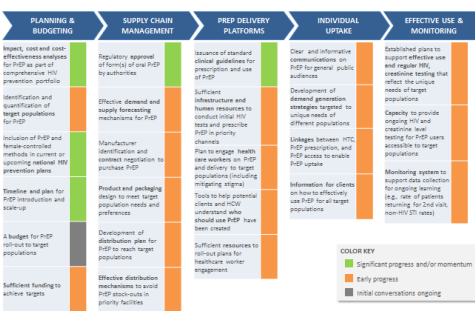
Value Chain Analyses

The following slides hold three analyses along the value chain

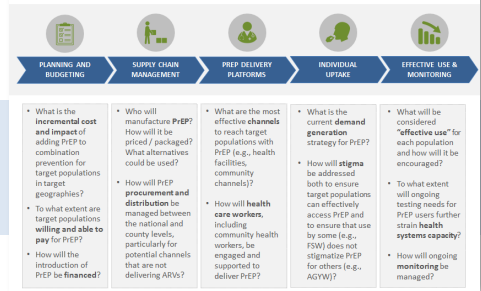
Resources and Gaps for PrEP in Kenya



Towards Introduction of PrEP in Kenya



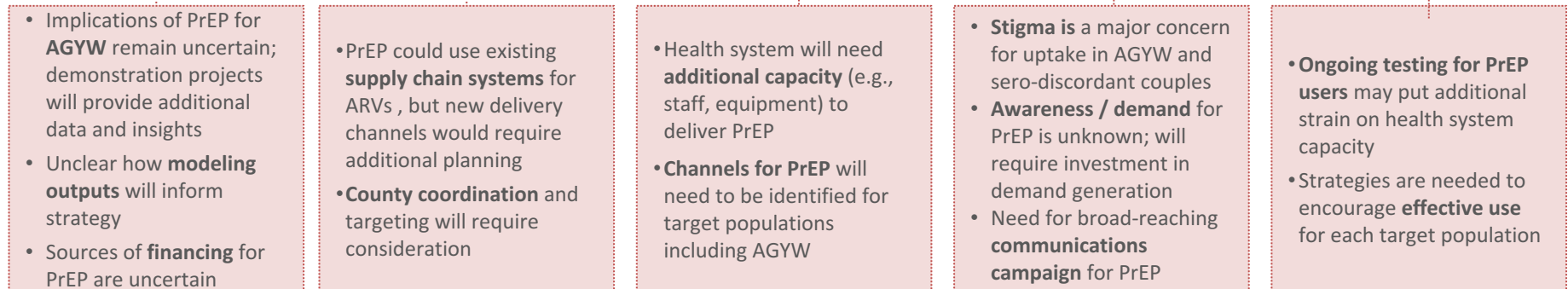
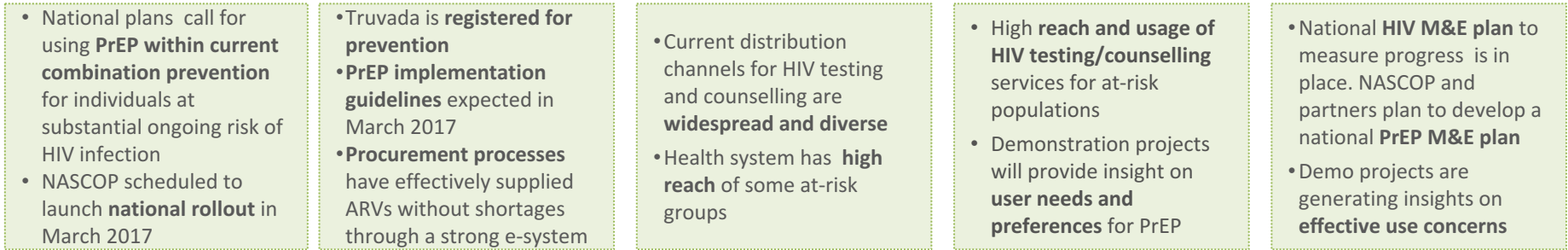
Key Questions for PrEP in Kenya



- 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

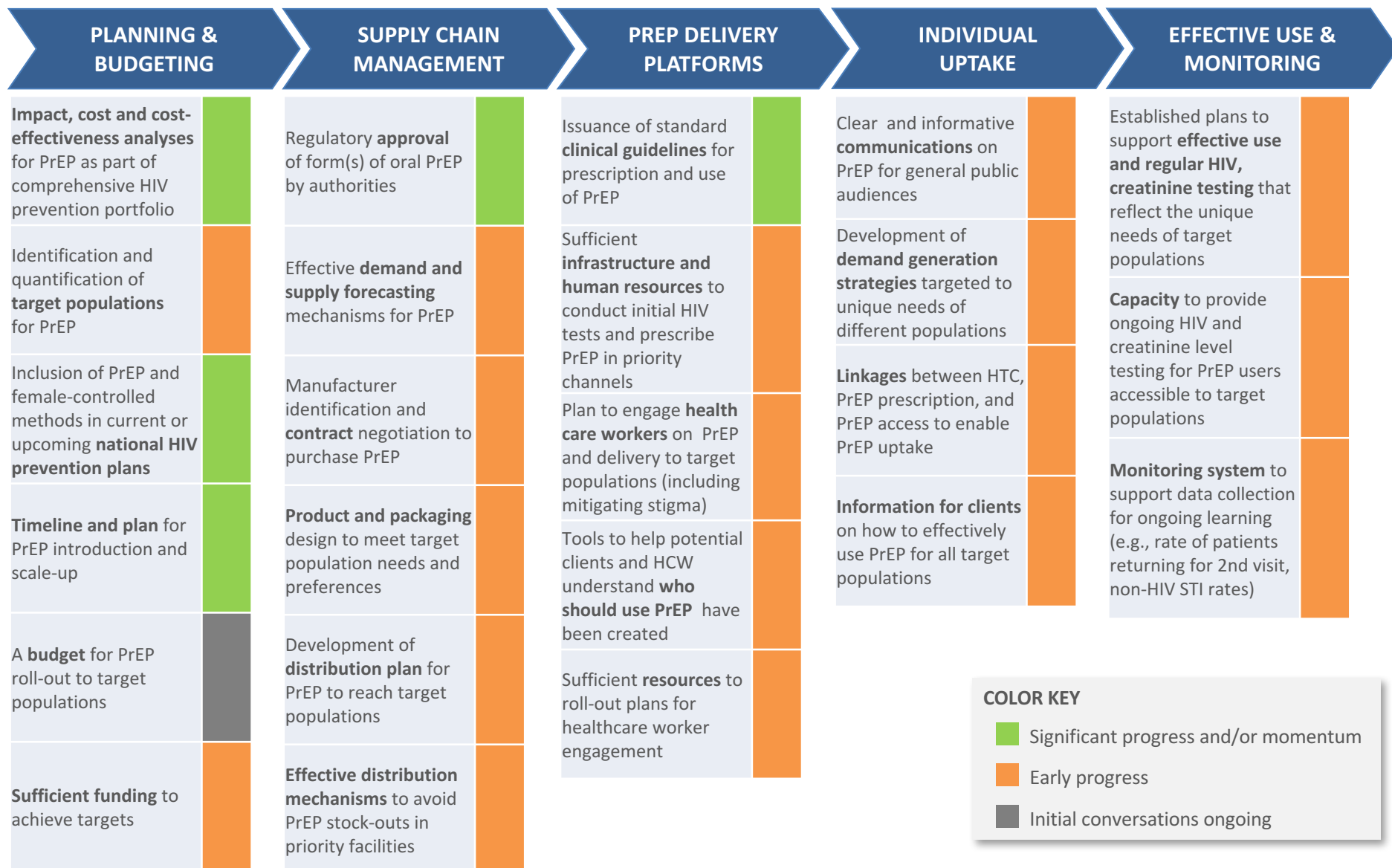
Resources and Gaps for PrEP in Kenya

Expected Strengths



Emerging Key Considerations

Towards Introduction of PrEP in Kenya



COLOR KEY

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

Key Questions for PrEP in Kenya



PLANNING AND BUDGETING

- What is the **incremental cost and impact** of adding PrEP to combination prevention for various populations in key geographies?
- To what extent are target populations **willing and able to pay** for PrEP?
- How will the introduction of PrEP be **financed**?



SUPPLY CHAIN MANAGEMENT

- Who will manufacture **PrEP**? How will it be priced / packaged? What alternatives could be used?
- How will PrEP **procurement and distribution** be managed between the national and county levels, particularly for potential channels that are not delivering ARVs?



PREP DELIVERY PLATFORMS

- What are the most effective **channels** to reach target populations with PrEP (e.g., health facilities, community channels)?
- How will **health care workers**, including community health workers, be engaged and supported to deliver PrEP?



INDIVIDUAL UPTAKE

- What is the current **demand generation and communications** strategies for PrEP?
- How will **stigma** be addressed both to ensure target populations can effectively access PrEP and to ensure that use by some (e.g., FSW) does not stigmatize PrEP for others (e.g., AGYW)?

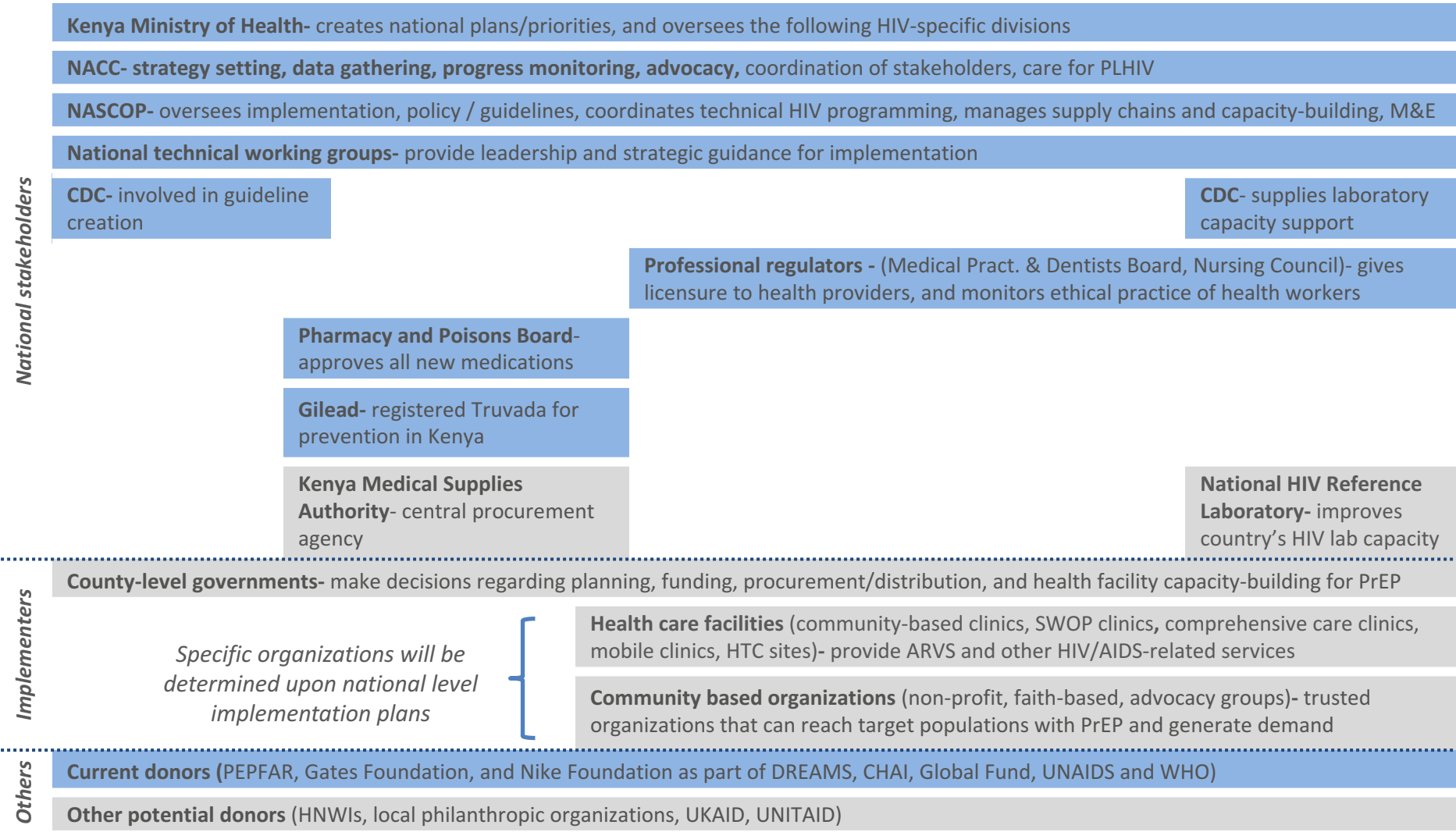


EFFECTIVE USE & MONITORING

- What will be considered **“effective use”** for each population and how will it be encouraged?
- To what extent will ongoing testing needs for PrEP users further strain **health systems capacity**?
- How will ongoing **monitoring** be managed?

Key Stakeholders for PrEP

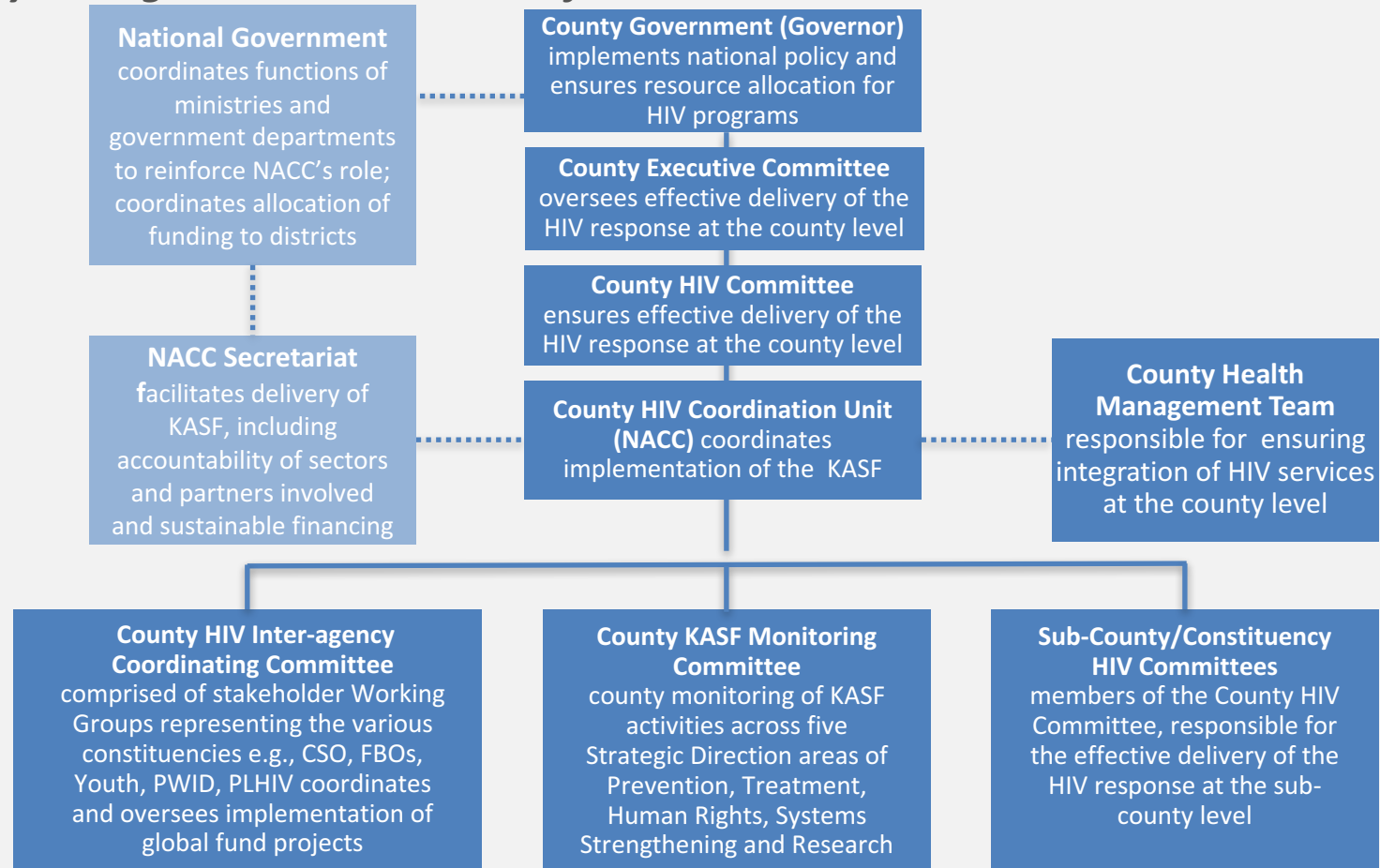
Currently involved
Potential/future involvement



County-level HIV structures in Kenya

County governments are responsible for developing HIV prevention budgets and implementation plans at the local level, and therefore will be critical partners in any efforts to introduce PrEP in Kenya.

County-level governance structures for HIV



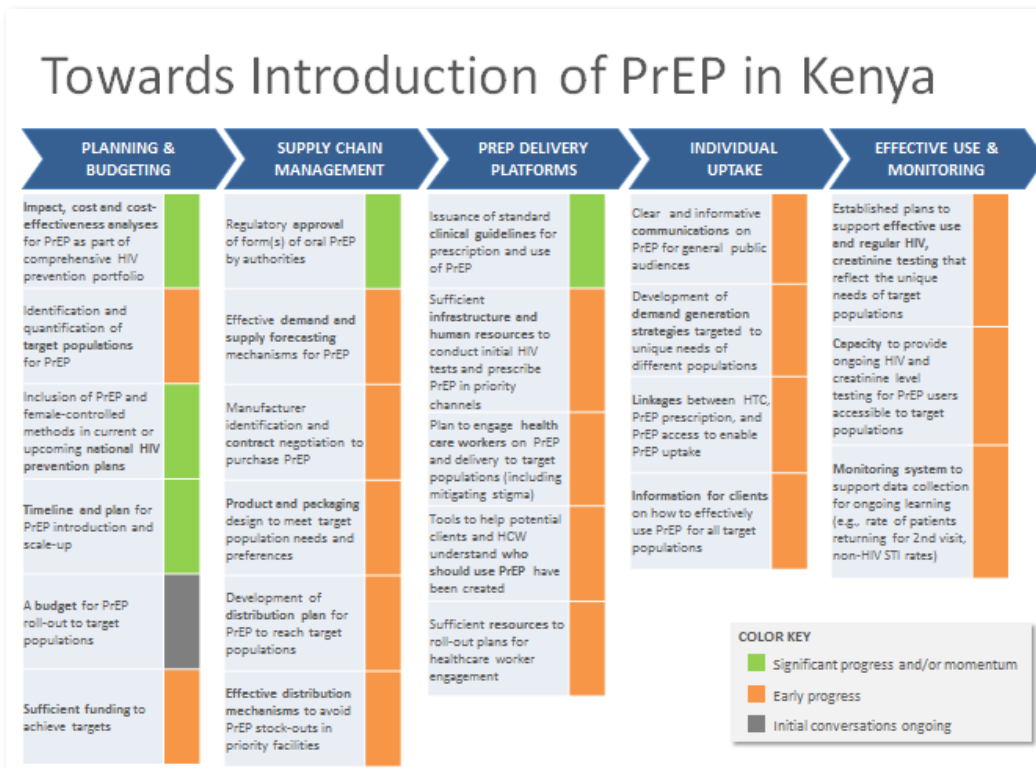
APPENDIX

A. Value Chain Detail

B. Timeline for PrEP

C. References

Appendix A: Value Chain Detail



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

Planning



Readiness for PrEP Introduction

Readiness Factor	Progress
Impact, cost and cost-effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio	<ul style="list-style-type: none"> Modelling studies underway to refine impact and cost-effectiveness estimates (Imperial College of London, Health Policy Project, Avenir) Costing studies underway (CHAI/LVCT Health); expected mid 2017
Identification and quantification of target populations for PrEP	<ul style="list-style-type: none"> Target populations in Revolution Roadmap include FSW, MSM, PWID, sero-discordant couples, varies by county Plans for AGYW remain uncertain
Inclusion of PrEP and female-controlled methods in current or upcoming national HIV prevention plans	<ul style="list-style-type: none"> PrEP is incorporated into the Kenyan HIV Prevention Revolution Roadmap and is also identified as an evidence-based intervention in the most recent Kenya National Strategic Framework (KASF). PrEP is also included in the Guidelines on use of ARV drugs for treating and preventing HIV infections
Timeline and plan for PrEP introduction and scale-up	<ul style="list-style-type: none"> NASCOP and partners are developing a PrEP introduction plan. Delivery will begin in January 2017 through DREAMS and B2S. A national campaign to be launched in March
A budget for PrEP roll-out to target populations	<ul style="list-style-type: none"> Early budget considerations and thinking happening as part of broader PrEP planning
Sufficient funding to achieve targets	<ul style="list-style-type: none"> DREAMS has resources dedicated to PrEP for AGYW Gates Foundation is funding Bridge to Scale, to accelerate PrEP scale-up

Key Stakeholders

- MoH** - creates national plans/priorities, and oversees the following HIV-specific divisions:
- NACC** - helps implement strategic plans, coordinates stakeholders, and provides care for PLHIV
- NASCOP** - has oversight on policy and guidelines, coordinates technical HIV programming, manages capacity-building, and performs M&E
- National technical working groups** - run by NASCOP and NACC, provide leadership and strategic guidance for implementation

Key Strengths and Opportunities

- Target populations** and **target geographies** for PrEP are defined
- Government is leading efforts to **further disaggregate data to segment youth population**, including AGYW
- Prevention Revolution Roadmap** makes the case for geographic targeting and combination prevention including PrEP for target populations. ARV treatment guidelines include guidance on PrEP
- NASCOP is engaging key stakeholders** such as county-level governments, civil society and advocacy groups
- Cost models** exist and are being refined for delivering and scaling PrEP to **FSW and MSM**

Key Emerging Considerations

- More prep-specific information is needed for target populations:** preferences, needs for access and support, effective use (some will be available through demo project and Population Council research)
- Translating a national strategy into **county-level action** will require significant guidance and incentives (financial and technical support, leadership of other counties)
- National funding is insufficient** for providing and sustaining PrEP; Kenya will need donors to scale-up PrEP



Potential Target Populations for PrEP

	Adolescent girls and young women (AGYW)	Sero-discordant couples	Female Sex Workers (FSW)	People Who Inject Drugs (PWID)	Men who have sex with men (MSM)
Key Indicators	<ul style="list-style-type: none"> ~4.1M total AGYW (ages 15-24) in Kenya, based on 2009 Census¹ 21% of new adult infections per year are among AGYW³ 4.5% prevalence; by age 24 the rate for AGYW is almost 4 times higher than for young boys² ~90% of young women test for HIV at least once by the time they are age 24² 	<ul style="list-style-type: none"> ~260,000 couples³ or 5-6%⁴ of couples are HIV sero-discordant 44.1% of new adult infections from sero-discordant couples³ Unknown level of access to testing and targeted HIV/AIDS intervention services Low awareness of partner status (48% for women; 61% for men)⁵ 	<ul style="list-style-type: none"> Unknown number, but estimated at ~1000,000^{4*} 29.3% HIV prevalence⁴ 14.1% of new adult infections per year are among sex workers and their clients³ 68% tested for HIV in the past year and know their status⁶ 70% receive targeted intervention services³ 	<ul style="list-style-type: none"> Unknown number of total PWID* 18.3% prevalence³ 3.8% of new adult infections per year³ 60% tested for HIV in past year and know their status⁶ 24% receive targeted intervention services³ 	<ul style="list-style-type: none"> Unknown number of total MSM* 18.2% prevalence³ 15.2% of new adult infections per year from MSM and prison³ 74% tested for HIV in the past year and know their status⁶ 55% receive targeted intervention services³
Prioritization	<ul style="list-style-type: none"> National plans define AGYW as a priority population for prevention; sometimes mentioned as targets for PrEP Demonstration projects: Confidence Project, MP3-Youth, POWER, IPCP 	<ul style="list-style-type: none"> Included in national plans as priority population for prevention Mentioned as targets for PrEP Demonstration projects: Fem-PrEP, Partners PrEP Ole 	<ul style="list-style-type: none"> National plans define FSW as a priority population for prevention; mentioned as targets for PrEP Demonstration project: IPCP Existing study on cost of PrEP scale-up for FSW 	<ul style="list-style-type: none"> National plans define PWID as a priority population for prevention Mentioned as targets for PrEP 	<ul style="list-style-type: none"> National plans define MSM as a priority population for prevention MSM mentioned as targets for PrEP Demonstration project: IPCP
Questions	<ul style="list-style-type: none"> What messages will be appropriate for encouraging use of PrEP without stigma? Which channels will be effective for PrEP delivery? What additional community support mechanisms need to be in place for PrEP's effective use? How much demand will there be for PrEP, especially relative to other prevention options in the pipeline? 				

Sources: 1-Kenya Population and Housing Census, Kenya National Bureau of Statistics, 2009; 2-Kenya Fast Track Plan to end HIV/AIDS in Adolescents and Young People, Ministry of Health, 2009; 3-Kenya Prevention Revolution Roadmap, Ministry of Health, 2014; 4-Kenya HIV Response and modes of transmission analysis, Ministry of Health, 2009; 5-Kenya Aids Strategic Framework 2014/15-2018/19, Ministry of Health, 2014; 6-Kenya AIDS Response Progress Report, National Aids Control Council, 2014

Budgeting



National budget

\$956.2M costs for HIV

\$210.3M of which is prevention

TBD what is committed to PrEP

Current Funding

- PEPFAR, Gates Foundation, and Nike currently fund PrEP-related efforts (\$39.5m allocated to DREAMS)¹
- PrEP research has been funded by BMGF, USAID, and NMHI/NIH
- Main fund sources for HIV/AIDS²:
 - >62% Bilateral funds (PEPFAR, UK)
 - >15% Public Funds (GoK)
 - >4% International non profits (CHAI)
- Current funding goes toward³:

Treatment & Care	52%
Prevention	21%
Social inclusion, human rights & gender	13%
Leadership & governance	7%
Health systems	4%

Summary

- Kenya's HIV/AIDS total **expenditures have risen over time**, accounting for 2% of total country GDP. Over **68%** of funding coming from **external sources**³
- The country has projected **funding gaps to implement** the new strategic plan (KASF), including the scale up of UTT
- Kenya will strive to close funding gaps by **maximizing program efficiency** to reduce costs, and **increasing domestic financing** by 50% by 2019

Remaining Gaps and Challenges

- It is likely that PrEP **will not be funded by GoK**, spelling the need for additional funding from external donors such as PEPFAR
- The **overall HIV/AIDS funding gap** (in \$USD M) will continue until 2019³:

Year	2015	2017	2019
Baseline funding	\$829M	\$797M	\$724M
Proposed funding	\$829M	\$852M	\$940M
Resource needs	\$956M	\$948M	\$833M
Gap	-13%	-10%	+13%

Potential New Funding Sources

- Funders such as the **Gates Foundation** have shown initial commitments to **further fund PrEP** through Bridge to Scale and requests for proposals
- The **National Hospital Insurance Fund (NHIF)** will finance the Kenyan government's universal health care. Kenya seeks to **increase the number of contributors** to this fund to cover costs of ART, and potentially fund additional HIV services
- **Kenya HIV Trust/Investment Fund** will raise national/county resources that will subsidize government HIV costs
- Determining the **ability and willingness to pay** for PrEP in a private healthcare setting might enable some cost-recovery

Sources: (1) "Project to cut new HIV cases in girls, women launched", SciDevNet, 2015; (2) Kenya National Aids Spending Assessment, Report for the Financial Years 2009/10-2011/12, NACC, MOH, and UNAIDS Kenya, 2014; (3) Kenya Aids Strategic Framework 2014/15-2018/19, Ministry of Health, 2014



Procurement & Distribution

Readiness for PrEP Introduction	
Readiness Factor	Progress
Regulatory approval of form(s) of oral PrEP by authorities	<ul style="list-style-type: none"> Truvada approved for prevention by the Pharmacy and Poisons Board Other forms of oral PrEP in pipeline
Effective demand and supply forecasting mechanisms for PrEP	<ul style="list-style-type: none"> Strong supply chain management in place for ARVs, which will likely translate to PrEP readiness CHAI is conducting demand forecasting
Manufacturer identification and contract negotiation to purchase PrEP	<ul style="list-style-type: none"> Manufacturers supplying PrEP include: Gilead, Cipla, Aurobindo, Hetero, and Cosmos (a domestic manufacturer)
Product and packaging design to meet target population needs and preferences	<ul style="list-style-type: none"> Currently a plastic pill bottle, to be refilled monthly; unknown if format will be consistent for other forms of oral PrEP Mylan and PSK are exploring different packaging preferences and options
Development of distribution plan for PrEP to reach target populations	<ul style="list-style-type: none"> NACC and other entities determining most effective channels and accompanying distribution plans NASCOP's RFPs for implementation of Prevention Revolution Roadmap will provide insight on distribution
Effective distribution mechanisms to avoid PrEP stock-outs in priority facilities	<ul style="list-style-type: none"> Kenya has historically maintained a strong supply chain for ARVs, with limited instances of shortages. Likely to translate to PrEP

Key Stakeholders

- **Gilead** licenses Truvada manufacturing globally. Its regional business partner in Kenya is currently Phillips Pharmaceuticals Limited
- **Pharmacy and Poisons Board**- approves all new medications
- **Kenya Medical Supplies Authority (KEMSA)**- central procurement agency under the MoH; partners with donors, county governments and community-based organizations (CBOs) to establish effective supply chains. Will be responsible for supply forecasting for PrEP
- **CBOs and county level governments** - will be responsible for the local supply chain of PrEP

Key Strengths and Opportunities

- **Strong supply chain for ARVs**, with limited instances of shortages
- **Strong E- Medical Record System (EMR)** to ensure ART coordination and **quality management system** in place
- Although the details on who will procure PrEP are still unclear, the GoK has committed to **supporting procurement for PrEP** to make it available wherever needed (pharmacies, HIV clinics)

Key Emerging Considerations

- Need for additional data on **target populations** demand estimates and user preferences to inform demand forecasts
- Lack of clarity on who will **manufacture and distribute PrEP**– likely not a challenge when handled by current ARV channels but questions remain about additional delivery channels not administering ART
- Need **procurement plan** through KEMSA and central coordination, establish the relevant HIV commodity management systems
- **High price of Truvada** – could shift with emergence of alternatives oral PrEP drugs



PrEP Delivery Platforms

Readiness for PrEP Introduction	
Readiness Factor	Progress
Issuance of standard clinical guidelines for prescription and use of PrEP	<ul style="list-style-type: none"> PrEP Clinical guidelines included in 2016 ARV guidance
Sufficient infrastructure and human resources to conduct initial HIV tests and prescribe PrEP in priority channels	<ul style="list-style-type: none"> High reach of HTC for high-risk populations, with lower rates for general public, through ~5000 testing sites. Human resources needs likely to be determined to meet PrEP guidelines
Plan to engage health care workers on PrEP and delivery to target populations (including mitigating stigma)	<ul style="list-style-type: none"> PrEP TWG working on developing specific PrEP modules to stack on to the current guidelines like KP and developing a comprehensive training for different levels of staff
Tools to help potential clients and HCW understand who should use PrEP have been created	<ul style="list-style-type: none"> Some materials already exist from demonstration projects LVCT Health supporting NASCOP to develop a risk assessment tool for PrEP use through the service delivery sub-committee
Sufficient resources to roll-out plans for healthcare worker engagement	<ul style="list-style-type: none"> Service provider toolkits are being developed

Key Stakeholders

- **PrEP TWG** – inform identification and planning for delivery channels
- **Comprehensive care clinics** (current ARV channels) - could distribute PrEP alongside HIV testing and treatment
- **Community-based organizations** - can support demand generation, distribution, and provide support for PrEP at the local level
- **County-level governments** – create county-level HIV plans as part of KASF delivery that would need to incorporate PrEP
- **Key population clinics**- provide HIV services to key populations directly

Key Strengths and Opportunities

- ARV clinics have a wide reach through ~2000 sites such as **comprehensive care centers and CBO-run clinics**. These could be leveraged for PrEP delivery
- Additional distribution plans are currently being developed by NACC, **taking into account the voice of communities (via focus groups)** to identify access needs, preferences, and support mechanisms necessary for effective distribution of PrEP to target populations
- Consider the **ability and willingness to pay** for PrEP through private health channels, some already reaching key populations (e.g., FHI’s Gold Star Network)

Key Emerging Considerations

- Health workers in many settings **are not equipped to distribute PrEP** to target populations, or address stigma. A plan and curriculum for **training** is needed
- **HIV testing kit shortages** could impede PrEP prescription/access
- Need better understanding of **full landscape of potential PrEP distribution channels** in order to most effectively reach target populations
- **Capacity-building** will be needed in order to equip non-ARV delivery channels as PrEP delivery/referral sites, including capacity to integrate with other care outlets (e.g., hospitals) to provide liver and kidney testing needed alongside PrEP
- **No ear-marked funding** for PrEP is available for capacity-building



Current PrEP Delivery Channels

	Demonstration Projects and Open Label Extensions	DREAMS
Background	<ul style="list-style-type: none">PrEP demonstration projects throughout Kenya have delivered PrEP through a number of projects. These projects include: Confidence Project; Fem-PrEP with adult women; LVCT and SWOP IPCP demo project with FSW, young women, and MSM; MP3-Youth with youth 15-24 years old; Partners PrEP demo project and OLE with serodiscordant couples.	<ul style="list-style-type: none">The DREAMS initiative (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women) will provide PrEP to young women in the districts of Homa Bay, Siaya, Kisumu and Nairobi beginning in 2016/2017. Oral PrEP in the form of Truvada will be donated by Gilead for use by DREAMS.
Key Strengths	<ul style="list-style-type: none">Demo projects already reaching individuals from target populations at high risk of contracting HIV (e.g., AGYW, FSW, MSM)Existing access to PrEP and associated testing, monitoring, and extensive counselling and adherence support servicesExperienced staff highly knowledgeable about PrEPValuable insights from recruitment and retention efforts thus farLow levels of stigma among staff working with PrEP users	<ul style="list-style-type: none">Targeted program reaching high-risk (as identified by community-led criteria) adolescent girls to start 2016/17PrEP delivery coupled with behavior change activities and extensive counselingFunding for PrEP secured (Truvada donated by Gilead, program costs from DREAMS funding)Potential to expand PrEP throughout these districts given other investments to make PrEP available to DREAMS participants, including logistics, procurement, demand generation, and community buy-in effortsPopulation Council implementation research will inform how to identify and reach AGYW, link them to services, and provide PrEP
Key Challenges	<ul style="list-style-type: none">Perception of PrEP as part of an “experiment” deters potential users fearing poor safety and efficacy of drugExtensive adherence support available in demo projects is likely to be prohibitively expensive at scaleHigher costs of delivery in demonstration project context	<ul style="list-style-type: none">DREAMS’ PrEP component to reach only adolescent girls in communities where many other populations could benefit from PrEPReach limited to Homa Bay, Siaya, Kisumu and Nairobi

Potential PrEP Delivery Channels

This is an area of focus for OPTIONS. Additional details expected to emerge

	Comprehensive Care Centers & other ART sites			Sexual and Reproductive Health (SRH) care providers
	Public (Gov't)	NGO	Private	
Background	<ul style="list-style-type: none"> Public hospitals, clinics, and other health care centers 	<ul style="list-style-type: none"> NGO-run clinics, care centers, other HIV service programs including those specifically for key populations (e.g., SWOP, LVCT Health, FHI, PSI) 	<ul style="list-style-type: none"> Private fee-for-service providers (e.g., FHI's Gold Star Network) 	<ul style="list-style-type: none"> A range of SRH care including family planning, post-abortion care clinics, pre-natal care & other SRH providers
Key Strengths	<ul style="list-style-type: none"> Most visible to general population Systems guided and linked with county and national standards/agendas 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Opportunities to deliver through private channels accessing key populations such as FHI's Gold Star Network clinics in Nairobi, the coastal region, and Riff Valley Discrete access to PrEP without stigma for those who can afford it Not dependent on aid 	<ul style="list-style-type: none"> Provide greater access to sero-discordant women and AGYW in female-friendly and trusted settings Staff may have lower levels of stigma against AGYW who seek family planning and HTC services Post-abortion care clinics have the potential to reach women at very high risk of HIV infection Low cost of demand generation since women are already visiting SRH services
	<ul style="list-style-type: none"> Over 2000 ART sites throughout Kenya Well-integrated procurement and delivery systems Laboratory capacity for necessary PrEP monitoring in place HTC-trained staff 			
Key Challenges	<ul style="list-style-type: none"> HCW stigma against target populations deters many from accessing care through these channels Staff and resources perceived to be stretched thin, resulting in suboptimal care May not effectively reach target populations at highest risk 			<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> • There is a sub-committee of the PrEP TWG focused on communications, advocacy, and community engagement. This sub-committee is developing a communications strategy • PSK is conducting communications work for DREAMS and Jilinde projects
Development of demand generation strategies targeted to unique needs of different populations	<ul style="list-style-type: none"> • PSK and McCann are working on early stages of demand generation strategies
Linkages between HTC, PrEP prescription, and PrEP access to enable PrEP uptake	<ul style="list-style-type: none"> • Necessary PrEP delivery elements have been outlined in PrEP treatment guidelines (initial and monitoring testing) • The actual capacity of various delivery channels to provide PrEP in-house or through linkages to other channels is yet to be assessed at scale
Information for clients on how to effectively use PrEP for all target populations	<ul style="list-style-type: none"> • Information exists for those participating in demo projects • Patient education toolkit has already been developed, and currently under review

Key Stakeholders

- **NASCOP**- oversee the development of communications strategies via TWGs and other partners
- **DREAMS**- will potentially have research and implementation practice for AGYW using PrEP that can be used to inform further scale-up (managed by Global Communities in Kenya)
- **Community-based and faith-based organizations** will play key role reaching target populations and influencing community PrEP buy-in
- **Local and national media**- to help accurate messaging on PrEP as an effective and safe prevention option

Key Strengths and Opportunities

- Some research exists on **user preferences for PrEP in key populations** (FSW, MSM, and sero-discordant couples), including: dosage patterns; willingness to consider using PrEP; potential demand for PrEP
- NASCOP has plans for additional research specifically on **delivery channels and access points for PrEP**
- **Communications sub-committee** of PrEP TWG has been established and is coordinating communications plans to reach all populations
- Implementation stakeholders acknowledge the importance of **addressing stigma** in order to reach AGYW and sero-discordant couples

Key Emerging Considerations

- Stigma is a major concern for uptake. This includes both the stigma associated with HIV and those normally thought of as “high risk” populations, as well as stigma against young women who might be sexually active and seeking SRH care. There is a strong need to normalize PrEP and **create a supportive communication strategy** for its use
- **Awareness / demand** for PrEP is unknown; will require investment in demand generation (CHAI is currently doing initial demand generation research to be completed by Q4/16)

Key End User Themes for PrEP



Key Considerations

Stigma	<ul style="list-style-type: none">• 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 most demo projects have been done with key populations. Any PrEP communications campaign will need to directly address the stigma associated with those populations.• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 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”• “Mpango Wa Kando”: potential to build-off of previous national campaign about the consequences of extramarital affairs to appeal to potential PrEP users by highlighting the risk associated with their own/their partners’ conduct• 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	<ul style="list-style-type: none"> • Effective use yet to be defined • Early considerations for encouraging and supporting effective use and adherence to regular testing are included in the national ARV guidelines
Capacity to provide ongoing HIV and creatinine level testing for PrEP users accessible to target populations	<ul style="list-style-type: none"> • While there is increasing HTC capacity for current efforts, gaps remain particularly for reaching target populations • Testing needs for oral PrEP have been identified in 2016 national test and treat guidelines
Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)	<ul style="list-style-type: none"> • The national Monitoring and Evaluation Framework 2014/15-2018/19 is the foundation for monitoring progress toward HIV national goals (key indicators include reducing stigma related to HIV-AIDS, and reducing infections within key populations) • PrEP and M&E TWGs are identifying key indicators for tracking PrEP service delivery at national level through DHIS_2 • B2S is leading the learning agenda process

Key Stakeholders

- **MOH/ NASCOP**- developing Detailed monitoring of oral PrEP rollout through DREAMS and Bridge-To-Scale (B2S) with support from UCSF
- **NACC** - holds country-wide responsibility to track KASF progress and HIV-related program success
- **CDC** - works closely with GOK and implementing partners to support lab systems and networks strengthening
- **National HIV Reference Laboratory(NHRL)** - leads policy and guidelines formulation on HIV-related lab services to strengthen country's laboratory capacity

Key Strengths and Opportunities

- **National monitoring and evaluation framework** includes priorities to increase funding toward healthcare capacity-building, reducing stigma, and targeting/prioritizing key populations such as MSM, FSW, youth
- Various **surveys exist to collect national data on the HIV epidemic**, including the **situation room tool** which will show live, local updates on HIV incidence and mortality
- NASCOP leading the development of **M&E plans** via TWG PrEP subcommittee, USAID SI team, and UCSF
- **Lessons on effective use from demo projects** to learn from and build on include consistent regimens, structured follow-up, and counselling/ community support

Key Emerging Considerations

- Mechanisms for **gathering local data** on PrEP impact are not established
- **Plans to increase effective use do not exist**; no roles have been assigned for generating the support systems needed to foster effective use at large
- Interventions used to encourage effective use among demo project participants would likely be too costly in many real-life settings (e.g. extensive counselling, use of peer educators)
- **Frequent, ongoing monitoring needs** likely to both drive up costs of delivery and discourage ongoing use of PrEP

Appendix B: Timelines for PrEP

	Q1, 16	Q2, 16	Q3, 16	Q4, 16	Q1, 17	Q2, 17	Q3, 17	Q4, 17	2018	2019	2020
Research	IPCP Kenya (LVCT Health and SWOP Kenya) study on PrEP for AGYW, MSM, and FSW	■	■	■							
	Partners Demonstration Project on PrEP for sero-discordant couples	■	■	■							
	MP3-Youth study to evaluate combination prevention for adolescent boys and girls	■	■	■	■						
	POWER demonstration projects for adherence / delivery support for women	■	■	■	■	■	■	■	■	■	■
	Confidence Project study (LVCT Health and LSHTM) on PrEP acceptability reports					■					
	Development of a national research agenda for HIV	■									
Planning/Implementation	DREAMS programming implemented in Homa Bay, Siaya, Kisumu, and Nairobi		■	■	■	■	■	■	■	---	?
	Bridge to Scale (B2S)			■	■	■	■	■	■	---	?
Policy	Next National AIDS Strategic Framework (KASF) developed									■	
Financing	NASCOP RFPs for Prevention Revolution Roadmap implementation, including PrEP				Exact timelines to be clarified						
Modelling	OPTIONS AGYW modelling results expected							■			
	B2S costing study				Exact timelines to be clarified						
	B2S impact and cost-effectiveness modelling				Exact timelines to be clarified						

Appendix C: References

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