MINISTRY OF HEALTH

Framework for the Implementation of Pre-Exposure Prophylaxis of HIV In Kenya

NASCOP
National AIDS and STI Control Program

JIPENDE JIPrEP

Framework for the Implementation of Pre-Exposure Prophylaxis of HIV In Kenya

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Abbreviations and Acronyms

ADR	Adverse Drug Reaction
AGYW	Adolescent Girls and Young Women
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARVS	Antiretroviral Drug(s)
CDC	Centers for Disease Control and Prevention
CHVs	Community Health Volunteers
DHIS	District Health Information System
DICEs	Drop In Centers
EMR	Electrical Medical Records
FSWs	Female Sex Workers
GBV	Gender-Based Violence
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
KASF	Kenya AIDS Strategic Framework
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KP	Key Population
LMIS	Logistics Management Information System
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
NEPHAK	Network of People Living with HIV/AIDS in Kenya

NHRL	National HIV Reference Laboratory
NPHLs	National Public Health Laboratories
OPD	Out Patient Department
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	Prevention of Mother-To-Child Transmission
PrEP	Pre-Exposure Prophylaxis
PPB	Pharmacy and Poisons Board
PWID	People who Inject Drugs
SOPs	Standard Operating Procedures
STIs	Sexually Transmitted Infection
SWOT	Strengths Weakness Opportunity Threats
TDF	Tenofovir Disoproxil Fumarate
TWG	Technical Working Group
USAID	United States Agency for International Development
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

Foreword

Kenya has made significant progress in the reduction of new HIV infections in the past decade through the scale up of HIV prevention programs. In addition, access to HIV treatment by over 1 million Kenyans has improved the quality of life of adults and children living with HIV. Despite this progress, an estimated 77648 Kenyans got infected with HIV in 2015. Half of these were young people aged 15-24 with young women bearing a third of all new infections.

As we expand the HIV treatment program, the war on the HIV epidemic may not be won until we reduce the rate of new HIV infections. This can only be done through greater investment in HIV prevention programs that will ensure those who are not HIV infected are kept uninfected. The Ministry of Health is now introducing Pre-Exposure Prophylaxis (PrEP) of HIV as an addition to existing HIV prevention interventions such as HIV Testing Services, Risk reduction counselling, Voluntary Medical Male Circumcision, Condoms and Elimination of Mother to Child Transmission. It adds impetus to the existing HIV prevention program to propel the country towards achieving the goal of eliminating new HIV infections by 2030.

This can only be realized by all players working towards this common goal. Working with counties to deliver health services to the people as well as enhanced partnerships with the community, people living with HIV, health providers, academic and research institutions, implementing partners and the all key actors we will deliver on our commitment to eliminate new HIV infections in Kenya by 2030.

It is my hope that this framework will provide guidance and impetus to all Kenyans towards eliminating transmission of HIV in every part of this country.

Dr. Jackson Kioko
Director of Medical Services,
Ministry of Health, Kenya

Preface

This framework for implementation of Pre-exposure prophylaxis (PrEP) for HIV in Kenya aims to provide guidance on the roll out of PrEP in Kenya. The target audience include policy makers, national and county governments, health program managers, regulatory authorities, health providers, potential PrEP users and the general population.

Kenya has been in the forefront of providing evidence on the efficacy, safety and feasibility of PrEP locally, regionally and globally, and uses this evidence as well as international evidence in the design of the program. It utilizes an evidence-informed approach to geographical prioritization and combination in line with the Kenya AIDS Strategic Framework (KASF) and Kenya HIV Prevention Revolution roadmap. This is presented as roll out scenarios and a 5-year scale up plan for PrEP in Kenya from 2017 to 2022. It outlines the service delivery models for PrEP, measures to ensure commodity security and includes a Monitoring and Evaluation Framework to measure progress.

The success of this program is underpinned by the communication and advocacy plan which has been well informed by previous demonstration projects and feasibility studies on PrEP roll out in Kenya. It proposes innovative communication and robust community engagement approaches to reach the target audiences. This framework adopts an implementation science approach with learnings incorporated in the programming to inform changes in policies or strategies as outlined in the research plan. It also estimates the resources needed and the plan to finance this intervention program.

It has been developed through consultations with researchers, policy makers at national and county level, and key actors including the religious groups, the private sector players, the community and more importantly the potential PrEP users.

The process of development of this framework was spearheaded by the PrEP Technical working group led by NASCOP and comprising experts from NASCOP, NACC, PEPFAR, World Health Organization (WHO), UN Programme of HIV/AIDS (UNAIDS), International AIDS Vaccine Initiative (IAVI), Kenya Medical research Institute (KEMRI), Jilinde Project, LVCT Health, CHAI, Partners PrEP Scale-up Project, Pharmaceutical Society of Kenya, Kenyatta National Hospital, University of Nairobi and Network of People Living with HIV/AIDS in Kenya (NEPHAK). I wish to appreciate the time, effort and dedication of these experts from the various institutions represented who worked under the leadership of Ministry of Health through NASCOP.

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This framework is drawn from contributions technical experts from different organizations across the country and internationally.

We wish to thank the National AIDS and STI Control Programme led multi-partners technical working group that steered the consultations at the national and county level including potential PrEP users to develop this framework.

We thank the following institutions for technical and financial support during the development of this framework:

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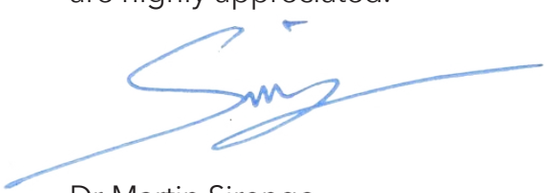
- Bill and Melinda Gates Foundation
- PEPFAR
- Joint UN team (WHO,UNAIDS)
- Jilinde Project partners led by JHPIEGO
- LVCT Health and OPTIONS Consortium Partners
- Partners PrEP Scale Up Project (University of Washington & KEMRI)
- Clinton Health Access Initiative (CHAI)
- Global Evaluation of Microbicide Sensitivity (GEMS), University of Pittsburgh
- Kenya Medical Research Institute (KEMRI)
- Network of People living with
- Kenyatta National Referral Hospital
- University of Nairobi
- International AIDS and Vaccine initiative (IAVI)

Special thanks to agencies that were involved in demonstration projects that provided evidence to inform scale up of PrEP in Kenya.

I also wish to acknowledge and appreciate the core writing team lead by Dr Sarah Masyuko of NASCOP, and included Olivia Ruturi, Phillip Muchiri, Tom Marwa, Dr. Elizabeth Irungu, Dr. Michael Kiragu, Patriciah Jeckonia, Jordan Kyongo, Dr. Mecha, Precious Otieno, Joel Mutinda who have worked tirelessly to make this a reality. Special compliments go to all the chairs and co-chairs of technical working group committees. To all individuals who participated in this exercise, your contributions are highly appreciated.



Dr Martin Sirengo,

Head, National AIDS and STI Control Program

Executive Summary

In 2015, the World Health Organization (WHO) released a series of recommendations supporting the use of Tenofovir containing drugs as pre-exposure prophylaxis (PrEP) to prevent the acquisition of HIV.[1] In July 2016, Kenya launched the new Guidelines on Use of Antiretroviral Drugs for Treatment and Prevention of HIV Infection, which recommended the immediate initiation onto ART and the provision of PrEP to all those at substantial ongoing risk of acquiring HIV infection[2].

Focus Areas for PrEP Implementation

- Leadership and governance
- Service delivery
- Commodity security
- Communication, advocacy and community engagement
- Monitoring and Evaluation
- Research and Impact Evaluation
- Resource Mobilization and Financing.

There is limited PrEP implementation experience in the context of developing countries, Kenya has had the opportunity to be part of 2 clinical trials and 2 demonstration projects from which the evidence generated uniquely positioned Kenya as an early adopter for the delivery of PrEP within the public health system.

This framework has adopted an implementation science approach, providing guidance on PrEP implementation at scale to policy-makers, national and county governments, health program managers, implementing partners, service providers, potential PrEP users and the general population. This framework has been written with the recognition that the delivery of oral PrEP at scale will inform the delivery of other upcoming HIV PrEP products like vaginal rings, Long acting injectable & vaccines.

Oral PrEP delivery will inform programs on how (where) to do effective delivery of HIV prevention among HIV-1 negative at risk that require longitudinal services.

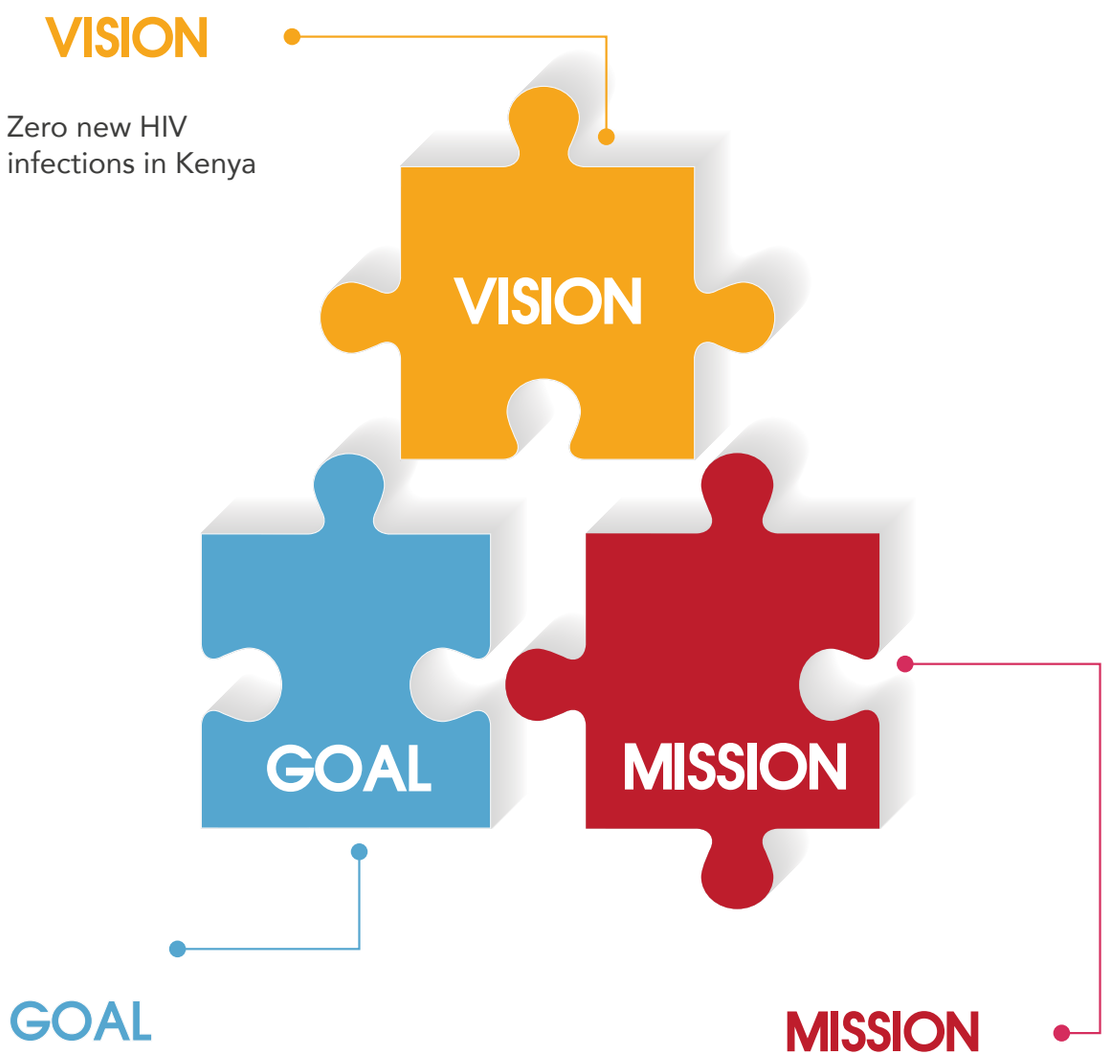
The framework views the delivery of PrEP in seven focus areas that will ensure a comprehensive approach to implementation. The focus areas identified within the framework aim to address the **availability, acceptability, accessibility** of PrEP and the holistic **integration** into the national HIV combination prevention strategy, with the goal of reducing HIV in Kenya.

1 World Health Organization (WHO). WHO Expands Recommendation on Oral Pre-Exposure Prophylaxis of HIV Infection (PrEP). 2015. Geneva: WHO

2 National AIDS and STI Control Programme (NASCOP). Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV infection in Kenya 2016. Nairobi, Kenya: NASCOP, July 2016. Print

Within the appendix of this framework are supporting documents including a PrEP service delivery toolkit, training packages for service providers and peer educators, a communication and advocacy plan, a research plan and monitoring and evaluation tools.

Figure 1: **The Vision, Goal and Mission of PrEP Implementation in Kenya**



Introduction

Pre-exposure Prophylaxis (PrEP) is a form of HIV prevention in which a HIV negative person at high risk of HIV infection takes daily antiretroviral medication to prevent HIV infection. Oral PrEP was first approved by the USA FDA in 2012 after which other countries followed. The Kenya Pharmacy and Poisons board approved the use of oral PreP in Kenya in December 2015. By April 2017, oral PrEP was approved by drug regulatory authorities in Australia, Canada, France, Israel, Kenya, Lesotho, Malawi, New Zealand, Peru, Scotland, South Africa, Swaziland, Switzerland, Taiwan, Tanzania, Thailand, United States of America (USA) and Zimbabwe[3].

Kenya will offer PrEP as part of HIV combination prevention for people at substantial ongoing risk of HIV infection. As part this is in line with the Kenya AIDS Strategic Framework 2014/15-2018/19 and the 2014 Kenya HIV Prevention Revolution roadmap, both of which identify PrEP as an evidence-based intervention delivered as part of a combination prevention approach, coupled with geographical prioritization, to achieve maximum impact in the reduction of HIV infections.

Kenya has set targets to reduce annual new infections by 75% among adults by 2019. At present, over 80% of new HIV infections occur in adults. While notable progress has been made in the reduction of new HIV infections, certain populations remain at risk of HIV infection. The HIV epidemic in Kenya remains high but shows "a pattern of stabilization"[4] presenting a particular challenge to HIV programming. Thus, new interventions such as PrEP implemented in a strategic and targeted approach are necessary in reversing the epidemic.

The 2016 revised national ART guidelines describe the priority population groups for PrEP, taking into consideration the epidemiology of new HIV infections in Kenya (Figure 5). Of the new infections in adults, half are among individuals aged between 15 and 24 years. Of particular concern are young females in this age group where a third of all new infections in 2015 occurred[5]. Key populations including sex workers, men who have sex with men (MSM) and people who inject drugs (PWID) contribute 35% of the new infections in Kenya; and are therefore a target group for PrEP[6]. Additional groups include HIV sero-discordant couples.

3 AVAC. *PrEP By the Numbers:Efficacy, Regulatory, Approval*, April 2017. http://www.avac.org/resource/prep-number-efficacy-regulatory-approaval-and-more

4 National AIDS Control Council (NACC). *Kenya AIDS Strategic Framework. 2014/15-2018/19*. Nairobi, 2015

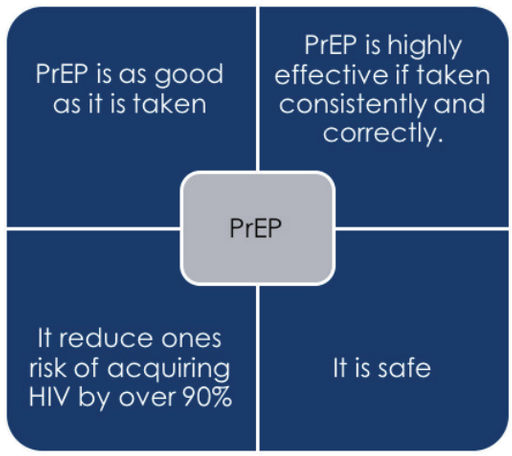
5 National AIDS Control Council (NACC). *Kenya AIDS Progress Report 2016.* Nairobi, 2016

6 National AIDS Control Council (NACC). *Kenya AIDS Strategic Framework. 2014/15-2018/19*. Nairobi, 2015

The PrEP implementation journey in Kenya

As of 2016, Kenya was one two African countries conducting a national roll-out of oral PrEP. The process of PrEP implementation in Kenya has progressed through three phases[7]. (Figure2).

Research and Evidence Generation



Four randomized clinical trials (Partners PrEP, iPrEx, TDF2 and Bangkok TDF study provided evidence around the efficacy of oral PrEP among HIV sero-discordant couples, MSMs, PWIDs and heterosexual individuals. The effectiveness of PrEP was shown to be strongly linked to adherence levels. High adherence with confirmation that HIV PrEP is effective is reflected in effectiveness rates 86-96%% across demonstration projects both in MSM and HIV serodiscordant couples studies. Additionally, demonstration projects (PROUD, IPERGAY, Partners PrEP Demonstration Project) provided evidence on the acceptability/willingness of users to take PrEP.

The LVCT Health-led IPCP (Introducing PrEP in Combination Prevention) and Partners PrEP Demonstration projects, have provided evidence on uptake promotion strategies for MSM, female sex workers, young women and sero-discordant couples at high risk of HIV in the Kenyan context. Final results of the IPCP project are expected in December 2017 will provide additional strategies for strengthening delivery and effective use of oral PrEP. The unit cost of delivering oral PrEP in public and private settings will be estimated.

Normative Guidance

2012: WHO recommended PrEP for sero-discordant heterosexual couples and transgender women and men who have sex with men.

The 2012 WHO guidelines recommended for demonstration projects to determine the most optimal delivery approaches[8].

2015: With additional scientific evidence, WHO expanded its recommendation to include use of PrEP by all population groups that were at substantial risk of HIV infection within a "comprehensive package of services"[9].

7 *PrEP Resources*. AVAC. 2016. http://www.prepwatch.org/about-prep/prep-resources/ [Accessed February 22, 2017)

8 Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV. WHO. 2012. http://www.who.int/hiv/pub/guidance_prep/en/ [Accessed February 20, 2017]

9 HIV Prevention, diagnosis, treatment and care for Key populations: Consolidated Guidelines. WHO 2014. http://apps.who.int/iris/bitstream/10665/128049/1/WHO_HIV_2014.8_eng.pdf?ua=1&ua=1 [Accessed February 20, 2012]

2016: NASCOP revised HIV care and treatment guidelines and included guidance on PrEP implementation.

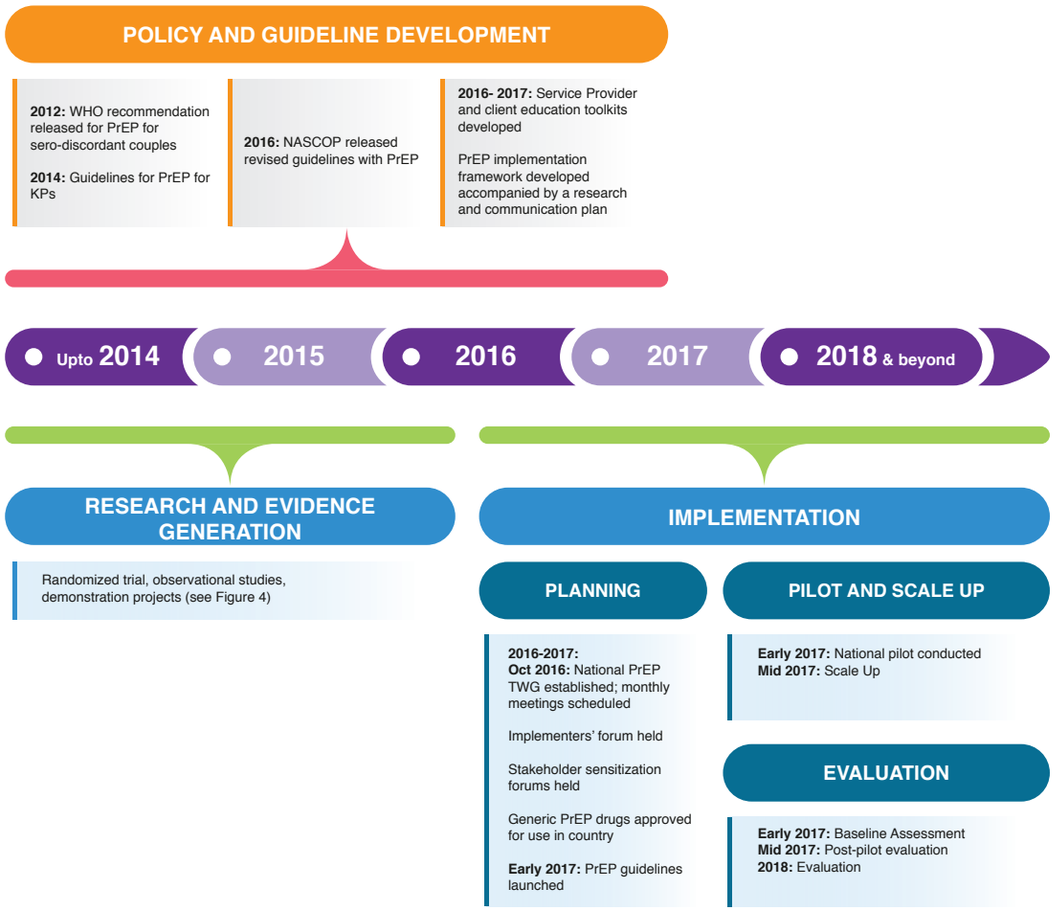
Following which, NASCOP initiated development of service provider tool kits, training manuals and IEC materials for providers and users on PrEP.

Implementation

The implementation phase for PrEP in Kenya began with planning and formulation of a national TWG. This has enabled Kenya to prepare for pilot and eventual scale up with evaluation phases occurring at defined points of implementation. This was formed in October 2016 and was made up of 6 subcommittees namely:

- Service delivery
- Commodity Security
- Monitoring and Evaluation
- Communications, Advocacy and Community Engagement
- Research and Impact Evaluation
- Resource mobilization and Financing

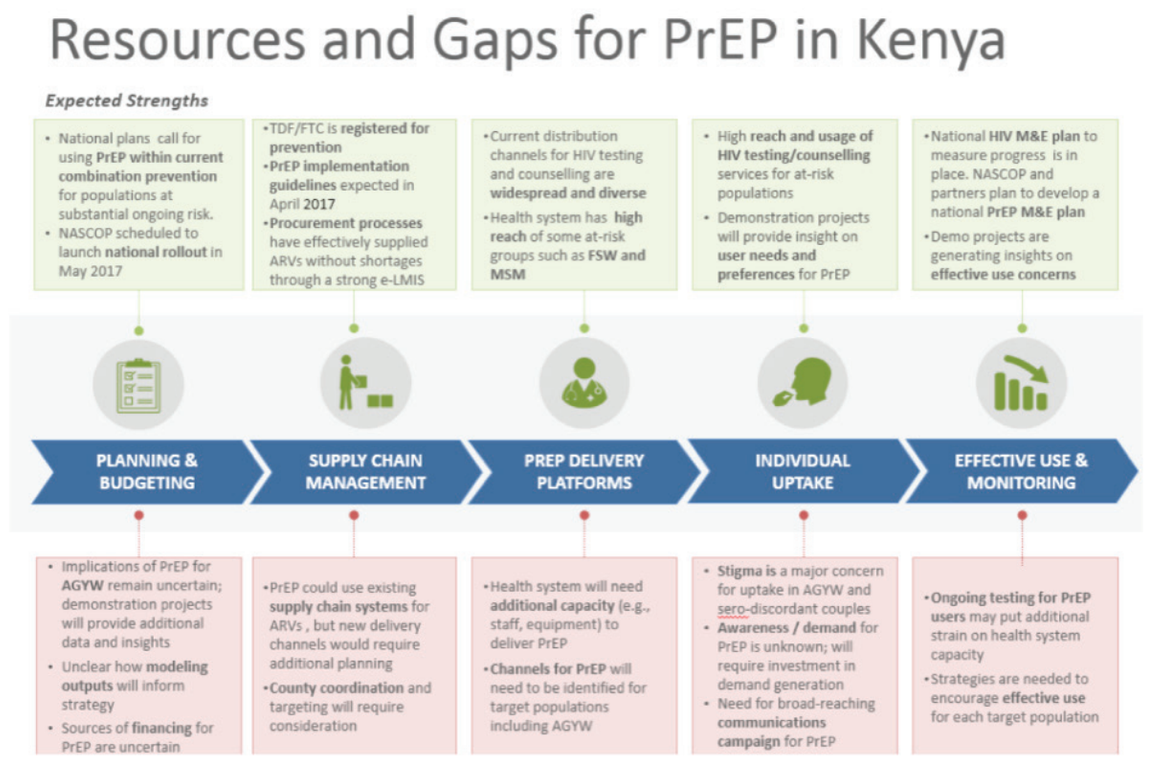
Figure 2: **Phases of PrEP rollout in Kenya**



Situation Analysis

In 2016, NASCOP in collaboration with partners conducted a situational analysis to identify gaps and opportunities for PrEP implementation across five-factor value chain that included planning and budgeting, supply chain management, delivery platforms, individual uptake and effective use and monitoring.

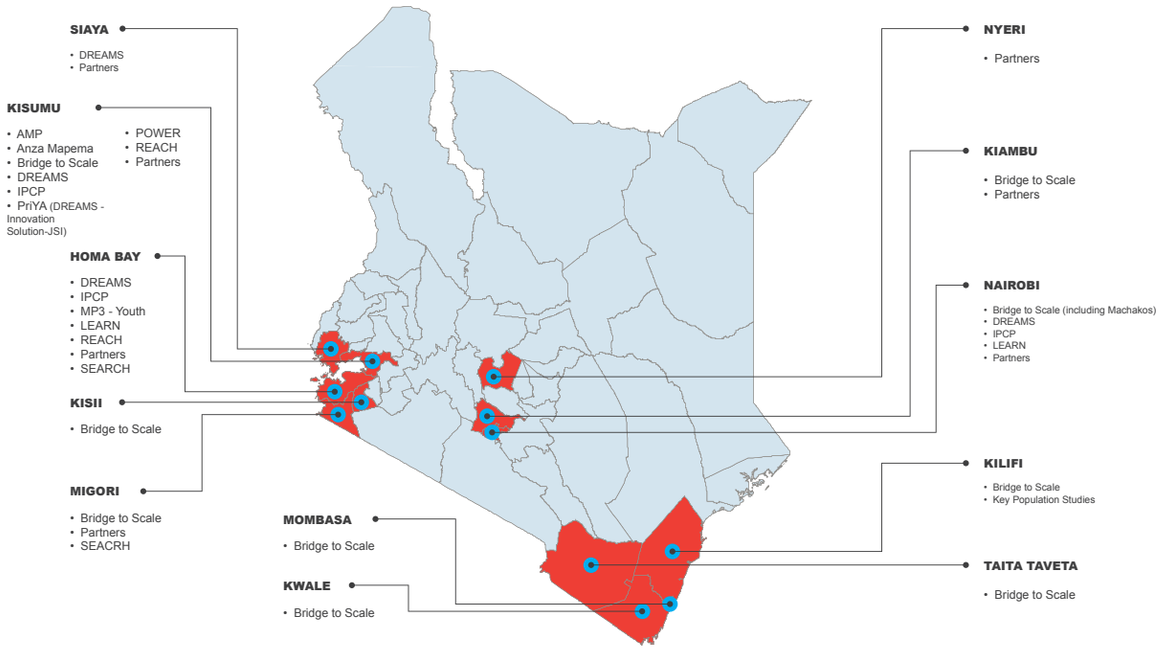
Figure 3: **Value Chain Analysis for PrEP**



Mapping of PrEP implementing projects, partners, objectives, targets, funding sources, target populations, geographical coverage, indicators and tools was conducted. The mapping highlighted underserved regions and populations for consideration in PrEP roll-out.

Figure 4: **Mapping of PrEP Projects in 2016**

PrEP projects are concentrated around Nairobi, Kisumu and the Lake Region



In the lead up to national roll-out of PrEP, counties conducted SWOT analyses and readiness assessments (see Annex 1 Table 6) to understand the gaps and opportunities that exist around successful PrEP uptake.

While all counties have AIDS strategic plans in place, less than 40% had included PrEP as an HIV prevention strategy. However, given the existence of a mature HIV care and treatment program in Kenya, there is ready infrastructure at both facility and community level to begin introduction of PrEP. This includes communication and community engagement structures, presence of national reporting tools for commodities and routine commodity quantification for ARVs and HIV test kits.

Currently, less than 30% of counties have previous experience through implementing partners or on-going demonstration projects around PrEP. Thus, counties are yet to determine PrEP and related commodity needs. Most counties have Electronic Medical Records (EMR) systems placed at Level 3 and 4 facilities, but still require capacity building in electronic data collection, biometrics and sentinel surveillance mechanisms. Limited HIV funding disbursements at county level and insufficient resources are common challenge for all counties. Most counties recognize the need to strengthen laboratory referral networks for specialized laboratory testing such as Creatinine clearance and drug resistance testing for sero converters

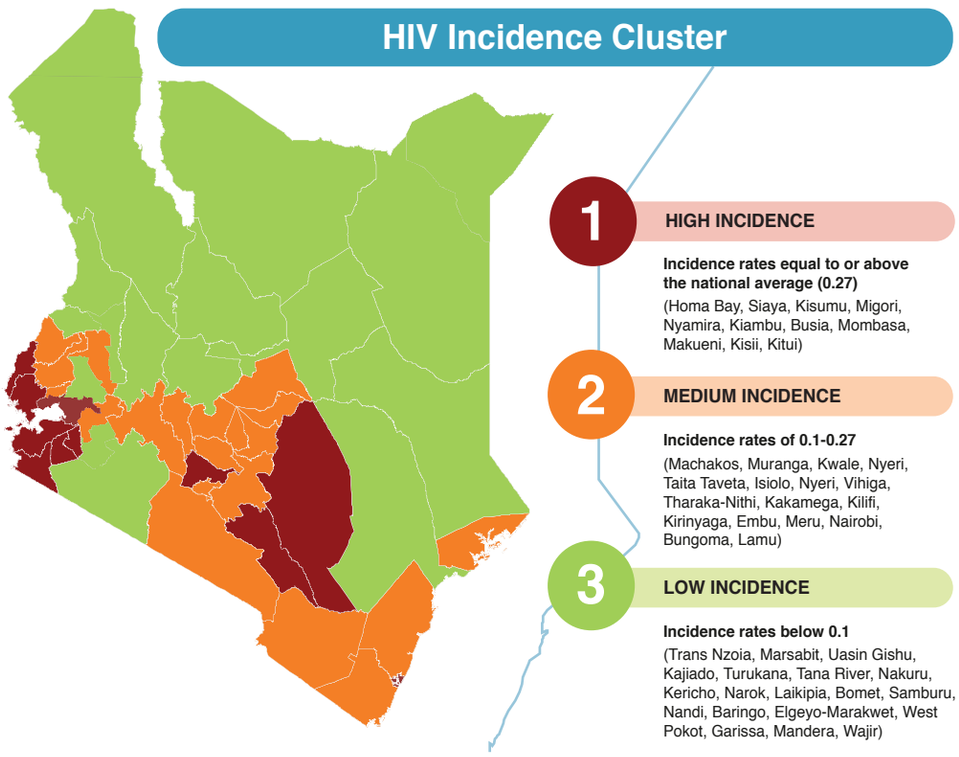
This situational and readiness assessment report at national and county level identified areas needing immediate action and investment. It also provided a baseline to measure performance and improvement following roll out of PrEP.

Implementation Focus Areas

To ensure that we maximize impact and minimize costs, several roll out scenarios are considered for implementation of PrEP programs. This considers the varied HIV incidence in the country, distribution of key populations, adolescents, MSM, SW, youth and HIV sero-discordant couples. Kenya's HIV epidemic by incidence at county level has been extensively profiled and documented. Together, the high and medium incidence county clusters comprise over 95% of all new HIV infections in Kenya therefore justifying the need for prioritization of these counties for immediate PrEP roll-out.

Figure 5: **County HIV Incidence clusters in Kenya, 2015**

Kenya's HIV epidemic is concentrated in several counties that would benefit most from PrEP access

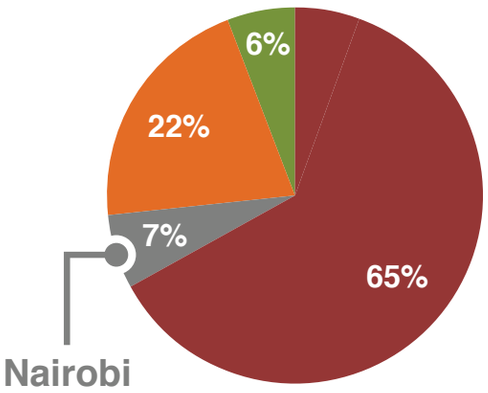


The high incidence counties are aligned with the Kenya Prevention Revolution Roadmap and the Kenya Aids Strategic Framework's geographic prioritization strategy

Figure 6: **Proportion of National Adult New HIV infections by Cluster, 2015**

The high and medium incidence county clusters comprise 95% of new HIV infections in Kenya

Proportions of National Adult New HIV infections by Cluster, 2015



	Incidence Cluster	Number of Counties	Total Populaton (15+)	Number of New Infections (15+)
1	High Incidence	11	7M	46K
2	Medium Incidence	17	11M	20K
3	Low Incidence	19	8M	5K

PrEP delivery should be prioritized in the high and medium county clusters

Scale up plan

There are five potential delivery approaches for PrEP implementation in Kenya based on the county incidence clusters.

Table 1: **Summary of Roll-Out Scenarios**

Scenario		Counties
1	Highest incidence cluster **4 counties**	• General population rollout (incl. sero-discordant couples, AGYW and bridging populations) in Homa Bay, Siaya, Migori • Key population and high-risk AGYW rollout in Kisumu via DICES and NGO programs • All four counties have current demonstration projects and relatively high HTC and ARV uptake (range from 60 - 75% for both)
2	High new infections **7 counties**	• General population rollout (incl. sero-discordant couples, AGYW and bridging populations) in Homa Bay, Siaya, Migori • Key population and high-risk AGYW rollout in Kisumu, Kiambu, Mombasa, and Nairobi • All seven counties have current demonstration projects and relatively high HTC and ARV uptake, except Kiambu (range from 50 - 75% for both)

Scenario		Counties
3	High + medium new Infections **19 counties**	• General population rollout (inclsero-discordant couples, AGYW, and bridging populations) in Homa Bay, Siaya, Migori, Muranga and Nyeri • Key population and high-risk AGYW rollout in Kisumu, Nairobi, Kiambu, Mombasa, Kisii, Kakamega, Machakos, Makueni, Kitui, Nyamira, Kilifi, Meru, Bungoma, and Kwale • Some medium-incidence counties included in Bridge to Scale; lower rates of HTC and ARV uptake (range from 30 – 75%)
4	High number of PLHIV to reach discordant couples **12 counties**	• Discordant couple rollout via comprehensive care centres in Nairobi, Homa Bay, Siaya, Kisumu, Migori, Kiambu, Mombasa, Kakamega, Nakuru, Busia, Kisii and Machakos • Partners study focused on sero-discordant couples will inform delivery • Note: This scenario uses PLHIV as a proxy for discordant couples
5	High + medium key populations **16 counties**	• Key population rollout via DICES in Busia, Migori, Kisumu, Kiambu, Kisii, Siaya, Mombasa, Nairobi, Kilifi, Nakuru, Bungoma, Kakamega, Machakos, Meru, Vihiga, and Uasin Gishu • Varied rates of HTC and ARV uptake; Bridge to Scale will inform rollout to medium-incidence counties

Counties for "general population" rollout

- Homa Bay, Siaya, and Migori have few key populations but high rates of HIV incidence amongst ***sero-discordant couples, AGYW, and bridging populations***
- Nyamira, Makueni, Busia, and Kitui have similar profiles but comprise far fewer new infections.

Counties for "targeted population" rollout

- Kisumu is a significant contributor of new infections driven by ***key populations (MSM, FSW) and bridging populations (e.g., fisher folk)***
- Mombasa, Kiambu, and Kisii have similar profiles but comprise far fewer new infections
- Nairobi has a moderate rate of incidence, but contributes significantly to new infections and may also be prioritized for targeted PrEP rollout

Objectives

The objectives of this framework are aligned to the provision of a holistic HIV prevention package. This is through promoting acceptability of PrEP, ensuring availability and access to PrEP and related services and overall health systems strengthening.

Availability

Provide PreP as part of HIV combination prevention to 500,000 Kenyans at substantial ongoing risk to HIV infections within 5 years

Acceptability

Raise PrEP awareness to 50% of Kenyan adults

Increase acceptability of PrEP to healthcare providers, potential PrEP users and the general public through targeted communication, community awareness and social mobilization

Accessibility

Increase availability of PrEP and capacity of PrEP delivery services in 80% of targeted facilities

Integration

Integrate PrEP into HIV prevention and reproductive health policies, programs and other primary care services

Impact

Determine the impact of PrEP through integrated surveilance, mathematical modelling and other appropriate approaches

Strengthen health systems to increase to PrEP services

Focus Area 1: LEADERSHIP AND GOVERNANCE

This section will address issues regarding leadership and governance to increase ownership and coordination of HIV PrEP response at all levels.

This implementation framework will be implemented in line with the Constitution of Kenya 2010 that recognizes distinct roles of the national and county governments[10].

The national level led by NASCOP and NACC will be responsible for policy formulation and will provide technical assistance to the counties in setting targets, operational planning, monitoring and evaluation as well as research and resource mobilization. This will be done with the support of the PrEP technical working group and in consultation with the counties and other key actors as outlined in the stakeholder profile (Table 2).

The counties will provide leadership in implementation planning, adaptation and dissemination of guidelines and policies, capacity building, community engagements, coordination of stakeholders. They will also be responsible for monitoring and evaluation and ensuring quality of HIV services in the county. In view of the shrink of resources, counties will advocate for inclusion of PrEP in their county plans and budgets to ensure sustainability of this response. This will also be accompanied with accountability of results from all implementing partners and players in the county. This can be achieved through incorporating PrEP in the technical working groups or taskforces in the counties.

Community leadership remains key and hence there is need for extensive community engagement in the implementation of this framework. This includes the religious and community leaders, the private sector, media, people living with HIV and the potential PrEP users. This will allow for increased demand of services, identification and addressing of gaps in service delivery and ownership/adoption of PrEP in the community.

All stakeholders have a role in advocating for investment in PrEP as an additional HIV prevention intervention. For successful implementation of PrEP, there is need to consider human resources for health approaches like task sharing/shifting and community based delivery approaches.

Regulatory authorities including the Pharmacy and Poisons Board, will ensure rational use of this antiretroviral both in public and private sector. Rational use will therefore be a joint activity with mutual accountability from both public and private sector.

10 *The Constitution of Kenya* [Kenya], 27 August 2010, available at: http://www.refworld.org/docid/4c8508822.html [accessed 13 April 2017]

Table 2: **PrEP Stakeholder Analysis**

Stakeholder		Roles and Responsibilities
Public Sector	Ministry of Health NACC, NASCOP, National HIV Reference Lab(NHRL)	Setting policy agenda, resource mobilization, financing, provide leadership and governance. Setting guidelines, provision of strategic information, commodity security through forecasting and quantification, technical and implementation assistance , drug resistance surveillance
	County Health Units	Service delivery, implementation planning, dissemination of guidelines, capacity building, M&E, resource allocation for PrEP service delivery
	KEMSA	Procurement and supply chain management of PrEP to health facilities. service delivery points,
	Pharmacy and Poisons Board	Drug registration, oversight of rational use of PrEP
Development Partners	USAID, CDC, GFATM, UN bodies	Support service delivery, support policy and guideline implementation, resource mobilization, financing, generate normative guidance on PrEP based on country experience
Implementing Partners	NGOs, Private sector/ private health institutions, Civil Society	Support service delivery, support policy and guideline implementation, generate evidence and best practices through operational research around PrEP
Research Institutions and Academia	KEMRI, Tertiary institutions and institutions of higher learning including universities and medical training colleges	Support implementation science research and capacity building on PrEP
Media	Print and Electronic media organizations	Create awareness and demand for PrEP use, Provide education to the public through mass communication on PrEP
Religious Sector	Religious leaders from all faiths and their congregations.	Provide support to users, sensitize audience on PrEP
Community Leaders	Community opinion shapers, Chiefs, police, informal group leaders	Provide support to users, sensitize audience on PrEP
General Public	Kenyans and those residing in Kenya.	Provide support to users, sensitize audience on PrEP, drive uptake of PrEP and provide feedback on PrEP use.

Focus Area 2: SERVICE DELIVERY

This section addresses issues regarding service provision approaches and operations around PrEP implementation including identification of PrEP clients, initiation and client follow-up mechanisms, capacity building and data management for program monitoring.

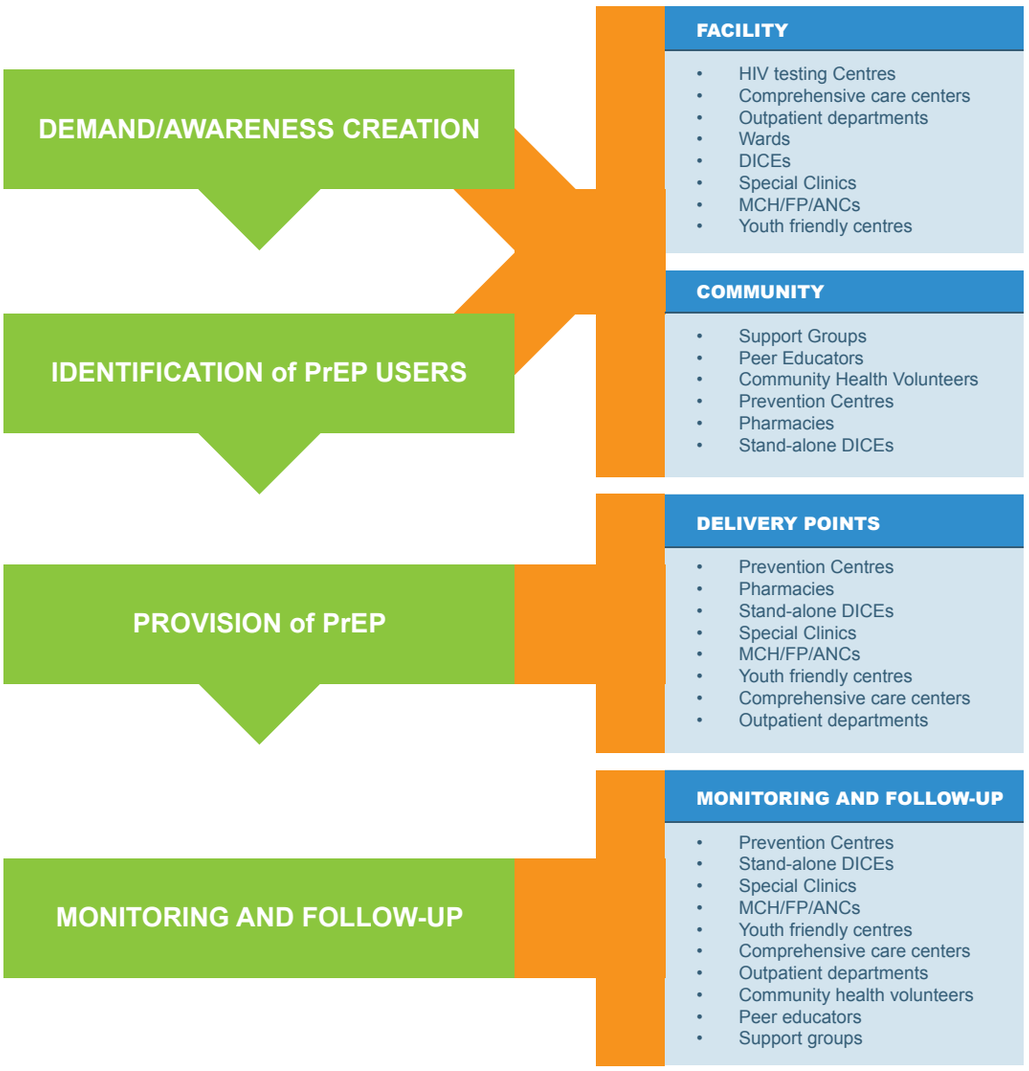
The delivery of PrEP through health system provides the opportunity to strengthen existing services and reinforce linkage between complementary services such as reproductive health services. With HIV testing as the gateway to PrEP initiation, novel approaches such as the use of HIV self-testing will provide an additional strategy for identification and establishment of on-going eligibility for PrEP. Self-testing is currently included in the Kenya HIV Testing Guidelines and the Self-testing operational manual.

PrEP will be delivered using community-based and facility-based delivery models (Figure 7). While both models can serve as identification points for potential PrEP candidates, service delivery points initiating clients on PrEP must meet minimum set criteria. At entry points where only identification is possible, providers will be equipped to link identified clients to PrEP service delivery points.

At the HIV testing point, clients will undergo a behavioral risk assessment, clinical evaluation and HIV testing prior to initiation of PrEP. HIV uninfected persons on PrEP will be assessed after 1 month of initiation, and then every 3 months thereafter. At each subsequent visit, clients will be tested for HIV, to ensure PrEP is not given to persons who may have acquired HIV and who require HAART. Clinical assessments such as adherence monitoring, adverse drug reaction/events monitoring as well as laboratory assessments for Creatinine Clearance and Hepatitis B are recommended as stated in the national ART guidelines[11]. Risk reduction counselling will be required, as will the periodic assessment to establish the need for continued PrEP use. (Refer to Annex 2: Service Profile Toolkit). Additional support required by PrEP users such as adherence support and client-follow up will be conducted at the community and facility level. Surveillance systems will be put in place for those who become infected as well as for resistance and sexually transmitted infections (STIs).

11 Ministry of Health, National AIDS & STI Control Programme. Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya 2016. Nairobi, Kenya: NASCOP, July 2016. Print.

Figure 7: **PrEP Service Delivery Models**



MINIMUM REQUIREMENTS FOR PrEP SERVICE PROVISION

Human Resource availability and training (Clinician Initiating)	**Commodity Management Procedures (ordering/ handling and reporting)**	**Monitoring and Evaluation Systems (documentation and reporting)**	**Laboratory (Baseline tests and monitoring)**

Human Resource Training

PrEP is a prescription only drug and hence has restrictions. PrEP will be prescribed and dispensed by trained health care providers, including doctors, clinical officers, nurses, pharmacists, pharmaceutical technologists. Peer educators, community health volunteers, youth networks among others will promote PrEP use at community level. Health care providers' training on PrEP delivery will be conducted through:

1. In-service training
2. Pre-service education for health professionals, including physicians, nurses, pharmacists, laboratory personnel, health managers.

A cascade approach for training of both health workers and peer educators will be utilized. This includes training of master Trainer of Trainers (TOT) s at national level, County Trainer of Trainers (TOT) s who will then build capacity of health workers and peer educators. This will also include a mentorship component. Staff at facilities will be continuously trained through CMEs or on-job-training using case scenarios. This may also adopt the use of technology such as tele and video conferencing and online learning. PrEP is not a standalone intervention and hence PrEP will be incorporated in other HIV training programs including HIV testing, care and treatment, key populations, VMMC and PMTCT. Training, mentorship and quality improvement will be an on-going process to ensure service providers are adequately trained and competent. Health education sessions will be done at the facilities to inform potential clients about PrEP with the intention of increasing uptake of PrEP as part of combination prevention package.

Monitoring and Evaluation and Quality Improvement

The national PrEP monitoring end evaluation framework will guide and measure performance of the program. The National and County work plans with PrEP specific indicators shall provide a basis for monitoring and evaluation of PrEP service provision. Supportive supervision and mentorship for PrEP uptake and use will be done quarterly and on-demand to ensure continuous quality control and improvement (CQI). This should be embedded at both county and facility level continuous quality improvement teams. The core responsibilities of health service providers under CQI will be to ensure that the services they provide are of the highest possible standard and meet the needs of individual service users, their families, and communities.

Public Private Partnerships

The services provided for PrEP in the private sector will be complementary to the public sector and will contribute towards expanding access to quality PrEP services. A structured engagement process of the private sector will be followed with the aim of providing of PrEP and HIV-testing services including HIV self-testing and laboratory services for required clinical tests in the private sector. This will however follow an agreed accreditation process that conforms to all national guidelines.

Commodity logistics for PrEP

PrEP will be managed as part of the national logistics management system. PrEP drugs will be availed by MOH and distributed to PrEP service delivery points through KEMSA. This is detailed in Focus Area 3: Commodity Security.

Focus Area 3: COMMODITY SECURITY

Access and availability of commodities to users underpins the success of PrEP implementation. As PrEP delivery is a new intervention to the existing package of HIV services, there is a dearth of consumption data to inform quantification and guide the supply and distribution chain for PrEP drugs and well as other associated commodities such laboratory tests. The aim of commodity security is to ensure consistent availability and supply of high quality and correct quantity of PrEP products at designated service delivery points when needed by potential users. This section will:

- Establish relevant methodology and model for forecasting and quantifying PrEP products
- Establish national, regional and site level monitoring mechanism to ensure security of supply
- Determine and address triggers to either slow or fast-track product uptake

To ensure commodity security, key operational areas for implementation that need to be considered include:

Product Selection

The 2016 ART guidelines incorporated Tenofovir/Emtricitabine (TDF/FTC) as the preferred regimen with Tenofovir/Lamivudine (TDF/3TC) and Tenofovir (TDF) as recommended options for HIV pre-exposure prevention. This has been included as part of the essential commodities for HIV prevention in addition to existing products like rapid test kits, lubricants and condoms.

Procurement

This will be based on national annual quantification and forecasting guided by annual national PrEP targets. Open tenders will be sought based on defined products' technical specifications and any donations will be managed in line with drug donation guidelines.

Warehousing and Distribution

Once PrEP commodities are in-country, they will be delivered to KEMSA for warehousing and distribution among other commodities usually supplied to implementing sites. Upon facility requests, and based on a national distribution plan, KEMSA will supply the commodities to ordering sites, which upon receipt will supply to sites under their jurisdiction. Counties will link new PrEP-offering facilities to ordering sites for accessibility of the commodities. Supplying of commodities

will be monthly upon reports by the facilities. Ordering of commodities by facilities will be done during the reporting period as is routine for other ARVs and HIV commodities.

The initial supply of drugs will be delivered based on facility requests for PrEP ARVs to NASCOP after a site readiness assessment has been done in line with the current reporting and requesting timelines (by the 5th every month) through designated ordering sites; and post capacity building on the new PrEP guidelines and sensitization on LMIS tools.

ARVs for treatment have largely been confined within public health facilities and mission hospitals while private clinics, some hospitals and drop in centers (DICEs) for key populations largely remain unreached. PrEP provision will largely involve providing ARVs to persons at substantial risk of HIV infection who are not sick, which will therefore require a different approach in reaching such a targeted population. This could include private sector retail points and community outreach programmes. New service delivery points will be linked to the national supply system through designated ordering sites to ensure their clients access the commodities.

Client Use

Adherence to treatment is imperative for users to maintain a HIV negative status while using PrEP. Monitoring drug adherence will therefore be an important function to ensure rational use of PrEP drugs. Adherence monitoring mechanisms already exist in the vast majority of facility and community based service delivery points. These mechanisms will continue to be used to enhance client support and optimize HIV prevention.

Pharmacovigilance will be integrated into the follow-up of product utilization to:

a. Monitor adverse drug reactions using existing Pharmacy and Poisons Board (PPB's) ADR Forms (Yellow in color) and any hypersensitivity reactions to PrEP documented using Patient Alert Card (White);
b. Monitor quality of PrEP commodities annually by conducting post-market surveillance in conjunction with Pharmacy and Poisons Board, KEMSA, NASCOP and other stakeholders. Poor quality medicines will be documented using the Poor Quality Medicines Reporting Form (Pink)

Logistic management information systems (LMIS):

PrEP commodities will be integrated into the existing ART commodity management information systems from facility to the national reporting system. Daily Activity Registers (DARs) or electronic dispensing tools will be utilized at facility level for consumption data capture while systems such as the DHIS2 will be used for the reporting platform.

Generating accurate assumptions for annual forecast and quantification to determine PrEP commodities will require strong LMIS mechanisms to provide the necessary consumption data. Monthly stock status monitoring for PrEP commodities (*i.e. daily activity register-DAR for ARVs and reporting at end of every month using facility consumption data report and request forms-CDRR*) will be availed to PrEP delivery sites to enable facility level consumption monitoring and monthly reporting to the national level to inform re-supply decisions.

Strengthening capacity of healthcare workers in commodity management to ensure responsive supply chain will be carried out to ensure continuous supply of PrEP commodities.

Undertaking operational research on PrEP to identify innovative distribution and dispensing channel for PrEP will be done to inform improvement interventions in the supply chain.

Resource mobilization mapping will be carried out to explore local financing mechanisms to ensure sustainability for PrEP commodities. Refer to Focus Area 7.

Focus Area 4: COMMUNICATIONS, ADVOCACY AND COMMUNITY ENGAGEMENT

This section outlines a plan that will help ensure meaningful engagement of stakeholders for successful rollout of PrEP in Kenya. A communication plan will aid in the management of the image and perceptions of PrEP with all stakeholders through a positive narrative about PrEP, effective and timely dissemination of information and a transparent relationship with all stakeholders. Furthermore, it will help ensure that there is increased knowledge of PrEP as a part of HIV combination prevention, and ensure that there is improved positive perception/attitude about the benefits of PrEP and create demand for PrEP. The communication plan will also help to address the issue of stigma and discrimination that can negatively impact uptake and adherence to PrEP.

The objectives of the communication plan are to:

1. Increase knowledge of PrEP services, the product and provide information on where it can be accessed
2. Create a positive perception and improve the attitude towards PrEP amongst all stakeholder groups
3. Increase demand for PrEP amongst the target audience

Situation Analysis

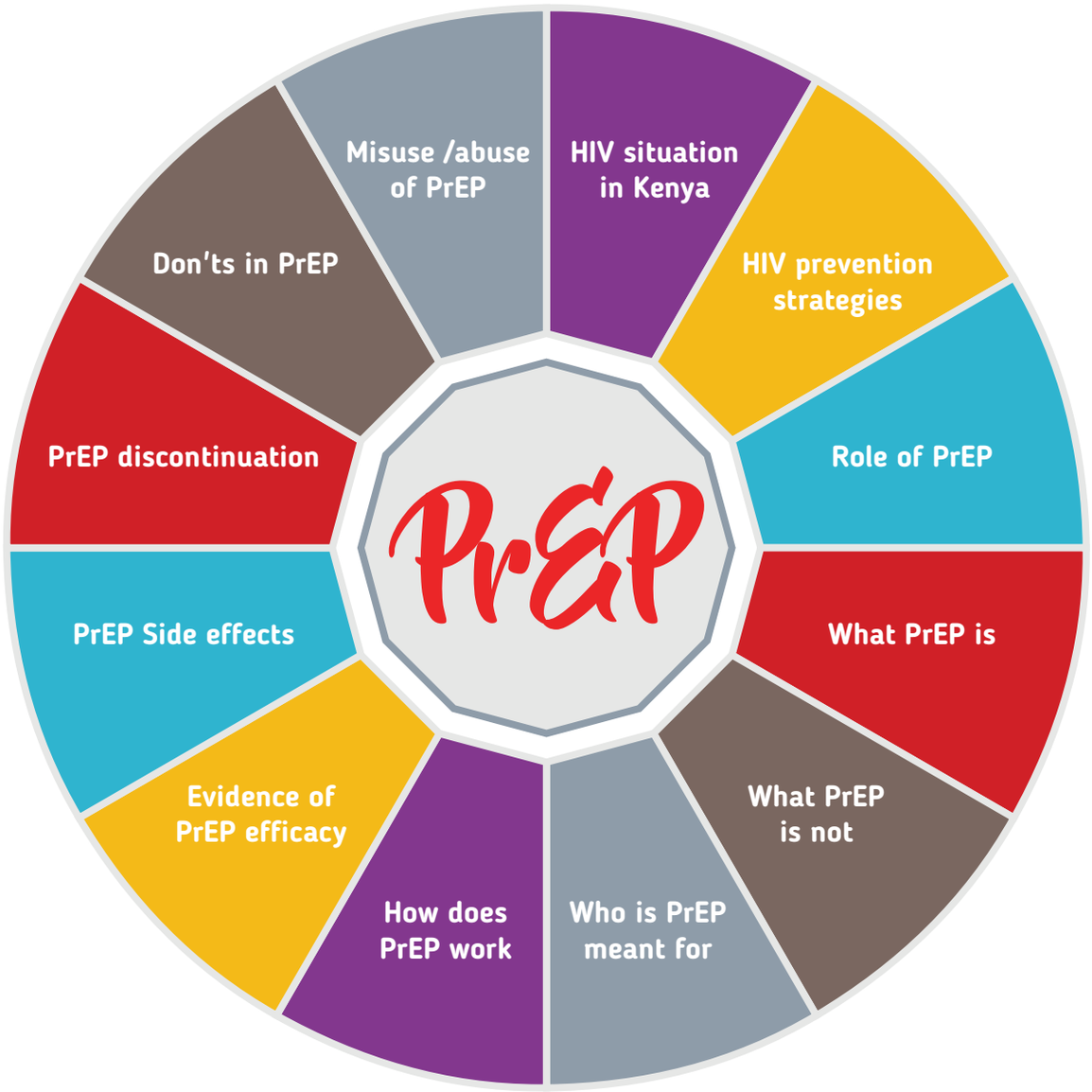
There has been heavy investment in communication and advocacy for HIV response. However, a number of gaps still exist that may affect uptake of PrEP. Table 3 (Annex 1) shows the SWOT analysis for PrEP communication and advocacy.

Communications Messages and Channels

Messaging for each audience group is anchored on the positioning statements, and the modes or channels of communication will depend on the nature of the audience.

Communications messages are aimed at creating knowledge, awareness and demand and are based on the following broad topics.

Figure 8: **Topics on PrEP communication**



The delivery of the message will be tailored to suit each audience segment. Serious considerations need to be made on the choice of communication channels to be used to reach specific populations. For example, you may have to use more of social media platforms to reach young people as opposed to policy makers who may need a more formal channel.

PrEP Positioning Statements

The following positioning statements will underpin and guide communications activities:

1. PrEP is an intervention used by HIV negative individuals to protect themselves from acquiring HIV.
2. If used consistently as prescribed, PrEP reduces HIV infection and leads to healthy communities.
3. PrEP does not protect you against other sexually transmitted infections and pregnancy and should be used with other prevention strategies.

These positioning statements will form the foundation of the key messages to be tailored to each stakeholder group.

Table 3 below outlines the communication needs by target audience. The communication needs for majority of the target audience address awareness, knowledge and attitudes towards PrEP. Current and potential users will require communication that targets their knowledge, attitude towards PrEP and move them to desire use (or trial) of the intervention.

Table 3: **Communication Needs Assessment for PrEP**

Audience	Communication Need
Phase 1: General Population, Religious Leaders, Community Leaders, Political Leaders, Policy makers, Media, professional bodies	Awareness, knowledge and attitude
Phase 2: Health care workers, Implementing partners, researchers, key population networks	Awareness, knowledge and attitude
Phase 3: Current and potential users	Knowledge, attitude, use

Advocacy

The success or failure of PrEP roll-out will be determined by advocacy work undertaken at all levels in society. There is need for aggressive advocacy at the grass root level including with community advisory boards, influencers, opinion leaders, among others to increase acceptability of PrEP and reduce stigma towards PrEP users. Policy and advocacy forums at county and national levels will be instrumental in ensuring advocacy around adequate resource allocation for PrEP delivery and response to implementation needs. Current PrEP users will be powerful advocates of PrEP through their testimonials.

Community Engagement

There is need to have structured, systematic and constructive engagement of stakeholders throughout the roll out of PrEP and beyond. By guiding PrEP partners on how and when to engage stakeholders, we can harness the influence of each group in order to have a successful roll out and uptake of PrEP in the country. However, stakeholder engagement should not end at national and county level. It should continue throughout to the implementation stages in order to manage issues of knowledge, perceptions and attitudes, and re-strategize where necessary.

Focus Area 5: MONITORING AND EVALUATION

Strategic information is vital to track and measure progress, program impact and inform decision-making. Systems should be in place to support routine data capture and surveillance data that will inform programming. This section will detail how PrEP national roll-out will be incorporated into the mainstream HIV M&E health sector reporting.

The objectives of the PrEP M&E framework are:

- Incorporate PrEP monitoring as part of routine HIV programme in the health sector reporting by
    - defining core set of indicators that are relevant to the programme
    - developing the relevant data collection tools
- Utilize routinely collected data to improve PrEP programming through
    - Routine data analysis and feedback to the various stakeholders
    - Use of programme data in models to determine targets and measure impact

Key Guiding Principles for PrEP M&E

1. Use of standard M&E tools: - This will ensure consistency and reliability of data collected across time and location. The definition of eligible population shall also be consistently applied.
2. Standard data elements: Standard data elements shall be defined for PrEP monitoring through a consultative process. The data collation and reporting to the upper aggregation levels shall also be defined.
3. Unique dynamics of target population: Consideration shall be taken that perception of ongoing risk is not static and the sub-populations mainly considered for PrEP are highly mobile – Use of electronic systems incorporating a unique identifier is highly recommended

This PrEP implementation framework shall be monitored regularly to track performance towards achievement of targets and objectives. This will be done through the M and E framework that outlines the targets to be achieved, indicators to be measured, process of data collection, frequency of collection, data source and the responsible person. Data will be routinely collected through standard MOH tools.

In addition to routine data collection, periodic assessments as well as surveys will be conducted. We will leverage surveys including the Kenya Population based HIV Impact Assessment (KENPHIA) formerly KAIS, Kenya Demographic and Health Survey(KDHS), and Integrated Bio-Behavioral Survey (IBBS) to provide strategic information on risk and PrEP uptake, knowledge and acceptability. Mathematical modeling will also be used to evaluate progress and assist in making future plans. Evaluation will be conducted every two years as part of the Kenya HIV response and to inform course correction.

Facility, sub-county, county and national teams will be involved in monitoring and evaluating the roll-out of the PrEP Implementation framework. This will be achieved through review meetings, service and data quality assessments, performance reviews, mentorship and support supervision.

Data collection

The following MOH tools will be used for PrEP data collection:

1. Rapid Assessment Screening Tool – used at all points of identification of potential PrEP clients for screening.
2. Clinical Encounter form – to determine eligibility for PrEP, initiate and follow them up on PrEP
3. Prep Register - for those enrolled and continuing on PrEP – This will be an electronic longitudinal register
4. Daily Activity Register – This will be used to monitor key processes such as HIV testing, STI screening and Risk perception screening.
5. Summary tool – MoH 731B

It is the intention of the entire M&E system to be electronically implemented to minimize challenges of manual management of longitudinal interventions.

The M and E framework outlines the targets and indicators for reporting Refer to Table 9, Annex 1: Data Collection Framework.

Focus Area 6: RESEARCH AND IMPACT EVALUATION

This section outlines the key research and impact evaluation agenda for PrEP implementation and defines strategies for formulating, conducting, coordinating and funding implementation science research within the context of PrEP.

Research into new HIV prevention technologies (NPT) is a critical part of comprehensive HIV prevention. One such technology for which there is strong scientific evidence of efficacy is PrEP.

To facilitate and inform scale up, it would be appropriate to identify and prioritize implementation science research needs related to PrEP. Further to this, documentation of the impact of PrEP in reducing HIV acquisition at the population level is fundamental. The PrEP research priorities are in line with the HIV research agenda for Kenya. This agenda aims at enhancing coherence in the choice of investigation areas and application of research with policy guidance and envisioned results as set out in the Kenya AIDS Strategic Framework (KASF).

Scope and Purpose

Implementation science research will guide and support decisions across PrEP roll-out. This document outlines, categorizes and prioritizes key resesarch gaps to be addressed as part of PrEP scale up with the aim of improving PrEP service delivery to populations in need. Where possible, the data sources as well as implemeting partners are identified. The reseach guide will help to guide PrEP programmers to allign their implementation strategies to help answer some of the broad questions in the research agenda. This research agenda will be regularly updated by the PrEP working group based on the emerging needs. The implementation of the reseach agenda will be prioritised as either high, medium or low based on several factors including country research needs and availability of funding.

High research priority will involve research that are required for initial program scale up and for which funding is readly available while low priority research are research that have limited funding and are considered not crucial for program scale up.

The research agenda questions are not exhaustive but reflect county's current needs. Further to this, it is acknowledged that research priorities evolve and research partners are encouraged to be innovative in order to add value to the proposed research needs. Finally, the research guide will be used for refining clinical and laboratory requirements for PrEP delivery and proposes the development of PrEP research financing strategy and resource mobilization.

Findings from this research will help to:

- Demonstrate program impact and effectiveness
- Improve service delivery
  - Demand creation
  - Commodity security
  - Strengthening of human resources for health
  - Quality assurance
- Guide policy formulation
- Improve access to PrEP
- Support sustained adherence to PrEP as well as providing safe and effective strategies for stopping PrEP.
- Guide financing and resource mobilization
- Provide lessons learnt/best practices
- Contribute to scientific knowledge base around PrEP

Guiding principles for the Research Agenda

PrEP implementation research in Kenya will be guided by the following principles:

- **Relevance:** Research should be of public health importance and contribute to achievement of the KASF goals.
- **Multidisciplinary and Intersectoral Complementary:** Promote partnerships among the different implementing agencies to ensure a harmonized delivery of the PrEP agenda.
- **Human Rights Based Approach:** Research to ensure people have access to PrEP services regardless of gender, race and ethnicity and to protect their privacy and confidentiality.
- **Ethical Soundness:** Abide by all ethical requirements set by the country.
- **Gender Sensitivity:** Integrate gender analysis and promote gender issues in all its facets.

Table 4: **PrEP Research Agenda**

Impact Evaluation

- Demonstrate population's impact of PrEP, over and above other combination prevention interventions in at risk populations in at least 3 high cluster counties.
- Coverage required to avert a proportion or a percent of new infections per risk group

Improving PrEP program efficiency

- "What is the most effective model of mobilization for demand creation for PrEP in different populations?
- Characterize within sub-populations, those at highest risk of HIV and who would qualify as a target for PrEP.
- Optimal HIV testing schedule 3 months, 6 months etc. (Frequency of HIV testing, by subpopulations).
- Piloting an intervention to improve PrEP adherence
- Evaluating interventions to improve adherence
- Evaluate the predictors of PrEP adherence in a routine service setting.
- Establish PrEP pharmacovigilance at national level
- Conduct cohort event monitoring as part of pharmacovigilance
- Studies on prevalence of HIV drug resistance (acquired and transmitted)
- tudies on prevalence of HIV drug resistance (acquired and transmitted)
- Evaluate the prevalence of PreP-related risk compensation. Develop predictive model for risk of

Access to Services

- Determine acceptability (end-user and provider) and uptake of PrEP (and other ARV based preventions) by sub-populations -Service providers' knowledge, attitudes and perceptions that affect PrEP service provision in at least the 9 priority counties
- "Define and develop a PrEP cascade (% at risk, % eligible, % initiated, % dropped off (good and bad), % actually taking, % restarting, % seroconverted, % linked, %resistance (+waning)
- To define characteristics including patterns of PrEP use
- What is the risk profile and matrix of people coming in for PrEP at service delivery points?
- Define HIV testing approach (Provider Initiated testing and counselling, HIV Self Testing) that will it increase PrEP uptake and/or provide early identification of sero conversion
- Define the short and long term safety of PreP (Biological and Social Harm)
- Define client/patient perceptions on PreP
- Pilot appropriate distribution channels for the product
- Define appropriate dispensing models for oral PreP
- Evaluate the appropriate packaging of the product

Service Integration

- Feasibility of integrating PrEP into existing models of service delivery such as family planning and/or retail pharmacies
- Determine strategies to promote and enhance partner testing and disclosure in PrEP settings.
- Feasibility of integrating PrEP into assisted partner services
- Effects of combination prevention (structural and behavioral) on PrEP uptake. Feasibility of integrating PrEP into assisted partner services
- Effects of combination prevention (structural and behavioral) on PrEP uptake.

Financing/Costing/Economic Evaluation

- Analyze the incremental cost of adding PrEP to the overall cost of combination prevention - for the combo counties initially,
- Analyze the incremental cost of adding PrEP to the existing programs Determine resources needed to reach a certain coverage of PrEP. Budget impact analysis i.e. what is it going to cost the government to provide PrEP
- Determine current national unit costs of providing PrEP by mode of service delivery, target population and geographic region
- Estimate direct cost incurred by clients (financial and opportunity costs) in accessing PrEP – policy and service delivery implications. Determine willingness to pay for PrEP services (medication, lab etc.)/cost sharing

Implementation methodology

Sources of data

This research agenda will utilize various information systems and specific studies to answer the questions outlined above. Specifically, these questions will be integrated in household surveys including the Kenya Population HIV Impact Assesment (KENPHIA). Further to this, routine health information data captured in the course of service delivery will be analyzed using the appropriate methodology. It is envisioned that PrEP service delivery data shall be captured electronically to ensure easy access to data for implementation science research It is desirable to apply case-based surveillance within HIV testing services sites to track new HIV diagnoses over time as a proxy for incidence meaurements. Implementation science research using routine data shall be complemented by special studies designed to answer specific questions. Mathetical modelling shall be applied where the above information systems will not be sufficient or appropriate.
To facilitate implementation science research, NASCOP shall coordinate the development of research protocols for high priority questions for ethical approval.

Mathematical modelling

The country recognizes the utility of mathematical modelling to answer some questions on PrEP delivery and scale up. Modeling can be able to help the country to:

- Quantify the estimated health impact
- Quantifying the estimated demand for PrEP in the country within different population groups
- Quantify the cost of providing PrEP to meet the demand within the different population groups (through existing or new infrastructure)
- Indicate where resources can be applied for maximum impact.

New mathematical models shall be developed and the existing ones refined to answer the relevant implementation science questions. To the greatest extent possible, data collection shall be of the highest level of granularity as possible to include but not limited to sub-county HIV prevalence and incidence, age-and sex-specific information as well as location and distribution of key populations, rate of condom use, sexual partnership dynamics, and knowledge of HIV status.

Once these models have been agreed upon, they shall be used to explore the prospective cost and impact of a wide range of intervention strategies including PrEP. County-specific models shall be explored (with an emphasis on the priority counties counties) and projected to the future course of the HIV epidemic under different prospective programmatic scenarios. Through exploring the range of possible intervention combinations which could be applied, and projecting their cost and impact, the optimal set of intervention strategies shall be identified. In this way interventions that would generate greatest impact would be identified for budgetary prioritization.

In addition to this optimization approach, specific scenarios and intervention sets under consideration by policymakers for implementation shall be reviewed to allow for their comparison and to directly aid decision making.

Coordination

NASCOP will oversee PrEP research and will coordinate stakeholders conducting various PrEP research projects in Kenya. Researchers interested in performing PrEP related research in Kenya should coordinate their work through NASCOP in collaboration with the county research units where available.

County research units where available will coordinate PrEP research forums within their counties. County research units are encouranged to come up with their own PrEP research questions unique to their settings and conduct research towards answering them.

Any PrEP research done should be tracked by NASCOP uisng approproate trackig tools and subsequently deposited with NACC under Maisha Maarifa platform. NASCOP will be notified of any PrEP research deposited under the Maisha Maarifa platform for purposes of tracking.

Consolidation of PrEP research for accessibility to stakeholders, tracking of future studies, on-going studies and dissemination of results is essential in the implementation of PrEP as well as in the translation of relevant research results into policy and practice. NASCOP/NACC will on a biennial basis organise a PrEP researchers' forum through the national PrEP TWG. This forum will provide an enabling environment for PrEP information sharing. Through the PrEP researchers' forum, NASCOP will share progress towards achievement of research priorities set out in the PrEP research agenda.

Funding

Various stakeholders will factor in PrEP operational research in their HIV/AIDS implementation plans. Stakeholders are encouraged to apply for PrEP research funding from various funding organizations including the National Institutes of Health. NASCOP/NACC/MOH will mobilize resources for PrEP operational research in line with KASF's plan on HIV research resource mobilization. This multi-approach to resource mobilization will ensure that there is sustainable funding for PrEP operational research.

In order to get value for funding invested into PrEP research, the M&E team will come up with an expenditure tracking tool that will be used by all stakeholders. This tool will help in efficiency analysis of resources in relation to the impact of research done. By tracking expenditure, stakeholders will be able to minimise wastage of resources invested while maximizing on impact. NASCOP will be the custodian of this tracking tool and its inputs.

To advance the PrEP research agenda, there needs to be investment in financing and building county research capacity: research arm and plan.

Focus Area 7: FINANCING AND RESOURCE MOBILIZATION

The overall aim of the costing and economic evaluation is to provide cost estimates and impact of PrEP as a prevention strategy to inform the implementation and scale-up of PrEP services among the key populations in Kenya. This will be informed by the cost and cost effectiveness studies as well as mathematical modelling that has been described in the previous sections. The objectives are to:

- Estimate the average annual cost of reaching one key population client with a comprehensive package of PrEP services through various service delivery models
- Estimate the resource needs of providing a comprehensive package of oral PrEP services to target populations in the country
- Determine the variations or cost components driving these costs
- Establish the economic impact of PrEP in averting new HIV infections
- Establish the financing gap in scaling up PrEP services
- Identify innovative strategies for mobilizing additional resources for the scaling up PrEP services in the country.

The costs and access factors related to pre-exposure prophylaxis (PrEP) for HIV prevention have not been adequately explored in health services. In Kenya, policy makers, development partners and other stakeholders have expressed the need for country-specific data on the resource requirements for initiating and rolling out oral pre-exposure prophylaxis (PrEP) to prevent HIV infection. This data is expected to contribute to the development of evidence-based PrEP policies and help ensure that the required resources are available for appropriate implementation and scale-up.

Estimation of Resource Need

PrEP is a new HIV prevention strategy with inadequate or if any determined resource requirement. It is critical to determine resource requirements for PrEP introduction to inform country and donor investments in prevention in the country as part of HIV combination prevention. Given that the country already have HIV prevention programs in place, PrEP is likely to be integrated into existing infrastructure rather than offered as a standalone service. Identifying and quantifying incremental resources for the implementation PrEP is paramount in determining the unit cost per year per client and essentially the total resource needs.

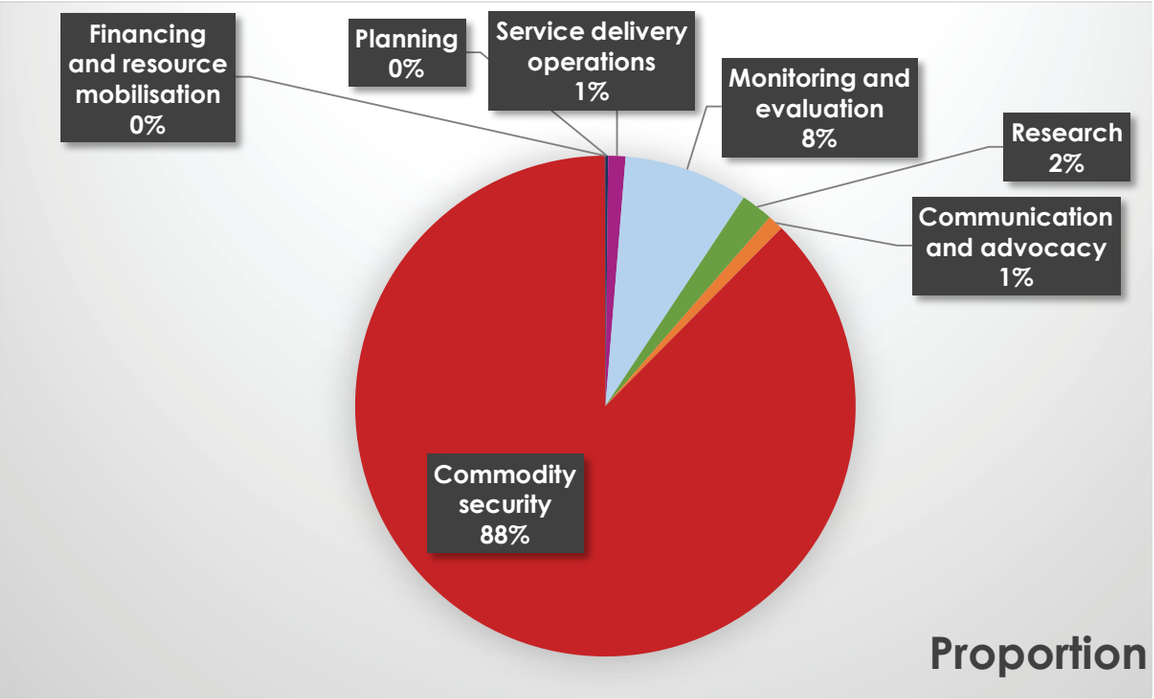
The resource requirement will be estimated using the following components: i) the unit cost of providing PrEP services per client per year ii) target population and iii) coverage rate. Thus, in estimating the resources required, the first step would be to estimate the unit cost of delivering PrEP to a client per year, defining the total population being targeted for PrEP services and the coverage per year. The table below presents a framework of resource estimates for PrEP implementation in Kenya.

Table 5: **Five Year PrEP Financial Needs (KES and US dollars)**

Kenya Shilling (KES)	FY2017/18	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	**Total (KES)**
Planning	18,346,650	15,411,186	10,113,591	8,495,416	6,690,140	**59,056,983**
Service delivery operations	66,807,258	70,147,621	73,655,002	77,337,752	81,204,640	**369,152,273**
Monitoring and evaluation	765,954,397	612,763,518	428,934,462	428,934,462	428,934,462	**2,665,521,302**
Communication and advocacy	87,395,805	91,765,595	78,000,756	58,500,567	20,475,198	**336,137,922**
Commodity security	2,368,652,666	2,723,502,667	5,472,517,607	7,044,224,573	11,416,666,334	**29,025,563,848**
Financing and resource mobilisation	1,808,958	1,899,406	1,994,376	2,094,095	2,198,799	**9,995,633**
Total (KES)	**2,672,936,373**	**3,105,967,747**	**5,875,272,650**	**7,286,582,525**	**11,612,570,262**	**30,553,329,558**

US Dollars ($)	FY2017/18	FY 2018/19	FY 2019/20	FY 2020/21	FY 2021/22	Total (US$)
Planning	181,650	152,586	100,135	84,113	66,239	**584,723**
Service delivery operations	661,458	694,531	729,257	765,720	804,006	**3,654,973**
Monitoring and evaluation	7,583,707	6,066,966	4,246,876	4,246,876	4,246,876	**26,391,300**
Research	1,246,875	1,932,656	2,222,555	777,894	642,318	**6,822,298**
Communication and advocacy	865,305	908,570	772,285	579,214	202,725	**3,328,098**
Commodity security	23,452,007	26,965,373	54,183,343	69,744,798	113,036,300	**287,381,820**
Financing and resource mobilisation	17,910	18,806	19,746	20,734	21,770	**98,967**
Total (US$)	**34,008,912**	**36,739,488**	**62,274,196**	**76,219,348**	**119,020,235**	**328,262,179**

Figure 9: **Proportion of resources by focus area**



Estimating resources available and Financing Gap

To mitigate against substantial HIV challenge in the country, it is important to understand who is involved in financing PrEP in Kenya. This requires identification of stakeholder's financial commitments toward implementation of PrEP and comparing the available resources with the estimated resources needs in order to obtain the funding gap. Engaging stakeholders prudently will assist to determine the resources available for PrEP implementation toward HIV prevention response in the country and the targeted population coverage. In Table 6 below, we demonstrate the process of deriving resources available from stakeholders supporting the introduction and scaling up of PrEP in Kenya.

The country's financial gap in PrEP implementation is estimated to be $314,298,668 over the years as demonstrated below

The funding gap will be determined by comparing the estimated resource needs with the available resources as shown below in Table 6.

Table 6: **Financing Gap for PrEP**

US Dollars	US$
Estimated resources	328,262,179
Available resources	13,963,511
Deficit (gap)	314,298,668

Resource Mobilization Strategy

A multi sectoral approach will be advanced to unify the strategy and obtain buy-in from the various stakeholders. Initial initiatives will involve engagements with stakeholders to elicit political goodwill in propelling resource allocation and commitment. This plan proposes to invest in a strategic framework for better management of HIV prevention response with greater impact.

Kenya response to PrEP implementation as part of combination prevention will be tied to the ability of the country to mobilize adequate resources from the various national and international sources and leveraging on efficiencies on existing prevention programs. The estimated cost to implement PrEP over the next five years is $328,262,179 against $13, 3963,511 available resources indicating a funding gap of $314,298,668. More financial commitment is required from various funding mechanisms and exploring non-traditional strategies to commit resources including:

- National Government/county government commitment in allocation of funds.
- Streamline existing donor and partner funds aligned to PrEP implementation.
- Availability of health insurance coverage (both private and National Health Insurance Fund) for PrEP.
- Improving efficiency in the use of available resources through integration of PrEP prevention into existing structures for sustainability and government ownership.

Annexes

Focus Area 1: Leadership and Governance:

Table 6: **County SWOT Analysis**

Internal

Strengths	Weaknesses
Leadership & Financing • There are existing leadership and governance structures in place • There is strong political will to provide and improve HIV services. • Counties have developed AIDS strategic plans- some have already included PrEP as a strategy • County based TWGs already established in most counties	**Leadership & Financing** • There is insufficient allocation of resources for HIV from county government. • There is heavy reliance on donor funding to support HIV activities in counties
Service Delivery • Some counties have previous experience in PrEP roll-out through demonstration projects • HIV taskforces and/or TWGs already exist in most counties • Functional community units exist • All counties have health facilities that provide HIV care and treatment services • Most counties have existing DICES • All counties have a health work force who are trained and offering HIV services • Majority of counties have implementing partner support • Complementing commodities are available e.g. condoms, family planning and test kits. • The revised guideline which include PrEP are available to all counties • There is a laboratory network in place	**Service Delivery** • Knowledge gaps on HIV exist among community health workers • There is sub-optimal HIV testing coverage. • Specialized laboratory tests e.g. Creatinine tests are charged in majority of counties • Not all counties have had full coverage of the dissemination of guidelines • There is weak supportive supervision in most counties • Many counties have health worker challenges (including understaffing and high turnover) • In geographically vast counties, accessibility of health facilities is a challenge for patients seeking services • Some healthcare workers have poor attitudes to some client • Existing laboratory networks are limited
Communication and Advocacy • Local radio stations are available for mass communication • Community engagements are regular in most counties	**Communication and Advocacy** • There is still high stigma towards HIV in the community • Mobilization and advocacy for PrEP not in place • Limited coverage of PrEP tools, job aids, IEC

Strengths	Weaknesses
Commodity management • There are commodities available from the national level • There is a national centralized supply systems in place • Some counties have commodity security TWGs to monitor HIV commodities • Reporting mechanisms to the national supply chain are in place for all counties	**Commodity management** • Some counties experience stock outs of key commodities e.g. test kits
Monitoring and Evaluation • There is an existing M&E system for health	**Monitoring and Evaluation** • PrEP is not yet included in the DHIS reporting system

External

Strengths	Weaknesses
Leadership & Financing • There are existing leadership and governance structures in place • There is strong political will to provide and improve HIV services. • Counties have developed AIDS strategic plans- some have already included PrEP as a strategy • County based TWGs already established in most counties	**Leadership & Financing** • There is insufficient allocation of resources for HIV from county government. • There is heavy reliance on donor funding to support HIV activities in counties
Service Delivery • Some counties have previous experience in PrEP roll-out through demonstration projects • HIV taskforces and/or TWGs already exist in most counties • Functional community units exist • All counties have health facilities that provide HIV care and treatment services • Most counties have existing DICES • All counties have a health work force who are trained and offering HIV services • Majority of counties have implementing partner support • Complementing commodities are available e.g. condoms, family planning and test kits. • The revised guideline which include PrEP are available to all counties • There is a laboratory network in place	**Service Delivery** • Knowledge gaps on HIV exist among community health workers • There is sub-optimal HIV testing coverage. • Specialized laboratory tests e.g. Creatinine tests are charged in majority of counties • Not all counties have had full coverage of the dissemination of guidelines • There is weak supportive supervision in most counties • Many counties have health worker challenges (including understaffing and high turnover) • In geographically vast counties, accessibility of health facilities is a challenge for patients seeking services • Some healthcare workers have poor attitudes to some client • Existing laboratory networks are limited
Communication and Advocacy • Local radio stations are available for mass communication • Community engagements are regular in most counties	**Communication and Advocacy** • There is still high stigma towards HIV in the community • Mobilization and advocacy for PrEP not in place • Limited coverage of PrEP tools, job aids, IEC

Strengths	Weaknesses
Commodity management • There are commodities available from the national level • There is a national centralized supply systems in place • Some counties have commodity security TWGs to monitor HIV commodities • Reporting mechanisms to the national supply chain are in place for all counties	**Commodity management** • Some counties experience stock outs of key commodities e.g. test kits
Monitoring and Evaluation • There is an existing M&E system for health	**Monitoring and Evaluation** • PrEP is not yet included in the DHIS reporting system

Table 7: **County Readiness Assessment Tool**

County Readiness Self-Assessment Tool for PrEP			
County:		**Date of assessment:**	
Please indicate **Yes or No**		Where appropriate please indicate on a scale of **0-5** **0** = weak/low/insufficient **5** = strong/high/sufficient	Comments
LEADERSHIP, GOVERNANCE & FINANCING			
Is PrEP included in your County's AIDS Strategic plan?			
Are there resources available for roll-out of PrEP e.g. existing in county budgets, ongoing implementing partner projects, and on-going private sector activities? Please indicate the level of resource sufficiency.			
Are there resources available to support additional laboratory testing for PrEP patients e.g. Serum Creatinine? Please indicate the level of resource sufficiency			
Is there a technical working group that can include HIV care and treatment including PrEP?			
Is there a structure for county engagement with key political and community leaders for issues such as PrEP?			
Has there been any previous engagement with key political and community leaders on PrEP. Please indicate the level of engagement			

County Readiness Self-Assessment Tool for PrEP			
Do you have any implementing partners supporting HIV services in your county?			
Are any of the implementing partners currently supporting PrEP scale up in the county?			
Has a SWOT analysis been on conducted on PrEP uptake?			
SERVICE DELIVERY			
Are toolkits and job aids or IEC materials for service providers on HIV prevention or PrEP available?			
Is there a list of facilities that can offer PrEP?			
Has the county had any previous experience with PrEP delivery e.g. through previous demo projects, private sector engagements etc.? If yes, please provide a list in the comments section			
Is there a referral system for specialized laboratory test e.g. Serum Creatinine testing. Please indicate the coverage/reach of specialized testing in the county			
Are there any programs or efforts at county level (including those by NGOs) that support adherence or adverse events monitoring? Please indicate the coverage of these activities in the county.			
COMMUNICATION AND ADVOCACY			
Has the county undertaken or been engaged in any HIV Prevention or PrEP awareness efforts? E.g. CMEs, campaigns. Please specify in the comments section			
Is there any on-going general messaging available on HIV Prevention and/or PrEP awareness? If yes, please specify			
Are any IEC materials available on HIV Prevention or PrEP for patients?			
Have HIV Prevention or PrEP champions been identified at county level?			

County Readiness Self-Assessment Tool for PrEP			
COMMODITY MANAGEMENT			
Does the county undertake commodity quantification exercises for ARVs/test kits?			
Has the county determined the commodity requirements for PrEP?			
Are all treatment sites mapped to ordering points?			
Are SOPs, Pharmacovigilance and LMIS data capturing tools available to facilities?			
Have the facilities been sensitized on the revised LMIS tools for ordering and reporting?			
For the facilities referred to above, what is the coverage of facilities sensitized on the revised LMIS tools for ordering and reporting?			
MONITORING & EVALUATION			
Have facilities been trained on reporting service data to the national level through the national M&E tools? Please indicate coverage of reporting in the county			
Have any Electronic Medical Records (EMR) systems been implemented in the county? If yes, please specify which			
Is HIV prevention and/or PrEP included in the county's M&E plan?			
RESEARCH			
Is there a research plan for the county?			
What is the level of readiness to collect electronic data, Biometrics, Open Data Kit– sentinel/ surveillance counties? Please provide comments			
Is there a Data Quality assessment system in place to collect routine M&E data required for research?			

Focus Area 4: COMMUNICATIONS, ADVOVACY AND COMMUNITY ENGAGEMENT

Table 8: **Communication SWOT Analysis**

Internal	**Strengths** • Government buy in for PrEP • Support from implementation partners/ NGOs • Government leadership and coordination mechanism for PrEP roll out in place • Resources available for roll out in some counties and populations • Mature HIV treatment programme • Demo projects and experience • Research evidence to support the product • Structured programmes and guidelines on that will guide national roll-out of PrEP already exist • Existing health systems structures that to support the roll PrEP • Strong community networks which support PrEP • Devolution	**Weaknesses** • Focus on treatment rather than prevention • Culture of not taking drugs for prevention • Product packaged like ARV for treatment resulting to stigma towards PrEP users • Lack of a critical mass of health care providers trained on dispensing PrEP • No clear definition of persons at substantial risk among the general population limiting the development of targeted strategies • Funding is donor dependent • Risk compensation behaviour; PrEP seen as a magic bullet and this will possibly reduce the use of other prevention methods • Limited dissemination of correct PrEP information • Low risk perception among different populations • Competing health priorities within counties which has led to counties not prioritising PrEP • Inadequate service delivery channels affected PrEP access
External	**Opportunities** • Global environment is receptive to scale up of PrEP • Kenya seen as a global leader in scaling up PrEP • Leveraging technology • Demo projects in multiple counties which provide opportunity for scale up and learning. • There is donor willingness to invest in PrEP • Global focus on AGYW and key populations	**Threats** • Shifting donor funding mechanism • High cost of drug (PrEP) • Anti-PrEP activism and negative messaging

Focus Area 5: Monitoring and Evaluation

Table 9: **M&E Data Collection Framework**

OBJECTIVE	INDICATOR	INDICATOR DEFINITION	DATA SOURCE	FREQUENCY OF COLLECTION	ENTITY RESPONSIBLE
To provide PrEP as part of combination HIV prevention to 500,000 Kenyans on substantial ongoing risk to HIV infections within 5 years	**Implementation Indicators**				
	Number of clinics offering PrEP	These are the service delivery points offering PrEP either to general population or key populations	Master facility list	Quarterly	NASCOP, COUNTIES
	Number of clients assessed for PrEP	These are the clients whose risk of acquiring HIV has been assessed at a service delivery point using a Clinical encounter record	Clinical encounter record	Routine data collection	Clinician
	Number of clients eligible for PrEP	Number of clients found to be at risk of acquiring HIV who have been assessed and have met the criteria for starting PrEP.	EMR	Routine data collection	Clinician
	Number of clients newly started on PrEP	Number of eligible clients who start PrEP	EMR	Routine data collection	Clinician
	Number of continuing PrEP clients(Refills)	Number of clients on PrEP who receive a PrEP refill	EMR	Routine data collection	Clinician
	Number of client currently on PrEP(New+Refills)	This is the sum of clients initiated on PrEP plus the refills within the reporting period	EMR	Routine data collection	Clinician
	Number followed up by end of first month after initiation	All clients started on PrEP who come back after the first month.	EMR	Routine data collection at facility level	Clinician
	Number stopping PrEP	These are number of enrolled clients who stopped using PrEP due to various reasons such as: ADR, Defaulters, sero-conversion and due to reduced risk	EMR	Routine data collection	Clinician
	Number of PrEP clients who sero-convert	These are the number of enrolled clients on PrEP who turn HIV positive while on PrEP.	EMR	Routine data collection	Clinician

OBJECTIVE	INDICATOR	INDICATOR DEFINITION	DATA SOURCE	FREQUENCY OF COLLECTION	ENTITY RESPONSIBLE
To provide PrEP as part of combination HIV prevention to 500,000 Kenyans on substantial ongoing risk to HIV infections within 5 years	Number PrEP clients diagnosis with a STI	Number of clients diagnosed with a STI while on PrEP	EMR	Routine data collection	Clinician
	Proportion of PrEP clients with satisfactory PrEP adherence	Adherence grading **Good** – Missed 0- 3 doses per week in the past one month **Fair** – Missed 4-8 doses per week in the past one month **Bad** – Missed 6-7 more doses per week in the past one month	EMR	Routine data collection	NASCOP
	Behavioral indicators				
	Median number of sexual partners that PrEP clients have.	Number of sexual contacts that the client enrolled for PrEP has within 12 months.	Survey	5 years,	NASCOP
	Number of PrEP clients who are Consistently using condoms	The number of clients on PrEP who report consistent use of condoms	Survey	5 years	NASCOP
	Impact Indicators				
	HIV incidence	Number of new HIV infections	Survey/Mathematical modelling	5 years	NASCOP

Table 10: **PrEP Summary Reporting Tool**

NATIONAL AIDS & STI PROGRAMME

PrEP Summary Reporting Tool

County: _____

Site Name/Facility: _____

Sub-County: _____

MFL-Code: _____ Reporting Month: _____ Year: _____

1. Number Assessed For HIV risk	
1.1 Males 15 - 19 Years	
1.2 Females 15 - 19 Years	
1.3 Males 20 - 24 Years	
1.4 Females 20 - 24 Years	
1.5 Males 25 - 30 Years	
1.6 Females 25 - 30 Years	
1.7 Males 30 Years and older	
1.8 Females 30 Years and older	
Total	

4. Number Continuing on PrEP (Refills)	
4.1 Males 15 - 19 Years	
4.2 Females 15 - 19 Years	
4.3 Males 20 - 24 Years	
4.4 Females 20 - 24 Years	
4.5 Males 25 - 30 Years	
4.6 Females 25 - 30 Years	
4.7 Males 30 Years and older	
4.8 Females 30 Years and older	
Total	

2. Number Eligible for PrEP	
2.1 Males 15 - 19 Years	
2.2 Females 15 - 19 Years	
2.3 Males 20 - 24 Years	
2.4 Females 20 - 24 Years	
2.5 Males 25 - 30 Years	
2.6 Females 25 - 30 Years	
2.7 Males 30 Years and older	
2.8 Females 30 Years and older	
Total	

5. Number currently on PrEP (New + Refill)	
5.1 Males 15 - 19 Years (3.1 + 4.1)	
5.2 Females 15 - 19 Years (3.2 + 4.2)	
5.3 Males 20 - 24 Years (3.3 + 4.3)	
5.4 Females 20 - 24 Years (3.4 + 4.4)	
5.5 Males 25 - 30 Years (3.5 + 4.5)	
5.6 Females 25 - 30 Years (3.6 + 4.6)	
5.7 Males 30 Years and older (3.7 + 4.7)	
5.8 Females 30 Years and older (3.8 + 4.8)	
Total	

3. Number Started (New) on PrEP	
3.1 Males 15 - 19 Years	
3.2 Females 15 - 19 Years	
3.3 Males 20 - 24 Years	
3.4 Females 20 - 24 Years	
3.5 Males 25 - 30 Years	
3.6 Females 25 - 30 Years	
3.7 Males 30 Years and older	
3.8 Females 30 Years and older	
Total	

6. Number retested HIV positive while on PrEP	
6.1 Males 15 - 19 Years	
6.2 Females 15 - 19 Years	
6.3 Males 20 - 24 Years	
6.4 Females 20 - 24 Years	
6.5 Males 25 - 30 Years	
6.6 Females 25 - 30 Years	
6.7 Males 30 Years and older	
6.8 Females 30 Years and older	
Total	

Focus area 6: RESEARCH AGENDA

Table11: **PrEP Research Agenda**

Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
High Priority							
Demonstrate population's impact of PrEP, over and above other combination prevention interventions in at risk populations in at least 3 high cluster counties.	Mathematical Modelling, Incidence measurements(cased based surveillance)	Mathematical Modelling	Demonstrated program impact	(Kenya HIV Research Agenda Annex 2 p. 21). Already being assessed in Combo. There are models that have been developed and can be used. Build on the current HTS registry	Long term	NASCOP, Options , Imperial College, UW	Options , Imperial College, UW
Coverage required to avert a proportion or a percent of new infections per risk group	Mathematical Modelling	Mathematical Modelling	Demonstrated program impact and guide service delivery	Find out if the models available can address this. Break down the models by at risk population. Include cost to this model. Data from research studies to model. Jilinde has funding to answer this question in 3 counties.	Immediate	Jilinde , Imperial College, Options, LVCT, NASCOP	Jilinde , Imperial College, Options, LVCT

Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
Determine acceptability (end-user and provider) and uptake of PrEP (and other ARV based preventions) by sub-populations -	Routine data, Special studies	Routine data, Special studies	To improve service delivery	These could involve bridging studies among sub-populations for which we don't have data	Immediate	Emotion, Power, UW-KNH, NHRS, NASCOP	Emotion, Power, UW-KNH, NHRS
Analyze the incremental cost of adding PrEP to the overall cost of combination prevention - for the combo counties initially,	Mathematical Modelling	Mathematical Modelling	To guide financing and resource mobilization	Can spread to other counties.	Medium term	Options, NASCOP	Options
Analyze the incremental cost of adding PrEP to the existing programs	Mathematical Modelling	Mathematical Modelling	To guide financing and resource mobilization	This may be population specific; delivery model specific	Medium term	Jilinde, CHAI, Partners, NASCOP	Jilinde, CHAI, Partners
Determine resources needed to reach a certain coverage of PrEP. Budget impact analysis i.e. what is it going to cost the government to provide PrEP	Mathematical Modelling	Mathematical Modelling	To guide financing and resource mobilization	Done alongside cost-effective analysis	Medium term	Jilinde, CHAI, Options, NASCOP	Jilinde, CHAI, Options
Determine current national unit costs of providing PrEP by mode of service delivery, target population and geographic region	Costing studies	Costing studies	To guide financing and resource mobilization	Will depend on targets set by the M&E sub-committee	Medium term	Jilinde, CHAI, Options, NASCOP	Jilinde, CHAI, Options
Estimate direct cost incurred by clients (financial and opportunity costs) in accessing PrEP – policy and service delivery implications. Determine willingness to pay for PrEP services (medication, lab etc.)/cost sharing	Costing studies	Costing studies	To improve service delivery and guide policy formulation	Private sector-out of pocket model may end up being the predominant	Medium term	Jilinde, NASCOP	Jilinde

Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
Map/Track resource flows across programs , thematic areas and across time	Costing studies		To identify efficiency gains	Over time, we could potentially achieve efficiencies as we identify best practices and as initial health systems have been strengthened	Medium term	NASCOP	Jilinde
Determine the appropriate dispensing models for the product	Special studies		To determine the appropriate service delivery channels	Consider private pharmacies, lay workers etc.	Medium	NASCOP	Jilinde, Product Marketing Manager, Mylan
What is the appropriate packaging for PrEP?	Marketing and branding studies		To enhance client satisfaction and improve uptake	Current approach using bottles that make noise appear unpopular	Medium	NASCOP	Jilinde, Product Marketing Manager, Mylan
Service providers' knowledge, attitudes and perceptions that affect PrEP service provision in at least the 9 priority counties.	Mixed methods, Pre and post training surveys, Quality Improvement, KENPHIA	Mixed methods, Pre and post training surveys, Quality Improvement, KENPHIA	To improve service delivery	(KHRA)	Immediate & continuous	Options, Partners PrEP, NASCOP	Options, KENPHIA, Partners PrEP
Evaluating interventions to improve adherence	Special studies	Special studies	To improve service delivery	Almost all demo projects are addressing these questions	Medium term	NASCOP	NASCOP
Studies on prevalence of HIV drug resistance (acquired and transmitted)	Special studies/ pharmacovigilance	Special studies/ pharmacovigilance	To improve service delivery	Can be part of an established pharmacovigilance	Immediate & continuous	GEMS	GEMS
Establish PrEP pharmacovigilance at national level.	Special studies/ pharmacovigilance	Special studies/ pharmacovigilance	To improve service delivery	Can be used to answer many questions. Link to pregnancy registry important	Immediate & continuous	GEMS	GEMS

	Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
	Define and develop a PrEP cascade (% at risk, % eligible, % initiated, % dropped off (good and bad), % actually taking, % restarting, % seroconverted, % linked, %resistance (+waning)	KENPHIA/special studies - Drug level testing - DBS for every nth sample	KENPHIA/special studies - Drug level testing - DBS for every nth sample	To improve service delivery	Consider having sentinel surveillance sites in counties as we start. PrEP cohort that each individual with a unique identifier linked to a central data base (EMR, biometrics)	Immediate & continuous	NASCOP	NASCOP
	To define characteristics including patterns of PrEP use	PrEP cohort longitudinal data bases in sentinel sites, qualitative studies	PrEP cohort longitudinal data bases in sentinel sites, qualitative studies	To improve service delivery	Characteristics of how, when and why people start, stop, and restart PrEP	Immediate & continuous	NASCOP	NASCOP
	Characterize within sub-populations, those at highest risk of HIV and who would qualify as a target for PrEP.	Data from risk assessment tools integrated into service delivery at different levels.		To improve service delivery and to enhance program efficiency	Not all Key populations have same risk profile	Immediate & continuous	Anza Mapema (MSM), Dreams, Options (AGYW), Fisher folk	Anza Mapema (MSM), Dreams, Options (AGYW), Fisher folk
	What is the risk-demand profile of people coming in for PrEP at service delivery points, create risk profile and matrix	KENPHIA and special studies		To enhance demand creation strategies	Understand matrix of risk-demand for PrEP – high demand & low risk, high demand & high risk, low demand & high risk, low demand & low risk	Immediate	NASCOP/OPTIONS	NASCOP/OPTIONS
	What is the most effective model of mobilization for demand creation for PrEP in different populations?	Consumer insight/market survey	special studies	To enhance demand creation strategies	Map out our population, comparing their risk with their demand for PrEP. Risk (self-perception or after assessment by provider), documentation by providers of those coming in	Immediate	NASCOP/OPTIONS	NASCOP/OPTIONS
	Feasibility of integrating PrEP into existing models of service delivery such as family planning and/or retail pharmacies	Implementation and operational research	special studies	To accelerate scale up and improve access	Feasibility of integrating PrEP into pharmacies and family planning	Medium	NASCOP, JILINDE	NASCOP, JILINDE
Medium Priority								

Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
Define HIV testing approach (Provider Initiated testing and counselling, HIV Self Testing) that will it increase PrEP uptake and/or provide early identification of sero conversion	Special studies	Special study	To guide policy formulation and service delivery	Outcomes =rates of seroconversion per strategy	Medium term	NASCOP	NASCOP
Identify the appropriate distribution models for the product	Special studies		To guide policy formulation and service delivery		Medium Term	NASCOP	NASCOP
Establish a cohort event monitoring	Pharmacovigilance, special studies		To enhance patient safety	Done as part of the broader pharmacovigilance	Medium term	NASCOP, GEMS	Jilinde, Product Marketing Manager, Mylan, Global Fund
Customer/client perception to PrEP	Special studies		To improve access	Done as part of routine service delivery	Continuous	NASCOP	NASCOP
Determine strategies to promote and enhance partner testing and disclosure in PrEP settings.	Special studies	Special study	To improve service delivery	Comparing different strategies to promote identification of negative partners of HIV positive individuals who are qualified for PrEP. (Kenya HIV Research Agenda Annex 2).	Medium term	NASCOP	NASCOP
Feasibility of integrating PrEP into assisted partner services	Special studies	Special study	Enhance program efficiency	Assisted partner services identifies a large number of HIV-negative sex partners of HIV-infected patients	Medium term	NASCOP	NASCOP

Research Question	Data Source/Methodology	Methodology - How	Rationale	Remarks	Timeline	Protocol Development Responsibility	Funding Sources
Evaluate the prevalence of PreP-related risk compensation.	Ecological study	Special study	To improve service delivery	How often will we be tracking HIV and STIs without it being a burden to the clients? o Track correlation between PrEP and STIs o Correlation of use of PrEP and other HIV prevention options Ecological study, with Syphilis as the best STI.	Long term	KEMRI Wellcome Trust, UoN, KEMRI	KEMRI Wellcome Trust, UoN, KEMRI
Define the short and long term safety of PreP (Biological and Social Harms).	Pharmacovigilance, special studies	Pharmacovigilance	To guide policy formulation and service delivery	Gender Violence, Pregnancy, Fetal/Infant exposure to PreP	Immediate & continuous	NASCOP	NASCOP
Develop predictive model for risk of seroconversion while on PrEP	Routine Data	Routine Data	To guide policy formulation and service delivery	Granular model can predict what group, social economic status and put someone at the highest risk group	Long term	NASCOP, KEMRI WELLCOME TRUST	NASCOP,KEMRI WELLCOME TRUST
Low Priority							
Optimal HIV testing schedule 3 months, 6 months etc. (Frequency of HIV testing, by subpopulations)	Mathematical Modelling	Mathematical Modelling	To guide on policy formulation and to improve on service delivery.	In collaboration with the cascade approach (Kenya HIV Research Agenda Annex 2 p. 21).	Medium term	GEMS	GEMS
Evaluate the predictors of PrEP adherence in a routine service setting.	Special studies	Special study	To improve service delivery	Include the appropriate minimum dose	Medium term	NASCOP	NASCOP
Piloting an intervention to improve PrEP adherence	Special studies	Special study	To improve service delivery	Need to identify those with poor adherence	Medium term	NASCOP	NASCOP
Effects of combination prevention (structural and behavioral) on PrEP uptake.	Cluster randomized study	Cluster randomized study	provide lessons learnt, for grant applications	Complex and requires meticulous planning	Long term	NASCOP	NASCOP

Focus Area 7: FINANCING AND RESOURCE MOBILIZATION

Table 12: **Costing Assumptions**

Activity Description	Inputs Required	Number	Unit Cost	Days	Total cost
Demonstrate population's impact of PrEP	External Consultant	1	$ 2,000	40	$ 80,000
	Internal Consultant	1	$ 600	40	$ 24,000
	Field Transport	2	$ 150	20	$ 6,000
	Data Collectors	6	$ 150	20	$ 18,000
	Overhead cost	0.2	$ 1	1	$ 25,600
Analyze the incremental cost of adding PrEP to the overall cost of combination prevention - for the combined counties initially,	Consultant	1	$ 1,000	60	$ 60,000
Analyze the incremental cost of adding PrEP to the existing programs					
Determine resources needed to reach a certain coverage rate. Budget impact analysis	Consultant	1	$ 1,000	20	$ 20,000
Determine current national unit costs of providing PrEP by Mode-of-service-delivery, target population and geographic region	External Consultant	1	$ 2,000	20	$ 40,000
	Internal Consultant	1	$ 600	60	$ 36,000
	Data Collectors	4	$ 150	60	$ 36,000
	Field Transport	2	$ 150	20	$ 6,000
	Overhead cost	0.2			$ 23,600
Estimate direct (financial and opportunity) costs incurred by clients in accessing PrEP	External Consultant	1	$ 2,000	20	$ 40,000
	Internal Consultant	1	$ 600	60	$ 36,000
	Data Collectors	4	$ 150	60	$ 36,000
	Field Transport	2	$ 150	20	$ 6,000
	Overhead cost	0.2	$ 1	1	$ 23,600

Activity Description	Inputs Required	Number	Unit Cost	Days	Total cost
Tracking resources being used	External Consultant	1	$ 2,000	20	$ 40,000
	Internal Consultant	1	$ 600	60	$ 36,000
	Data Collectors	4	$ 150	60	$ 36,000
	Field Transport	2	$ 150	20	$ 6,000
	Overhead cost	0.2	$ 1	1	$ 23,600
				Total	$ 658,400

Annex 2:

National PrEP Implementation Plan

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
PLANNING		Start	End					
Conduct a situational assessment of PrEP in Kenya	A situational assessment analysis of Kenya and a report	11/7	11/18	day meetings, validation meetings	$ 720.00	2 meetings for 30 people with meals @ $12	Partners, OPTIONS, NASCOP	Q1 2017
Develop an implementation approach for PreP in Kenya with possible scenarios	Identification of priority counties and listing of scenarios based on readiness assessment	11/10	12/6	day meetings, validation meetings	$ 540.00	3 meetings for 15 people with meals @ $12	NASCOP, PrEP TWG	Q1 2017
Develop readiness assessment tool	a county and facility assessment tool to determine which counties are implementation ready through gap analysis	11/9	1/31	residential meeting	$ 360.00	2 meetings for 15 people with meals @ $12	NASCOP, OPTIONS, Jilinde CHAI	Q1 2017
Conduct a readiness assessment of counties for PrEP implementation	Analysis of PrEP preparedness levels at county level		2/28	residential meeting	$ 540.00	3 meetings for 15 people with meals at $12	Counties	Q1 2017
Facility assessment for readiness (To include GBV centres)	Analysis of facilities in counties on PrEP implementation readiness			field visits, day meetings	$ 120.00	2 meetings for 5 people with meals at $12	Counties, Partners, NASCOP	Q1 2017
Develop PrEP implementation framework	A national document outlining the PrEP roll-out strategy with a costed work plan	1/17	2/28	residential meeting; consultants	$ 600.00	meetings for 10 people for 1 week	NASCOP, TWG	Q1 2017
Conduct a stakeholders analysis(implementers, key actors)	A mapping of key players in PrEP rollout	11/28	12/6	meeting; desk work	$ 240.00	1 half day meeting with 20 people with meals at $12	NASCOP, OPTIONS	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Documentation of roll out of PrEP in Kenya	A longitudinal detail of activities undertaken to implement prep in-country that can be used to advise those beginning a PrEP program	continuous					NASCOP	Q1 2017
Learning visit from the FP and VMMC program	a learning meeting to understand dynamics of driving uptake of new products	12/8	12/8	half-day meeting	$ 240.00	1 half day meeting with 20 people with meals at $12	NASCOP, DCH	Q1 2017
Approval of PrEP work plan (PS and Council and Governors)			12/8				NASCOP	Q1 2017
Define County clusters based on epidemic	a list of counties categorized by HIV epidemic to further advise implementation approach			desk work	$ 120.00	2 meetings for 5 people with meals at $12	NASCOP	Q1 2017
Develop guidance to supported counties				residential meeting	$ 400.00	2 meetings for 5 people with conference package $40	NASCOP	Q1 2017
Conduct costing for resource mobilization	Cost Modelling data for use to advocate for funding			full day meeting	$ 1,200.00	meetings for 10 people for 3 days with conference package at $40	NASCOP, Avenir Health, CHAI	Q1 2017
SERVICE DELIVERY & OPERATIONS								
Conduct regular TWG and sub-committee meetings	minutes from meetings			day meeting	$ 19,200.00	monthly full day meetings for 40 people; conference package at $40	NASCOP	
Develop operational guideline	risk assessment tool to define who is eligible, SOPs for enrollment, clinical monitoring, follow-up, define service delivery points, duration of treatment,	11/10	12/31	residential meeting, consultants	$ 4,800.00	1 Review workshop meetings for 40 people for 3 days	NASCOP	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Review/update existing training curriculum	incorporation of PrEP into HTS, ART, PMTCT, ANC, VMMC, Infection Prevention Control (IPC) and KP, commodity management and IPV/GBV training curriculums	11/10	12/31	residential meeting	$ 4,800.00	1 review workshop for 40 people for 3 days	NASCOP	Q1 2017
Discussion with ART and KP team on inclusion of PrEP in new guideline dissemination plan		11/10	11/15	meeting		in-house meeting	NASCOP	Q1 2017
Develop and inventory of PrEP referral centres	A directory of centres	1/1	2/28	desk work	$ 360.00	2 meetings for 15 people with meals at $12	NASCOP	Q1 2017
Develop an inventory of GBV centres	A directory of centres	1/1	2/28	desk work	$ 360.00	2 meetings for 15 people with meals at $12	NASCOP	Q1 2017
Develop a national training and mentorship plan	certificates, training module, training and trainee manuals for PrEP	11/10	12/15	day meetings	$ 720.00	4 meetings for 15 people with meals at $12	NASCOP	Q1 2017
Develop a service provider tool kit and job aid	A comprehensive service provider tool kit for PrEP implementation	11/10	12/31	residential meeting; consultants	$ 720.00	2 meetings for 30 people with meals at $12	NASCOP	Q1 2017
Develop patient education tool kit	A patient education tool kit for PrEP use	11/10	12/31	residential meeting	$ 720.00	2 meetings for 30 people with meals at $12	NASCOP	Q1 2017
Format and print training curriculum, service provide tool kit and job aids and patient education materials		1/2	1/13	Consultant, validation meetings	$ 480,000.00	Printing of materials 4 packs for 6000 facilities at 20 dollars per package	NASCOP, Partners	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Conduct trainings of TOTs	A pool of master trainers on PrEP	1/16	2/10	one day training	$ 40,360.00	1 day hotel training for 188 ToTs (4 per county) in 4 regions; conference package at 30 dollars allowance of 80 dollars for 2 days; allowance for 8 NASCOP officers $140 for 2 days; fuel/air travel $300 per region	NASCOP, Partners, Counties	Q1 2017
Conduct training of service providers	training of all service providers for PrEP	2/13	3/23	one day training	$ 42,880.00	1 day training for 200 staff at $80 allowance; $30 conference package; allowance for 8 NASCOP officers $140 for 2 days; fuel/ air travel $300 per region	NASCOP, Partners, Counties	Q1 2017
Hold CMEs at facility level		4/1		facility CME		to be included as part of facility CMEs	NASCOP, Partners, Counties	Q2 2017
Develop training inventory of service providers	inclusion in train smart/ registry of trained service providers	1/16		desk work	$ 120.00	2 meetings for 5 people with meals at $12	NASCOP	Q1 2017
Conduct supportive supervision post implementation		4/1	QUART	facility visits	$ 8,800.00	5 day quarterly visits for 4 MoH personnel at $140 per day; allowances; transport at $300;	NASCOP, Partners, Counties	Q2 2017
Conduct a mapping of availability PrEP monitoring laboratory tests	CD4, creatinine, Hepatitis B serology, viral load, HIV DR, Molecular HIV testing,	11/9	1/31	day meeting	$ 360.00	3 meetings for 10 people with meals at $12	NPHLS, NASCOP, Counties	Q1 2017
Plan for sample referral networks		11/9	1/31	day meeting		as above	NPHLS, NASCOP, Counties	Q1 2017
Issue a circular on PrEP			2/28			in-house	NASCOP	Q1 2017
Outline prevention package	define service delivery points, interventions and the package	11/28	11/30	day meeting	$ 1,800.00	3 meetings for 15 people with conference package at $40	NASCOP	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Outline Adherence monitoring plan	outline adherence monitoring methods	11/28	11/30	day meeting	$ 540.00	3 meetings for 15 people with meals at $12	NASCOP	Q1 2017
HIV DRT plan	include PrEP users in national HIV DRT plan	11/28	12/6	day meeting	$ 60.00	1 meeting for 5 people with meals at $12	NASCOP, NPHLS	Q1 2017
Adverse events monitoring (spontaneous and cohort event monitoring)	outline and integrated into the existing plan	11/28	3/31	day meeting	$ 600.00	1 meetings for 15 people with conference package at $40	NASCOP	Q1 2017
Develop a resource mobilization plan including investment case/strategy			3/31	day meeting	$ 1,200.00	2 meetings for 15 people with conference package at $40	NASCOP	Q2 2017
Round table discussions on PrEP funding		11/10	3/31	day meeting	$ 1,200.00	2 meetings for 15 people with conference package at $40	NASCOP	Q2 2017
Private sector engagement	inclusion of prep and HIVST linkages, reporting mechanisms for PrEP into the national system		1/31	day meeting	$ 3,200.00	2 meetings for 40 people conference package at $40	NASCOP, Private sector players	Q1 2017
Key stakeholder engagement meetings	A series of meetings to get buy-in on PrEP implementation			day meetings			NASCOP and relevant stakeholders	Q1 2017
Identify ready counties/ facilities	Phased roll out							
MONITORING & EVALUATION								
Develop national PrEP targets		11/16	12/6	day meetings	$ 1,080.00	3 meetings for 30 people with meals $12	NASCOP	Q1 2017
Define monitoring indicators	community, facility, national indicators	11/16	12/6	day meetings	$ 360.00	1 meeting for 30 people with meals at $12	NASCOP	Q1 2017
Outline reporting pathways		11/16	12/6	day meetings		as above	NASCOP	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Review existing tools/develop PrEP specific tools	HTS, cohort registers, ART registers, screening tools, laboratory request form, PrEP enrollment forms, KP tools/registers, PrEP registry, LMIS tools, PrEP card	11/28	1/31	day meetings	$ 2,400.00	3 meetings for 20 people with conference package $40	NASCOP	Q1 2017
Develop HIV prevention cascade	Document outlining HIV prevention cascade	11/28	1/31	day meetings	$ 2,400.00	3 meetings for 20 people with conference package $40	NASCOP	Q1 2017
Conduct baseline assessment				field visits, meetings	$ 8,620.00	3 planning meetings of 15 people at $12 to develop evaluation protocols, $140 of allowances for field visits to 30 facilities by 8 officers for 4 days in 3 teams, fuel for 4 days at $300; data analysis and report dissemination meeting at TWG meeting	NASCOP, Counties, Partners	Q1 2017
Conduct mid-term assessment			12/31	field visits, meetings	$ 8,620.00	3 planning meetings of 15 people at $12 to develop evaluation protocols, $140 of allowances for field visits to 30 facilities by 8 officers for 4 days in 3 teams, fuel for 4 days at $300; data analysis and report dissemination meeting at TWG meeting	NASCOP, Counties, Partners	Q4 2017
Conduct end term evaluation			12/31	field visits, meetings	$ 8,620.00	3 planning meetings of 15 people at $12 to develop evaluation protocols, $140 of allowances for field visits to 30 facilities by 8 officers for 4 days in 3 teams, fuel for 4 days at $300; data analysis and report dissemination meeting at TWG meeting	NASCOP, Counties, Partners	Q4 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Discussions on software, hardware for PrEP (ODK, EMR)	unique IDs (biometrics) for PrEP users	11/28	1/31/2017	day meeting	$ 720.00	2 meetings 30 people with meals	NASCOP, Partners	Q1 2017
Develop quarterly progress reports		3/31	quart	day meeting	$ 240.00	meeting each quarter with 5 people with meals	NASCOP	Q2 2017
Development of dashboards/ data visualization tools	tracking work plan, data reports, prevention cascade	1/16	2/28	day meeting	$ 4,570.00	2 meetings with 5 people with tea; system developer hired for 6 months at $750 per month	NASCOP	Q2 2017
RESEARCH								
Conduct desk review of evidence for PrEP in Kenya	Define what do we know, where do we want to be (national priority), what are the gaps?	12/1	12/31	Consultant	$ 1,800.00	program officer hired for 3 months at $600 per month	NASCOP, Consultant	Q1 2017
Create a PrEP evidence data repository at NASCOP- past, current and planned studies	Data repository at NACC/ NASCOP	12/1	12/31	Consultant		as above	NASCOP, Consultant	Q1 2017
Rapid assessment of providers' knowledge, attitude and perceptions towards PrEP in selected counties	Survey results	1/1	30/1	N/A	$ 300.00	5 meetings 5 people with meals @ $12	Jilinde	Q1 2017
Convene meeting between GEMS, NASCOP and NHRL to agree on data/sample collection mechanisms	Data collection agreement	30/11	15/12	day meeting	$ 180.00	1 meeting 15 people with meals at $12	NASCOP	Q1 2017
Readiness assessment at county level	Readiness assessment tool and report	1/1	30/1	day meeting		by research groups	County CASCOs	Q1 2017
Finalization of implementation framework	Research & Impact Area Focus Area	30/11	5/12	N/A	$ 300.00	5 meetings 5 people with meals @ $12	NASCOP	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Costing and cost effectiveness of PrEP in Kenya	Includes all populations, standardized assumptions and methodologies,	1/3	12/31		$ 300.00	5 meetings 5 people with meals @ $12	NASCOP, Consultant, Jilinde; CHAI/LVCT Health	Q3 2017
Finalize research agenda	Outline unanswered questions for Kenya	30/1	1/16	Day Meeting			Dr Cherutich	Q1 2017
Conduct research as agreed on research agenda	Research protocols	3/3					NASCOP & Implementing partners	Q3 2017
COMMUNICATION & ADVOCACY								
Identification of specific persons/groups to engage	List of target and contacts	Dec. 2016	Dec. 2016	desk review, phone calls, meetings etc.		covered in other activities	NASCOP & Partners	Q1 2017
Develop audience specific materials	Policy briefs, media pack, PowerPoint presentations, fact sheets, FAQs, brochure	Jan. 2017	Jan. 2017	Consultants, validation meetings, funds to print and disseminate	$ 3,000.00	5 day meetings for 15 people; conference package at $40	NASCOP & Partners	Q1 2017
Develop advocacy agenda for PrEP	agenda per specific target group	Jan. 2017	Jan. 2017			covered in other activities		Q1 2017
Engagement of various stakeholders	action plans	Feb, 2017	Feb, 2017	funds for workshops, meetings information materials	$ 4,800.00	3 meetings for 40 people; conference package at $40	NASCOP & Partners	Q1 2017
Support advocates in development of talking points for PrEP	leaflet, palm cards	Feb, 2017	Feb, 2017	day meetings	$ 3,000.00	5 meetings for 15 people; conference package at $40	NASCOP & Partners	Q1 2017
Support advocates to map and participate in forums	list of forums/meetings in the community, media forums, blogs	Feb, 2017	Feb, 2017	funds to support mapping and key forums		covered in other activities	NASCOP & Partners	Q1 2017
Develop a monitoring plan for advocacy	monitoring plan	Jan. 2017	Jan. 2017	meeting/ workshop		covered in other activities	NASCOP & PrEP sub-committee on communication	Q1 2017
Quarterly feedback sessions (monthly as necessary)	meeting reports	#####	#####	meeting/ workshop		covered in other activities	NASCOP & Partners	Q2 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Conduct communication needs assessment for health workers	A document outlining identified gaps	1/1	Jan-17	capacity assessment tools; field visits		covered above	NASCOP, Counties	Q1 2017
Develop interpersonal communication materials and IECs for health workers	Interpersonal and IEC materials	2/1	Feb-17	Retreat, Consultant	$ 3,000.00	5 meetings for 15 people; conference package at $40	NASCOP, Partners	Q1 2017
Conduct whole site sensitization on PrEP for health workers	Every staff oriented on PrEP	3/1	#####	meetings, IEC materials, training manual		covered in training	Counties, Partners	Q1 2017
Mapping of implementing partners (situation analysis)	Inventory of partners	Nov. 2016	Nov. 2016	resource person		covered in other activities	NASCOP, PEPFAR	Q1 2017
Development of communication materials , rapid advice for implementing partners	Communication package for implementing partners	Feb. 2017	Feb. 2017	working retreat, Consultant	$ 3,000.00	5 meetings for 15 people; conference package at $40	NASCOP, PSI-K,	Q1 2017
Conduct dissemination and sensitization workshops	Partners sensitized	Feb.2017	Feb.2017	day meeting	$ 8,000.00	1 meeting for 200 people conference package at $40	NASCOP, PEPFAR	Q1 2017
Develop and print communication materials for the general population	posters, fliers, billboards, communication script for the media	Feb	Feb	Consultants/ Graphic designers	$ 300,000.00		NASCOP	Q1 2017
Dissemination of materials to the general population	radio spots, adverts, road shows, public forums	Feb	Feb	Workshop		covered above	NASCOP	Q1 2017
Landscape analysis of PrEP use in Kenya	Findings report	Jan. 2017	Jan. 2017	desk review, meeting		covered in other activities	NASCOP, LVCT Health (OPTIONS)	Q1 2017
Target audience formative research for current and potential users of PrEP	user insights report	May. 2017	May. 2017	FGDs, meetings, funds for research		covered in other activities	NASCOP, Jilinde	Q2 2017
Market shaping research for PrEP users in Kenya (current and potential)	Market guide for PrEP	Aug. 2017	Aug. 2017	FDGs, KIIs, funds for research, meetings		covered in other activities	NASCOP, LVCT Health (OPTIONS)	Q3 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Dissemination of research results	dissemination meeting report	May. 2017	Sept. 2017	meetings	$ 2,800.00	1 meeting for 70 people conference package at $40	NASCOP, Jilinde/LVCT Health	Q2 2017
Development of communications strategy for current and potential PrEP users	Communication strategy	Aug. 2017	Aug. 2017	meetings, consultant		covered in other activities	NASCOP, Jilinde, PEPFAR	Q3 2017
Dissemination of communication strategy	dissemination meeting report	Sept. 2017	Sept.2017	meetings,		covered in other activities	NASCOP, Partners	Q3 2017
Review and production of IEC materials for current and potential PrEP users	IEC materials	Jan. 2017	Jan. 2017	meetings, consultant		covered in other activities	NASCOP, Partners	Q1 2017
Development of audience specific materials (current and potential PrEP users)	IEC materials	Jul. 2017	Jul.2017	meetings, funds		covered in other activities	NASCOP, Partners	Q3 2017
Dissemination of communication materials for current and potential PrEP users	Quantities disseminated, meeting reports	Aug. 2017	Aug. 2017	meetings, online platforms, media		covered in other activities	NASCOP, Partners	Q3 2017
Mapping community entry points	List and contacts	Feb	Feb	desk reviews, meetings		covered in other activities	NASCOP, Counties, Implementing Partners	Q1 2017
Development of community engagement toolkit	Community engagement toolkit	Jan	Jan	meetings, consultant		covered in other activities	Communications sub-committee	Q1 2017
Undertake community entry process/engagement	Community entry process guide, meeting notes	Feb	Feb	meetings, community forums	$ 10,000.00	5 meetings for 50 people; conference package at $40	Communications sub-committee	Q1 2017
Identify and train PrEP Champions	List of PrEP Champions, Communications training report	Jan	Jan	meetings, training materials, facilitators		covered in training	Implementing partners	Q1 2017
Identify and train peer educators for demand creation	List of peer educators, communications training report	Jan	Jan	meetings, training materials, facilitators		covered in training	Implementing partners	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Identify and train CHVs	List of CHVs, communications training report	Jan	Jan	meetings, training materials, facilitators		covered in training	Implementing partners	Q1 2017
Development of talking points and demand creation materials	IEC materials	Jan	Jan	meetings, consultant		covered in other activities	Communications sub-committee	Q1 2017
Quarterly feedback sessions (monthly forum as necessary)	Feedback meeting notes	Feb	Feb	meetings, facilitators		covered in other activities	Implementing partners/ NASCOP	Q1 2017
Develop communication strategy for the community	community engagement, advocacy and communication, define key stakeholders/champions,		1/31	day meetings		covered above	NASCOP, Partners	Q1 2017
Develop plan for implementing communication strategy			12/6	day meetings		covered in other activities	NASCOP, Partners	Q1 2017
Develop communication material by target groups (in the community)	IEC materials, messages for different platforms (social, electronic users); media training package		1/31	day meetings		covered in other activities	NASCOP, Partners	Q1 2017
Develop survey for service providers in the community on PrEP	views on prep		1/31	day meetings		covered in other activities	NASCOP, Partners	Q1 2017
Conduct survey for community service providers			2/28	field visits		covered in other activities	NASCOP, Counties	Q1 2017
Printing of communication materials (community)			2/28	printing		covered in other activities	NASCOP	Q1 2017
Plan for launch of PrEP	identify partners, participants, invitees, venue, guest of honor		3/31	half-day meeting	$ 4,000.00	1 meeting for 100 people conference package at $40	NASCOP, Partners	Q1 2017
County engagement meetings			2/28	day meetings	$ 8,000.00	1 meeting for 200 people; conference package at $40	NASCOP, Counties	Q1 2017
Community consultations			3/1	day meetings		covered in other activites	NASCOP, Counties, Partners	Q1 2017

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Formation of a national advisory group on communication	press briefing		1/31	day meeting		covered in other activities	NASCOP	Q1 2017
Training of media teams			3/31		$ 4,000.00	1 meeting for 100 people conference package at $40		Q1 2017
COMMODITY SECURITY								
Define supply chain for PrEP products			11/30	day meetings		covered in other activities	NASCOP	Q1 2017
Document /profile incoming PrEP donations		11/7	11/18	day meetings		covered in other activities	NASCOP	Q1 2017
Draft national quantification for PrEP and related laboratory products	PrEP, laboratory tests CD4, creatinine, Hepatitis B serology, HIVDRT incl. HIV self-testing,	11/9	1/31	day meetings		covered in other activities	NASCOP	Q3 2017
Conduct product indication variation (engagement with PPB and manufacturers)	products listed for HIV prevention		1/31/2017	day meetings		covered in other activities	NASCOP	Q1 2017
Finalize LMIS tools	incl lab		11/30	day meetings		covered in other activities	NASCOP	Q1 2017
Develop distribution plans (PrEP and Lab commodities)	which facilities are offering, quantities, tool availability,		11/30	day meetings		covered in other activities	NASCOP	Q1 2017
Lobby for inclusion in essential drug list			3/31	day meetings		covered in other activities	NASCOP	Q2 2017
document patient views on package for discussion with manufacturers	survey report		3/31	day meetings	$ 3,240.00	2 meetings of 30 people; 3 facility visits by 3 people; allowances for NASCOP officers for 3 days at $140; fuel for 3 days $300	NASCOP	Q2 2017
Annual Data Quality Assessment(DQA)	DQA report		Annual	meetings, field visits,		covered in other activities	NASCOP	
Quarterly support supervision	Supervision report		Quarterly	meetings, field visits,		covered in other activities	NASCOP	

Activities	Key outputs	Timeline		Resources needed (day meetings, Residential meeting, Consultants etc.)	Budget	Budget Assumptions	Responsible persons	Priority for next 3 months
Develop National SOPs guide book	SOPs guide developed		28/2/2017	day meetings		covered in other activities	NASCOP	Q1 2017
Monthly Stock status monitoring	Monthly stock status report		Monthly	day meetings		covered in other activities	NASCOP	
Printing of tools i.e. SOPs and job aids	Tools printed		28/2/2017			covered in other activities	NASCOP	Q1 2017
Dissemination of tools i.e. SOPs and job aids	Tools disseminated		28/2/2017		$ 1,015,230.00	covered in other activities	NASCOP	Q1 2017

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