REPUBLIC OF KENYA

MINISTRY OF HEALTH

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

NASCOP

National AIDS and STI Control Program

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Foreword

Kenya has made commendable progress in the HIV response, achieving a decline in prevalence among adults (15 -49 years), from a peak of about 10% in the mid-1990s to 4.5% in 2020. Prevalence in Kenya continues to be significantly higher among females (5.8%) than males (3.1%). The epidemic is generalized across the country, with clear concentrations among sub-populations and in some geographical locations. The HIV epidemic in Kenya is characterized as concentrated among key and vulnerable populations, who disproportionately bear the burden of infection. NASCOP therefore targets these populations with a combination of behavioral, biomedical, and structural interventions that are tailored to reduce their HIV risk and vulnerability while scaling up PrEP as an effective HIV prevention approach for all populations at risk.

The HIV epidemic not only affects the health of individuals, but also impacts on households, communities and the development and economic growth of nations. Many countries hardest hit by HIV suffer from other infectious diseases, food insecurity and serious social problems. Stigma, discrimination, socioeconomic inequalities, and exclusion are barriers to attaining the global goal of controlling the spread of HIV. Kenya was one of the first countries in sub-Saharan Africa that rolled-out oral PrEP to reduce the rate of new infections among the various sub-populations vulnerable to HIV infection. The Country participated in the clinical trials and implemented demonstration studies to provide context specific data that informed national roll-out of oral PrEP.

The Kenya AIDS Strategic Framework 2020/21 - 2024/25 (KASF II) recognizes some of the high-risk groups as Key and vulnerable populations for HIV programming in the road towards achieving epidemic control. This, coupled with an unsupportive policy and legal environment, puts such populations at higher risk of contracting HIV and infecting others. To address this gap, NASCOP Prevention Unit in partnership with community members, implementing partners, and donors, has developed this framework to standardize programming and the provision of PrEP services in the country.

It is our hope that this framework will enable the Country to reduce the number of new HIV infections by improving PrEP program coverage, quality, and effectiveness among all populations.

Dr. Patrick Amoth, EBS
Ag. Director General of Health
Ministry of Health

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 (TWG) 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), Jhpiego , LVCT Health, CIHEB-Kenya, 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.

Acknowledgements

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, the members of the National Technical Working Group (TWG) 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)
- Jhpiego
- LVCT Health and OPTIONS Consortium Partners
- FHI 360
- Clinton Health Access Initiative (CHAI)
- Global Evaluation of Microbicide Sensitivity (GEMS), University of Pittsburgh
- Kenya Medical Research Institute (KEMRI)
- Network of People living with HIV
- Kenyatta National Referral Hospital
- University of Nairobi
- Center for International Health, Education, and Biosecurity—Kenya (CIHEB-Kenya)
- International AIDS and Vaccine initiative (IAVI)

Special thanks to all implementers who have supported successful scale up of PrEP across the country and researchers who continued to generate new evidence on PrEP.
I also wish to acknowledge and appreciate the core writing team lead by Dr. Jonah Onentiah and Mary Mugambi (NASCOP)
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. Rose Wafula.
Head, Division National AIDs & STI Control Program.
Ministry of Health

Executive Summary

Since the inclusion of Pre-Exposure Prophylaxis in the Guidelines on Use of Antiretroviral Drugs for Treatment and Prevention of HIV Infection in 2016 and subsequent launch of the Framework for Implementation of PrEP in July 2017, the country has made significant progress in the scale up. PrEP is currently available across the 47 counties.

The country continues to document experiences on PrEP implementation from real life implementation and ongoing research on oral PrEP and other long-acting PrEP products. There was significant progress achieved towards achievements described in the Initial Framework Launched in 2017. PrEP has successfully been integrated in the HIV combination prevention package with focusing shifting to decentralizing PrEP from the HIV Care Clinics and wholistic integration with other services such as contraception, general outpatient etc. Additionally, adoption of new service delivery models such as community delivery, and adoption of technology such as telemedicine with the aim of increasing accessibility and acceptability of PrEP.

This framework adopts 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.

It provides key highlights on learning from implementation of oral PrEP at scale since 2017and an updated value chain analysis as at 2022 and updated rollout scenarios for continued scale up of Oral PrEP and for adoption during introduction of new products.

Focus Areas for PrEP Implementation

1. **Leadership & Governance**
2. **Service delivery**
3. **Health Products & Technologies**
4. **Communication, advocacy and Community engagement**
5. **Strategic Information**
6. **Resource Mobilization and Financing**

The framework views the delivery of PrEP in six focus areas that will ensure a comprehensive approach to implementation. They include; **Leadership & Governance Service delivery, Commodity security, Communication, advocacy and Community engagement, Strategic Information and Resource Mobilization and Financing**. The focus areas identified within the framework aim to address the **availability, acceptability, accessibility of PrEP and the holistic integration** of PrEP into the national HIV combination prevention strategy, with the goal of reducing HIV in Kenya.

INTRODUCTION

Kenya has made significant progress in reducing new HIV infections but still falls short of targets in the Kenya prevention revolution roadmap. There are still some sub-populations in specific geographical locations that record high new HIV infections despite the options available in the prevention basket (HIV estimate report, 2020). This is evident that more options need to be made available. As a country, Kenya is known as an early adopter of new HIV prevention technologies. In 2015, the Kenya Pharmacy and Poisons Board approved the use of oral Pre-Exposure Prophylaxis (PrEP) as a HIV prevention method. The Ministry of Health went ahead to revise the guidelines on the use of ARVs for treatment and prevention to include oral PrEP.

In 2017, PrEP framework was officially launched, and implementation began after participating in clinical trials and demonstration studies. In July 2021, the Dapivirine vaginal ring was approved in Kenya as an additional technology for HIV prevention for women. The injectable long acting cabotegravir (CAB-LA) will soon be in the Kenyan market after going through the approval processes before implementation. Other products and technologies still at research stage, will go through approval processes prior to adoption. This framework seeks to provide a general guide on the in implementation and scale up of biomedical HIV prevention technologies in Kenya.

Policy documents that support PrEP service delivery in Kenya include: Guidelines on use of Antiretroviral Drugs for Treating and Prevention HIV Infection (2022), Kenya HIV Prevention Revolution Roadmap, Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya (2017-2022) and Kenya AIDS Strategic Framework (KASF) II (2020/21-2024/25).

HIV Situation in Kenya

The Kenyan Health Policy (2014-2030) prioritizes the elimination of communicable diseases including HIV and AIDS in line with the right to the highest attainable standard of health mandated by the Constitution of Kenya (2010). Despite the tremendous progress made in more than three decades of the HIV and AIDS response, the epidemic continues to be a significant contributor to the national disease burden.

The HIV prevalence in Kenya has significantly reduced from 10% in the mid-1990s to 5.9% in 2015 (KAIS, 2015 report) and currently 4.5%. (Kenya HIV Estimates, 2020). New infections declined from 75,000 in 2010 to 41,416 in 2019, a 44% reduction in new HIV cases. which is indicative of substantial progress, but short off the reduction by 75% as envisioned by 2020. New HIV infections among children declined from 18,000 to 6,806, while new HIV infections among adults declined from 56,000 to 34,610.

The HIV epidemic in Kenya continues to disproportionately affect females more than males and the burden of HIV remains highest for the age category of 15-29 years at 61%.

The epidemic shows a pattern of generalization across the country with concentration among sub-populations, and a mix of both in some geographical locations (Kenya HIV Epidemic Appraisal Report, 2021).

The geographical diversity of HIV prevalence ranges from a high of 20.1% in Homa Bay County to a low of 0.2% in Mandera and Wajir counties (Kenya HIV Estimates 2020).

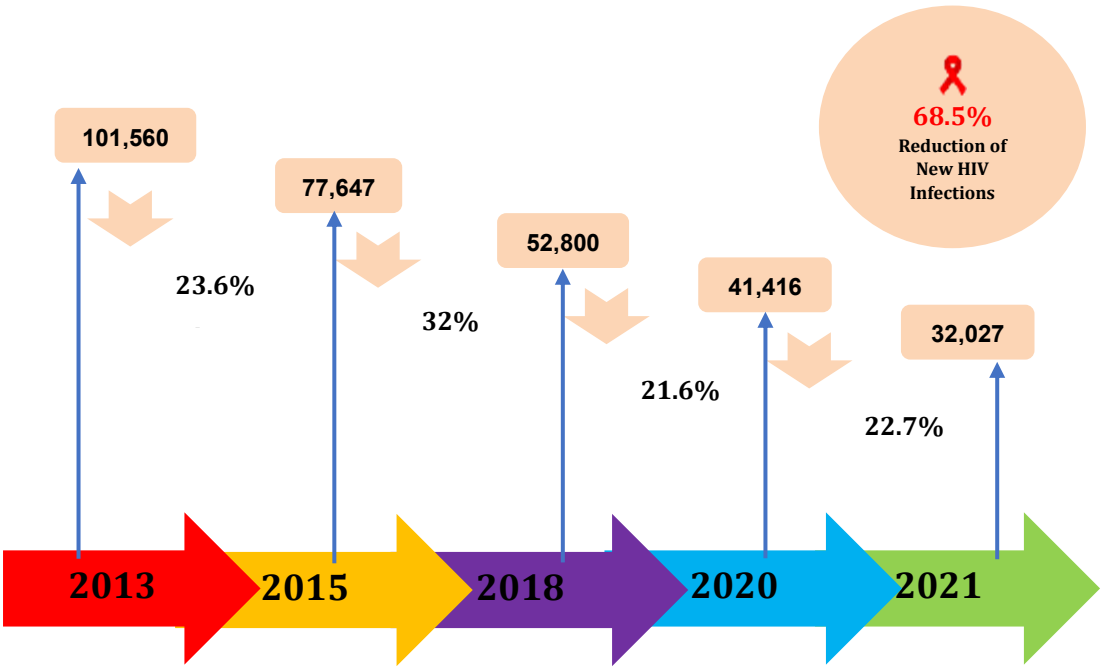


Figure 1: Reduction of HIV new infections 2013-2021

Kenya has made significant progress in preventing the transmission of HIV through the implementation of evidence-based interventions. According to HIV Estimates and projections for 2013, there were approximately 1.6 million people living with HIV of whom 191,840 were children while an estimated 101,560 HIV infections occurred compared to 32,027 new infections in the year 2021 HIV Estimates. HIV related deaths have significantly reduced over the years due to the increase of the number of people accessing treatment.

Kenya signed into the UNAIDS HIV goals of 90-90-90 by 2020 and though the overall performance shows that Kenya achieved these targets, certain sub-populations including children and adolescents did not. Treatment outcomes for adolescents and children remained low, gaps in knowledge of HIV status and high rates of vertical transmission (MTCT) are still a challenge. Kenya however, as a commitment to the new UNAIDS targets of 95-95-95, will continue to invest in interventions that address implementation gaps to meet these targets amongst the various sub-populations.

Kenya needs to accelerate progress in the reduction of new infections in view of the evolving HIV epidemic, emerging issues such as COVID-19 pandemic, the increasing role of new technologies and a rapidly changing society. Altogether, this requires an HIV prevention response that is persistent in its drive towards core objectives but reflecting innovation.

PrEP implementation in Kenya

Kenya was among the first countries in sub-Saharan Africa that rolled-out oral PrEP to reduce the rate of new HIV infections among vulnerable populations. Kenya participated in the clinical trials and implemented demonstration studies to provide context specific data that informed national roll-out of oral PrEP.

Kenya continues to align to the WHO guidance for new HIV prevention technologies as necessary. Introduction processes of the new technologies are anchored on global and local evidence. For that reason, Kenya participates in various stages of studies to inform decisions on adoption and implementation of approved technologies.

Since the launch of oral PrEP in 2017, Kenya has cumulatively initiated 157,538 individuals on PrEP as at December 2021, with 58,204 individuals reported as currently on PrEP as of the same period. (KHIS Dec 2021). PrEP is available in all the 47 counties in more than 2000 public and private health facilities.

The implementation has not been without challenges and the program has also learnt lessons that will inform introduction and implementation of new HIV prevention technologies.

Table 1: PrEP Implementation Challenges

Focus Area	Gaps	Mitigation Strategies
Leadership and Governance	• Conflicting policies Guidelines and Government Directives	• Develop client-centered policies
		• Strengthen multi-sectoral advocacy forums at national level
	• Non-vibrant County PrEP TWGs	• Revive and strengthen County PrEP TWGs
Service Delivery	• High self-discontinuation rates	• Enhance PrEP preparedness before initiation, intensify adherence counseling as well as linking to psychosocial support groups.
	• Negative attitudes among HCWs	• Continuous PrEP mentorship
	• Knowledge gap among HCWs and the community	• Capacity building of HCWs and other stakeholders
	• Weak link between biomedical, behavioral, and Structural intervention	• Strengthen the combination prevention approach
Commodity Security	• Stock out of HIV test kits and oral PrEP drugs	• Separate allocation of HIV test kits for HIV prevention
		• Strengthen PrEP drugs forecasting, quantification, and reporting
	• Packaging of PrEP resembling ART	• Advocate for non-stigmatizing packaging like blister packs for PrEP
Communication, Advocacy and Community Engagement	• Myths and misconceptions	• Demystify myths and misconceptions on PrEP through awareness creation
	• Infodemic (conflicting information on PrEP from different unverified sources to the users)	• Capacity building and sensitization of both community and HCWs. Community PrEP engagement forums. PrEP campaigns through road shows, health education in institutions and media platforms
	• Knowledge gap among service providers on how to conduct demand creation and advocacy	• Capacity building and sensitization of service providers
	• Sub optimal social marketing on PrEP use	• Community sensitization and demand creation on PrEP

Focus Area	Gaps	Mitigation Strategies
Strategic Information and Research	• Sub optimal reporting rates by facilities	• Capacity build HCWs on indicator definitions
	• Inadequate data collection and reporting tools in the facilities	• Provision of adequate M/E tools
	• Sub optimal utilization of Electronic Medical Records (EMR)	• Scale up EMR sites and use of PrEP module
	• Inadequate community feedback mechanisms	• Community PrEP forums and dialogue days
Financing and Resource Mobilization	• Inadequate domestic funding for PrEP implementation	• Advocate for domestic financing of HIV prevention activities at the counties.
		• Conduct costing and economic evaluation for PrEP implementation

Lessons Learnt

1. Client education on personal vulnerabilities and product information are important in helping the client decide to initiate and continue PrEP
2. Continuous capacity building of health care providers should also include values clarification training to address provider biases and attitudes that hinder service delivery.
3. Availability of HIV test kits and oral PrEP commodities is key in initiating and maintaining clients who are seeking oral PrEP as a prevention method
4. Ongoing demand creation for PrEP needs to be targeted and sustained at community and facility level
5. Peer-led models have proved to create a conducive environment and support for those on PrEP
6. Delivery of PrEP in private pharmacies has the potential to increase PrEP availability, access, acceptability and uptake among clients
7. There is a need to structure the introduction of new PrEP products /technologies ensuring engagement of all key stakeholders.
8. Meaningful engagement of the community and stakeholders in designing, implementation and monitoring PrEP delivery is important to promote acceptance and sustainability
9. Availability of data collection & reporting tools is key for successful PrEP programming
10. Integrating providers self-care activities in PrEP training help to navigate through different experiences that may hinder service delivery
11. Client centered integrated service delivery models help to remove barriers to service uptake.

Combination Prevention

Kenya adopted a combination prevention approach to HIV prevention. However, a lot of focus has been on biomedical interventions. Since no single intervention can address all the HIV prevention needs of individuals, there is need to strengthen linkages to the behavioral and structural interventions that is the gap affecting the impact of biomedical interventions. Oral PrEP has successfully, been integrated into the HIV combination prevention, the new products such as long acting Cabotegravir injection and future PrEP product and technologies will also be integrated by layering to offer client choice upon their approval by the regulatory authorities. The follow up schedules for clients on PrEP provide an opportunity to also implement behavioral interventions that may require clients follow up.

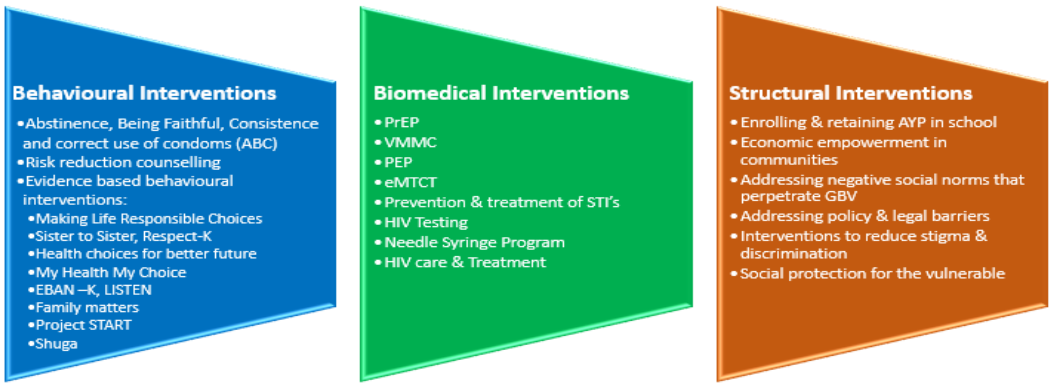


Figure 2: HIV Combination Prevention Options

More strategic interventions and investments need to be put in place to address issues of gender inequities, stigma and discrimination, gender-based violence, poverty and other factors that exacerbate vulnerabilities to HIV infections among adolescent girls and young women who continue to contribute significantly to the new HIV infections.

The PLHIV stigma index 2.0 (Kenya Country report, 2021), confirms that although tremendous progress has been made in reduction of new HIV infection in Kenya, HIV related stigma and discrimination remains a challenge in HIV response. There is delay in HIV testing attributed to fear of others knowing their status at 62.05%. Regarding ART interruption/stoppage, 47.15% attributed to a fear of being discovered to be HIV positive and 25.0% only attribute it to forgetfulness. These findings have a potential impact on PrEP implementation since PrEP initiation is dependent on HIV testing.

Integration of PrEP service delivery into Sexual Reproductive Health (SRH) services such as family planning clinics, Antenatal Clinics, Maternity and Post-natal Clinics can contribute to reducing new HIV infections among women of reproductive age who have disproportionately higher HIV prevalence. This also has the potential benefit of increasing PrEP uptake and reduce stigma. Screening for HIV risk and discussions on HIV prevention options available need to be institutionalized in all departments in a health facility. The potential benefit of these is to increase individual's awareness of their HIV risk and offer support to individuals' in making informed choice on HIV prevention interventions to take up including PrEP. Gaps still exist in programming for persons who inject drugs (PWIDs) who require ongoing supply of clean needles and syringes and other medically assisted therapies as a way of HIV prevention. The government needs to put more efforts in PWID and transgender (TG) programmes for sustainability of HIV prevention.

Key lessons on effective implementation can be learnt from family planning services, HIV care and treatment services to continuously inform introduction, scale-up and sustainability of new HIV prevention technologies. Policies need to be adaptable to accommodate new PrEP interventions as they emerge.

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.

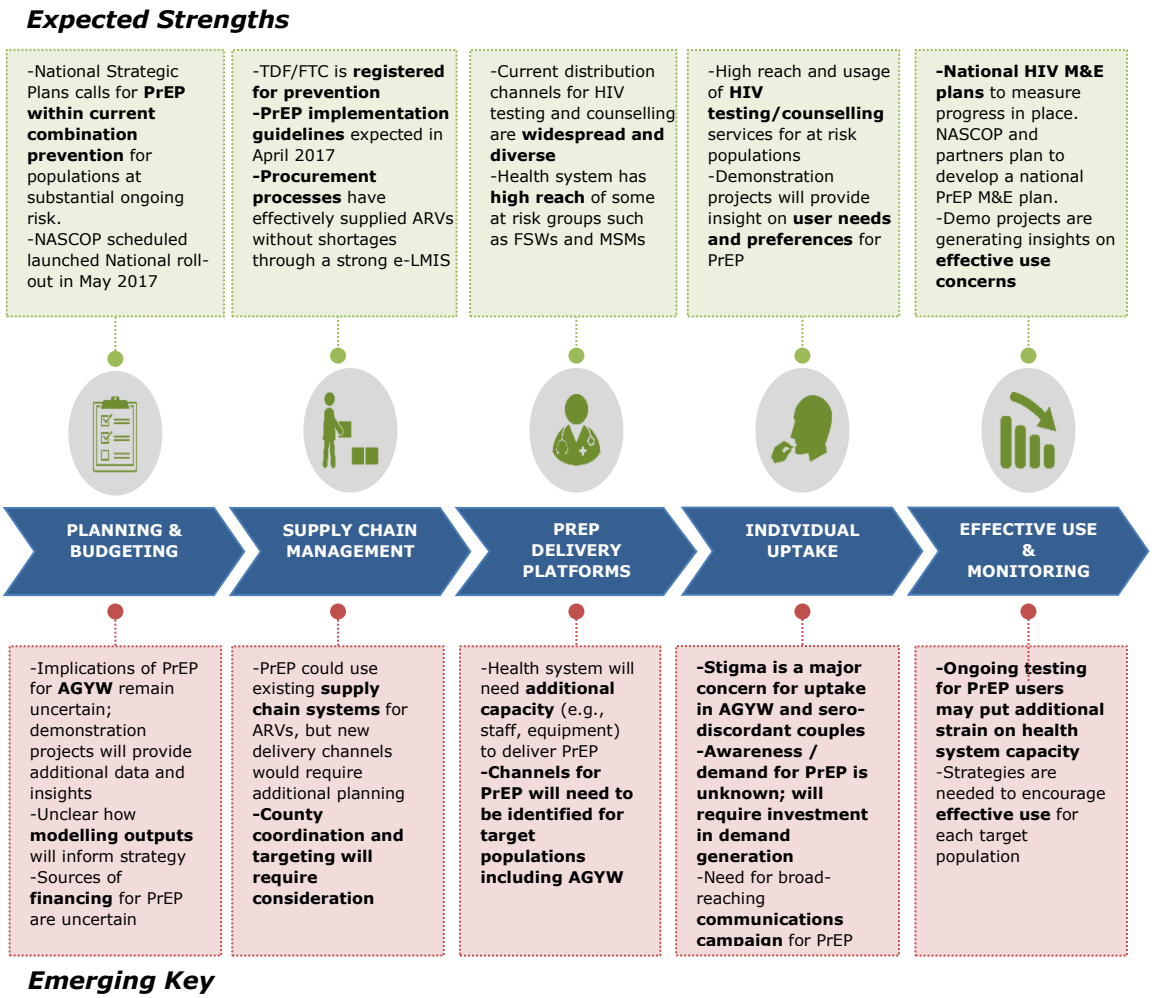
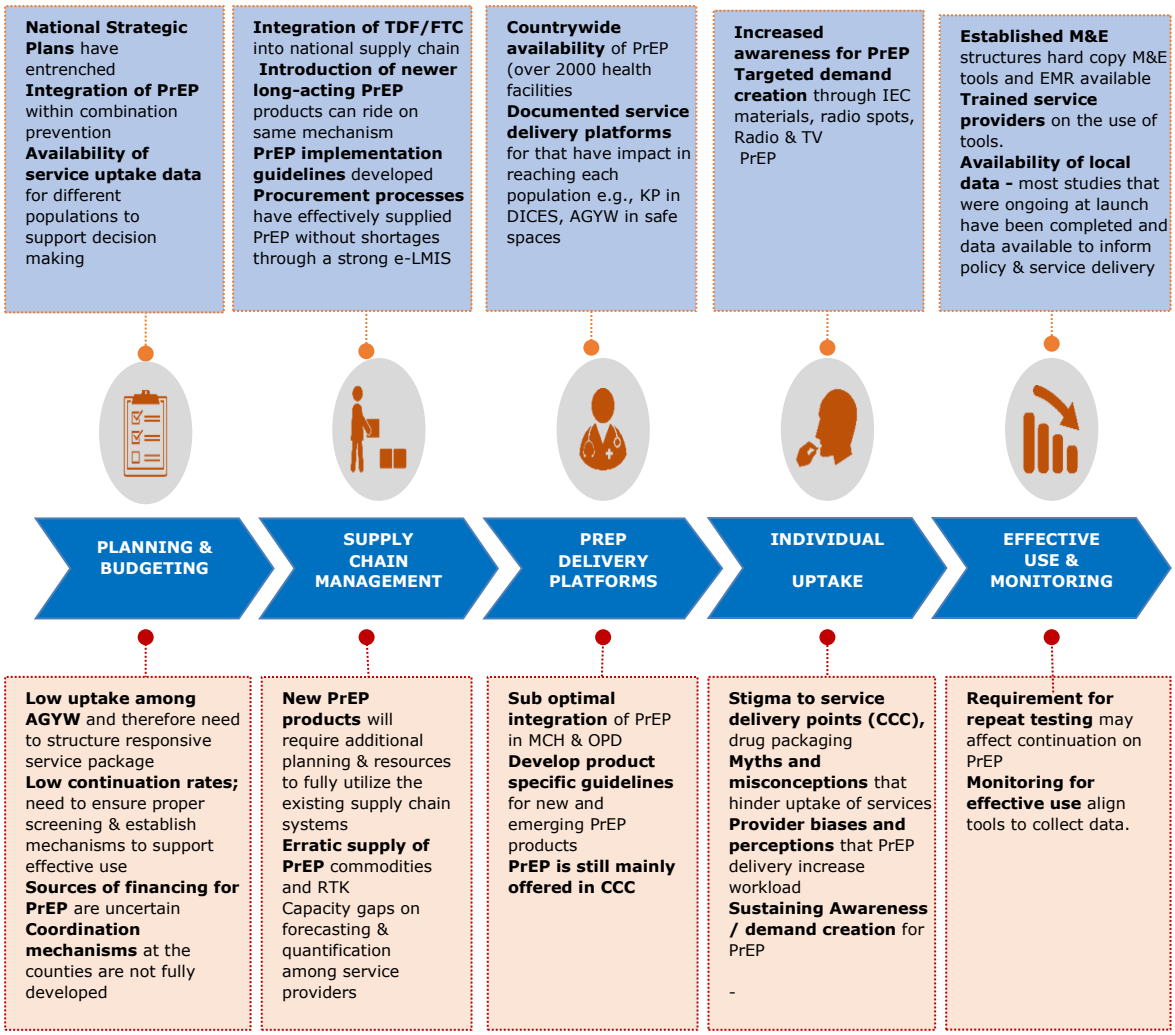


Figure 3: Value Chain Analysis for PrEP (2016)

A review of PrEP implementation across five-factor value chain five years after the launch of PrEP in the country shows that significant progress has been achieved across the five areas i.e. planning and budgeting, supply chain management, delivery platforms, individual uptake and effective use and monitoring. (Figure 4)

Expected Strengths



Emerging Key Considerations

Figure 4: Value Chain Analysis for PrEP (2022)

PrEP uptake has been increasing over time from 5,927 in 2017 to 82,986 in 2021 while PrEP current on PrEP has progressively increased from 1171 in 2017 to 58,204 in 2021 as shown in the figure 5.

This is an indication that with proper advocacy, availability of more PrEP options and availability of commodities, PrEP uptake is likely to increase. However, a further analysis on the patterns of use by clients initiated on PrEP needs to be done.

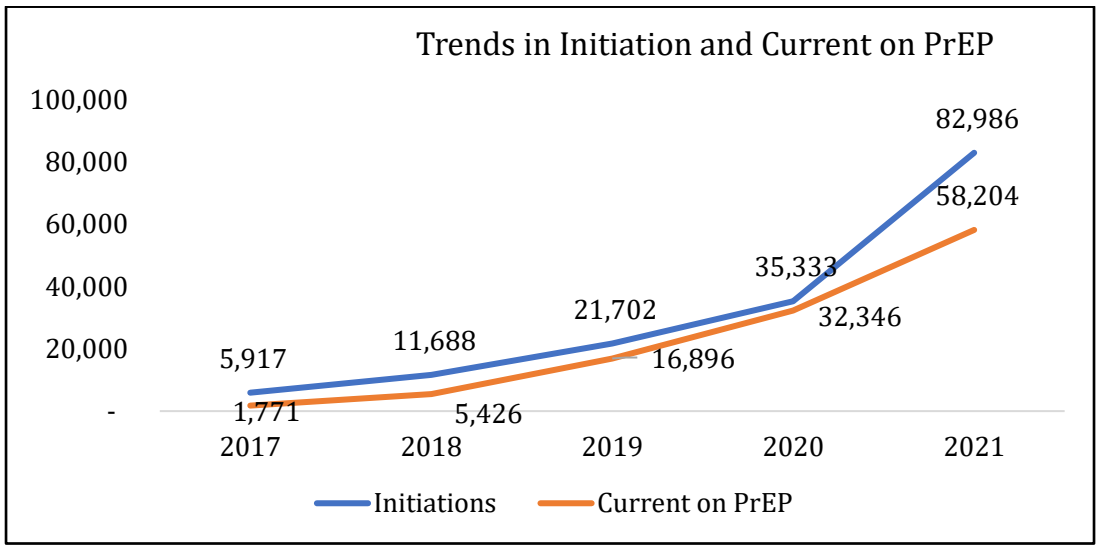


Figure 5: PrEP Uptake Trends (KHIS Data)

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 (FSW, MSM, PWID and Transgender), and Vulnerable populations (AYP, Discordant Couples, Fisher folk, Truckers). 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 continued focus on the scale up. Kenya's HIV epidemic is concentrated in several counties that would benefit most from PrEP access.

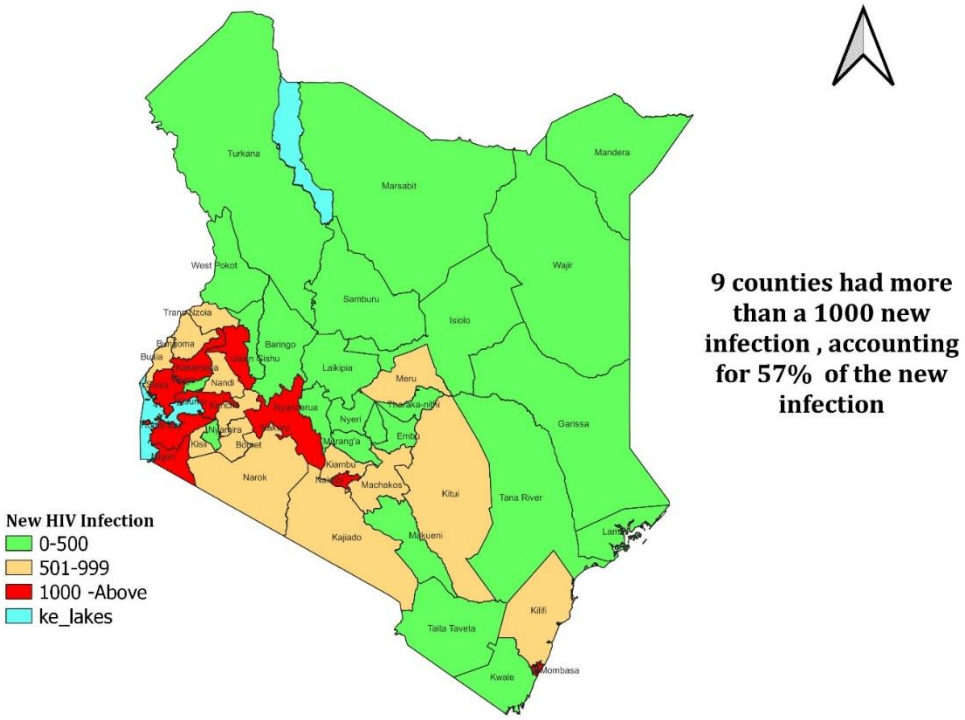


Figure 6: County HIV Incidence Clusters in Kenya, 2021

The counties with high burden of new infections are aligned with the Kenya Prevention Revolution Roadmap and the Kenya Aids Strategic Framework's geographic prioritization strategy.

Scale Up Plan

As the country continue to scale up oral PrEP and support introduction of new products, four potential prioritization approaches (Table 2) were evaluated based on the county incidence clusters, Scenario 3 was recommended by the National Technical working group as the best approach to support introduction of new products and to support continued rollout of oral PrEP

Table 2 : 2022 Kenya PrEP Rollout Scenario Overview

Scenarios	Priority counties	Percentage of new infections originating in priority counties	Size of population aged 15+ in priority counties
Scenario 1 Focus on counties with the highest HIV incidence among key and general populations	**4** counties Homa Bay, Kisumu, Migori, Siaya	**34%** (11,909) annual new infections among population aged 15+	**9%** (2.0M) of the Kenyan population aged 15+
Scenario 2 Scenario 1 + counties with large numbers of new HIV infections, particularly among key populations and AGYW	**9** counties **4** counties above + Busia, Kisii, Mombasa, Nairobi, and Uasin Gishu	**60%** (20,678) annual new Infections among population aged 15+	**36%** (8.5M) of the Kenyan population aged 15+
Scenario 3 Scenario 2 + a wider range of counties that are above the national average for HIV incidence and key population (KP) presence, with a focus on delivery to KPs	**14** counties **9** counties above + Kajiado, Kakamega, Kiambu, Machakos, Nakuru	**73%** (25,167) annual new infections among population aged 15+	**48%** (11.2M) of the Kenyan population aged 15+
Scenario 4 Scenario 1 + rollout to key populations and serodiscordant couples in all counties	**All counties**	**100%** (34,610) annual new infections among population aged 15+	**100%** (23.5M) of the Kenyan population aged 15+

Objectives

The objectives of this framework are aligned to the provision of HIV combination prevention package. This is through promoting acceptability, availability, access to PrEP and related services.

Availability

- To provide PrEP as part of HIV combination prevention to 500,000 individuals at ongoing risk to HIV infections within 5 years.

Acceptability

- To raise PrEP awareness to 80% of the population
- To increase uptake of PrEP in health facilities, potential PrEP users and the general public through targeted communication, community awareness and social mobilization

Accessibility

- To increase availability of PrEP and capacity of PrEP delivery services in 100% of care and treatment facilities and private facility

Integration

- To integrate PrEP into HIV prevention and reproductive health policies, programs and other primary care services
- To support integration of PrEP services into outpatient care services and sexual reproductive health services

Impact

- To determine the impact of PrEP through integrated surveillance and research, mathematical modelling and other appropriate approaches

FOCUS AREA 1: LEADERSHIP AND GOVERNANCE

This section outlines the requisite leadership and governance structures for effective coordination, implementation, and regulatory mechanisms for PrEP programs in Kenya. This PrEP Framework is aligned to the Constitution of Kenya 2010 and the Kenya AIDS Strategic Framework II (2019/2020- 2024/25). This document recognizes the distinct roles of the national, county governments and other stakeholders. The national government is responsible for policy formulation, regulation, oversight and technical assistance to the counties while county governments and implementing partners are responsible for operationalization of policies and guidelines.

The counties provide leadership on implementation planning, adaptation and dissemination of guidelines and policies, capacity building, community engagements and coordination of stakeholders. The coordination and implementation of the PrEP program at the national and county level is done through Technical Working Groups (TWGs). The national TWG is coordinated by NASCOP and the County TWG is coordinated by CASCO. County governments through the department of health are expected to advocate for PrEP inclusion in the county implementation and development plans and health budgets for sustainability. All PrEP stakeholders will be accountable for resources and results.

Multisectoral engagement plays a pivotal role in the success of implementation of the PrEP program as guided by the PrEP framework. Meaningful multisectoral engagement leads to increase in awareness, acceptability and consequently demand for and access to PrEP services. Multisectoral engagement helps to understand priorities and gaps in HIV prevention.

All stakeholders have a role in advocating for investment in PrEP products and services towards HIV prevention interventions. For successful implementation, there is need to consider other models of delivery of PrEP services like community-based delivery approaches and use of technology. The approaches may include telemedicine/ tele-health, E- Health, pharmacy delivery and community-based delivery among others. These approaches will also guarantee continuity of services during emergency situations as learnt during COVID-19.

To enhance continued access for PrEP to people who are vulnerable to HIV, adoption of task shifting/sharing guidelines for PrEP services delivery and utilization of differentiated approaches outside the traditional healthcare facilities is key as evidence of their effectiveness emerge.

Leadership and Governance structure

Effective leadership is a vital component for PrEP delivery and has an extensive range of functions in improving effectiveness and efficiency of the health care system. Leaders at National, county, sub-county, health facilities and community levels provide guidance in PrEP program by creating enabling environment, analyzing situations, and dealing with emerging issues in delivery of PrEP products.

Stakeholder Roles

Different stakeholders have key roles for successful implementation of PrEP. These ranges from policies, leadership and governance, resource mobilization, service delivery, demand creation, monitoring and evaluation among others.

Table 3: PrEP Stakeholder Roles

Stakeholder	Roles and Responsibilities
Ministry of Health,	Development of policy, resource mobilization, financing, provide leadership and governance.
NSDCC, NASCOP, NPHL	Development of guidelines, provision of strategic information, commodity security through forecasting and quantification, technical and implementation assistance, drug resistance surveillance, quality and standards.
County Governments	Service delivery, implementation planning, dissemination of guidelines, capacity building, M&E, Domestic resource mobilization for PrEP service delivery.
Health regulatory bodies	Certification of clinical practitioners, product registration and approvals, oversight rational use of PrEP
Health Products & Pharmacovigilance	Procurement and supply chain management of PrEP to health facilities; service delivery points
Development Partners	Support service delivery, policy and guidelines development and implementation, financing, Transition support to county government, generate normative guidance on PrEP
Implementing Partners	Support service delivery, policy and guidelines implementation, generate evidence, dissemination of guidelines and best practices through operational research on PrEP
Research Institutions and Academia	Conduct research, Publish, disseminate findings and capacity building on PrEP
Media	Create awareness and demand for PrEP use
Faith Sector	Provide support to users, sensitize congregation on PrEP, address stigma, create a conducive environment
Community and opinion Leaders	Provide support to users, reducing stigma and discrimination, create a conducive environment, sensitize communities on PrEP
General Public	Users of PrEP, demand creation, provide feedback on PrEP use.

FOCUS AREA 2: SERVICE DELIVERY

This section addresses service provision approaches and operations around PrEP implementation including identification of PrEP clients, initiation and method switching, client follow-up mechanisms, capacity strengthening, data management and quality improvement for program monitoring.

For this framework, PrEP and dosing strategies include Daily Oral PrEP, Event Driven PrEP for people assigned male at birth who are not using estradiol-based exogenous hormones and monthly Dapivirine vaginal ring. The Framework is however cognizant of the other products that are in different stages of research and approval that may become available during the life of the framework and therefore provides guidance on their adoption. These studies may include long acting Dapivirine ring, long-acting dual prevention ring, injectables like Cabotegravir (CAB-LA), long-acting orals, implants, patches, antibodies, and multipurpose technologies.

The delivery of PrEP through the health system provides the opportunity to strengthen existing services and reinforce integration between complementary services including HIV and reproductive health. With HIV testing as the gateway to PrEP initiation, other novel approaches such as the use of HIV self-testing that is under study should be explored to provide an additional strategy for establishment of eligibility for PrEP.

Service Delivery Models

The country has been implementing both facilities based and community-based delivery of PrEP. Within the health facilities irrespective of the level of health care, PrEP should not be offered as a standalone service but should be integrated within other services in inpatient and outpatient care including specialized clinics such as Antenatal, Family planning, medical, surgical clinics etc. The preferable model of integration is one stop-shop where client is offered all services by one provider. However, the level of integration may vary in different departments depending on the capacity of the provider and the service delivery point. (Figure 7) Efforts should be made to decentralize PrEP from the HIV Care Clinics in an effort to foster accessibility and acceptability of PrEP.

Community service delivery models have been instrumental in moving health services closer to the people. In the context of PrEP, the range of services may include; targeted communication, demand creation, advocacy, initiation and follow up of PrEP clients and support to individuals taking up health services. Integration of HIV prevention services into community health systems offer opportunities to simplify implementation of PrEP by increasing efficiency. Delivery of PrEP in the community should also be integrated in nature and can ride on the already existing community service delivery models for other services such as community FP or ARV distribution.

Adoption of new community service delivery models is also recommended as evidence of their effectiveness becomes available. Some of the existing and emerging health platforms and innovations such as; private pharmacy delivery of PrEP, Online pharmacies, use of ATM dispensers and telemedicine are at different stages of research and are showing promising results. These will be considered for scale up upon completion of the research studies. However,

prior to adoption of these models, it is paramount to clearly describe the commodity supply chain and monitoring and evaluation structures to ensure accountability and availability of data. It is important to note that the standard M&E tools may require to be reviewed and adapted for that context.

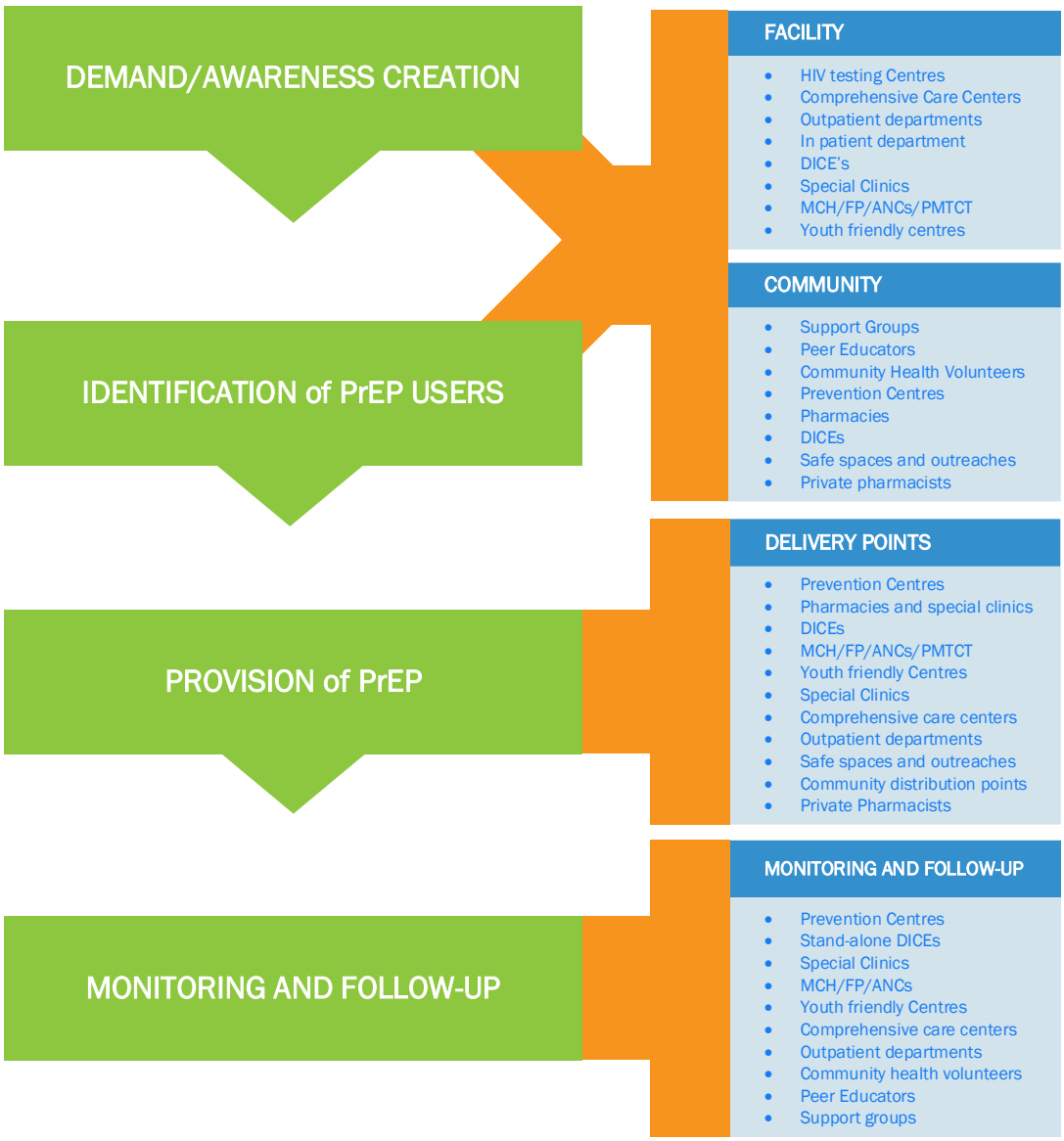


Figure 7: Community and Facility Based Delivery Model

Client Management in Service Provision

All potential PrEP clients will undergo behavioral assessment using the standard risk assessment questions, eligibility assessment, clinical evaluation and counselling prior to initiation of PrEP. . During counselling the clients will be informed of the options available for use as PrEP and be supported to make an informed choice. Clients on PrEP will be followed up and assessed routinely as indicated for the different PrEP methods as per the national Guidelines for the use of ARVs for Treatment and Prevention of HIV. Clients will be allowed to switch between different PrEP methods as per their needs and/or as defined in the guideline. Clinical assessments such as adherence monitoring, adverse drug reaction/events monitoring, laboratory investigations are recommended for various forms of PrEP as stated in the guidelines.

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 clients, service delivery points where clients will be initiated and followed must meet minimum requirements (Table 4). At entry points where only identification is possible, providers will be equipped with skills and knowledge to sensitize, and link identified clients to PrEP service delivery points. Health education sessions will be done at the service delivery points to inform potential clients about PrEP with the intention of increasing uptake of PrEP as part of combination prevention package and making informed choices on PrEP methods. Service providers will be expected to follow the Flow Chart of PrEP Service Package as outlined in the national guidelines.

Table 4: Minimum Requirements for Service Provision

Human Resource	Infrastructure	Commodity management	Monitoring and Evaluation
Availability and Training of: ✓ **HTS providers** ✓ **Records Officers** ✓ **Clinicians,** ✓ **Peer Educator/ Community Volunteers**	✓ Service delivery points/rooms ensuring privacy for client) (Can be integrated) ✓ Access to laboratory services (offsite, onsite).	✓ Availability of PrEP Commodities ✓ Availability of commodity management tools ✓ Proper documentation, reporting & ordering ✓ Carryout Pharmacovigilance	✓ Availability of PrEP data tools ✓ Proper documentation and timely reporting ✓ Electronic Medical Records for data management

Management and follow up of PrEP clients will be done by a multidisciplinary team including PrEP champions to support effective use of PrEP.

HIV risk assessment and reduction counselling will be conducted as per the guidelines, to establish the need for continued PrEP use. 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 are in place for those who seroconvert to monitor for HIV drug resistance. The program will also continue monitoring for sexually transmitted infections (STIs) among individuals using PrEP.

PrEP is prescribed by licensed practitioners who have completed training on the national guidelines for the use of ARVs as PrEP. Additionally, opportunities for self-care, task shifting, and sharing have been identified through the PrEP continuum to increase PrEP uptake and continuation and are implemented as per the National ART guidelines.

Capacity Strengthening

PrEP is not a standalone intervention and hence it is integrated in the existing HIV training programs which is an on-going process to ensure service providers are adequately trained and competent. Capacity strengthening of health care providers on PrEP delivery is conducted through In-service and Pre-service training.

A cascade approach for training of both health workers and PrEP champions is utilized. This includes training of master Trainer of Trainers (TOTs) at national and county level who then build capacity of health workers and PrEP/champions through site based modular training and mentorship. Training is tailor made for specific cadres based on their roles. Staff at facilities are continuously trained through continuous medical education (CME) forums or on-job-training. Training of PrEP modules will be delivered through various modalities including tele and video conferencing, online learning, and in-person meetings.

Quality Improvement

The PrEP monitoring and evaluation framework for Kenya guides and measures performance of the program at the National and County levels. Oral PrEP uptake and continued use has been suboptimal thus quality improvement methodologies need to be intensified to improve these outcomes for all PrEP products. Supportive supervision, mentorship and service quality assessments for PrEP uptake and use will be done quarterly and on-demand to ensure continuous quality improvement (CQI). This should be embedded at both county and facility level CQI teams. The core responsibilities of health service providers under CQI will be to take into consideration feedback from clients, data trends and service quality assessment reports to provide services that are of the highest possible standards and meet the needs of individual service users, their families, and communities.

Public Private Partnerships

Private facilities complement services offer by the public sector and have the potential to contribute towards expanding access to quality PrEP services. Key lessons can be learnt from successful delivery of HIV self-test kits through public private partnerships (PPP)where individuals can purchase HIV self-test kits from private pharmacies for those who do not wish to access kits at the public facilities and online platforms. Lessons learnt from this, and other PPP engagements will be adopted to improve efficiencies in PrEP delivery through the private sector. There is need to harmonize reporting for PrEP delivery in private sector to align with the national reporting mechanisms. The Private Sector Engagement Framework will provide further guidance once finalized.

Commodity logistics for PrEP

PrEP commodities are integrated into the national logistics management system and availed to facilities through the national supply chain mechanism to ensure continuous supply. PrEP commodities are included in the HIV forecasting and quantification from facility to county to national level. The facility consumption data report and request (FCDRR) should be done in a timely manner to avoid stockouts (see focus area 3 on commodity security).

FOCUS AREA 3: HEALTH PRODUCTS AND TECHNOLOGIES

Commodity security (CS) is the ability to choose, obtain and use affordable health commodities when and where they are needed. This entails access to regular supply of available essential health commodities as a necessary part of primary health care services. Access and availability of commodities to users underpins the success of PrEP implementation. It is a critical pillar in the achievement of the objectives stipulated in the Kenya AIDS Strategic Framework II (KASF II) and the HIV Prevention revolution roadmap.
PrEP delivery is reported through the KHIS, and the data is used for forecasting and quantification.

The following are the objectives of Commodity Security.

1. To guide forecasting and quantification of PrEP products.
2. To strengthen monitoring of PrEP products through Pharmacovigilance.
3. To identify and mitigate bottlenecks of PrEP access.
4. To strengthen PrEP supply chain and reporting.

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

Product Selection

The preferred oral PrEP regimen, Tenofovir/Emtricitabine (TDF/FTC), and the alternatives, Tenofovir/Lamivudine (TDF/3TC) and Tenofovir (TDF) are part of the essential commodities for HIV prevention. The long-acting products such as Dapivirine vaginal ring (approved by PPB), Long-acting injectable Cabotegravir (under review for approval) have recently been included in the guidelines and will later be included in the essential commodities. Other long-acting products e.g., orals are at different stages of research and will be incorporated when they become available.

Procurement

Procurement of the PrEP products is based on national annual quantification and forecasting guided by the annual national PrEP targets and product consumption data reported in KHIS/LMIS. At entry level of new PrEP products forecasting and quantification will be based on the estimated need. PrEP commodity procurement process follows the process outlined in the public procurement Act. Any donations are managed in line with drug donation guidelines.

Warehousing and Distribution

Once PrEP commodities are received in-country, they are delivered to the supply agencies for warehousing and distribution alongside other HIV commodities. The distribution to the facilities is based on the national commodity management guidelines.

ARVs for treatment have been scaled up beyond public and faith-based health facilities into private health facilities and drop-in centers (DICEs). PrEP provision has largely followed a similar pattern, however, new ways of reaching untapped populations need to be considered. These could include private sector retail points, PrEP dispensing machines 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

Effective use of PrEP by clients during periods of potential HIV exposure is imperative for users to maintain a HIV negative status. Monitoring drug adherence will therefore be an important function to ensure rational use of PrEP products. Adherence monitoring mechanisms already exist in most facility and community-based service delivery points. These mechanisms will continue being used to enhance client support and optimize HIV prevention.

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

a. Monitor adverse drug reactions (ADR) using existing Pharmacy and Poisons Board (PPB's) forms and any hypersensitivity reactions to PrEP documented using Patient Alert Card.
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 are documented using the Poor-Quality Medicines Reporting Form.

Logistic management information systems (LMIS)

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

To improve LMIS, continuous capacity strengthening of healthcare workers in commodity management should be done to ensure a responsive supply chain of PrEP commodities. Generating accurate assumptions for annual forecast and quantification to determine PrEP commodities requires strong LMIS mechanisms to provide the necessary consumption and PrEP service data. Monthly stock status monitoring and reporting tools for PrEP commodities (i.e., daily activity register-DAR for ARVs, FCDRR, Facility Monthly ARV Patient Summary Report-FMAPS and monthly HIV service delivery summary tool) will be availed to PrEP delivery sites to inform re-supply decisions.

New product Introduction

Manufacturers are expected to meet legal requirements during the introduction of new products such as the provision of product samples to the Kenya Bureau of Standards and National Quality Control Laboratory for quality checks and certification in compliance with national policy regulations adopted by the Ministry of Health. MOH recommends studies e.g., demonstration studies, implementation science studies among others that generate local data and evidence to inform roll-out and scale-up of PrEP methods.

In Kenya, the Pharmacy and Poisons Board (PPB), established under Chapter 244 of the Pharmacy and Poisons Act (2002), is responsible for the registration of pharmaceuticals and medical devices. This includes an essential drugs list, using WHO guidelines, the objective of which is to promote the availability of quality pharmaceutical products at affordable prices.

FOCUS AREA 4: COMMUNICATIONS, ADVOCACY AND COMMUNITY ENGAGEMENT

This section outlines how to successfully launch, implement and sustain demand for PrEP products in Kenya. It gives guidance on effective approaches to reaching communities and stakeholders with correct, consistent and timely information on PrEP services. PrEP promotion requires a detailed communication plan[1] that outlines enhanced choices for the user and a transparent relationship with all stakeholders. This will also help address stigma and discrimination and other prohibitive factors that affect uptake, effective use and continuation of PrEP services.

Objectives of PrEP Promotion

1. To increase and sustain knowledge of PrEP products and services among targeted sub-populations.
2. To increase demand and effective use of PrEP products amongst the target audience.
3. To create a positive perception and improve the attitude towards PrEP amongst all stakeholders.

Situation Analysis

Key milestones have been made in communications, advocacy and community engagement since the introduction of PrEP in Kenya (2017) including user-centered design of messages, implementation of national communication campaigns (*Jipende JiPrEP*), and national level advocacy interventions. Despite the milestones made in demand creation, there are challenges that remain unaddressed. Conducting a Strength, Weakness, Opportunity, and Threats (SWOT) analysis based on the context is key in identifying these challenges. Table 5 provides guidance on the SWOT.

[1] National HIV Communication Guide 2021

Table 5: Communication SWOT Analysis

Internal	**Strengths** • Engagement of target audience in development of harmonized messages at national, county and community level. • Market research to inform evidence-based PrEP implementation and In-depth understanding of the population • Investment on Human Centered Design (HCD) • Evaluation of the demand creation models • Availability of PrEP audio visual materials for PrEP promotion • Availability of a combined communication strategy. • Availability and implementation of PrEP demand creation, advocacy and communication plan.	**Weaknesses** • Inadequate domestic funding on PrEP activities • Sub optimal messaging on use and dissemination of PrEP information • Inadequate community feedback mechanisms-- Weak Monitoring and Evaluation mechanism for advocacy and communication strategies. • Inadequate advocacy strategies for buy-in and support from different stakeholders.
External	**Opportunities** • Global environment is receptive to scale up of PrEP • Kenya classified among priority countries globally in scaling up PrEP • Leveraging on information and communication technology to promote PrEP products use. • Readiness of healthcare facilities to promote PrEP use. • Existence of oral PrEP campaign to incorporate upcoming PrEP products. • Global focus on AGYW and key populations • Leverage on Community health strategy for demand creation • Strong PrEP champions	**Threats** • Inadequate funding for demand creation • Cultural and religious barriers • Emerging issues e.g. Pandemic and Emergencies that hinder implementation of communication strategies (COVID-19, Political instability) • Infodemic (Conflicting information on PrEP from different unverified sources)

PrEP Demand generation

The demand generation process should endeavor to communicate PrEP within the combination prevention[2] context. It entails a full range of Social Behavior Change (SBC) strategies to increase and sustain awareness and creation, and effective use of PrEP. It should be evidence-based (studies, baseline/end line and routine program data) to address emerging social, behavioral determinants and underlying contextual factors that increase HIV risk and vulnerability. Some of the barriers to effective demand generation include lack of awareness, low risk perceptions, self-efficacy, prohibitive cultural and religious beliefs and practices, negative attitudes, knowledge and skills.

Message development should explore the use of Human-Centered Design (HCD) approach that includes user needs assessment, insight generation, co-creation, pre-testing, and rollout of successful strategies and messages.

Planning and costing: There should be deliberate effort to develop an annual work plan and budgets for demand generation activities. This is an activity that should be undertaken by the communication subcommittee of the TWGs both at the national and county levels involving development and implementing partners.

Implementation: Demand creation of PrEP should be guided by the national HIV communications strategy. Capacity building (training, mentorship, OJT, refresher training) of demand generators and service providers should be conducted regularly to sustain demand for PrEP. Job aids are instrumental in enhancing demand generation. A 360-degree approach should be employed by stakeholders whereby demand generators take an informed and holistic view of the entire PrEP client's journey – from discovery, all the way through to PrEP uptake and continued use, with an informed and data-led action plan designed to move this process along as smoothly as possible.

[2] https://www.malecircumcision.org/resource/human-centered-design-approach-demand-creation-vmmc-zambia-and-zimbabwe

Some of the communication approaches that can be applied include:

Above the line – Used when the focus is on mass media promotion to reach a large audience. These includes Mass media like TV, Radio, digital media, and billboards.

Below the line – Diverted to reach a small, targeted audience and these include, interpersonal communication, brochures, direct mails, flyers, social media messages, emails, and Print media.

Monitoring and Evaluation: There is a need for an established M&E mechanism for PrEP demand generation. This will include defining demand creation key performance indicators, M&E tools including surveys, and incorporation into KHIS2.

[2] Reaching and Targeting More Effectively: The application of market segmentation to improve HIV prevention programmes, https://www.prepwatch.org/resource/reaching-targeting-effectively/

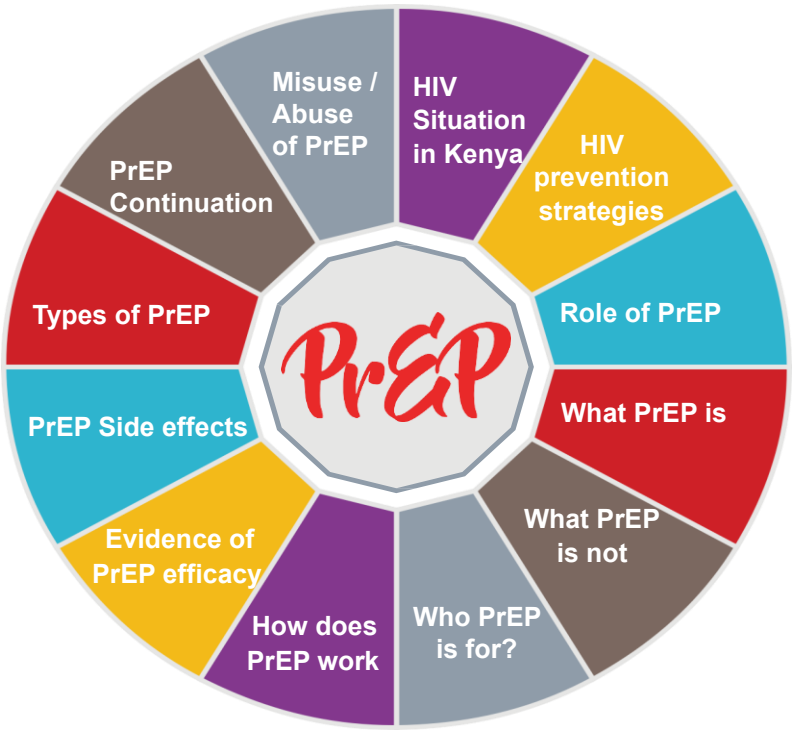


Figure 8: Topics on PrEP Communication

In reference to figure 9, the delivery of the message will be tailored to suit the targeted population. Specific considerations on communication channels are required to reach targeted populations for example, more use of social media platforms to reach young people as opposed to policy makers who may need more formal channels.

PrEP Positioning Statements

PrEP positioning refers to the place PrEP occupies in the mind of clients.

Communication, demand creation and advocacy should take into consideration all key stakeholders using, offering or supporting service provision including but not limited to potential users, faith sector, local authorities, community gatekeepers, healthcare workers, parents, and caregivers among others.

The following positioning statements will underpin and guide communications activities:

1. PrEP methods are self-care interventions for HIV negative individuals who are vulnerable to acquiring HIV to protect themselves.
2. Effective use of PrEP products reduces the chance of acquiring HIV.

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

Table 6 outlines the communication needs by the target audience at different phases. For majority of the target audience, it addresses awareness, knowledge and attitudes towards PrEP. Figure 8 highlights the various stakeholder's roles in PrEP communication.

Table 6: 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 change
Phase 2: Health care workers, Implementing partners, researchers, key and priority population	Awareness, knowledge and attitude change
Phase 3: Current and potential users	Knowledge, attitude change, increased and sustained use

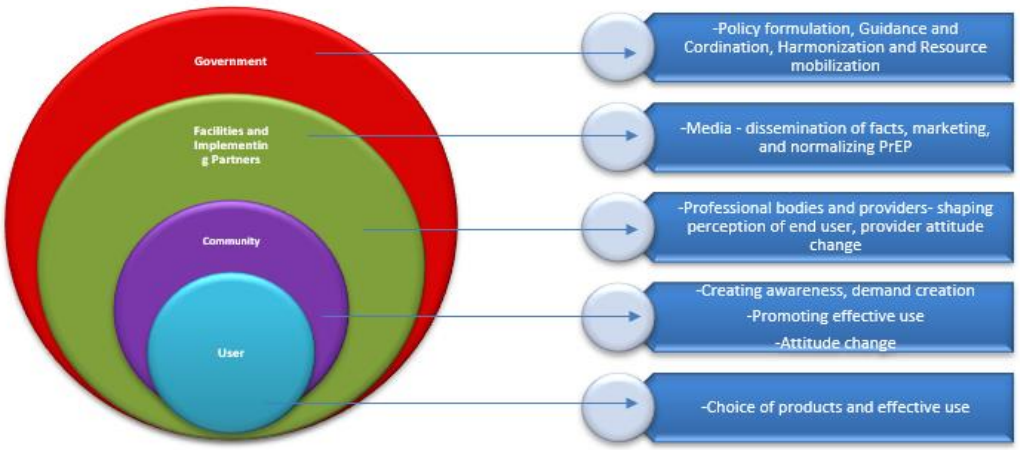


Figure 9: Stakeholders Roles in PrEP Communication

Advocacy

Advocacy[3] is aimed at influencing decisions at various levels to support successful implementation of PrEP. There is need to strengthen adaptive structured advocacy strategies at the grass root level in collaboration with community advisory boards, influencers, opinion leaders, champions among others to increase acceptability of PrEP services and reduce stigma and discrimination. Advocacy efforts should aim to strengthen and amplify the voices of end users at the community level. Policy and advocacy forums at county and national levels are instrumental in ensuring increased access, uptake and adequate resource allocation for PrEP implementation. Current PrEP users will be powerful advocates of PrEP through their testimonials.

Table 7: Advocacy Strategies at Different Levels

Advocacy Level	Advocacy Strategies	Target stakeholder
Community Level	• Community PrEP Engagement forums	• Community Advisory boards, Opinion leaders, religious groups, Community Units, PrEP Champions, and ambassadors
	• PrEP Campaigns through road shows, Health/PrEP education in institutions	• General community, Higher Institutions of learning, workplaces
County	• PrEP engagement forums	• MCAs, Other ministries -Education, Executive leadership, CHMTS, Implementing partners, Private Sector (PPP)
	• Advocate for domestic financing of HIV prevention activities	• MCAs, Executive leadership, CHMTS, Implementing partners
National	• Engagement forums on PrEP	• MOH, MOE, Donors, Development Partners

[3] https://www.ncbi.nlm.nih.gov/books/NBK195431/

Community Engagement

Community engagement[4] is a deliberate action to engage communities in planning, designing, implementation and monitoring of demand generation interventions and delivery of PrEP.

There is need to have structured, systematic and constructive engagement of gatekeepers and PrEP beneficiaries. Community engagement aims at managing knowledge, bursting myths and misconceptions, addressing negative attitudes and perceptions and re-strategizing where necessary. Engagement of communities also informs the design and delivery of PrEP at the preferred service delivery points and at community level.

Efforts should be made to ensure that community entry processes with local authorities, gate keepers and beneficiaries are done to get community buy-in and support. Throughout implementation, communities should be put at the center and be included in dissemination and utilization of information generated as in figure 11

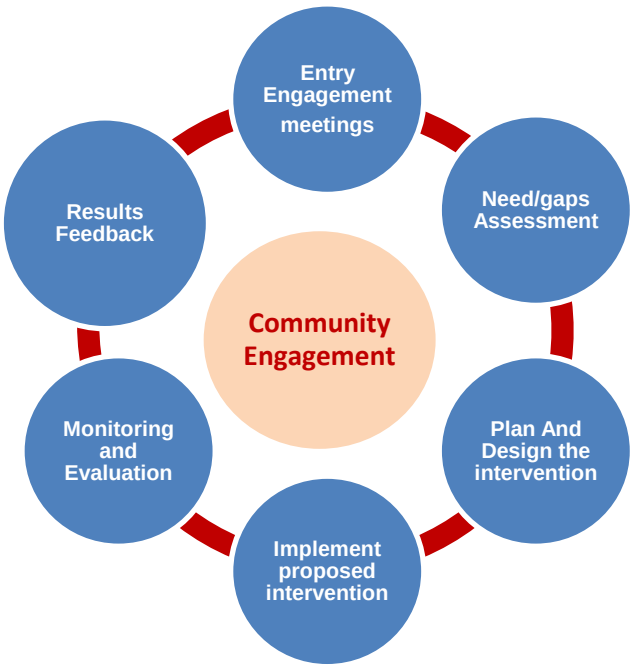


Figure 10 : How to do Community Engagement for Demand Creation

[4] http://guidelines.health.go.ke:8000/media/COMMUNICATION_STRATEGY.pdf

FOCUS AREA 5: STRATEGIC INFORMATION AND RESEARCH

Strategic information, research and innovation, is vital for PrEP implementation as it defines strategies to track and measure program progress and impact to inform decision-making. It ensures that systems are in place to support routine and surveillance data capture to inform programming. Strategic information includes routine monitoring, periodic assessments and evaluation, supervision as well as surveys.

The PrEP research priorities are as outlined in the HIV research agenda indicated in the Kenya AIDS Strategic Framework II (KASF II), which aims at enhancing coherence in the choice of investigation areas and application of research with policy guidance and envisioned results. Research into New HIV prevention technologies (NPTs) is a critical part of comprehensive HIV prevention. Oral PrEP studies have shown that the efficacy of PrEP is high when there is optimal effective use. In Kenya three-year evaluation of Tenofovir associated mutations were found but approximately one fifth of this population had emtricitabine associated mutations (M184I/V), highlighting the importance of continuing to monitor for HIV resistance in PrEP clients who become HIV positive (Chohan, CROI 2021). PrEP products including the Dapivirine Ring and the long acting injectable Cabotegravir have also been shown to be efficacious and recommended by WHO. The evidence generated on the products and subsequent approval in the country will inform implementation of other HIV prevention products under development. It is therefore imperative that approval, adoption, use and scale up of any PrEP product is informed by research conducted.

Scope and Purpose of Research

This section outlines, categorizes and prioritizes key research learnings to be addressed as part of implementation of different PrEP products with the aim of improving PrEP service delivery to targeted populations. Undertaking operational research on PrEP to identify distribution and dispensing channels for PrEP is done to inform improvement interventions in the supply chain. Where possible, the data sources as well as implementing partners are identified. The research guide will help to guide PrEP programmers to align 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 technical working group based on the emerging needs. The implementation of the research agenda will be prioritized 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 is required for introduction and scale up of new PrEP products while low priority research is research that is considered not a priority for program implementation at the time.

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

The research objectives will help:

- To demonstrate program impact and effective use of PrEP products
- To guide policy formulation
- To provide Timely Evidence-Based Guidance
- To contribute to key scientific knowledge base around the different PrEP Products.
- To determine cost implication of products
- To evaluate efficacy of the product particularly those still under development
- To inform PrEP implementation strategies targeting various populations

Table 8: PrEP Research Agenda

Improving PrEP program efficiency
• "What is the most effective model of mobilization for demand creation for the PrEP products in different populations? • Frequency of HIV testing for the various PrEP products. • Piloting and Evaluating interventions to improve PrEP products effective use • Evaluate the predictors of PrEP effective use for the different PrEP products and technologies in a routine service setting. • Conduct cohort event monitoring as part of pharmacovigilance of PrEP products • Studies on prevalence of HIV drug resistance (acquired verses transmitted) • Explore method switching of PrEP products both current and emerging technologies. • Evaluate HIV behavioral risks among PrEP users. • Determine the cost of offering different PrEP products • Evaluate models/approaches for task shifting the PrEP products to increase efficiency • Monitor STI rates among PrEP users

Access to Services

- Determine acceptability (end-user and provider) and uptake of PrEP products (and other ARV based preventions) by sub-populations.
- Service providers' knowledge, attitudes and perceptions that affect PrEP service provision in high HIV prevalence counties.
- Define a cascade client flow path and create the flow chart of service package.
- Define characteristics including patterns of PrEP use for the different products including the switching needs.
- Determine the risk profile and matrix of clients seeking different PrEP products at service delivery points.
- Define HIV testing approach (Provider Initiated testing and counselling, HIV Self Testing) that will increase PrEP uptake and/or provide early identification of HIV seroconversion.
- Define the short and long-term safety of PrEP. (Biological and Social Harm)
- Pilot expanded dispensing models for PrEP to include telemedicine and private pharmacies.
- Evaluate the appropriate packaging of the PrEP product.

Service Integration

- Feasibility of integrating PrEP into existing models of service delivery such as family planning clinic and/or retail pharmacies
- Feasibility of using telemedicine, e-pharmacy to offer PrEP to at risk clients
- Feasibility of PrEP self-care to reduce workload of health providers
- Determine strategies to promote and enhance partner testing and disclosure in PrEP settings.
- Effects of combination prevention (structural and behavioral) on PrEP uptake.

Financing/Costing/Economic Evaluation

- Determine current national unit costs (average/marginal) of providing PrEP based on cost, and type of product, mode of service delivery, target population, facility tier and geographic region
- Determine the cost of delivering PrEP by provider's perspective (Public, Private or faith-based facilities), client perspective and societal perspective
- Determine willingness to pay for PrEP services and the different products (medication, lab etc.)/cost sharing
- Analyze the incremental cost of adding new PrEP products to the overall cost of combination prevention
- Analyze the incremental cost of adding new PrEP products to the existing programs
- Determine resources needed to reach a certain coverage of PrEP.
- Budget impact analysis i.e. what's going to cost the government to provide PrEP

Implementation Methodology

Sources of data

The research agenda will utilize data collected from studies, KHIS and surveys reported at national level. Specifically, these questions will be integrated in household surveys. To facilitate research, NASCOP shall coordinate the development of research protocols for high priority questions for ethical approval.

Mathematical modelling shall be applied where the above information systems will not be sufficient.

Mathematical modelling

The country recognizes the utility of mathematical modelling to answer some questions on PrEP delivery and scale up. Modelling will aid the country to:

- Quantify the estimated health impact
- Quantifying demand for different PrEP products in the country within different sub-populations
- Quantify the cost of providing PrEP

Research implementation and Coordination.

NASCOP will oversee, coordinate and authorize PrEP research conducted by various stakeholders in Kenya. Counties that have research units are encouraged to come up with their own PrEP research questions unique to their settings, coordinate PrEP research initiatives and conduct research towards answering them. Having secured approvals from necessary research and ethics approval bodies, all PrEP research done should be tracked and archived in a central repository housed by NASCOP.

Research funding

The National and County Governments and other stakeholders are encouraged to mobilize resources for PrEP operational research in line with KASF II plan to and ensure sustainable funding for PrEP operational research.

Resource mobilization mapping will be carried out to explore local financing mechanisms to ensure sustainability for PrEP commodities. Public Private partnerships are another potential source of research funding and piloting of evidence informed innovations.

Monitoring and Evaluation

This PrEP implementation services in the country is monitored regularly to track performance towards achievement of targets and objectives.
The objectives of the PrEP M&E framework are:

- To incorporate PrEP monitoring as part of routine HIV Programme defining core set of indicators.
- To utilize routinely collected data to improve PrEP programming.

PrEP data collection and reporting is part of MOH reporting, all health facilities offering PrEP should be allocated data sets on Kenya Health Information Systems (KHIS) and are expected to report by 5th of every month. This will be done through defined indicators and tools. Data will be routinely collected through standardized MOH tools. The National program has been setting targets and sharing with the counties to monitor and measure the success of the program. A recently developed decision-making tool PrEP it (available at: www.prepitweb.org) has been adopted to support counties to set targets and monitor their performance. Data will be routinely collected through standardized MOH tools

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, collection, 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.

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 periodic data review meetings, service and data quality assessments, performance reviews, mentorship and support supervision as outlined in the ART guideline.

Data collection

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

1. Clinical Encounter form – to determine eligibility for PrEP, initiate and follow them up
2. Daily Activity Register – This will be used to monitor key processes such as HIV testing, STI screening and Risk perception screening.
3. Summary tool – MoH 731

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 (Annex 1)

FOCUS AREA 6: FINANCING AND RESOURCE MOBILISATION

Kenya has made significant strides in tackling its HIV pandemic. The Kenyan government is committed to strengthen the health system while working towards increasing the domestic financing for HIV response. The country's domestic resource envelope for HIV response increased from 13% in 2013 to 32% in 2020 against a target of 50% for the same period. Following the devolution of health services, there are deliberate efforts from various players to advocate for the county governments to allocate and ring fence their budgets for HIV response. Private sector plays a critical role in sustaining HIV prevention, care and treatment service in Kenya and therefore there is need for continuous engagement to sustain the response. The inclusion of HIV combination prevention in the UHC agenda as an essential package will increase access for PrEP services and should be a major advocacy agenda.

According to Kenya AIDS Strategic Framework (KASF II 2019/2020- 2024/2025), Kenya will require Ksh.647.7 billion to fully finance the HIV response for the next five years. Based on funding trends, a deficit of Kshs. 288.2 billion exists which requires an aggressive resource mobilization to support the response fully. The current impact of COVID-19 on the global economy coupled with donor fatigue, will negatively influence HIV program funding which ultimately may erode the gains achieved in HIV response. More domestic financing for and financial efficiency in HIV programmes is needed urgently to sustain the gains.

The costs and access factors related to pre-exposure prophylaxis (PrEP) for HIV prevention have not been adequately explored in health services. Therefore, there is a critical need to conduct costing and economic evaluation of the PrEP Program to inform future implementation and identify innovative strategies for resource mobilization.

The objectives of the costing and economic evaluation include:

- To identify the resource needs of providing a comprehensive package of PrEP services to target populations in the country
- To determine the variations or cost components driving these costs
- To estimate the average annual cost of reaching one eligible client with a comprehensive package of PrEP services through various service delivery models (oral, injectable, ring, and others in the pipeline)
- To evaluate the economic impact of PrEP in averting new HIV infections
- To assess the financing gap for PrEP service delivery

Estimation of Resource Need

PrEP is a HIV prevention strategy whose resource requirement has not been effectively determined. It is critical to determine resource requirements for PrEP program to inform country and donor investments in PrEP as part of HIV combination prevention. Given that the country already has HIV prevention programs in place, integration of PrEP into existing prevention program requires to be strengthened to provide efficient services.

ANNEXES

Annex 1: M&E Data Collection Framework

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 500,000Kenyans on ongoing risk to HIV infections within 5 years	**Implementation Indicators segregated by Method, Age. Gender and population type**				
	Number of facilities /Dices/Private pharmacy offering PrEP	These are the service delivery points offering PrEP either to general population or key populations	Master facility list/Survey /Assessment	Quarterly	NASCOP, COUNTIES
	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/Register	Routine data collection	Clinician
	Number of clients newly started on PrEP	Number of eligible clients who start PrEP	EMR/Register	Routine data collection	Clinician
	Number of continuing PrEP clients (Refills)	Number of clients on PrEP who receive a PrEP refill	EMR/Register	Routine data collection	Clinician
	Number of clients currently on PrEP (New+ Refills+ Restart)	This is the sum of clients newly initiated on PrEP plus + restarted on PrEP plus the refills during the reporting period	EMR/Register	Routine data collection	Clinician

OBJECTIVE	INDICATOR	INDICATOR DEFINITION	DATA SOURCE	FREQUENCY OF COLLECTION	ENTITY RESPONSIBLE
	Number followed up by end of first month after initiation	All clients started on PrEP who come back after the first month.	EMR/Register	Routine data collection at facility level	Clinician
	Number discontinued PrEP	These are number of enrolled clients who stopped using PrEP due to various reasons such as: client tested positive while taking PrEP, ADR, Defaulters, sero-conversion and due to reduced risk	EMR/Register	Routine data collection	Clinician
	Number of clients who restarted PrEP	Any client who has not been on PrEP > 7 seven days from the last TCA and has been reinitiated on PrEP	EMR/Register	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/Register	Routine data collection	Clinician
To provide PrEP as part of combination HIV prevention to 500,000Kenyans on substantial ongoing risk to HIV infections within 5 years	Number of PrEP clients diagnosed with STI	Number of clients diagnosed with a STI while on PrEP	EMR/Register	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 **Poor** – Missed 6-7 more doses per week in the past one month	EMR/Register	Routine data collection	NASCOP

OBJECTIVE	INDICATOR	INDICATOR DEFINITION	DATA SOURCE	FREQUENCY OF COLLECTION	ENTITY RESPONSIBLE
	Number of clients switching between methods	Number of clients switching from one method of PrEP to another method.	Commodity tool	Routine data Collection	Clinician
	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	NACC

Annex 2: PrEP Summary Reporting Tool

PrEP Summary Reporting Tool

County:

Site Name/Facility:

Sub-County:

MFL Code:_____ Reporting Month:_____ Year:_____

1. Number currently on PrEP (New + Refill)	
1.1 Males 15 - 19 Years (3.1 + 4.1)	
1.2 Females 15 - 19 Years (3.2 + 4.2)	
1.3 Males 20 - 24 Years (3.3 + 4.3)	
1.4 Females 20 - 24 Years (3.4 + 4.4)	
1.5 Males 25 - 30 Years (3.5 + 4.5)	
1.6 Females 25 - 30 Years (3.6 + 4.6)	
1.7 Males 30 Years and older (3.7 + 4.7)	
1.8 Females 30 Years and older (3.8 + 4.8)	
Total	

2. Number Started (New) on 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	

3. Number tested HIV positive while 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	

Annex 3: List of Contributors

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NASCOP
National AIDS and STI Control Program

PEPFAR

CLINTON HEALTH ACCESS INITIATIVE

jhpiego

ciheb KENYA

lvct health

World Health Organization