

IMPROVING AVAILABILITY, AFFORDABILITY & ACCESSIBILITY OF HIV PREVENTION TOOLS IN KENYA

POLICY REPORT
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1.0 Introduction

Kenya is among the top 12 high HIV burden countries in Africa, with an estimated 1.5 million people living with HIV and 36,000 new infections annually [1]. An incidence rate of 0.14% is beyond the epidemic control target of 0.01% [2]. Despite tremendous efforts to curb the generalized epidemic, a significant proportion of the population remains at risk. The need for effective combination prevention to drive towards zero HIV infections, and curb the epidemic by 2030, remains a necessity.

The government currently provides oral pre-exposure prophylaxis (PrEP) at public health facilities, which require daily ingestion by the client over period of risk. Novel HIV prevention methods such as cabotegravir injection (CAB-LA) and the dapivirine vaginal ring (DVR), offer alternative acceptable, discrete and convenient choices for highly effective HIV prevention [3]. Cabotegravir injection (CAB-LA), shown to be superior to oral PrEP [4, 5], and dapivirine vaginal rings (DVR), offering choice for women [6, 7], have been approved in some countries but remain inaccessible to most individuals at risk in Kenya. There is strong appeal for wider product access in regions where those at high risk currently lack choice of effective preventive interventions.

We evaluated HIV prevention interventions with the aim of classifying available tool including those in the research pipeline, and investigated intellectual property, legal and policy barriers that may affect their availability, accessibility and affordability in Kenya. This brief summarizes the key findings from the desktop research, and provides policy recommendations for addressing availability, access and affordability of these novel HIV prevention interventions.

2.0 Key Messages

- The Kenya government, with support from global partners, has made available most of the HIV prevention interventions already proven to be safe and efficacious including condoms, antiretroviral for both pre- and post-exposure prophylaxis, voluntary male medical circumcision, and treatment as prevention.
- HIV prevention research pipeline is delivering more effective and acceptable products such as cabotegravir injection (CAB-LA), determined to be superior in HIV prevention compared to current oral PrEP standard of care, and dapivirine vaginal ring (DVR).
- Access to CAB-LA and DVR is currently limited to those who will be participating in the implementation research projects, with national rollout of the novel HIV interventions likely to delay due to a mix of factors including intellectual property rights, delayed regulatory approvals, global partner priorities, inability to drive down prices and country preparedness for new interventions.
- The projected shortage in government-provided free condoms is a cause for concern, as it forces individuals to spend out-of-pocket hence potentially limiting affordability for vulnerable populations.
- We recommend proactive approach by government entities to incorporate proven interventions into the combined prevention package, including using legal systems to enforce access, fast-track regulatory approvals, engaging global partners to finance roll-out, utilizing pooled purchasing across African regions, reviewing product delivery pathway and sustaining provision of affordable condoms.

3.0 Key Findings

1. Richness of HIV prevention pipeline

The HIV prevention research pipeline has delivered more effective and acceptable prevention products such as CAB-LA, which was determined to be superior in HIV prevention compared to current oral PrEP standard of care [4, 5]. It has offered choice for women at risk through DVR, a vaginal microbicide and local acting PrEP. There is promise for multi-purpose technology, offering dual benefit of HIV and pregnancy prevention for women, the closest to approval being dual prevention pill (DPP) which combine oral PrEP and oral contraceptive in a fixed-dose combination for daily use.

- Research is ongoing on how to formulate these interventions for easier utilization through gels, implants, films and inserts.
- Antibody formulated interventions offer hope for a vaccine product.

2. Limited access to PrEP alternatives such as cabotegravir injectable (CAB-LA) and dapivirine vaginal ring (DVR)

While the Kenyan HIV prevention toolkit is almost full, novel efficacious options are still missing without clear plans of how they will be made available. PrEP options such as CAB-LA and DVR will soon be available but only within demonstration projects, which are targeting women enrolled in designated counties. This limits access to those able to join the CATALYST study or former participants of the ViiV Healthcare sponsored study.

For these novel products, market entry is congruent upon:

- **Intellectual property rights:** For CAB-LA, while voluntary licensing has been provided to three generic manufacturers, market entry is likely to delay for at least 2-3 years, with monopoly of source and brand in the interim. International partnership for microbicides (IPM) through product development partnership has been able to provide access for DVR.
- **Regulatory approval:** CAB-LA regulatory approval in Kenya is yet to be secured, despite approved by stringent regulatory authorities and recommendation by World Health Organization (WHO), however submission has been made. Lengthy and delayed regulatory approvals limit access to CAB-LA to the local population. DVR is already approved for the local market in Kenya.
- **Financing:** Kenya is tentatively listed among countries to receive PEPFAR support for CAB-LA roll-out from 2025. PEPFAR funding cannot be used to procure DVR for country roll-out, except for implementation research, without US Food and Drug Administration (US FDA) regulatory approval of DVR. IPM withdrew submission of DVR to US FDA on perception that it is unlikely to be approved.
- **Delivery pathways and demand:** KEMSA and government public health facilities have established the required machinery to effectively roll-out injectable PrEP, however, there is need to evaluate product integration into the existing pipeline, financing for cascaded systems, and consider appropriate service delivery mechanisms which are sensitive to HIV prevention uptake barriers such as stigma, product characteristics, and socio-cultural issues.

3. Concerns of affordability following stock out of government provided condoms

Projected shortage in government-provided free condoms forces individuals to spend out-of-pocket hence potentially limiting affordability. While relatively inexpensive and locally manufactured, government has provided condoms in quantity capped at 150 million against an estimated 400 million annual demand. Despite less than desired condom utilization, a pack of condoms trading at between KSh. 50 to 400 may be unaffordable especially for vulnerable populations.



4.0 Conclusion

HIV prevention research has advanced to provide more efficacious and acceptable alternatives in the fight against HIV. Kenya needs to accelerate the incorporation of CAB-LA and DVR into the national prevention toolbox, including sustaining condom supply, to realize the potential of combined intervention. Access, affordability, and availability play a significant role in determining implementation timeline and success, hence should be navigated with support from global partners and input from local stakeholders.

5.0 Recommendations

- a. Incorporate new HIV prevention interventions into the country's combination prevention package, with emphasis on potentially impactful and cost-effective interventions. Priority should be given to intervention proven superior to existing standard of care, such as CAB-LA.
- b. Utilizing local legal systems to exploit the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities such as 'Bolar provision' and 'limits on test data protection' to allow faster market entry for generic CAB-LA products upon patent expiry. Relatedly, 'research exemption' could be utilized to determine cheaper ways to manufacture CAB-LA locally. In addition, utilization of 'voluntary licenses' and 'parallel importation' should be encouraged for these highly effective HIV prevention options.
- c. Ensure approval of CAB-LA by the Pharmacy and Poisons Board by utilizing fast-tracked marketing approval channels including partial reliance on stringent regulatory authorities, request for joint-reviews with countries in which review is still ongoing or initiating information sharing with stringent regulatory authorities or WHO as they have already approved the product.
- d. Engage global partners including PEPFAR and Global Fund to fast-track Kenya's consideration for purchasing and roll-out financing of CAB-LA and DVR, while the planned implementation research projects are underway with the aim of implementation amidst the demonstration projects to quickly effect lessons learnt.
- e. Consolidate PrEP demand across regions and countries and utilizing pooled procurement to negotiate better prices. Identifying countries with high PrEP uptake and utilization such as South Africa, Nigeria, Uganda and Zambia may help to build consensus rapidly with adequate demand to drive negotiations.
- f. Evaluate product delivery and integration pathway, including planning for finances for cascaded systems and service delivery mechanisms which are sensitive to HIV prevention uptake barriers such as stigma, product characteristics, and socio-cultural issues. Product introduction and related services should be designed with the end user in mind, obtaining their input and addressing their concerns to ensure utilization and sustained demand.
- g. If not supported by donor funding, free condoms should be subsidized to the extent possible or declared tax free to ensure affordability.

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