






OPEN LETTER

# An implementation model for scaling up oral pre-exposure prophylaxis in Kenya: *Jilinde* project [version 1; peer review: 3 approved]

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## Abstract





Oral pre-exposure prophylaxis (PrEP) is an efficacious way to lower the risk of HIV acquisition among high-risk individuals. Despite the World Health Organization's 2015 recommendation that all persons at substantial risk of HIV infection be provided with access to oral PrEP, the rollout has been slow in many low- and middle-income countries. Initiatives for national rollout are few, and subtle skepticism persists in several countries about the feasibility of national PrEP implementation. We describe the conceptual design of the *Jilinde* project, which is implementing oral PrEP as a routine service at a public health scale in Kenya. We describe the overlapping domains of supply, demand, and government and community ownership, which combine to produce a learning laboratory environment to explore the scale-up of PrEP. We describe how *Jilinde* approaches PrEP uptake and continuation by applying supply and demand principles and ensures that government and community ownership informs policy, coordination, and sustainability. We describe the “learning laboratory” approach that informs strategic and continuous learning, which allows for adjustments to the project. *Jilinde's* conceptual model illustrates how the coalescence of these concepts can promote scale-up of PrEP in real-world conditions and offers critical lessons on an implementation model for scaling up oral PrEP in low- and middle-income countries.

## Open Peer Review

Reviewer Status 

Invited Reviewers

	1	2	3
version 1			
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## Keywords

Oral PrEP, scale up, demand, supply, ownership, learning laboratory, key populations, adolescent girls and young women

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## Introduction

The global HIV response has seen positive developments over the past two decades, characterized by a decline in both the number and rate of new HIV infections and AIDS-related deaths<sup>1</sup>. However, AIDS-related sequelae still contribute a considerable burden to morbidity and mortality in countries in sub-Saharan Africa (SSA), which continue to disproportionately bear the brunt of the epidemic and accounted for the majority of the new HIV infections in 2019<sup>1</sup>. While 72% of new HIV infections in east and southern Africa occurred among the general population, nearly 30% of the overall new HIV infections were attributed to adolescent girls and young women (AGYW) aged 15–24 years<sup>2</sup>. In the same region, key populations (KP) including female sex workers (FSW), men who have sex with men (MSM), persons who inject drugs (PWID), transgender individuals, and their sexual partners contribute the remaining 28% of new HIV infections<sup>2</sup>.

Kenya, one of the high HIV burden countries in SSA, has made considerable progress in its HIV response. The national HIV prevalence declined from 5.6% in 2012 to 4.9% in 2018, and further reductions in new HIV infections occurred among adults (106,000 to 36,000) within the same period<sup>3,4</sup>. Despite these gains, HIV prevalence and incidence remain high in certain geographic pockets and among specific populations. Kenya has a geographically disproportionate epidemic that is mainly concentrated around the Lake Victoria region. In 2017, half of Kenya's estimated new HIV infections among adults occurred in six of Kenya's 47 counties, four of them in the Lake Victoria region<sup>5</sup>.

A 2008 study on the modes of HIV transmission reported that KP contribute approximately one-third of new infections in Kenya<sup>6</sup>, and this has persisted to date. More recent estimates show that AGYW aged 15–24 years accounted for a third of all new adult HIV infections in 2017<sup>5</sup>. Furthermore, AGYW are four times more likely to acquire HIV infection compared to their male counterparts<sup>7</sup>. Substantial work remains to lower HIV transmission rates among these groups, who have a higher prevalence and incidence than the general population, as this high HIV prevalence and incidence threatens the sustainability of gains made in the general population.

To address these disparities in prevalence and incidence, Kenya has mounted a robust HIV response modeled on the combination prevention approach, with geographic and population prioritization<sup>8</sup>. However, several gaps hinder the optimization of this strategy including a large number of HIV-infected individuals who do not know their HIV status and therefore are not on HIV treatment. Similarly, despite wide availability of condoms, many high-risk individuals do not use them consistently<sup>9–11</sup>. While voluntary medical male circumcision

will likely eventually reduce overall community HIV prevalence in Kenya, it does not provide direct prevention benefits for AGYW and FSW, or MSM at risk from engaging in receptive anal sex. Further, while treatment as prevention, treatment of sexually transmitted infections (STIs), and post-exposure prophylaxis<sup>12–15</sup> are all available to KP and AGYW, the use of most of these interventions is less than optimal. This is mainly due to contextual barriers including gender-based violence, stigma and discrimination, legal obstacles, gender and cultural norms, and access barriers<sup>16–19</sup>. These gaps signal that a substantial proportion of individuals engaging in high-risk sexual encounters require a reliable prevention alternative.

Oral pre-exposure prophylaxis (PrEP) has proven to be highly efficacious at lowering the risk of HIV transmission when consistently taken daily<sup>20</sup> as well as intermittently among a sub-group of MSM<sup>21</sup>. In September 2015, the World Health Organization recommended that people at substantial risk of HIV infection should be offered oral PrEP as an additional prevention choice as part of a comprehensive prevention services package<sup>22</sup>. After the release of these recommendations, UNAIDS set an ambitious target of starting 3 million people on oral PrEP by 2020<sup>23</sup>. Realization of this target was dependent on rapid scale-up of oral PrEP across multiple countries, especially those most affected by the epidemic. By December 2020, an estimated 930,000 people had received PrEP<sup>24</sup>. The availability of oral PrEP in low- and middle-income countries has largely been limited to research initiatives and demonstration projects, with few examples of national rollout<sup>25</sup>. In spite of the documented benefits and global recommendations, many countries are still skeptical about the feasibility of national rollout of oral PrEP<sup>26,27</sup>. This skepticism is fueled by a gap in evidence on the feasibility and effectiveness of population-level PrEP interventions in low- and middle-income countries. This paper describes the conceptual design of an oral PrEP scale-up model implemented by the *Jilinde* project in Kenya.

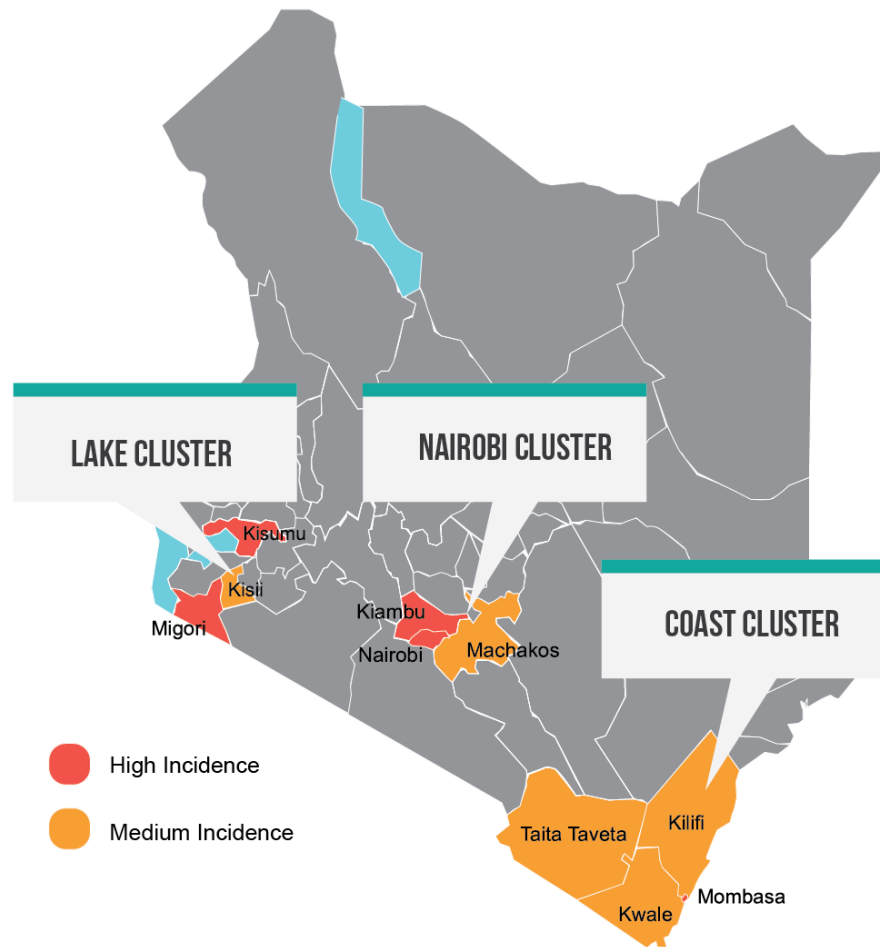
## The *Jilinde* project

The *Jilinde* (Bridge to Scale) project is designed as a “learning laboratory” to implement oral PrEP at scale, while simultaneously deriving lessons to understand the barriers and enablers to PrEP scale-up. *Jilinde* is a Kiswahili word that means “protect yourself.” This five-year (2016–2021) project is implemented in Kenya by a consortium of five partners that includes: Jhpiego, the National AIDS and STIs Control Program (NASCO), International Center for Reproductive Health - Kenya, Population Services Kenya, and Avenir Health.

## The setting

The project is implemented in 10 priority counties in Kenya, which were selected according to the severity of the HIV epidemic as illustrated in [Figure 1](#).

Data on the geographic incidence and burden of HIV was used to prioritize intervention counties based on an incidence threshold of 0.081% - 0.13% for medium incidence and 0.131% or more for high incidence, per 100 person-years<sup>28</sup>.



**Figure 1. Geographic coverage of the *Jilinde* project based on HIV incidence.**

Consequently, *Jilinde* is implemented in five high-incidence counties (Kisumu, Migori, Nairobi, Kiambu, and Mombasa) and five medium-incidence counties (Machakos, Kisii, Kilifi, Kwale and Taita Taveta). These counties were selected because they have high concentrations of KP, high HIV prevalence (and incidence) rates among the general population, and are the focus of existing HIV prevention, care, and treatment efforts.

#### *Jilinde's* conceptual framework

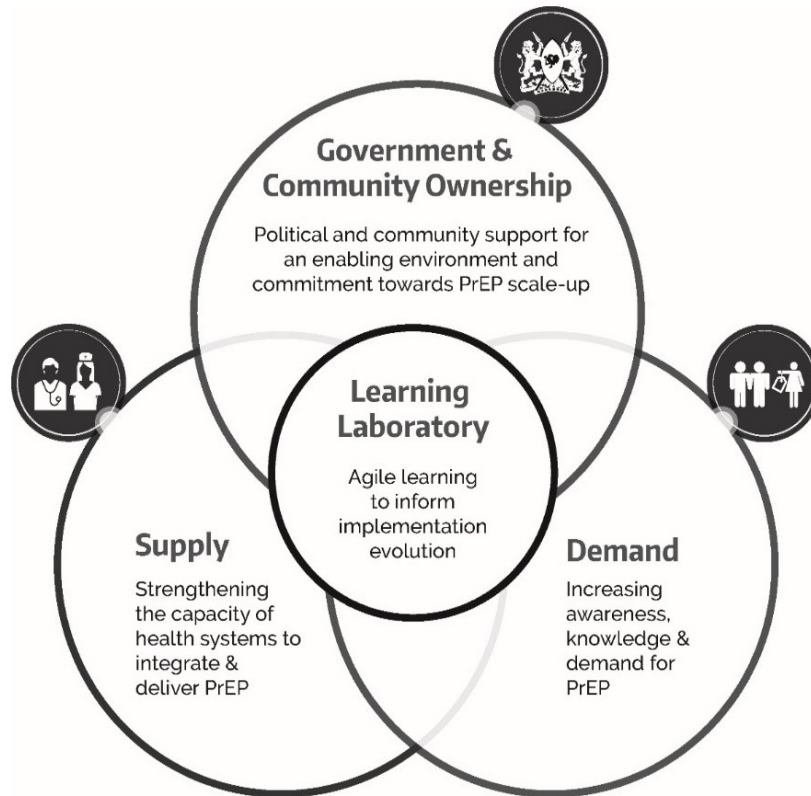
The overlapping domains of supply, demand, and government and community ownership all contribute to a learning laboratory approach to improving implementation of PrEP. [Figure 2](#) outlines this framework showing the interrelatedness of the domains.

*Jilinde's* theory of change is premised on this framework as a model for sustainable PrEP scale-up in Kenya. Implementation of this model should lead to increased political will and demonstrate the feasibility and effectiveness of PrEP scale-up. If successful, this should contribute to successful PrEP scale-up

in Kenya. Dissemination of lessons from Kenya should contribute to successful PrEP scale-up in other countries and an overall reduction in HIV incidence in the long-term. The anticipated outcomes and potential impact from this model are summarized in [Figure 3](#).

#### Supply of PrEP services

Service delivery is the cornerstone of the *Jilinde* project, which leverages existing health infrastructure, staff, and outreach of existing clinical sites to scale up routine delivery of oral PrEP. The project strengthens clinical sites that were already serving KP and AGYW clients, integrating PrEP into existing combination HIV prevention activities. These clinical sites include: drop-in-centers (DICES), which are stand-alone clinics that mainly serve KP; public health facilities; and private health facilities. To address access challenges, these sites also provide PrEP services through community delivery models that include safe spaces for AGYW and hotspot outreaches for KP. Service delivery points are being strengthened to provide oral PrEP by ensuring availability of commodities, building health



**Figure 2.** *Jilinde's* framework for implementation of PrEP at scale in Kenya.

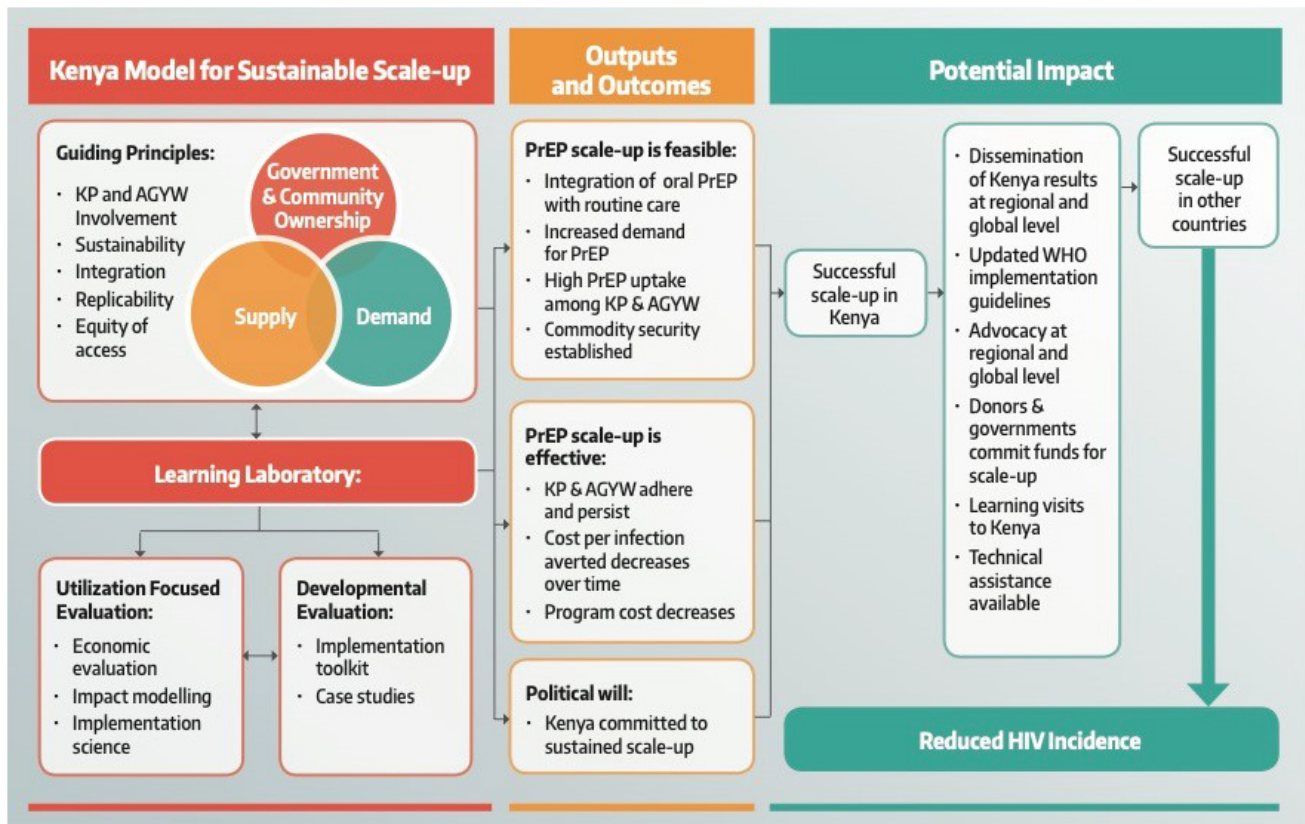
service provider PrEP competency, enhancing referral pathways, and offering outreach services in times and places convenient for KP and AGYW.

Systematic delivery of PrEP clinical services was preceded by engagement meetings with the county health management teams to build a consensus on the implementation agenda. Once county scale-up roadmaps were developed, health facilities were selected by the project team and the county health management team to take part, by way of a facility assessment to establish capacity gaps in providing HIV services and status of infrastructure for delivering PrEP. *Jilinde* supported NASCOP to train a pool of PrEP national master trainers drawn from all 47 counties, who have since cascaded the PrEP training to health service providers within their respective counties, using the nationally approved training curriculum. Additional training focuses on sensitivity in working with KP and AGYW. The trainings are building service providers' knowledge and skills to initiate and follow up with PrEP clients and increase health service providers' sensitivity and willingness to work respectfully with KP and AGYW.

The project collaborated with NASCOP to establish a centralized national supply chain for PrEP commodities that leveraged the existing antiretroviral drugs pipeline via the

Kenya Medical Supplies Authority (KEMSA). Initial donations of PrEP medication to jumpstart the scale-up were integrated into KEMSA for national-level distribution. To ensure seamless ordering, consumption, and reporting on PrEP commodities, existing logistics management information system tools were revised by NASCOP to include PrEP and then printed and distributed. Health service providers were trained on recording of site-level consumption data and ordering of commodities. DICES were linked to government-owned health facilities as satellite sites in order to receive PrEP commodities through the national pipeline. An initial "push" order of commodities was initiated by NASCOP to select sites to jumpstart the national scale-up. Subsequently, health facilities shifted to a "pull" system through routine reporting of commodity consumption.

Establishing client flow, especially for the high-volume facilities, was critical, since PrEP clients often needed to visit multiple service points within a facility, including the HIV testing room, clinical diagnosis room, and pharmacy. Whole-site orientations with all staff in the facilities were conducted to build support for the intervention across all cadres within the sites. Health facilities began client enrollment once all these critical steps were implemented. Subsequently, sites also established measures for client follow-up to enhance adherence and continuation. In addition, service providers are offered continuous



**Figure 3. Jilinde project theory of change.** (KP, key populations; AGYW, adolescent girls and young women; PrEP, pre-exposure prophylaxis).

support and mentorship for quality improvement. Figure 4 summarizes the stepwise process of setting up PrEP services in the clinical sites.

The project is also strengthening the capacity of the county health management teams to provide ongoing supportive supervision and mentoring of trained providers and counselors. This is intended to ensure the retention of knowledge and skills, as well as the maintenance of high-quality services. Periodic supportive supervision visits are enabling sharing of real-life implementation challenges that inform scale-up and case studies that drive changes in approach if needed.

**Demand for PrEP**

Jilinde’s approach to demand generation is two-fold: use of mass media for raising awareness of PrEP in the general population and targeted communication to the priority populations to generate demand for PrEP, primarily through interpersonal communication. The project has invested in awareness creation for the general population through mass media platforms including television, national and local radio advertising, and talk shows. Furthermore, social media platforms (mainly Facebook, Twitter, and WhatsApp) have been used to facilitate discourse

on PrEP. In addition, promotional events and community engagement fora have given visibility to and ignited community conversations on PrEP. This has proven to be important as it provides an environment that enables clients to start and continue using PrEP.

To determine targeted demand creation components, the project is employing innovative methodologies including behavioral economics research, consumer market research, and human-centered design processes to ensure resonance and relevance of messaging. The project is ascertaining end-user perceptions through insights derived from market research and behavioral economics to adequately segment the target audience for demand creation purposes. Through this audience segmentation, the demand creation strategies are adopting a multipronged and multifaceted approach that takes into account the diversity of KPs and AGYW. This has enabled the project to adopt a targeted approach as opposed to a mass “one size fits all” approach. Using human-centered design methodologies, the project developed messages and materials that address the key barriers identified by users themselves. The project used a rapid, iterative process that included pre-testing, piloting, and scaling up of proven interventions. The choice of messengers is also



**Figure 4. Systematic process of setting up PrEP service delivery sites.** (M&E, monitoring and evaluation).

fundamental, and the project is leveraging the robust peer outreach system currently employed as part of the national KP service standards. *Jilinde* is engaging gatekeepers, KP community members, and civil society organizations with strong roots and experience in KP programming to roll out the demand creation activities identified as most promising.

**Adherence support.** Evidence from clinical trials shows that PrEP effectiveness is dependent on medication adherence; studies reporting high adherence reported high efficacy, while those that reported low adherence reported little or no efficacy<sup>29–31</sup>. Given that *Jilinde* is implementing PrEP in routine service delivery, adherence support has been integrated into existing activities through the following approaches:

- Community-based approaches:** Growing evidence suggests that health outcomes are improved when clients participate in care as part of a supportive cohort and different types of peer support are a mainstay of KP programs<sup>32,33</sup>. *Jilinde* is tapping into existing KP and AGYW networks to support both PrEP uptake and adherence, which are inseparable. KP and AGYW networks, support groups, and peer educators who mobilize clients for services play a dual role in ensuring uptake as well as continuity through adherence support and physical tracing of clients lost to follow-up. PrEP clubs, peer support groups, and networks meet periodically in community venues to address adherence challenges and provide peer support. Clients using PrEP
- Health facility-based approaches:** PrEP delivery sites have been implementing several client-centered interventions to improve continuation of care. Clients who are enrolled on PrEP and provided consent, receive short message service (SMS) reminders to take pills and upcoming appointments. The popularity of social media platforms, such as Facebook and WhatsApp, with the priority populations has also provided a platform for virtual support groups especially since the start of the COVID-19 pandemic. Active tracing of clients who miss their clinic appointments is done through phone calls by health service providers and in some cases through peer educators. Finally, the project is providing refills in the community as well as empathetic adherence counseling where counselors help

clients develop adherence strategies that support them, rather than judging them for failing to adhere or for missing an appointment.

### Community and government ownership

For effective and sustainable oral PrEP scale-up, ownership of the intervention by the community and the government at all levels is critical – institutionalization will help ensure the sustainability of both demand and supply. *Jilinde* is working with the national government through NASCOP's leadership to formulate and update appropriate policies and guidelines, coordinate national PrEP rollout through strengthened technical working groups, enhance integration and quality of PrEP service delivery, and develop and roll out a national combination prevention communication strategy. Through participation in the quantification and forecasting of PrEP commodity requirements, the project is contributing to the formulation of a long-term national commodity security strategy. At the county level, *Jilinde* is working closely with devolved government stakeholders to prioritize PrEP in work plans, establish coordination structures, effectively integrate PrEP in routine service delivery, and support county leadership in the scale-up efforts.

Successful implementation of the project is dependent on a supportive and enabling policy environment. Keeping these insights in mind, *Jilinde* is collaborating closely with critical stakeholders, influencers, decision-makers, and target beneficiaries such as AGYW and KP networks in the design, implementation, and monitoring of PrEP rollout, informed by a stakeholder engagement plan developed through stakeholder mapping and analysis. Through this plan, key stakeholders – including bar and brothel owners, parents of AGYW, religious leaders, and general community members – are engaged routinely by the project to create an enabling environment for the delivery of PrEP services, thereby creating safe spaces for health promotion events and outreaches for PrEP provision and protecting KP and AGYW on PrEP from harassment. *Jilinde* is using the evidence generated by the project to make decisions on adaptations needed to galvanize support and ownership for sustainability.

### *Jilinde* as a learning laboratory

*Jilinde* is using two evaluation approaches: developmental evaluation (DE) and prospective utilization-focused evaluation (UFE). Participatory DE is being used to guide continuous, iterative program learning through implementation experiences and documentation of learning toward the goal of evolving the implementation approach. The critical feature of DE is the right people reflecting on the right data at the right time and then using those reflections to inform changes in the intervention<sup>34</sup>. Use of DE is enabling *Jilinde* implementation to be agile, making iterative adjustments to minimize program risks and maximize learning. *Jilinde* is also collecting formative, process, and summative data to answer a set of essential learning questions in a structured and rigorous way. In addition, *Jilinde* is using UFE to help answer specific national oral PrEP research questions

outlined in the national framework for the implementation of PrEP in Kenya<sup>35</sup>. The UFE is focused on understanding client and user experiences, health managers and service provider experiences, community perceptions, user feedback on demand generation, and client acceptability and adherence. *Jilinde* is using this evidence to ensure real-time feedback on the effectiveness of interventions, rapidly identify the need for course corrections or changes in strategy, and enable the sharing of learning with different groups. This learning is essential to inform improvements in routine service delivery and specific recommendations for scale-up of PrEP in Kenya and other countries.

### Costing and modeling

As part of the learning laboratory, *Jilinde* is also assessing the cost of implementing and delivering PrEP from a service delivery perspective and the client perspective. By understanding both the full cost and unit cost of a PrEP program, it will be possible to estimate and project future resource needs associated with scaling up PrEP nationally. Contingent valuation analysis will provide information about the factors that influence the valuation of services by PrEP clients by assessing their maximum willingness to pay for PrEP services. In addition to assessing the costs of oral PrEP to service providers and clients, *Jilinde* is also conducting modeling to estimate the impact and cost-effectiveness of PrEP for different populations in Kenya using the Goals Model<sup>36</sup>. Modeling of the impact of PrEP services' use on HIV incidence and costs (e.g., cost of PrEP vs. cost savings due to HIV infections averted) will provide evidence in the Kenyan situation for scale-up, provide specific recommendations on where and how to rapidly take oral PrEP to scale, and what programmatic outcomes to improve to increase epidemic impact and cost-effectiveness.

### Conclusion

The *Jilinde* project is serving as a “learning laboratory,” which informs as well as evaluates programmatic decisions, and is facilitating iterative explorations of different models of PrEP implementation at scale to fit a real-market, low-resource context. Through addressing the critical domains of demand, supply, and government and community ownership of oral PrEP, *Jilinde* is generating critical lessons on the feasibility and effectiveness of scaling up oral PrEP in low- and middle-income countries. By demonstrating significant saturation of the two groups – AGYW and KP – that are widely recognized and targeted in an effort to reduce HIV incidence in most countries, the findings of this model will be broadly applicable to other countries and, ultimately, other target groups within Kenya in a full national scale-up. Subsequently, these lessons may also provide critical learnings that will be applicable to the introduction of similar HIV prevention products and technologies in the future.

### Data availability

No data are associated with this article.



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## Open Peer Review

Current Peer Review Status:   

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### Version 1

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**Douglas Krakower** 

Division of Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

**Elizabeth Christian** 

Division of Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

This well-written letter describes a model for implementing and scaling up access to oral PrEP in 10 counties in Kenya where incidence of HIV acquisition is highest, with a focus on reaching the populations with the highest rates of new HIV infections, comprised of adolescent girls and young women, female sex workers, men who have sex with men, people who inject drugs and transgender people. The theory-driven model seeks to engender political and community support for wide-spread access to PrEP, as well as increase demand for PrEP through a variety of public outreach campaigns. It also directly addresses anticipated supply chain issues by using already existing infrastructure and systems, to ensure that as demand for PrEP increases, the medication remains widely available in the community. Significant resources were devoted to supporting PrEP adherence and continuation, including integration of peer support interventions, as well as ongoing assessment and support to service providers to ensure quality care. A system of real-time feedback was used to allow for rapid revision of processes in response to issues as they were identified, which is a major methodological strength for this program.

This is a thorough approach to large-scale PrEP implementation, and the emphasis on identifying and addressing potential systematic barriers, as well as the high value placed on community engagement, is notable. The emphasis on building patient support for PrEP adherence and continuation is particularly impressive and represents a best-practice in terms of patient-centered health care.

The discussion of cost is addressed briefly, and focuses mainly on collecting data about the implementation and service delivery cost, as well as potential cost savings from a reduction in new HIV diagnoses and associated costs. Could the authors clarify how the direct cost to the patients of PrEP medications and associated care was being addressed, as lack of insurance coverage or

inadequate insurance coverage for PrEP and associated services has been a major barrier to PrEP roll-out in the US?

Could the authors also describe any plans to protect confidentiality for adolescents who may be accessing PrEP without their parents' knowledge, especially as adolescent girls experience one of the highest rates of new HIV infections in Kenya? The article describes the provision of safe spaces for adolescents to access care, and efforts to engage parents of adolescent girls and young women, which are strengths. However, the cost of PrEP, as well as the outreach to promote adherence, may be a barrier to girls who don't want their parents to be aware of their sexual activity. Any additional description of ways to address these challenges would strengthen the manuscript.

Please consider the following comments and suggestions for the Introduction:

1. "Substantial work remains to lower HIV transmission rates among these groups, who have a higher prevalence and incidence than the general population, as this high HIV prevalence and incidence threatens the sustainability of gains made in the general population." Consider revising this sentence to reflect that there is inherent value in decreasing HIV incidence among key groups, and not only to sustain gains in the general population?
2. Consider replacing the term "high-risk individuals" with "individuals at risk for HIV", and "high-risk sexual encounters" with "sexual encounters associated with HIV exposure" (or similar), as these may represent less stigmatizing language?
3. "...many countries are still skeptical..." Could the authors clarify if this represents viewpoints of national leaders and policymakers or general population opinions, or something else?

Overall, this letter will be of great interest to public health practitioners and policymakers who seek to scale up PrEP in additional nations and regions, as it offers a clear and compelling description of a multilevel program to improve PrEP use on a national level. If the authors could add any data on the program's successes with PrEP, even if preliminary, that would further strengthen this important letter.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** Dr. Krakower has participated in research on PrEP funded by Gilead Sciences and Merck, and has received personal funds for authoring medical education content on PrEP for Virology Education, UptoDate, Inc., Medscape, Med-IQ, and DKBMEd.

**Reviewer Expertise:** Infectious diseases; HIV prevention; preexposure prophylaxis

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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**David A.M.C. van de Vijver** 

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Were and colleagues introduce the Jilinde project which is a “learning laboratory” approach that informs strategic and continuous learning on implementation and use of PrEP in Kenya. This is an important topic as the roll-out of PrEP has been slow in low- and middle-income countries, despite of the high efficacy of PrEP in preventing HIV. Many countries are sceptical about the feasibility of national rollout of oral PrEP due to a gap in evidence on the feasibility and effectiveness of population-level PrEP interventions in low- and middle-income countries.

The Jilinde project will implement oral PrEP at scale, while simultaneously deriving lessons to understand the barriers and enablers to PrEP scale-up. The project will be implemented in ten counties in Kenya with a medium or high HIV incidence. The counties also have a high concentration of key populations in whom about one third of all HIV infections in Kenya are reported. Jilinde also pays special emphasis to adolescents and young women that in whom also one third of new infections are found. The emphasis on young women is important due to their reported low adherence to PrEP. The Jilinde project will include adherence support to ensure that individuals at high risk of infection will continue the use of PrEP. The project will also ensure community and government ownership and will perform modelling and costing studies.

I was impressed by the work that is proposed and looking forward to read about the results of the Jilinde project in the future.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Infectious disease epidemiology, mathematical modelling and cost-effectiveness, HIV drug resistance, virology

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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**Deborah J. Donnell** 

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This report details a 6 year effort to implement PrEP at scale in 10 countries in Kenya. The project was ambitious, including in its "Learning laboratory" framework of demand creation, supply chain management and local government and community ownership, a scope incorporating key populations, adolescent girls and young women, public health and private clinics.

The letter usefully lays out the succession of processes and engagement across the spectrum of entities involved in setting up PrEP for success at scale. No data about the success of the project is yet available, but this is a clear description of the framework, approaches taken in each entity, that will be useful for setting out the steps for success, if the project ultimately demonstrates increase in uptake, persistence of PrEP and good adherence for those persons at high risk of HIV infection.

The approach is well justified, and the letter is clearly written, and well organized. Details of the

processes are high level and it would be useful if the authors could be sure that references to manuals or other detailed materials developed during the project are available for those interested in learning from this project.

The authors correctly note that rollout of PrEP, in spite of its known effectiveness, has been slow, and the barriers are complex. This description of the Jilinde project's comprehensive approach to implementation, encompassing skepticism, demand creation, training, logistics, and supply chain, if successful, has the potential to provide a proven road map to PrEP implementation.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Infectious disease epidemiology, implementation, PrEP, statistics.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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