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# Frontier Health Markets (FHM) Engage

## HIV PRE-EXPOSURE PROPHYLAXIS IN THE PRIVATE SECTOR

### Comparing Tanzania, Kenya, South Africa, Zambia, and Thailand

September 9, 2022

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**Authors:**
Dr. Andrew Corley, Metrics for Management
Dr. Yuen Wai Hung, Metrics for Management

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1275 New Jersey Ave. SE, Ste 200,
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# Acronyms

| | |
|---|---|
| AGYW | Adolescent girls and young women |
| AIDS | Acquired immunodeficiency syndrome |
| ART | Antiretroviral therapy |
| CBOs | Community-based organizations |
| CSOs | Civil society organizations |
| DREAMS | Determined, Resilient, Empowered, AIDS-free, Mentored and Safe |
| FHM | Frontier Health Market |
| FSWs | Female sex workers |
| F/TAF | Emtricitabine plus tenofovir alafenamide |
| F/TDF | Emtricitabine plus disoproxil fumarate |
| HIV | Human Immunodeficiency Virus |
| HIVST | Human Immunodeficiency Virus self-testing |
| KPs | Key populations |
| LINKAGES | Linkages across the Continuum of HIV Services for Key Populations Affected by HIV |
| LMICs | Low- and middle-income countries |
| MSM | Men who have sex with men |
| NASCOP | National AIDS and STIs Control Programme |
| NGOs | Non-governmental organizations |
| OPTIONS | Optimizing Prevention Technology Introduction on Schedule |
| PEP | Post-exposure prophylaxis |
| PEPFAR | U.S. President's Emergency Plan for AIDS Relief |
| POWER | Prevention Options for Women Evaluation Research program |
| PrEP | Pre-Exposure Prophylaxis |
| PWID | People who inject drugs |
| STI | Sexually transmitted infections |
| TB | Tuberculosis |
| TDF | Disoproxil fumarate |
| TGW | Transgender women |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| USAID | United States Agency for International Development |
| WHO | World Health Organizations |

# Executive Summary

The private health sector provides a significant source of health care services and product provision in many low- and middle-income countries, including in Tanzania. The private sector in Tanzania has for many years been an important provider of maternal and child care, family planning services and commodities, and HIV testing. While Tanzania continues to experience a generalized HIV epidemic, along with concentrated sub-epidemics among key populations, the country's private health sector has remained underutilized in providing HIV prevention services and treatment.

In 2016, oral pre-exposure prophylaxis (PrEP) for HIV was recommended by the World Health Organization as an additional prevention measure for individuals at substantial risk of HIV infection. Since then, additional PrEP products have been approved for use. PrEP is highly effective at preventing HIV infection when used as directed. While many countries have incorporated PrEP in their comprehensive HIV prevention and treatment framework, the involvement and roles of different actors in the private sector in providing and distributing PrEP is unclear.

The Frontier Health Markets (FHM) Engage project – aims to strengthen health markets to improve health outcomes in mixed health systems. In Tanzania, FHM Engage will support the mission's priority of expanding HIV/AIDS commodities distribution, including PrEP, through the country's private market. To facilitate the FHM Engage team in designing and delivering mission critical activities, this desk review summarized peer-reviewed and grey literature to describe how Tanzania and four comparator countries – Kenya, Zambia, South Africa, and Thailand – have involved their private health sectors in increasing access to oral PrEP.

This review found that all five countries have approved oral PrEP medication (both brand-name and generic) for use, although the requirement of completed laboratory assessments prior to PrEP initiation differs by country. Three of the countries' guidelines specify the delivery channels, of which Kenya and Thailand include relatively diverse delivery methods. The private not-for-profit sector has predominantly been involved in generating demand and facilitating oral PrEP distribution across the five countries, and only one program described including a user-fee model. Multiple approaches involving varying levels of collaboration between public and private sectors actors have been implemented to facilitate access by key and target populations, such as men who have sex with men, transgender women, female sex workers, sero-discordant couples, and adolescent girls and young women. Besides leveraging existing health infrastructure to distribute PrEP, programs have demonstrated the importance of building the capacity of community-based organizations to develop differentiated services for key populations and ensuring such services are informed, led, and delivered by members of these key populations.

The review found only two examples of private for-profit channels being involved in the distribution of PrEP - a pilot pharmacy study and an ongoing online pharmacy model. Both models have been subsidized and therefore willingness to pay for oral PrEP was not tested. Across the five countries, only one user-fee model was found, but it was administered by a not-for-profit organization. In most countries, private not-for-profit providers, such as non-governmental organizations (NGOs) and other social marketing organizations, have taken the lead in scaling up private market PrEP distribution. Future market research into the ideal private market channels for PrEP distribution in Tanzania should be conducted.

# Background

The private sector is an important source of health care service and product provision in many low- and middle-income countries (LMICs). As a key actor in many countries' health systems, the private health sector continues to garner greater attention from policymakers, health services researchers, and other related stakeholders[1,2]. In many regions throughout the world, the private sector is responsible for delivering nearly half of all healthcare[3]. In Tanzania, the private health sector has been for many years an important provider of services such as family planning; maternal care; HIV testing; and under-five childcare[4,5].

Frontier Health Markets (FHM) Engage is a United States Agency for International Development (USAID) project that aims to strengthen health markets to improve health outcomes in mixed health systems. FHM Engage focuses on strengthening local health markets to optimize public and private sector engagement to contribute to sustainable market efficiencies and increased access to family planning, maternal and child health, and other health services, products, and information. This will be achieved through two main result areas: 1) improved market environment for greater private sector participation in the delivery of health products and services, and 2) improved equal access to and uptake of high-quality consumer driven health products, services, and information.

In Tanzania, FHM Engage's activities will directly support two Mission objectives: 1) enhance the enabling environment for private sector and civil society organizations, and 2) increase economic opportunities. To facilitate the FHM Engage team in designing and delivering mission critical activities, Metrics for Management is conducting a series of desk reviews exploring how Tanzania and selected comparator countries have leveraged their private sectors to expand access to the prioritized commodities and services. The current report focuses on PrEP distribution and details the current state of private health market engagement in PrEP distribution in Kenya, Zambia, South Africa, and Thailand.

## HIV in Tanzania

An estimated 1.7 million Tanzanians are living with HIV and the country continues to experience an incidence rate of 1.55 per 1,000 person-years in adults aged 15 to 49. There is significant heterogeneity in HIV prevalence and incidence rates in Tanzania. While the HIV incidence among all individuals aged 15 and older is 0.96 per 1,000 person-years, youth aged 15 to 24 has a higher rate of HIV incidence. Additionally, the HIV prevalence of men who have sex with men (MSM) and female sex workers (FSW) nearly doubles and more than triples that of the general population (MSM: 8.4%, FWS: 15.4%, all adults aged 15 and above: 4.8%)[6]. The HIV burden is also found to be greater in urban areas of Tanzania than in rural ones - 7.5% versus 4.5%[7].

Pre-exposure prophylaxis (PrEP) for HIV is the use of antiretroviral medication by HIV-negative individuals to prevent the acquisition of HIV. The World Health Organization (WHO) recommends PrEP to those members of key populations (KPs) at substantial risk of acquiring HIV as well as to those other individuals engaged in behavior placing them at high risk of infection. PrEP is not only a pill, but a comprehensive strategy that includes counseling, HIV and laboratory testing service, and, if later necessary, transition to provision of antiretroviral therapy (ART)[8]. Over the past eight years, PrEP has

become an important prevention measure in many countries' HIV prevention and treatment frameworks.

Since its approval for use, an estimated 104,000 Tanzanians have been initiated on PrEP. These initiations are a laudable achievement. In order to advance the cause of further reducing the burden of HIV in Tanzania, additional efforts must be made to increase the public's awareness of PrEP and its uptake amongst KP members.

## Scope

This report summarizes a desk review of private sector distribution of PrEP in Tanzania and four comparator countries, Kenya, South Africa, Zambia, and Thailand. It provides country-specific information on various facilitators and barriers to private health sector engagement in PrEP distribution, including types of PrEP currently available; national guidelines surrounding PrEP distribution in each country; and delivery modalities employed within countries' private health markets. This report is designed to facilitate discussion around activities that will improve access to PrEP through private health channels in Tanzania.

# Methods

## Desk review methodology

Peer-reviewed and grey literature sources were searched for relevant documents. Documents reviewed included published national guidelines and frameworks related to PrEP provision along with peer-reviewed and grey literature reports describing PrEP distribution through private sector channels.

Policy documents and guidelines on HIV testing were searched through countries' Ministry of Health websites and general keyword searches. To identify private sector interventions from funding organizations, searches were conducted of several funding agencies' websites (the United States International Agency for Development; the President's Emergency Plan for AIDS Relief (PEPFAR); the Joint United Nations Programme on HIV/AIDS (UNAIDS); and the Bill and Melinda Gates Foundation), a PrEP program consolidating website (PrEPWatch), as well as non-profit organizations that have focused on private sector interventions (Pathfinder International, FHI360, and Population Services International). Relevant academic literature was identified through keyword searches on PubMed and Google Scholar.

## Country selection

Private sector involvement in the distribution of PrEP in Tanzania is compared to Kenya, Zambia, South Africa, and Thailand. The comparator countries were selected either for their similarities to Tanzania or following initial investigations indicating that the country had sufficient relevant policy and report documents available online to gain an understanding of how they had approached integrating their private health sector into national PrEP distribution frameworks.

## Limitations

Given the scope, the search strategy has some limitations. The review provides background information on the topic; it should not be considered a comprehensive report on all relevant aspects of PrEP distribution through private channels. Web searches were conducted in English; information that was only available in other local official languages was not included in the report. The report reflects the most up-to-date documentation available related to each country's policies. However, these policies may not reflect the on-the-ground practice reality within the country. Future iterations of this report may broaden the methodology to include additional stakeholder interviews to expand findings.

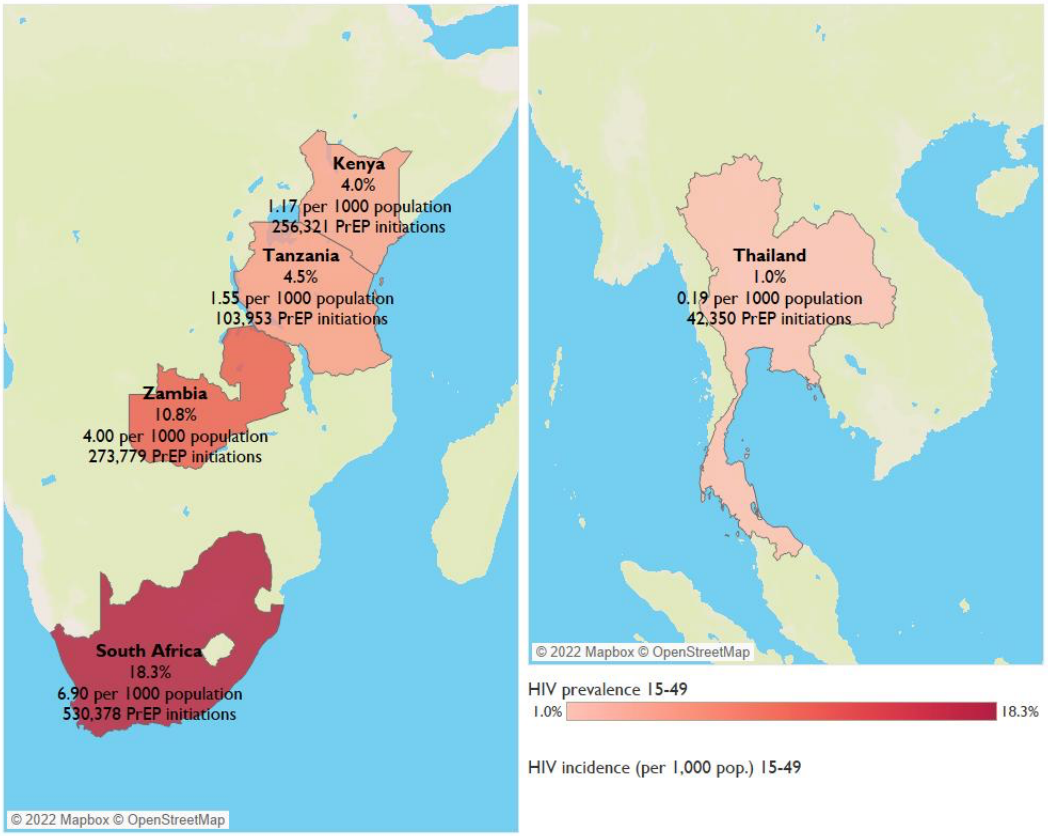
# Review summary

## Context

### What is the current state of the HIV epidemic and HIV burden among key populations in each country?

To facilitate the understanding of the need for PrEP in each country, it is important to contextualize the HIV epidemic and identify populations at substantial risk of HIV infection. As shown in Figure 1, the five countries have varying levels of prevalence in the general populations and may be grouped into three prevalence categories: relatively low (Thailand), moderate (Tanzania and Kenya), and high (Zambia and South Africa) HIV prevalence.

FIGURE 1: HIV PREVALENCE, INCIDENCE (AGES 15-49) AND CUMULATIVE PREP INITIATION IN THE FIVE COUNTRIES




As PrEP is designed to be used by individuals at substantial risk of HIV infection, the market for PrEP is considerably smaller than testing needs in each country. While eligibility for PrEP is based on an individual's risk, eligibility on the population level depends on the epidemiological context and populations in need due to high HIV incidence and/or engage in behaviors that put them at substantial risk in acquiring HIV. Across the countries, key populations have substantially higher risk of HIV infection than the general population, besides additional target populations specific to each country's epidemiological situation (e.g., adolescent girls and young women, migrant workers). Table 1 shows the

estimated size and HIV prevalence of selected key populations in the five countries. Simple targets may include offering PrEP to these key populations, as well as sero-discordant couples and pregnant women, besides the consideration of other populations of substantial HIV risk such as adolescents and young women in high prevalence regions who engage in higher risk behaviors.

TABLE 1. ESTIMATED KEY POPULATION SIZE AND HIV PREVALENCE IN THE FIVE COUNTRIES.

| | | **Tanzania** | **Kenya** | **Zambia** | **South Africa** | **Thailand** |
|---|---|---|---|---|---|---|
| Sex workers | Population size | 155,500 | 197,100 | 126,000 | 146,000 | 43,000 |
| | HIV prevalence | 15.4% | 29.3% | 48.8% | 62.3% | 1.1% |
| Men who have sex with men (MSM) | Population size | 50,000 | 32,600 | 6,500 | 310,000 | 528,000 |
| | HIV prevalence | 8.4% | 18.2% | - | 29.7% | 11.9% |
| People who inject drugs (PWID) | Population size | 36,000 | 26,700 | 26,800 | 82,500 | 42,000 |
| | HIV prevalence | 15.5% | 18.3% | - | 21.8% | 20.5% |
| Transgender people | Population size | - | 4,400 | 4,000 | 179,000 | 63,000 |
| | HIV prevalence | - | - | - | 58.0% | 11.0% |

*Data obtained from UNAIDS estimates[9].

# Key guidelines for PrEP

## What is the state of PrEP registration in each country?

**World Health Organization**

Section 3.2.1 Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring

"Oral pre-exposure prophylaxis containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (strong recommendation, high certainty evidence)."

Section 3.2.2
"The dapivirine vaginal ring may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate certainty of evidence)."

Section 3.6 Guidelines on Long-Acting Injectable Cabotegravir for HIV Prevention
"Long-acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection, as part of combination prevention approaches (conditional recommendation; moderate certainty of evidence)."

A number of different routes of administration have been developed for pre-exposure prophylaxis for HIV. The most common form is oral PrEP, an oral combination medication that individuals take daily or during high-risk acquisition periods[10]. Vaginal and injectable forms of PrEP have also been developed. Since 2016, the World Health Organization (WHO) has strongly recommended that oral PrEP containing disoproxil fumarate (TDF) be offered to those people at substantial risk of HIV infection as part of an integrated HIV prevention approach. WHO also offers a conditional recommendation for the use of the dapivirine vaginal ring in some women[11]. Most recently, the United States' Food and Drug Administration granted regulatory approval to injectable cabotegravir, the first long-acting injectable form of PrEP[12]. WHO followed suit in 2022 with their own conditional approval. For most populations, "substantial risk" is frequently defined as an incidence rate of three per 100 person-years. While this recommendation was initially made because it was considered a point at which PrEP becomes cost-effective in a population, PrEP may still be cost-effective at lower incidence levels[8,11].

In three of the five countries included in this desk review – Tanzania, Zambia, and Thailand - the only forms of PrEP currently approved for distribution are the brand-name and generic forms of the oral combination medication emtricitabine 200 mg with tenofovir disoproxil fumarate 300mg (F/TDF)[13–15]. Kenya has approved the use of F/TDF oral PrEP as well as emtricitabine 200 mg with tenofovir alafenamide 25 mg (F/TAF)[16]. South Africa has approved F/TDF oral PrEP along with the dapivirine vaginal ring[17]. No countries, as of yet, have approved the cabotegravir intramuscular injection for use. Table 1 summarizes the forms of PrEP currently registered by country.

TABLE 2. PREP FORMULATION APPROVED IN EACH COUNTRY

| | Tanzania | Kenya | Zambia | South Africa | Thailand |
|---|---|---|---|---|---|
| Truvada (F/TDF) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Generic F/TDF | ✓ | ✓ | ✓ | ✓ | ✓ |
| Descovy (F/TAF) | | ✓ | | | |
| Dapivirine Ring | | | | ✓ | |
| Cabotegravir | | | | | |

## Who are the target populations for PrEP?

**World Health Organization**

**Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention: Update to WHO Implementation Guidance**

*"Oral PrEP containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches."*

*"HIV acquisition risk varies considerably within populations and geographical locations. Population-level HIV incidence is an important determinant of individual-level risk of HIV acquisition. However, when considering who could benefit from PrEP, it is important to consider the characteristics and behaviors of individuals and their partners that could lead to HIV exposure… Individuals requesting PrEP should be given priority to be offered PrEP since requesting PrEP indicates that there is likely to be a risk of acquiring HIV."*

While WHO guidelines do establish a minimal HIV acquisition rate for the term "substantial risk", the guidelines also recognize that risk also depends on the context and countries' epidemiological profiles. All five countries' guidelines described targeted populations identified for PrEP and several key populations have been included in all five countries (Table 3). Besides target populations, all countries also identified the need for PrEP among people who recognize their own risk and request PrEP.

TABLE 3. KEY POPULATIONS INCLUDED AS TARGET POPULATIONS FOR PREP IN EACH COUNTRY

| Key populations | Countries that included key populations as target for PrEP |
|---|---|
| HIV sero-discordant couples | All five countries |
| MSM | All five countries |
| Female sex workers (FSW) | All five countries |
| PWID | All five countries |
| Adolescent girls and young women (AGYW) | Tanzania, South Africa, Zambia, Thailand (adolescents) |
| Transgender people | Zambia, Thailand (trangender women) |
| Migrants | Zambia |
| Pregnant women | Thailand |

## Where can PrEP be delivered?

**World Health Organization**

**Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention: Update to WHO Implementation Guidance**

"*A differentiated PrEP service delivery approach is person- and community-centered and adapts services to the needs and preferences of the people who are interested in and could benefit from PrEP.*"

*"WHO already recommends community-based and lay provider-delivered HIV testing services and HIV self-testing as well as ART initiation and refills outside of healthcare facilities. WHO also recognizes the benefits of decentralized and community-based services for key populations. A range of differentiated oral PrEP service delivery models outside of healthcare settings has been implemented, including in fixed and mobile community sites, pharmacies and telehealth models. Some of these models provide PrEP services outside of healthcare facilities for initiation and continuation, while others provide initiation at health care facilities and continuation in community settings. Research suggests that community-based PrEP delivery models are acceptable to PrEP providers and are recognized to improve uptake of services."*

Not all five countries' guidelines specify the settings where PrEP can be delivered and the type of personnel who can distribute it. Among those that describe requirements for delivery settings (Kenya, Tanzania, and Thailand), the range of delivery settings differ by country. At present, for instance, Thailand is the only country that allows for alternative PrEP delivery methods, including through telemedicine appointments, online pharmacies, and postal delivery[18].

In order to be authorized to provide PrEP and its ancillary services, Tanzania's guidelines require sites to have at least three PrEP-trained healthcare workers on staff, to be able to provide integrated HIV services, and to have in place the proper reporting systems[13]. Kenya's framework for the implementation of PrEP specified a range of settings that can integrate PrEP[16]. These include prevention centers; pharmacies; stand-alone drop-in centers; special clinics; maternal child health, family planning, and antenatal clinics; youth-friendly centers; comprehensive care centers; and outpatient departments. In terms of personnel requirement, Kenya's guideline specifies that PrEP service provision requires a clinician for initiating PrEP, commodity management procedures, monitoring and evaluation systems, and ready access to laboratory services for baseline testing and monitoring. In addition to PrEP service units, Thailand's guideline describes postal service or intra-provincial transportation system and a mobile service vehicle as potential service delivery settings for PrEP[18].

## What clinical services are required to be provided with PrEP and what is the recommended follow-up schedule for PrEP clients?

**World Health Organization**

**Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention: Update to WHO Implementation Guidance**

- *Hepatitis B and C*

*"Testing PrEP users for HBV surface antigen once, at or within one to three months of PrEP initiation, is strongly encouraged where feasible, particularly in highly endemic countries"*

- *Kidney function*

*"Measuring kidney function is optional for those aged under 30 years without kidney-related comorbidities. Individuals aged 30 years and older without comorbidities may be screened once, at or within one to three months of oral PrEP initiation. Depending on available resources, this can be considered optional for those aged 30-49 years, particularly those aged 30-39, given the low risk of kidney impairment."*

*"Waiting for kidney function test results should not delay initiation or continuation of oral PrEP."*

- *HIV self-testing and follow-up*

*"HIVST-supported PrEP delivery models that reduce clinic visits should be balanced with the benefits of provision of comprehensive services to address the diverse needs of PrEP users."*

As PrEP is a prescribed medicine, its eligibility for initiation requires clinical assessment. Additionally, as eligible individuals have a high risk of HIV infection, a service package is recommended for initiation and follow-up to provide comprehensive and integrated services. However, WHO recommends that while integrated service should be provided along with assessing eligibility with PrEP, the results of most clinical assessments should not delay initiation or continuation of oral PrEP, with the one exception to this being a negative HIV test being required before initiating PrEP. WHO guidelines suggest that HIV self-testing could also be considered for PrEP initiation outside of clinics, while noting that current evidence is limited on such practice. All five countries include a varying package of clinical assessments for PrEP initiation, but all require hepatitis B surface antigen test and creatinine clearance or estimated glomerular filtration rate renal function tests[13,14,16–18].

Although impaired kidney function is a contraindication for TDF-based oral PrEP, the latest WHO technical guidelines indicate that renal function tests should be optional for individuals under 30 years of age with no known kidney-related comorbidities, and that subsequent follow-up renal function tests should also depend on individuals' age and initiation test results. All countries' guidelines currently require a kidney function test but the result is not required for initiation of PrEP, except for South Africa and Thailand. However, to minimize the delay of PrEP initiation, Thailand's guideline underlines the need for same day results. Table 4 details the laboratory testing requirements by country for PrEP initiation.

TABLE 4. LABORATORY TESTING REQUIREMENTS BY COUNTRY FOR PREP INITIATION

| | Tanzania | Kenya | Zambia | South Africa | Thailand |
|---|---|---|---|---|---|
| **HIV and other STI tests** | | | | | |
| HIV testing service | ✓- before initiation | ✓- before initiation | ✓- before initiation | ✓- before initiation | ✓- before initiation |
| Syndromic STI diagnosis | Optional | Optional | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP |
| Rapid plasma Reagin | | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | | |
| **Liver function tests** | | | | | |
| Creatinine clearance test / Urinalysis | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- before initiation | ✓- Same day |
| Alanine Amintransferase | | | ✓- results not needed to begin PrEP | | |
| **Hepatitis screening** | | | | | |
| Hepatitis B surface antigen | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP |
| Hepatitis C antibody | Optional | ✓- results not needed to begin PrEP | | | ✓- results not needed to begin PrEP |
| **Other test** | | | | | |
| TB screening | | | ✓- results not needed to begin PrEP | ✓- results not needed to begin PrEP | |

Compared with the other countries, mainland Tanzania's guidelines have the most frequent follow-up requirements, which indicate a monthly follow-up schedule for the first six months. South Africa allows a three-month prescription that should be dispensed monthly to ensure a monthly HIV test, which potentially reduces the burden on the health care facilities. Other countries follow a 3-month prescription after the first 1-month follow-up. Thailand is the only country that includes telehealth as an option for follow-up in its PrEP guidelines. Table 5 summarizes countries' national guidelines on PrEP follow-up and initial prescription lengths.

TABLE 5. PREP FOLLOW-UP SCHEDULE AND PRESCRIPTION PERIOD BASED ON NATIONAL GUIDELINES

| Key populations | Countries that included key populations as target for PrEP |
|---|---|
| Tanzania | Monthly for the first 6 months. After the sixth visit the provider can assess the client's use and offer three month's supply, to align with HIV testing service visits. |

| | |
|---|---|
| Kenya | 1 month, then every 3 months |
| Zambia | 1 month, then every 3 months |
| South Africa | 1 month supply; then 3-month prescription that is collected monthly with HIV test; then every 3 months for a 3-month prescription |
| Thailand | 1 month, then every 3 months (follow-up can be performed via telehealth service) |

# PrEP in the private sector

## How do we characterize the types of private health channels involved in PrEP distribution?

The private health sector in many LMICs plays an important role in healthcare provision and is often composed of a heterogeneous collection of both for-profit and not-for-profit providers. These providers range in sophistication from small drug dispensation shops to large, technologically advanced hospitals[19]. A country's private health sector is not monolithic and different actors have an array of different distribution, service, and financing models. Rather than referring collectively to the entire private health sector of a country, this report differentiates between for-profit and not-for-profit actors when reporting how countries' private health sectors have contributed to the scaling-up of PrEP distribution. For-profit providers can include private pharmacies, unlicensed or licensed drug sellers, and private primary, secondary, and tertiary care providers. Not-for-profit entities include commodity social marketers, social franchises, and similar NGO health service providers.

Drawing a distinction between for-profit and not-for-profit channels is essential when considering how to utilize private health market channels to increase access to PrEP. For-profit and not-for-profit private health channels possess relative advantages and drawbacks in facilitating PrEP distribution. For instance, due to their ability to generate revenues capable of supporting their ongoing operations, for-profit entities may be able to provide quality health services and products with little to no external subsidization, while not-for-profit structures often require external financial or other in-kind support from government or aid organizations to continue their operations. However, the profit motive means that for-profit health providers are frequently incentivized to establish points of service only in relatively wealthy regions in which there is strong demand for private health services. Not-for-profit providers on the other hand, may be less encumbered by the need to ensure sufficient operating revenues and more free focus operations in those regions requiring greater service access.

## How have for-profit private health channels contributed to PrEP distribution?

Few examples were found of for-profit health channels scaling up PrEP distribution. In Kenya, while PrEP distribution has taken place primarily in HIV clinics, retail pharmacies have also been included in the national PrEP framework, through a pharmacy-led care pilot. A retail pharmacy-based PrEP delivery pathway was developed following stakeholder meetings around improving access to PrEP[20]. The stakeholders proposed to train pharmacy providers using existing PrEP materials and guidelines in Kenya, enable oversight through remote clinician-led monitoring, and to assist clients with HIV self-testing (HIVST) to determine HIV status. The pilot research study is being conducted at five private retail pharmacies and preliminary findings found similar uptake and adherence of PrEP when compared to Ministry of Health clinics[10]. While this research hints at the potential of for-profit providers as PrEP distributors, more research is needed on the acceptability and cost-effectiveness of the model.

Along with physical retail pharmacies, a donor-funded program in Kenya similarly aimed to implement PrEP distribution through an online pharmacy in Kenya[21]. Through the program, clients can access the online pharmacy's website for a free telemedicine consultation with one of the site's clinicians, who can prescribe PrEP following HIV risk assessment and confirming the client's negative HIV status using blood-based HIV self-testing. Prescribed PrEP medications are then delivered to the clients. Both the telemedicine consultation and PrEP medication are fully subsidized by the donor. The program is ongoing and details on its implementation are not yet available.

While entirely for-profit private health market actors have had little involvement in widespread scale-up of PrEP, these market channels might still prove useful distribution models. Private market analyses of Zambia, Kenya, and South Africa have identified private market actors as potentially useful partners. These reports noted, though, that PrEP remains prohibitively expensive for most individuals and that in order to leverage these private market channels, governments and aid organizations would need to subsidize the cost of medication. Private providers, for their part, would benefit from participating in PrEP distribution by making more money on other products and services from the additional foot traffic brought in by offering PrEP. This hybrid financing approach may offer the business case that private medical providers and retailers would need to justify expanding into PrEP distribution[22].

## How have not-for-profit private health channels contributed to PrEP scale-up?

Most of the PrEP demonstration and scale-up programs within countries' private health sectors were carried out by not-for-profit private providers. These programs were frequently either directly subsidized by government and aid organizations or supported through public-private partnerships in which pharmaceutical manufacturers donated the necessary medication. Demand generation and distribution through not-for-profit entities has until now been the dominant means by which private health markets have participated in PrEP scale-up because the medication continues to be prohibitively expensive for many in LMICs. External donor support has been necessary to extend access to most key populations. Not-for-profit private health sector's provision of PrEP services have been implemented in several models designed to reach various target populations.

### Collaboration with public sector to provide PrEP

The Determined, Resilient, Empowered, AIDS-free, Mentored and Safe (DREAMS) partnership is a public-private partnership funded by PEPFAR whose goal was to reduce rates of HIV among adolescent girls and young women (AGYW) in high HIV burden countries. Implementation began in 10 countries in late 2015 and expanded to 5 additional countries in 2017, and included Kenya, Tanzania, South Africa, and Zambia. The program was designed using a layered interventions approach, with interventions and services received based on the age and needs of the AGYW[23]. PrEP is among the core adolescent-friendly health services. Demand generation has been led by community-based organizations (CBOs), which includes mobile vans for outreach efforts and HIV testing. CBOs have also organized meetings with local chiefs and community members to inform them of the benefits of PrEP for AGYW. Potential PrEP users have been identified and recruited by trained peer mentors and overseen by expert nurses or clinical officers from public health facilities.

Once an individual's eligibility is determined, PrEP is offered and initiation conducted at a nearby government clinic, and PrEP medications are provided through public sector channels. In Kenya, subsequent follow-up appointments and refills take place either at those public facilities or through MoH health care workers in the community safe space maintained by CBOs. The use of safe spaces, peer mentors, and linkages to other health services have been identified as facilitators to PrEP uptake[24]. To ensure AGYW receive different services at the safe space and maintain PrEP adherence, peer mentors also have the responsibility of ensuring AGYW attend follow-up appointments and communicating with service providers about potential barriers AGYW may face in returning for follow-up services and medication.

### Leverage existing health infrastructure to distribute PrEP

Kenya's *Jilinde* Bridge to Scale program was a large five-year public-private PrEP distribution program whose goal was to reach vulnerable AGYW, MSM, and FSW - all key groups known to experience a disproportionate share of new HIV infections in the country[25]. The *Jilinde* program focused scale-up efforts in three geographical clusters of 10 counties around Lake Victoria, Nairobi, and Mombasa that contain large numbers of key populations (KPs) and have high HIV prevalence rates[26]. The project collaborated with NASCOP and the Kenya Medical Supplies Authority to leverage existing supply chains for antiretroviral drugs for ensuring reliable delivery of oral PrEP[26]. Existing public and private facilities were also used as the backbone for medication distribution in all 10 *Jilinde* counties. The project strengthened clinical sites by integrating PrEP into existing combination HIV prevention activities that

served KP and AGYW clients, including drop-in-centers (clinics that mainly serve KPs) and private health facilities. The drop-in-centers served as government-owned health facilities satellite sites that received PrEP commodities through the national pipeline.

To standardize service provision, the project supported NASCOP to train a group of PrEP national master trainers from all 47 counties, who then cascaded the PrEP training to health service providers within their respective counties by using the national training curriculum. Besides utilizing existing health facilities' infrastructure, the project mobilizes KP and AGYW networks, support groups, and peer educators to ensure uptake of PrEP and continuity through adherence support and physical tracing of clients lost to follow-up. Satisfied clients were also engaged as PrEP champions to share their experiences during PrEP demand generation activities.

The *Jilinde* program provided evidence that PrEP services are oftentimes viewed as more acceptable when they are delivered by members of the KPs targeted for outreach. For instance, qualitative work and market segmentation of *Jilinde* clients found that health information originating outside of MSM communities is frequently not well received by its community members. Members of stigmatized communities, such as MSM, transgender women (TGW), and FSWs, are oftentimes mistrustful of medical professionals, politicians, and public health officials. *Jilinde's* use of MSM peer educators and AGYW peer mentors for outreach likely contributed to the program's overall effectiveness[27]. Further, the program's success in integrating PrEP services into existing public and private HIV service structures suggests that similar scale-up strategies may prove effective in other countries. Finally, the program demonstrated that private providers can be effective partners in PrEP distribution. While the majority of PrEP consultations and initiations took place in the public sector, private sector providers screened a greater proportion of their clients for PrEP eligibility. Between May 2017 and October 2019, private providers screened 35% of their HIV negative clients for having behavioral risks for HIV infection, while public facility providers screened 27%[28].

## User-fee model at existing non-profit organization facilities

One user-fee based program identified was PrEP-30, a demonstration project that took place in Bangkok, Thailand and designed to assess the feasibility and acceptability of a user-fee-supported delivery model for providing PrEP to MSM and other individuals at risk of acquiring HIV[29]. Led by the Thai Red Cross AIDS Research Center, the program's goal was to reach MSM, a group that continues to experience persistently high rates of HIV infection in Thailand[30]. The project was launched at the end of 2014 during a time in which PrEP was not yet a treatment covered by Thailand's national health coverage system. The PrEP-30 program charged users about 30 Thai baht (approximately $1 USD) per day for oral PrEP, counseling, and laboratory testing at a non-profit HIV testing and counseling center[30]. While uptake was slow for the first year and a half, initiation increased quickly following 18 months of in-person and online outreach efforts. Results after three years showed that PrEP programs can be incorporated relatively quickly to existing ART distribution structures and that MSM and other high-risk individuals are willing to pay for PrEP that is provided at an affordable price point. While the program offered strong evidence that certain populations within a middle-income country would be willing to pay user fees for PrEP and additional HIV services, it remains unclear whether similar groups in lower income countries would be willing or able to cover the cost of generic oral PrEP. Additionally, it is unclear whether the daily fee of around 30 baht covers the entire cost of medication and services and

can be considered an entirely unsubsidized, self-sustaining business model. As of 2020, PrEP-30 is responsible for covering 25% of all users of PrEP in Thailand[31].

## Key population led health service model for PrEP distribution

Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) program was a PEPFAR-funded project that had activities focused on reducing HIV transmission among key populations such as FSWs, MSM, TGW, and PWID in over 30 countries between 2014 and 2021. The project provided support for organizational capacity building by local KP partner organizations to deliver a comprehensive range of HIV services, including PrEP enrollment and follow-up. The project supported civil society organizations (CSOs) to establish drop-in centers serving KPs. In Kenya, 16 out of 35 CSOs established drop-in centers and expanded their service offerings to become community ART sites[32]. Some of these sites offered flexible hours, including being open on weekends and late at night to enable access by KP clients. Peer educators were engaged in the operation of these drop-in centers, and served on community advisory boards and quality assurance improvement committees. LINKAGES in Kenya partnered with the Jilinde project to provide PrEP, and six of the local implementing partners were involved in PrEP provision in reaching FSWs and MSM.

In Thailand, the LINKAGES project partnered with community-based, nongovernmental organizations and hospitals to improve the cascade of HIV services for MSM and TGW[33]. The project focused on implementing a differentiated service delivery model that was tailored to the different needs and preferences of key populations and provided community-based service delivery. Partnering with CBOs, the project developed a key-population-led health services (KPLHS) model, which trained lay providers recruited from among key populations to provide point-of-care HIV services (ranging from prevention, diagnosis, to treatment, support, and follow-up). The CBOs' management, community outreach, and recruitment were all conducted by trained KP peer outreach workers. The model underscored the importance of having members of a key population act not only as PrEP clients but also as critical actors in PrEP program administration and demand generation. Additionally, the program identified the need for differentiated service delivery for trans-friendly comprehensive health care, including hormone-level monitoring, mental health support and referral, and legal rights support.

The project collaborated with the Princess PrEP program, which has been the largest PrEP program in Thailand and supported the cost of generic PrEP medication through the Thai Red Cross Princess Soamsawali HIV Prevention Fund. Through the collaboration, the KPLHS sites have been dispensing free same-day PrEP since 2016. In 2017, the model was responsible for contributing 38% of all HIV counseling and testing service requests and 26% of all new HIV diagnoses in Thai MSM and TGW[34]. The model has been shown to be highly acceptable to KPs. In a survey of MSM and TWG, 60% of respondents reported preferring to receive services from KP-led private CBOs. As time has gone on, the KPLHS model has become further standardized, and today comprise accredited health service sites registered as equivalent to health centers in the national public health system. KP lay providers have been approved to deliver HIV services, such as HIV testing and PrEP, post-exposure prophylaxis (PEP), ART, and sexually-transmitted infections (STI) treatment[31]. Under the Princess PrEP and LINKAGES Thailand programs, KPLHS sites have supported 55% of all Thai PrEP users. Besides MSM and TGW populations, the model was also expanded to other key populations including PWID.

## Outreach and delivery through a community-based mobile clinic

In South Africa, community-based mobile clinics have been utilized to deliver PrEP through the Prevention Options for Women Evaluation Research (POWER) and FastPrEP projects[35,36]. Both projects focus on reaching AGYW, while the FastPrEP project also aims to scale up PrEP delivery to both the partners of AGYW and young MSM. The projects' mobile clinics integrated PrEP delivery into existing sexual and reproductive health services and aim to increase healthcare access by providing services in locations and at times that are convenient for young people. The community-based mobile clinic model has been shown to be more acceptable by adolescent and young adult clients for sexual and reproductive health service provision than traditional primary health clinics[37]. The mobile clinics also provide point-of-care HIV and pregnancy testing and collect the laboratory samples required for same-day PrEP initiation by eligible individuals. Occasional visit reminders are sent via phone calls and WhatsApp communication.

An assessment of the mobile clinic model in the POWER study found the model makes PrEP services highly accessible, visible, and convenient, and that the service has been tailored to meet the needs of young people[35]. Integrated sexual and reproductive health services also provide a holistic approach to access related services. However, the unsafe environment where the mobile clinic operates and lack of predictivity of AGYWs' lives also present the challenge of unplanned PrEP user interruptions. Both programs have incorporated other delivery channels such as local government clinics, community-based PrEP club, and courier PrEP delivery service.

## Expanding access through online approaches

Besides in-person demand generation, programs often extend interventions into online platforms commonly visited by target populations, including social media platforms that young KP members use to socialize. LINKAGES Thailand program supported online peer education and demand creation through online competitions and campaigns to promote HIV testing and PrEP uptake across social media channels such as Facebook, Twitter, YouTube, and a range of online dating applications[33]. The project also created an online reservation application to link clients online to physical HIV testing and PrEP services. Program data identified high HIV case finding of MSM populations through online dating applications, indicating the need of online approaches to identify high-risk individuals.

The use of online approaches have also been essential during the COVID-19 pandemic. To ensure continuity of PrEP access, the Princess PrEP service adapted their service provision to include telehealth for routine clinical follow-up and use of STI self-sampling[31]; while the DREAMS program in Kenya established a virtual safe space led by DREAMS mentors to discuss accessing PrEP[38]. In the DREAMS program, AGYW could reach out to health care providers through the assigned WhatsApp group and individually, and to initiate PrEP enrollment. Eligibility was then confirmed through an in-person health facility appointment that could be scheduled through the virtual safe spaces.

However, while effective adaptations have been found in some PrEP programs[39], including use of SMS, internet, and smartphone apps, limited evidence has been found in the acceptability and effectiveness of online and mobile approaches in the five countries. Only one study was conducted using SMS surveys to assess PrEP adherence and sexual behavior in Kenya and two trials of SMS reminders and a mobile phone app on adherence of PrEP among young women in Kenya and young people in Thailand[40–42]. Both trials found no effect of the interventions on PrEP adherence in the two settings[41,42].

TABLE 6. PROGRAMS INVOLVING PRIVATE SECTOR IN PREP ACCESS AND IMPLEMENTING COUNTRIES

| Program | Number of implementing countries (countries in the current review) |
|---|---|
| DREAMS | 16 (Tanzania, Kenya, Zambia, and South Africa) |
| LINKAGES | 30 (Kenya and Thailand) |
| POWER | 2 (Kenya and South Africa – mobile clinic in South Africa only) |
| Jilinde | 1 (Kenya) |
| PrEP-30 | 1 (Thailand) |
| Princess PrEP program | 1 (Thailand) |
| FastPrEP | 1 (South Africa) |

Note: some of the current projects on PrEP are not listed here due to limited detailed information on implementation and/or their limited involvement with the private sector.

## What challenges emerge when scaling-up PrEP with private sector?

As described in the section above, the private sector has been engaged in PrEP distribution predominantly through not-for-profit organizations in the five countries. While the pharmacy model has been piloted in Kenya and an online pharmacy model is being implemented, PrEP medication has been fully subsidized in those models. Among all programs reviewed, only one program, in Thailand, applied a user-fee model. It likely has a different socio-demographic profile compared to Tanzania. The high cost of PrEP medication and need for high demand generation is likely prohibitive for the private for-profit sector to distribute PrEP.

Throughout many scale-up programs across countries, wide-scale acceptance and medication initiation is not immediate. In Kenya, the DREAMS program, reported that median time between program enrollment and PrEP initiation for those AGYW meeting criteria was 299 days[43]. In Thailand, the PrEP-30 program took roughly one year to reach its first 200 PrEP initiations, six more months to reach 400, and an additional five months to reach 600[44].

Among KPs and AGYWs, high discontinuation was found in the *Jilinde* program in Kenya. While over 86000 clients deemed eligible for PrEP, only about 25,000 clients were initiated on PrEP and 7700 clients returned for their refill after their first month[26]. Researchers in the Kenya DREAMS program found that adherence time on PrEP was only 56 days for those who initiated[43]. Qualitative work conducted with PrEP clients found that a lack of motivation of commitment, stigma, and health system and product challenges were all explanations for discontinuation. These high discontinuation rates are similar to those found in other studies around barriers to PrEP continuation[45,46].

As the prescription and continuation of PrEP requires trained healthcare providers and accompanying laboratory services, limitations in financial and human resources have been reported by community-based programs[24,47]. In programs where PrEP provision depends on the public sector, low clinic staffing and lack of transportation available to providers in reaching the community safe spaces and events restricted availability of PrEP. Despite the focus on improving accessibility through community-based PrEP delivery, PrEP adherence was low among AGYW in Kenya[43,46], especially among younger AGYW or those engaged in transactional sex.

## What should be considered when scaling-up PrEP through private sector channels?

As illustrated in the earlier sections, numerous different private market actors have been engaged in PrEP scale-up efforts in the four comparator countries. Private sector market actors are a diverse group and not all organizations have operation models equally suited to PrEP distribution. Thailand's PrEP-30 program demonstrated that some groups view themselves at high risk of acquiring HIV and have the financial resources necessary to help pay for PrEP and its related services. Many high-risk populations in LMICs, though, simply do not have the resources needed to pay for PrEP. For this reason, there have been few examples of purely for-profit private sector organizations significantly contributing to PrEP distribution scale-up. More frequently, partially or wholly subsidized social marketing distribution, non-governmental, and community-based organizations are the private market actors best positioned to aid in reaching key and other target populations.

In Kenya, the USAID-funded Optimizing Prevention Technology Introduction on Schedule (OPTIONS) consortium conducted a market analysis meant to uncover the private sector actors best positioned to distribute PrEP to women[22]. The program found that among the six private sector delivery channels evaluated, based on their acceptability, affordability, proximity to target clients, and capacity in the country, that private doctors and NGO clinics and social franchises offer the greatest opportunity for private market PrEP distribution. This analysis does not treat the private market as a single homogeneous entity, but rather as a complex system whose constituent members all have relative strengths and limitations. As stakeholders approach the question of how to further integrate private sector institutions into a larger PrEP distribution scheme, they should consider conducting a similar analysis using an adapted form of the OPTIONS private sector channel assessment framework (Table 7).

TABLE 7. ADAPTED OPTIONS PRIVATE SECTOR CHANNEL ASSESSMENT FRAMEWORK

| Accessibility Factors | Capacity Factors |
|---|---|
| Can key and target populations at risk for HIV access this channel? | Does this channel have the capacity to deliver oral PrEP? |
| **Acceptability**<br>Key and target populations at risk for HIV are comfortable with accessing family planning and other sexual and reproductive health services through this channel | **HIV counseling and testing services**<br>Channel currently offers HIV counseling and testing services |
| **Affordability**<br>Services are affordable for key and target populations at risk for HIV with a range of income levels | **Healthcare workers**<br>Channel has healthcare workers who can prescribe oral PrEP and support adherence |
| **Proximity**<br>Sufficient number of facilities located in regions with high HIV incidence for key and target populations | **Ability to provide necessary follow-up**<br>Channel enables oral PrEP users to easily follow-up for prescription pick-up and ongoing testing |

Note: Framework adapted from OPTIONS private sector channel assessment[22].

# Discussion

This desk review compares the state of private market development for PrEP in Tanzania, Kenya, Zambia, South Africa, and Thailand. PrEP has been shown to be effective against HIV infection when taken routinely or before and after high-risk acquisition periods[10,11], and offers unique opportunities for addressing the needs of high-risk groups. Integrating the private health sector into PrEP distribution has taken many forms across the comparator countries. While readers may glean their own list of themes from the many programs and studies highlighted here, the following lessons merit consideration.

***Key population and target population-led, client-centered services are effective strategies in reaching target communities***

In many countries, members of MSM, TGW, FSW, and other key population communities face significant institutional and social stigma[27]. Understandably, members of these communities are reluctant to identify themselves and frequently turn inward toward their communities and are distrustful of information that emanates from outside sources. The documents reviewed for this desk review strongly suggest that KP-led services and community outreach can be powerful strategies for increasing awareness, acceptance, and uptake of PrEP. In Thailand and Kenya for instance, community-based KP-led services targeted to MSM and TGW were considered highly acceptable[25,31–33]. In Thailand, these services to this day remain responsible for a large share of all HIV testing requests and PrEP initiations. Services targeted to young people can similarly benefit from engaging youth in community outreach and promotion efforts. The DREAMS and *Jilinde* programs experienced much of their success due to the involvement of youth mentors who conducted much of the outreach to other youth necessary for the programs to gain traction. Private, community-based PrEP programs should be designed and administered in close consultation with members of the KPs that they seek to serve.

***PrEP initiation and retention are challenging***

Throughout many programs to scale-up PrEP, the process to reach scale often took time, as demand creation for PrEP is critical to scale-up and program success. There are many approaches to creating demand for PrEP that vary by target population and by level. Promotion activities such as provider training, facility-level advertising, community and public awareness campaigns are strategies that intervene at different levels of one's social-ecological environment and can be adapted to meet the particular information needs of the intended target population[8].

Retention is similarly challenging. In the *Jilinde* program, only about 32% of clients initiated on PrEP between May 2017 and October 2019 returned for their one-month refill and similar low retention has been reported in other programs[43]. Barriers to adherence may include stigma, health systems inaccessibility, medication side effects, pill burden, competing life stressors, and changes in risk perception[48,49]. At the individual level, to promote adherence, It is important for providers to acknowledge that clients face many barriers to medication adherence and to provide clients clear descriptions of how PrEP works and how to manage potential side effects. At the programmatic level, it is useful to focus not only on initiation, but also adherence and retention. This shift in program priorities may mean devoting additional resources to community outreach through peer educators of community health workers whose jobs are to stay in contact with and support those clients already initiated on PrEP[8].

# Conclusion

Of the 5 countries, Kenya and Thailand have had the widest array of trials and programs devoted to expanding use of PrEP in the private sector. Notably, in all countries, the not-for-profit sector, or donor supported and subsidized interventions, appear most successful in meeting intervention goals. None of the interventions described had clear goals of financial sustainability, and given the high cost of PrEP, other program objectives likely take precedence. The private sector may have a role to play in marketing PrEP programs and in increasing access, although such programs will continue to be subsidized.

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Frontier Health Markets (FHM) Engage is a five-year cooperative agreement (7200AA21CA00027) funded by the United States Agency for International Development. We work to improve the market environment for greater private sector participation in the delivery of health products and services and to improve equal access to and uptake of high-quality consumer driven health products, services, and information. Chemonics International implements FHM Engage in collaboration with Core Partners: Results for Development (co-technical lead), Pathfinder, and Zenysis. FHM Engage Network Implementation Partners include ACCESS Health India, Africa Christian Health Association Platform, Africa Healthcare Federation, Amref Health Africa, Ariadne Labs, CERRHUD, Insight Health Advisors, Makerere University School of Public Health, Metrics for Management, Solina Group, Strategic Purchasing Africa Resource Center, Scope Impact, Stage Six, Strathmore University, Total Family Health Organization, and Ubora Institute.


1275 New Jersey Ave. SE, Ste 200,
Washington, DC 20003