ABSTRACT

Introduction  Daily pre-exposure prophylaxis (PrEP) for HIV prevention is highly effective, but not yet widely deployed in sub-Saharan Africa. We describe how Zambia developed PrEP health policy and then successfully implemented national PrEP service delivery.

Policy development  Zambia introduced PrEP as a key strategy for HIV prevention in 2016, and established a National PrEP Task Force to lead policy advocacy and development. The Task Force was composed of government representatives, regulatory agencies, international donors, implementation partners and civil society organisations. Following an implementation pilot, PrEP was rolled out nationally using risk-based criteria alongside a national HIV prevention campaign.

National Scale-up  In the first year of implementation, ending September 2018, 3626 persons initiated PrEP. By September 2019, the number of people starting PrEP increased by over sixfold to 23327 persons at 728 sites across all ten Zambian provinces. In the first 2 years, 26953 clients initiated PrEP in Zambia, of whom 31% were from key and priority populations. Continuation remains low at 25% and 11% at 6 and 12 months, respectively.

Lessons learnt  Risk-based criteria for PrEP ensures access to those most in need of HIV prevention. Healthcare worker training in PrEP service delivery and health needs of key and priority populations is crucial. PrEP expansion into primary healthcare clinics and community education is required to reach full potential. Additional work is needed to understand and address low PrEP continuation. Finally, a task force of key stakeholders can rapidly develop and implement health policy, which may serve as a model for countries seeking to implement PrEP.

INTRODUCTION

Daily pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine for the prevention of HIV infection is a highly effective prevention tool, recommended for persons at substantial risk of HIV infection by WHO since 2015. PrEP effectiveness is highly correlated to adherence, with studies showing that PrEP is most effective when adherence is >70%. PrEP has the potential to limit HIV acquisition among at-risk populations, including those who may not be able to negotiate condom usage or who engage in high-risk activities. PrEP can be taken discreetly, it offers high rates of protection, and does not require negotiation with partners, unlike barrier methods and microbicide gels. PrEP is also associated with few safety risks, and there is limited evidence of behavioural risk compensation. Despite these promising results, PrEP roll-out has been slow in sub-Saharan Africa with only a handful of countries implementing large scale national PrEP programmes, including South Africa, Kenya, Uganda, Zimbabwe and Zambia.

Initial PrEP demonstration implementation projects have shown high uptake among serodiscordant couples (SDCs), adolescent girls and young women (AGYW), female sex workers (FSWs) and men who have sex with men (MSM). Interest in, and
uptake of PrEP is high but PrEP continuation remains a challenge in many groups, particularly AGYW. Successful national PrEP programmes in Africa have invested in creating PrEP awareness and demand via mass media and community health talks, have streamlined PrEP delivery via not only ART clinics but also drop-in centres for key populations (KPs) and DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, Safe) centres for AGYW, and have built PrEP capacity among healthcare workers (HCWs) via trainings and mentorship. Challenges in PrEP programming persist, including the need to improve PrEP access, streamline PrEP delivery models, increase HCWs trained in PrEP and finally increase PrEP continuation.

Zambia’s HIV epidemic is generalised, with a persistently high prevalence of 12.0% and annual incidence of 0.61% among adults 15–59 years old. Concentrated pockets of high HIV transmission disproportionately affect populations who face substantial psychosocial and structural barriers to accessing health services and continue to drive epidemic transmission. These include SDCs; AGYW; FSW and their clients; MSM; transgendered (TG) individuals and high-risk men, particularly those under 30, engaged in migrant work (eg, truck drivers, cane cutters or in prison). These groups have a higher HIV prevalence compared with the general population, and would benefit the most from HIV prevention methods, including biomedical interventions such as PrEP.

Beginning in 2016, Zambia introduced PrEP as a component of combination HIV prevention services, which also includes counselling, family planning, voluntary male medical circumcision and condom distribution. In this paper, we present a model of integrated health policy and technical service delivery accomplished by government agencies, donors, and implementing partners for the roll-out of PrEP in Zambia. We also report on the current status, challenges faced, and lessons learnt from PrEP policy and service delivery implementation in Zambia.

PrEP policy and implementation
Development of PrEP health policy and implementation guidelines in Zambia
In 2016, the Zambian Ministry of Health (MOH) adopted the 2015 WHO guidelines recommending daily oral PrEP for people at substantial risk of HIV infection, defined as HIV incidence greater than 3 per 100 person-years (see figure 1 for a timeline of PrEP policy and implementation). PrEP was introduced in the 2016 Zambia Consolidated Guidelines for Treatment and Prevention of HIV Infection and further expanded in the 2018 version. In September 2017, the National PrEP Task Force was established, comprising key personnel from MOH, National HIV/AIDS/STI/TB Council, WHO, UNAIDS, US President’s Emergency Plan for AIDS Relief (PEPFAR), US Agency for International Development (USAID), US Centers for Disease Control and Prevention (CDC), PEPFAR implementing partners (IPs) and civil society organisations (CSOs). The Task Force’s mandate was to lead policy advocacy and formulate a national PrEP implementation framework to guide PrEP service delivery. The Task Force created three sub-committees: (1) medical/technical service delivery and monitoring and evaluation (M&E); (2) logistics and supply chain and (3) social behavioural change communication and policy advocacy. Within each subcommittee, technical experts reviewed the latest evidence and guidelines for the larger Task Force (table 1, next page). Additionally, the Task Force...

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**Figure 1** Timeline of PrEP policy and implementation in Zambia. PrEP, pre-exposure prophylaxis; SDC, serodiscordant couples; UMB, University of Maryland Baltimore; UTH, University Teaching Hospital.
### Table 1  Subcommittee membership, mandates and activities for PrEP policy development

| Subcommittee                  | Chaired by                                      | Members                                                                 | Mandates                                                                 | Activities                                                                                                     |
|-------------------------------|-------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Medical/Technical             | MOH and University of Maryland Baltimore        | Doctors and nurses from the MOH, PEPFAR implementing partners, and WHO, all of whom had clinical experience in HIV service provision. | ➤ Guide the development of the 2018 PrEP guidelines.  
➤ Guide the development of the PrEP M&E processes.  
➤ Guide the development of the PrEP training manual. | ➤ Reviewed PrEP implementation literature.  
➤ Assessed PrEP deployment in other sub-Saharan countries.  
➤ Developed monitoring and evaluation (M&E) forms for PrEP service provision, including an initial clinical physical and history form as well as several PrEP follow-up forms focused on tracking evolving risk factors and PrEP eligibility over time.  
➤ M&E forms were optimised to interface with SmartCare, the national electronic health record system in Zambia.  
➤ Developed a national PrEP training manual, which serves as standard framework for the education and training of healthcare professionals in Zambia on PrEP provision. |
| Logistics and Supply Chain    | MOH and Chemonics Global Health Supply Chain Programme-Procurement and Supply Management. | PEPFAR implementing partners. | ➤ Guide supply chain management (including quantification).  
➤ Guide the registration and procurement of PrEP drugs to ensure an uninterrupted supply of quality PrEP commodities. | ➤ Engaged the Zambia Medicines Regulatory Authority to ensure that the tenofovir +emtricitabine (TDF/FTC) registration and approval was amended to include PrEP.  
➤ Worked closely with the Medical Stores, responsible for the medicines supply chain in Zambia, to include TDF/FTC in the national supply chain system.  
➤ Ensured that there was adequate TDF/FTC in Zambia to meet the national targets, with financial support from PEPFAR. |
| Social Behaviour Change       | MOH and JSI DISCOVER-Health                     | Representatives from MOH, implementing partners, people living with HIV CSOs, and potential end-users from target populations. | ➤ Improve PrEP knowledge among providers and clients. | ➤ Developed relevant training manuals.  
➤ Led a human-centred design study to understand the best approach to disseminating info about PrEP in Zambia.  
➤ Developed the national ‘Zambia Ending AIDS Campaign’ to promote awareness of PrEP among target populations. |

CSOs, civil society organisations; M&E, monitoring and evaluation; MOH, Ministry of Health; PEPFAR, President’s Emergency Plan for AIDS Relief; PrEP, pre-exposure prophylaxis.
Box 1 Zambia PrEP Risk-based eligibility criteria 2018

Persons at substantial risk for HIV infection, defined as engaging in one or more of the following activities within the last 6 months:
► Vaginal/anal intercourse without condoms with more than one partner.
► Sexually active with a partner who is known to be HIV-positive or at substantial risk of being HIV-positive.
► Sexually active with an HIV-positive partner who is not on effective treatment (defined as on cART for <6 months or not virally suppressed).
► History of STI.
► History of PEP use.
► Sharing injection material or equipment.

cART, combined antiretroviral therapy; PrEP, pre-exposure prophylaxis; PEP, post-exposure prophylaxis; STI, sexually transmitted infection.

PrEP pilot and policy implementation and service delivery roll-out

Between October 2017 and March 2018, the University of Maryland Baltimore (UMB) and the University Teaching Hospital in Lusaka, with special permission from the MOH, piloted a PrEP intervention package at two public health facilities in Lusaka and Livingstone. The intervention included community education on PrEP alongside training of HCWs on KP sensitivity and PrEP service delivery. Initial results from this pilot demonstrated high levels of interest and uptake among users, but low PrEP continuation by 3 months: among 1002 clients that tested negative for HIV, 326 (33%) were eligible for PrEP, of whom 116 (36%) elected to begin PrEP; 95 (82%) of these clients presented for 1-month follow-up and 31 (27%) clients for 3-month follow-up.30

The lessons learnt from this pilot were crucial to informing the broader national PrEP strategy. Additional training on community awareness and PrEP demand was required to ensure successful programme scale-up. To address this, UMB developed peer-led promotion of PrEP uptake through targeted messaging in KP communities, and also created social media platforms (WhatsApp and Facebook) where current and potential clients could discuss PrEP with mentor users and knowledgeable HCWs. Additionally, the pilot emphasised the need for expanded HCW training and community support for PrEP and KP-friendly services, with services provided in KP safe spaces by HCWs trained to provide services in a non-discriminatory manner. Trainings in PrEP service provision were extended to community health workers (CHWs) and peer supporters who created demand for PrEP and encouraged PrEP continuation. KP peer promoters were recruited from the KP community to disseminate HIV prevention and testing messages with a focus on the benefits of PrEP. Finally, operating hours at PrEP clinics were adjusted to include evenings, and PrEP services were provided closer to target populations in order to mitigate access barriers observed in the pilot study.

The MOH, with financial and technical support from PEPFAR and IPs, began the national roll-out of PrEP in 2018. Activities ranged from policy development, health system strengthening, commodity procurement (laboratory and drug requirements), service delivery (staff, training/mentorship, etc), M&E and demand creation. Concurrently, in early 2018, the Task Force set targets for national PrEP roll-out, focusing on facilities offering ART in high-burden areas. PEPFAR partners developed and implemented differentiated service delivery (DSD) models to serve the unique needs of each targeted population for early PrEP roll-out. To identify high-risk areas in the community hotspot mapping was conducted. KP safe spaces were set up where PrEP could be provided to MSM and FSWs. Nearby health facilities supported these safe spaces with HCW staff trained in PrEP service delivery as well as KP sensitivity, safety and security.
For all models of service provision, IPs supported the MOH to train clinicians, nurses, CHWs, and peer supporters in PrEP service delivery, demand creation, and M&E.

To aid in public education and demand creation, the Zambia Ending AIDS national HIV prevention campaign was implemented in 2019, with technical support from JSI/USAID DISCOVER-Health. The campaign provided information on HIV prevention with a key focus on PrEP, and disseminated information on PrEP via social media and cellular phone text messages. The campaign was driven by findings from a human-centred design study that found: (1) low awareness of PrEP, including among HCWs, with safety and tolerability concerns; (2) higher awareness among youth and KPs, who viewed PrEP favourably for high-risk situations; (3) AGYW saw PrEP as a way to exercise control over their own HIV prevention; (4) older men viewed PrEP as a way to have safer sex without a condom; (5) young people concerned about parents finding out they were on ARVs; (6) high levels of judgmental and discriminatory attitudes among HCWs.

These findings were used to design the PrEP subcampaign in the broader Zambia Ending AIDS campaign. The key tenets of the campaign include sex positivity (ie, sex without judgement or stigma) and addressing low risk perception: PrEP and combination HIV prevention, as well as a focus on men’s health and male-specific health programming; education of HCWs as caring providers of sexual health; and, enhanced health communication tools (figure 2).

PrEP programme M&E
In accordance with the national framework M&E guidance, aggregated PrEP service delivery data including age, sex, KP type and geographical reach are reported semi-annually by IPs into the PEPFAR reporting database (DATIM). The PEPFAR fiscal year (FY) is from October 1 to September 30 each year. To evaluate early PrEP programme scale-up, we analysed deidentified aggregate PrEP service delivery data from DATIM, with ethical clearance granted by ERES, NHRA, UMB and CDC. Data included sex, age, KP type, rates of uptake and follow-up at each clinical visit. We also conducted geo-mapping to overlay provision of PrEP services with population density and HIV prevalence.

Patient and public involvement
Only aggregate patient data was used in this study. Patient advocates and civil society representatives formed part of the National PrEP Task Force and participated in drafting policy and setting the national policy agenda. Key results about PrEP have been routinely disseminated to the public at national meetings and conferences and other venues.

Figure 2 Selected materials from Zambia ending AIDS campaign. PrEP, pre-exposure prophylaxis.
National PrEP scale-up

Early scale-up

Between October 2017 and September 2018 (PEPFAR FY 18), a total of 3603 persons initiated PrEP, with particular focus on populations most at risk of contracting HIV, namely AGYW (n=1272, 34%), FSWs (n=312, 9%) and MSM (n=92, 3%). During this period, nearly half of all PrEP initiates were KPs or priority populations (PPs) (ie, FSW, MSM, TG, PWID, AGYW): 52% from April to September 2017, 48% from October 2017 to March 2018, and 46% from April to September 2018, with the other half being SDCs or general population (figure 3). During this first year of PrEP provision, prior to the national launch, programme scale was limited and IPs largely focused on KPs/PPs.

National HIV prevention campaign

Between April 2019—when the Zambia Ending AIDS campaign was launched—and September 2019, over 4.5 million people were reached on social media with campaign messaging. PrEP advertisements were broadcast in six major Zambian languages over 90 million times on 22 national and community radio and television stations. From January to September 2019, 140 933 people accessed the national toll-free Unstructured Supplementary Service Data (USSD) code for information about PrEP. Of these, 27 889 requested information about the nearest PrEP facility. People tended to access the USSD code when there was high rotation of the PrEP adverts on radio, highlighting the importance of sustained PrEP sensitisation (figure 4).

Full scale-up

By March 2019, access and availability of PrEP had substantially increased, with services available across all ten provinces in 340 sites (of approximately 2000 ART-providing sites across Zambia). By September 2019, PrEP services delivery had expanded to 728 sites and included health facilities, health outreach posts and non-traditional sites such as PEPFAR DREAMS Centres (community centres for prevention services for AGYW), police camps, prisons, markets and universities. The data did not allow for breakdown of clients served per facility; however, service delivery mapping indicates that PrEP is currently provided in the areas of greatest population density where the HIV burden is most concentrated (figure 5).

Both the HIV prevention campaign and the increase in number of sites offering PrEP has led to a substantial increase in the number of people initiating PrEP. From April–September 2018 to October 2018–March 2019, the number of PrEP initiates more than doubled, from 3248 to 7018, and this increased an additional two-fold to 16 309 new initiates in April–September 2019 (figure 3). By September 2019, a total of 26 953 clients had initiated PrEP.

There was also a concurrent increase in KPs accessing PrEP; new FSW initiates increased fourfold (248 to 1062) and MSM initiates increased ninefold (55–504) in the same time period. Interestingly, despite this increase in KPs accessing PrEP, the proportion of KPs as a total of all PrEP users has declined, showing the relative broad uptake and appeal of PrEP among the general population. From April to September 2019, just 26% of all new PrEP initiates were KPs, a significant decline from 46% just a year prior. This shift in PrEP user-type may result in continued increased demand for PrEP and PrEP normalisation, and is in line with the aims of the national HIV prevention campaign. This increased proportion of non-KP PrEP users highlights the Zambian PrEP policy’s success in not targeting KPs alone, but making PrEP available to any individual at significant risk of acquiring HIV.
Continuation data are not consistently collected and reported in the national system or in DATIM. However, in the UMB pilot study, among 116 clients who enrolled on PrEP, 95 (82%) returned at 1 month and 31 (27%) returned at 3 months. PrEP continuation at 3 months was highest for SDCs (42%), then TG (33%), then MSM (23%) and lowest among FSWs (21%).

JSI conducted a snapshot analysis of data at their supported sites for persons initiated on PrEP from January 2018 to April 2020, whereby only those on PrEP for a certain duration of time were included in the corresponding denominator. In this analysis, 42% (6358/15110) of persons who had been initiated on PrEP returned at 1 month for PrEP refills. Persistence at 3 months was 35% (4709/13383), 6 months 25% (2507/10199), 9 months 13% (980/7413) and by 12 months was only 11% (570/5246).

**DISCUSSION**

Between 2016 and 2018, Zambia developed health policy and a national framework to support the introduction and national scale-up of PrEP to those most at risk of HIV infection. In the first year, initial guidelines were developed and pilot implementations were conducted, serving less than 4000 people. In year two, more expansive, risk-based criteria were adopted, and scale-up led to a sixfold increase with over 23000 persons starting PrEP. The introduction of PrEP is reflective of a collaborative effort from a multidisciplinary task force comprised of the Zambian government, PEPFAR, WHO, UNAIDS, PEPFAR IPs and CSOs with the mandate to rapidly develop the national strategy and improve access and delivery of PrEP to at-risk groups. Mapping of PrEP services to HIV prevalence demonstrates that PrEP services are largely being provided where there is greatest need. Provision of DSD models such as PrEP service delivery in community safe settings is needed for continuation.

**Figure 5** Geographic distribution of HIV PrEP sites in Zambia in 2019. Panel (A) Zambian government health facilities providing PrEP in orange, overlaying HIV prevalence by Province. Panel (B) Zambian government health facilities providing PrEP in orange, overlaying population density by Province. PrEP, pre-exposure prophylaxis.
spaces was found to support PrEP uptake among KPs. Further support by IPs is needed to ensure that PrEP is available to all populations at substantial risk of HIV, including those in rural areas. Further research and innovative service delivery models are needed to address barriers to access and continuation of PrEP services for those who continue to be at risk of HIV infection.

While Zambia was able to achieve rapid roll-out and implementation of PrEP, estimates of continuation on PrEP remains low. It should be noted that these estimates are partner-specific and more targeted studies are needed. However, when compared with other real-world implementations in Africa, 25% continuation at 6 months and 11% at 12 months is in line with other studies: the Kenya demo project found 6 months continuation rates of 15% among MSM, 14% among FSWs, and 10% among women, while the TAPS study found 30% continuation at 6 months among South African FSWs.

Further understanding the drivers of PrEP discontinuation is needed to improve uptake and continuation of PrEP for those at continued risk of HIV infection, as well as ongoing community education and demand generation. Avenues to reduce PrEP stigma and discrimination should be explored, such as using different branding for PrEP drugs versus ARVs. For PrEP to reach its full potential it needs to be available at all primary health facilities and through DSD models. Finally, augmenting advocacy efforts may help increase PrEP access in contexts where KPs are largely stigmatised.

Limitations of this study include the reliance on aggregate data and the lack of patient perspective. Patient-level analyses are needed to understand who stays on PrEP and who does not, while qualitative studies are needed to illuminate why certain people take up PrEP while others decline, as well as reasons for adherence or discontinuation. Further study in these areas is critical to ensure that PrEP is provided to those who can most benefit from it.

The PrEP roll-out in Zambia can be compared with the successful PrEP scale up effort in Kenya. Similar to Zambia, Kenya established a PrEP Technical Working Group; however they opted for six thematic subcommittees instead of three. Kenya also achieved quick roll-out, from launching guidelines in July 2016 to launching national PrEP scale-up in May 2017. Kenya similarly recognised the strategic importance of partnerships among government, IPs, and CSOs. They also highlighted the need for training of HCWs, the importance of demand creation and social marketing, community-led programmes, PrEP integration into commodity management systems, and the importance of engaging with MOH from the outset.

A unique element of Zambia’s PrEP scale-up was the decision to use risk-based criteria as opposed to population-based criteria. It has been argued that national PrEP programmes often follow a certain sequence, the ‘first wave’ being PrEP delivery for KPs followed by a ‘second wave’ for PPs, especially AGYW. By eliminating KP/PP-typology from the eligibility criteria, we ensure that all persons at risk for HIV can access PrEP, regardless of how they identify. This is critical in the setting of a generalised epidemic such as Zambia, where multiple groups of persons are at ongoing risk. Given that certain KPs are at high risk of stigmatisation, by not associating the PrEP programme with KPs we avoided issues around PrEP being used as a marker of certain activities.

However, a potential drawback of this approach is that it risks not reaching groups most at risk. Indeed initial uptake of PrEP in Zambia included a high proportion of general population (including SDCs) compared with KPs and PPs. This mirrors the uptake in both Kenya and Uganda, both of which saw over 60% of PrEP being taken up by general population and SDCs. This may be due to broader inclusion criteria which may also be related to low continuation rate as we may not have reached the most at-risk persons who are likely to continue. This type of broad approach may also reduce overall cost-effectiveness of the PrEP programme more generally. However, though Zambia employed a risk-based approach, there was substantial investment in KP-specific programming to ensure uptake by those most at risk of infection.

Another advantage of a risk-based approach is that it allows for evaluation of ‘seasons of risk’ with persons starting and stopping PrEP based on an objective assessment of their risk at any point in time. This data can also be used to compare different strategies for PrEP roll-out, using our recently developed programme evaluation metric, which allows for comparison of PrEP programmes serving KPs and PPs.

Lessons learnt
We present an example of health policy development that led to rapid national implementation and service delivery scale-up. Key elements of success included a firm grounding in evidence-based approaches which enabled a strong case for PrEP implementation; a multi-sector, interdisciplinary task force which allowed for rapid advancement of policy and implementation; and a well-planned implementation pilot, which provided key lessons that informed the national scale-up. A particular strength of Zambia’s PrEP guidelines is the risk-based approach, making it an intervention available to all persons at risk, not just members of certain populations. Conducting a client-centred public awareness campaign is key to disseminating knowledge about PrEP and driving demand creation. Further detailed quantitative and qualitative research is needed to understand drivers of uptake, continuation and discontinuation. Such approaches to PrEP health policy development and service delivery implementation can serve as a model to other countries seeking to implement PrEP for HIV prevention.

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