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PrEP for Africa: What we have learnt and what is needed to move to program implementation

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Abstract

Purpose—An investment in PrEP delivery must have public health impact in reducing HIV infections. Sustainable delivery of PrEP requires policy, integration of services and synergy with other existing HIV prevention programs. This review discusses key policy and programmatic considerations for implementation and scale up of PrEP in Africa.

Recent Findings—PrEP delivery has been delayed by concerns about adherence and delivery in ‘real world’ settings. Demonstration projects and clinical service delivery models are providing evidence of PrEP effectiveness with an impact much higher than that found in randomized clinical trials. Data confirm that PrEP uptake, adherence and retention has been high, more so by persons who perceive themselves at high risk for HIV infection, and PrEP is well tolerated. PrEP delivery is more than dispensation of a pill and programs should address other risk drivers, which differ by population. In Africa, barriers to PrEP uptake and adherence include stigma among MSM and low HIV risk perception among young women. Additional data have provided insight into optimal points of service delivery, provider training requirements and quality assurance needs. Of the 2 million new HIV infections in 2014, 70% were in Africa. PrEP use is not lifelong and use limited to periods of risk may be both effective and cost-effective for the continent.

Summary—HIV prevention programs should determine strategies to identify those at substantial risk for HIV infection, formulate and deliver PrEP in combination with interventions that target social drivers of HIV vulnerability specific to each population. Policy guidance for optimal combination of interventions and service delivery avenues, clinical protocols, health infrastructure requirements are required. Cost-effectiveness and efficiency data are essential for policy guidance

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to navigate ethical questions over use of antiretroviral therapy for HIV negative individuals when treatment coverage has not been attained in many parts of Africa. Countries need to invest in purposeful advocacy at both local and global forums. Failure to implement PrEP will be a failure to protect future generations.

Keywords

PrEP; HIV prevention; Programs; Implementation

Introduction

The scientific evidence of PrEP efficacy as a strong HIV prevention tool is indisputable and has gained additional strength from recent data from demonstration projects. Initial randomized clinical trial data reported efficacy ranging from 44–75% [1–4], while demonstration projects have demonstrated even higher effectiveness (>80%). [5–9] These data have diminished doubts about adequate adherence to oral PrEP by populations at greatest risk for HIV infection and provided the impetus required to motivate the translation of research evidence to implementation. However, translation of important health solutions to clinical practice is often slow, uneven or left unapplied.

To avoid this pitfall and maximize the benefits of PrEP, there is a need to assess key considerations for policy, communities and health care systems in sub-Saharan Africa required to move PrEP to clinical care practice in the region. This review summarizes key points for transitioning PrEP from research to programmatic implementation for Africa.

Policy and Programs Considerations for PrEP Implementation in Sub-Saharan Africa

Domesticated Policy Cognizance of Health Systems

In many countries policy drives access to important health interventions and policy guidelines could be key to scale up of HIV PrEP in sub-Saharan Africa. The World Health Organization (WHO) has recently released combined HIV treatment and prevention guidelines that recommend PrEP be offered to people at substantial risk for HIV infection as part of combination HIV prevention. [10] Currently, in sub-Saharan Africa, PrEP cannot be accessed through public programs. In Kenya, PrEP is recommended for key populations in high and medium cluster counties in the Kenya HIV Prevention Revolution Road Map (www.nacc.or.ke). This national government document used geographic prioritization dividing the country into clusters of high, medium and low risk based on disparities in HIV incidence. Biomedical, behavioural and structural interventions are matched by geographic clusters and target populations. The South Africa HIV Society published guidelines for PrEP use by MSM. These documents provide an entry point for implementation. Considerations for policy makers in PrEP policy formulation touch on safety of product, social acceptability, willingness and ability of systems to deliver HIV PrEP to service delivery points and to the populations at substantial risk of HIV infection, health care worker attitudes, monitoring and evaluation of process, impact and costs.

Health systems considerations—Public health policy guidance in Kenya, similar to other countries in Africa, often faces tensions between the vertical systems that have single-purpose machinery in facilities, human resources [11], management, information, logistics and supplies and horizontal systems that deliver integrated services. Implementation of PrEP should take cognizance and test both systems in order to provide guidance for practical application. The issue of cost is pertinent, as consideration is needed for additional resources in terms of personnel, procurement and supplies, and monitoring and evaluation, as well as how PrEP interfaces with other competing local health problems.

Supply chain: PrEP access to service points requires being a part of the logistics and supply chain systems. Policy guidance for PrEP approval as part of national pipelines for ART drugs or other prophylactic commodities will secure drug availability and is essential for sustained access and effectiveness.

Educating Health Care Providers: Across multiple studies, willingness to prescribe PrEP has been associated with knowledge of PrEP and self-identification as an HIV expert. [12–14] Awareness of PrEP as an effective HIV prevention intervention is associated with provider prescription and end user demand. PrEP policy must consider developing standards for sensitizing and educating private and public sector health care workers on PrEP and creating effective linkages to services outside the routine health system. Stigma towards MSM and sex workers from communities and health workers is a barrier to uptake. [15] HIV care programs are best placed to advocate and spearhead training materials targeted toward health care workers [15] (www.marps-africa.org).

Costs: Prospective PrEP users and decision makers have identified cost as a potential barrier to access. Using micro-costing and time and motion analysis, the Partners Demonstration Project in Uganda estimated cost of delivery of a combination package of ART and PrEP to HIV serodiscordant couples was less than 100 USD/year in public health settings. [16] Policy makers require data on the cost savings made from provision of HIV PrEP to ART programs, cost effectiveness data that also includes other populations and different service delivery settings. The current global drive towards zero HIV infection and the current PEPFAR, through its DREAM agenda in particular, places a focus and opportunity for successful PrEP delivery advocacy.

Delivery Avenues And Access Aligned to Population Needs

Delivery avenues—There are lessons to be learnt from the initiation of ART in Africa, where delivery started with private provider prescription, which built demand in public sector and wide scale access. Delivery venues should also reflect the needs of vulnerable populations, which may be vastly different for MSM, FSW, young women in high prevalence settings, fisher folk and other mobile populations. Avenues for delivery for young women, assisted with tools to identify those at substantial risk, should consider family planning and maternal child health facilities as options for delivery, as well as innovative approaches such as youth services and HIV testing venues. The adolescent population has less well-defined delivery avenues and few demonstration projects to inform delivery strategies. As often stated by civil society ‘nothing for us without us’ we should engage

populations to inform strategies on effective delivery of HIV PrEP. Delivery to MSM populations in sub-Saharan Africa will require special considerations, given heavily stigmatized social and political environment. Outside of South Africa, there is only one MSM demonstration project in Kenya, perhaps due to these challenges. Yet, MSM contribute significantly to the epidemic in every country, including as a bridging group to other populations (for example, men who have sex with men and with women).

Addressing Concerns and Making a Case for Social Marketing

PrEP use is not life-long—Young women, MSM, sex workers and HIV serodiscordant couples are not at uniform risk throughout their lives, and thus PrEP need not be life-long. Vulnerability to HIV is usually time limited to a ‘season in life’ where economic dependency, self-determination and decision-making are limited by social-economic environment. [17–22] Some work has been done to evaluate HIV risk and predict incidence with development of an HIV ‘risk scores’ for HIV serodiscordant couples [23] that could be implemented in clinical evaluation. PrEP programs need to develop tools to determine individuals’ ‘season of risk’ and provide PrEP alongside other appropriate interventions for a limited duration. Time limited use of PrEP, as a product to be used during the ‘seasons of high risk’ is an important message for both the health provider and end user and has a strong impact on acceptability of product, and separates use of PrEP from ART for treatment.

Addressing Providers, Policy Makers and End Users Concerns—Concerns that PrEP will increase risk of resistance to antiretroviral treatment medications, reduce condom use and compete with resources to expand access to HIV treatment have been raised, although open label studies and demonstration projects provide evidence to the contrary. Interviews with female sex workers in Kenya cited the blue color of the Truvada® pill being similar to local mood altering drug and a possible barrier to adherence (unpublished LVCT-Health). Communication strategies that target potential users providing current and correct information regarding PrEP benefits and risks should be part of implementation. Social marketing strategies need to work with policy makers and target population, influence perceptions that oppose PrEP as a potential inhibitor to expanding antiretroviral therapy for treatment and mobilize communities to encourage those at HIV risk to access HIV PrEP.

Safety and laboratory assessment—The frequency of creatinine testing and need for hepatitis B screening for programs may limit access to PrEP especially in areas in sub-Saharan Africa. Recently released WHO guidelines for ART and PrEP are permissive to limited or no testing, so as not to make testing a barrier to PrEP. [10] The PROUD study initiated PrEP without a screening visit and reviewed renal safety data with no safety breach after one month. [8] There is a high safety threshold for disease prevention drugs for use by healthy populations such as PrEP. Health care providers’ and communities’ concerns about safety can impede uptake. Across all studies, PrEP has demonstrated high tolerability and low toxicity profile. Questions of rare renal toxicity, reduction in bone mineral density, and safety in persons with chronic hepatitis B require research in parallel to delivery. [24–26] Similarly, additional research is needed to define a minimum safety package for PrEP, analogous to the scale back of treatment safety monitoring.

Adherence—A range of novel treatment adherence strategies have been employed globally and particularly in sub-Saharan Africa with varying degrees of success. [27] Although treatment offers lessons, it is different from PrEP, which is for a shorter duration but in a healthy population. The majority of countries in Africa have a strong community strategy for delivery of health services, including for HIV treatment, and community health workers have been an important partner in supporting adherence and retention. A similar strategy should be considered for supporting PrEP adherence and retention.

Learning from PrEP demonstration projects—Adherence has been high in demonstration projects, as reflected in >80% effectiveness [5,8]. Confirmation from clinical trials that PrEP works when taken has greatly influenced uptake and adherence. Clinic visits for participants in the majority of demonstration projects have been quarterly with less follow up for retention than in the randomized clinical trials.

In the South Africa, ADAPT study (HPTN 067) site has demonstrated an adherence of 79% among young women confirming that young women in Africa are able and willing to use PrEP. [28] Similar high adherence and effectiveness with almost near elimination of HIV among HIV serodiscordant couples was demonstrated in the Partners Demonstration Project (Kenya and Uganda) with an effectiveness of 96% (95% CI 81–99%). [5] Interestingly in both Partners Demonstration Project and the PROUD study [5,8], there was no breakthrough infection among participants using PrEP as confirmed by investigators. The majority of PrEP demonstration projects (Table 1) in Africa will have results on feasibility and acceptance by 2016. However, there are very few studies among MSM, which may be related to a hostile political and social environment that make it more difficult to provide health interventions to this community, and too few studies among young women at risk. Projects that bridge demonstration to true implementation are needed, and step-wise advancement needs to accelerate, in multiple populations and multiple countries.

Identifying populations to prioritize for PrEP

Addressing individual barriers to PrEP uptake—Qualitative studies in Kenya and Nigeria have identified population level stigma as a key barrier to PrEP uptake [29]. Similarly, interviews with women enrolled in the VOICE and FEM-PrEP studies reported stigma to use of an antiretroviral treatment, lack of risk perception, uncertainty about efficacy and lack of partner support as barriers to product use. [30,31] Interviews with policy makers and community leaders reported lack of access to services, compounded by fears, lack of awareness and misinformation as barriers to PrEP uptake. Social marketing campaigns will be required to reduce community and individual level stigma.

Prioritizing Couples—In Nigeria stakeholders [29] proposed HIV serodiscordant couples as the appropriate population for initiating demonstration projects. The respondents cited that condoms are a barrier to conception and PrEP would bring hope, assist mutual adherence resolve the discordance dilemma. Data from the Partners PrEP Study and Partners Demonstration Project supported these findings, with high adherence when PrEP was provided as a bridge to ART. [5] HIV serodiscordant couples in Uganda felt that PrEP helped them resolve ‘discordance dilemma’ safeguard the health of the HIV-negative partner

and allow them to retain the relationship. [32] Natural conception for HIV serodiscordant couples carries substantial risk of HIV transmission, however, in qualitative interviews of HIV-serodiscordant couples conception desires outstrip fear of HIV acquisition. [33] PrEP provides an option for couples to achieve fertility desires with reduced risk of HIV-transmission. We have substantial evidence to commence PrEP delivery to HIV-serodiscordant couples. Politically, this population may de-stigmatize PrEP and allow for informing PrEP delivery models for MSM and young women in Africa, where there may be greater reticence and fewer delivery models.

Targeting those at greatest risk for HIV infection—For PrEP implementation to be cost effective, it should be for a limited duration during the ‘period of risk’ and targeted to those at substantial risk for HIV infection. Among HIV serodiscordant couples, the number needed to treat (NNT) to avert one HIV infection was less than 30, when targeted to couples with an HIV incidence of 5/100 person years, similarly among MSM in the iPrEx study [34] [23,35]

The HIV epidemic in Africa is complex, and outside of ‘key populations’ fisher folk [21,36], and slum dwellers [21,22] are examples of populations at substantial risk HIV infection [19]. In addition young women [37,38], pregnant and post-partum women are at high risk for infection, more so those who live in high prevalence geographic locations [39,40]. In implementing PrEP, the approach of targeting can be stigmatizing and become a barrier to uptake. PrEP should not be branded only for ‘promiscuous’ individuals, which may limit access and backfire by limiting demand. We need practical strategies for reaching those who need PrEP, including but not limited to self-referrals. Defining a marketing approach, using epidemiologic data and offering an appropriate, convenient safe avenue for delivery may get to the people at greatest risk without introducing stigma.

PrEP uptake is highest among those at high risk for HIV infection—The majority of MSM PrEP studies have been done outside of Africa, however, they have shown substantial PrEP uptake among those with a history high risk sexual behaviour. [41] In the Partners PrEP study, tenofovir 40 ng/mL (indicating low adherence) was associated with periods when participants reported no sex with their HIV infected partner compared to periods of unprotected sex. [42] In a program setting risk assessment should be part of evaluation prior to initiation of PrEP. During follow up risk assessments should be done to identify periods of high risk when adherence is critical [27].

Risk compensation—Often voiced is the concern that PrEP would reduce condom use and increase risks for other STIs. PrEP clinical trial data do not suggest substantial risk compensation, and instead suggested reduced risk over time, perhaps reflecting synergies with counseling and periodic HIV testing. [43,44] What is most compelling is the evidence that PrEP uptake and adherence in demonstration projects seems to map those individuals with greatest risk-i.e., users respond to their own risk by initiating PrEP (rather than PrEP leading to risk).

Summary—Policy guidance is essential to PrEP Implementation through programs in Africa. To initiate the process of implementation, policymakers need to be convinced that

HIV PrEP will be cost effective, affordable and deliverable through an integrated horizontal health system. Communities' and PrEP users' perceptions of PrEP will also determine uptake, and a strong advocacy strategy is needed to create awareness and safeguard against stigma towards users and PrEP itself. PrEP holds substantial potential for Africa – actions to deliver PrEP are needed now to assess whether we can realize that potential.

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Key Points

1. Domesticated policy that takes cognizance of health systems, delivery avenues, drug approvals and availability and provider training is required for scale up to population level
2. Points of PrEP delivery in the health care system should be informed by the needs of the target population
3. Prevention interventions such as universal access to early HIV treatment should not be positioned in competition but as complementary interventions towards a common goal of 'ending HIV epidemic'.
4. Multiple populations in Africa are potentially appropriate for PrEP – serodiscordant couples, MSM, young women at risk, sex workers, injection drug users; readiness for delivery and strategies to deliver to each of these may evolve differently in each setting.
5. Advocacy and social marketing PrEP is required to create awareness but messaging should be carefully crafted to avoid social perceptions that have been a barrier to wide scale use of condoms in Africa.

Table 1

PrEP Demonstration in Africa (www.avac.org)

Project	Location	Population	Current status		Outcome
			1013 couples	Expected to close follow up 2016	
Partners Demonstration Project	Kenya, Uganda	HIV-serodiscordant couples			[5] 96% reduction in HIV infection at 48% follow up time
LVCT Health and SWOP Kenya (IPCP-Kenya)	Kenya	Young women, MSM, female sex workers	Completed formative work, Initiated PrEP delivery		PrEP project started 2015
Nigerian National Agency for the Control of AIDS	Nigeria	HIV serodiscordant couples	[19] completed formative research expected to start 2015		pending
The TAPS Demonstration Project (Wits RHI)	South Africa	Female sex workers	Initiated 2015		On going
Senegal Demonstration Project	Senegal	FSW (venue-health centers)	Formative research To be followed by PrEP delivery Start date 2015		Expected completion 2016
Benin Demonstration Project with CHU de Québec (Canada)	Benin	FSW	Started Oct. 2015		Expected completion 2017
Sisters Antiretroviral Therapy Programme for Prevention of HIV –an Integrated Response (SAPH-Ire)	Zimbabwe	FSW	Ongoing: started July 2014 Providing PrEP and ART as indicated (slow uptake)		Expected completion late 2015
Gender-Specific Combination HIV Prevention for Youth in High Burden Settings (MP3-Youth)	Kenya	Adolescent men and women ages 15–24 (only female on PrEP)	Started 2014		Expected completion 2016
Sibanya Health Project:	South Africa	MSM	Comprehensive HIV Prevention Package in Southern AfricaPilot Study		Expected completion 2016
Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)	South Africa	Heterosexual adolescent men and women ages 15–19	Combination prevention packages for men and women		Expected completion 2016
Anova Health Institute's Health 4 Men initiative	South Africa	MSM			Pending to start