



Community-led Consultative Think Tank Meeting on

PrEP ACCESS AND USE

MEETING REPORT
MAY 2017



ITPC

INTERNATIONAL TREATMENT
PREPAREDNESS COALITION

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About ITPC

The International Treatment Preparedness Coalition (ITPC) is a global network of people living with HIV and community activists working to achieve universal access to optimal HIV treatment for those in need. Formed in 2003 by a group of 125 HIV activists from 65 countries at a meeting in Cape Town, South Africa, ITPC actively advocates for treatment access in eight regions across the globe, including Africa, Asia, Latin American and the Caribbean, Eastern Europe, and the Middle East. ITPC believes that the fight for HIV treatment remains one of the most significant global social justice issues.

ITPC embarked on an initiative to develop and implement innovative community-led demand creation solutions for access to and use of oral pre-exposure prophylaxis (PrEP) for HIV by key populations. This initiative included conducting a preliminary literature review of global community perspectives on PrEP, hosting a community-led consultative global think tank meeting, articulating key PrEP messages by key population networks and PrEP experts in a position statement, and developing the Key Population Activist Toolkit on PrEP.

Table of Contents

ACKNOWLEDGEMENTS	1
PARTICIPANTS / PRESENTERS	1
ABBREVIATIONS.	3
EXECUTIVE SUMMARY	4
INTRODUCTION	6
1. Background	6
2. Objectives of the consultative think tank meeting	7
PrEP: THE SCIENCE	8
1. PrEP is safe and effective	8
2. PrEP is for situations of HIV infection risk, not particular people	8
3. PrEP research should response to community and country-level concerns	8
PrEP: THE COST	9
1. Factors that influence affordability and accessibility of PrEP	9
2. The status of PrEP drug patents	9
PrEP: CONCERNS AND SUPPORT FROM THE COMMUNITY PERSPECTIVE	9
1. Support for PrEP	9
2. Concerns about PrEP	10
PrEP: THE IMPLEMENTATION & PRACTICE.	11
1. Oral PrEP Demonstration Projects in Swaziland	11
2. PrEP Demonstration Programs in Thailand	11
3. Perspectives on PrEP in India	12
4. PrEP use in the US	12
5. PrEP in Latin American and the Caribbean.	12
6. PrEP feasibility and implementation in Botswana	13
7. PrEP in Morocco	13
8. PrEP in Kenya	14

PrEP: COMMUNITY-LED STRATEGIES, SOLUTIONS, AND KEY MESSAGES	14
1. Women & Young Girls	14
i. Operational Solutions	14
ii. Priority Messages	14
2. Transgender People	15
i. Operational Solutions	15
ii. Priority Messages	15
3. Sex Workers	15
i. Operational Solutions	15
ii. Priority Messages	15
4. People who inject drugs (PWID)	16
i. Operational Solutions	16
ii. Priority Messages	16
5. Men who have sex with men (MSM) and other gay men	17
i. Operational Solutions	17
6. Adolescents	17
i. Operational Solutions	17
ii. Priority Messages	17
PrEP: THE WAY FORWARD FOR COMMUNITIES	17
ANNEXES	18
Annex 1 What’s Out There on PrEP: A Literature Review	18
Annex 2 Position Statment	18
Annex 3 Women & Young Girls	19
Annex 4 Transgender People	20
Annex 5 Sex Workers.	21
Annex 7 Men who have sex with men (MSM) and other gay men	22
Annex 8 Adolescents.	23

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Acronyms

FDA	U.S. Food & Drug Administration	PWID	People who inject drugs
FTC/TDF	emtricitabine/ tenofovir	KPIF	PEPFAR's Key Population Investment Fund
GFATM	Global Fund to Fight AIDS, TB and Malaria	PrEP	Pre-exposure prophylaxis
ITPC	International Treatment Preparedness Coalition	SW	Sex workers
KPS	key populations	TDF	tenofovir
LATCA	Latin America and the Caribbean	TG	Transgender
MSM	men who have sex with men and other gay men	USAID	United States Agency for International Development
PEPFAR	United States President's Emergency Plan for AIDS Relief	WHO	World Health Organization



Executive Summary

Pre-exposure prophylaxis (PrEP) for HIV consists of daily use of HIV medication to prevent HIV infection. The World Health Organization (WHO) currently recommends PrEP as an important prevention tool to complement existing HIV prevention strategies. However, there remains great debate about access to and use of PrEP, particularly among key populations (KPs). To discuss key considerations of PrEP implementation across key population groups, and develop strategies and solutions on community-led KP demand creation, the International Treatment Preparedness Coalition (ITPC) hosted a global community-led consultation on PrEP. The two-day event brought together more than 45 participants from 20 different countries representing civil society, key populations, governments, and technical expert groups. Open discussions and working groups focused on key considerations of PrEP implementation across key population groups, and the development of innovative strategies to create better access to PrEP for communities.

To inform the content of the meeting, ITPC undertook a Literature Review to collate and examine views from key populations on use and access to PrEP. Key findings of the suggested that there is general acceptability and demand for PrEP among KPs as an additional option for HIV prevention within a comprehensive approach. However, there are a number of concerns, risks and barriers that will need to be addressed for successful PrEP uptake. Generally, knowledge of PrEP remains low among KPs globally, even among countries where PrEP trials and demonstration projects have been implemented. Punitive laws against sex work, MSM, and drug use, coupled with low PrEP knowledge, strong stigma and discrimination against key populations, could undermine access, uptake and adherence. Although other community consultative meetings have taken place to unpack the perceptions on PrEP use and access, based on findings of the literature review, ITPC identified an opportunity to gather the diverse groups of representative to discuss community-led demand creation as a strategic gap in upscaling PrEP services.

Presentations on PrEP research and implementation shared at the meeting, demonstrated that efforts to align PrEP programmes to KP community needs and concerns and to promote community-led demand for PrEP are getting underway. These included the design and implementation of differentiated models of care (researcher-, facility- and community-led) in demonstration projects and implementation research in some areas like Thailand and the United States. Peer-based models in which trained key population community members and their networks themselves provide a host of clinical and support services have been associated with increased PrEP uptake among key populations. Social marketing strategies that challenge HIV stigma and portray PrEP use as a positive and responsible personal choice, are being generated with great reviews, including facilitating platforms for PrEP users to share real-life experiences on PrEP. Countries such as Kenya are conducting capacity strengthening activities with healthcare workers to mitigate stigma and heightened awareness around KP needs. Countries like Thailand which are on the cusp of introducing national public PrEP programmes, are backing up their commitments with clearly articulated national policies on PrEP in which the protection of human rights has been central.

Case studies presented at the meeting revealed that, at the national level, various countries are gradually considering PrEP as an additional HIV prevention intervention (part of a combination prevention programme). Implementation research and demonstration projects with a view to provide strong evidence supporting national scale-up are underway in the US, Western Europe, Southern and East Africa and in the Asia-Pacific quarter. Key populations remain the focus for now; however, access by others at substantial risk is also a consideration. As is to be expected with the introduction of any new intervention, governments are grappling with implementation questions and concerns including drug- and programming costs, sustainability and decisions around appropriate implementation models. Brazil recently announced its intention to launch a public-sector PrEP program and Botswana is currently designing a short-term private-public partnership project model which involves a collaboration between local NGOs to perform outreach and service monitoring and private practitioners providing clinical services. The pricing of PrEP

medicines is a major factor enabling or hindering access. National registration of cheaper generic drug formulations is expected to facilitate greater affordability and thus greater access.

Community-led demand creation solutions for access to and use of oral PrEP by key populations (KPs) are critical for the success of PrEP programming. *Key messages & strategies for PrEP implementation were recommended as an outcome of this meeting, in that the urgent need for:*

- engagement in PrEP awareness raising and knowledge building among key populations (i.e. need for treatment education focused on PrEP);
- rapid scale-up of HIV testing and PrEP access through peer-based (i.e. KP-led) organisations and offering as many options for access as possible;
- promoting further social and scientific research on PrEP, to demonstrate how adherence to PrEP can be achieved, impact of PrEP scale-up and implementation, unpack more scientific evidence on drug toxicity & resistance, etc;
- utilizing existing successful healthcare programmes for key populations to introduce PrEP;
- ensuring the provision of other HIV prevention and sexual and reproductive health care services in line with combination prevention strategy; and
- promoting PrEP champions and advocacy at country-level for greater PrEP affordability.

These key recommendations will inform the development of a position statement.

Introduction

Pre-exposure prophylaxis (PrEP) for HIV consists of daily use of HIV medication to prevent HIV infection. The WHO currently recommends PrEP as an important prevention tool to complement existing HIV prevention strategies. However, there remains a great debate about access to and use of PrEP, particularly among key populations (KPs).

To discuss key considerations of PrEP implementation across key population groups and develop strategies and solutions on community-led KP demand creation, the International Treatment Preparedness Coalition (ITPC) hosted a global community-led consultation on PrEP. The two-day event brought together more than 45 participants from 20 different countries representing civil society, key populations, governments, and technical expert groups. Open discussions and working groups focused on key considerations of PrEP implementation across key population groups, and the development of innovative strategies to create better access to PrEP for communities.

This report provides participants and other interested stakeholders with an overview of the discussions and outcomes of the global consultation. An annotated desktop review on PrEP and key global perspectives informed the consultation and is documented separately.

1. Background

ITPC is a global network of community activists unified by our mission to enable people in need to access optimal HIV treatment. Over the last 15 years, ITPC's work has uncovered glaring gaps along the HIV treatment cascade — pointing to on-going needs of people living with HIV in Africa, Asia, the Middle East, Eastern Europe, and Latin America and the Caribbean. In the context of our overall work on treatment access, it has become clear that discussions about PrEP must be better integrated into issues related to treatment access. “Treatment as prevention” and similar frameworks reinforce that all steps of the cascade are linked and should be treated as such. As an extension of our existing work in community-led advocacy for HIV treatment, ITPC has initiated a community-led process to develop and implement innovative community-led demand creation solutions for access to and use of oral PrEP by KPs.

Community-led demand creation is based on the understanding that supply-driven programming alone is insufficient and must be met with community demand. Communities will only access services that they themselves want, which meet their needs and aspirations and which involve them meaningfully. Creating community-led demand for PrEP by key populations, thus requires that affected communities are educated about PrEP, empowered and involved in all aspects of PrEP policy, research and implementation, and that their concerns are not ignored.

Meaningfully involving communities and enabling their leadership in the HIV discourse is as much about respecting the rights of those affected as about meeting a strategic objective geared towards strengthening community systems that are critical for meeting overall health care outcomes. To create community demand for PrEP and ensure sustainable access and uptake, it is critical to deliberate on perceptions and capacities around readiness to operationalize PrEP in different national contexts, paying close attention to addressing key barriers and gaps which may impede community demand for and sustained uptake of PrEP.

On May 17-18, 2017, ITPC began this process with a global consultative think tank meeting hosted in Port of Spain in Trinidad and Tobago. With support from the M·A·C AIDS Fund and LINKAGES / FHI360 funded through the United States President's Emergency Plan for AIDS Relief (PEPFAR) / United States Agency for International Development (USAID). The two-day event brought together more than 45 participants from 20 countries representing civil society, key populations, governments, and technical expert groups. Open discussions and working groups focused on key considerations of PrEP

implementation across key population groups, and the development of innovative strategies to create better access to PrEP for communities.

Building on the foundation of this meeting, ITPC will develop a global policy statement and activist toolkit to help communities better understand the most pressing issues around PrEP. Using the toolkit, ITPC will also conduct hands-on treatment education training in select countries in Asia, Africa, and the Caribbean.

2. Objectives of the consultative think tank meeting

The objectives of the **Community-led Consultative Think Tank Meeting on Access to and Use of PrEP** were to:

1. Share results of the PrEP literature review – “what is the latest science on PrEP & how it has been operationalized in countries”
2. Discuss key considerations of PrEP implementation across key population groups – “what are the barriers for effective PrEP implementation specific to each KP”
3. Develop strategies and solutions on community-led KP demand creation – “tease out innovative strategies to operationalize and create better access to PrEP”

The purpose of the meeting was to facilitate an international forum of treatment activists and researchers, governmental ministries of health, UN-agencies, key populations and their support and service networks. The objectives of the meeting were to share the preliminary findings of the literature review conducted by ITPC, discuss the progression of PrEP to date from research to implementation, explore related challenges and gaps, share best practices around access, utilization, and scale-up of PrEP globally.

The principal outcome of the meeting was the generation of evidence-based innovative community-led demand creation solutions and strategies to operationalize and create better access to PrEP among key populations. The information shared and solutions formulated at the meeting will subsequently be used to inform the development of an ITPC policy position statement and a training / advocacy tool for use by treatment activists to promote community-led demand for PrEP. A series of treatment education trainings in four countries (Mexico, Vietnam, Swaziland and India) will subsequently be rolled out to build KP organisational capacity to engage in community-led demand creation for PrEP among key populations.

The following are highlights and key points based on presentations and discussions held during the meeting.

PrEP: The Science

1. PrEP is safe and effective

In 2016, the World Health Organization (WHO) published the following updated recommendation on PrEP:

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

(Strong recommendation, high quality evidence)

The recommendation is based on a comprehensive review of high quality research that demonstrates both the effectiveness and the safety of WHO approved PrEP drug formulations of tenofovir (TDF), and the combination of tenofovir and emtricitabine (FTC/TDF).

Clinical research findings reveal that TDF and FTC/TDF are safe to use and effective for preventing HIV infection with proper use. PrEP drug formulations are effective in preventing HIV infection through sexual transmission, and evidence demonstrates that FTC/TDF is effective for preventing HIV infection through injecting drug use as well.

2. PrEP is for situations of HIV infection risk, not particular people

The WHO PrEP recommendations are intended to enable and catalyze the uptake of PrEP in countries. PrEP is particularly recommended for 'people who are at **substantial** HIV risk', in that, populations that have HIV incidence that is greater than 3 per 100 persons, in the absence of PrEP. Thirdly, the WHO recommends PrEP as an additional choice provided within combination prevention programming where users are also offered other services and prevention tools including condoms and lube, harm reduction services, HIV testing and links to ART. In addition, the WHO recommends that PrEP users are offered comprehensive support that includes adherence counselling, legal and social support, mental health and emotional support, contraception and other reproductive health services.

3. PrEP research should respond to community and country-level concerns

The future research agenda must reflect and respond to ongoing country-level programming concerns and challenges. Health ministries must ascertain the cost-benefit of prioritizing PrEP programmes in resource constrained contexts, where prior commitments to prioritise HIV treatment are in effect. Countries that do decide to implement PrEP programming need reliable evidence to inform programme design, including answering questions about where to provide PrEP and to whom. Future research should also respond to questions about potential PrEP drug toxicity, resistance and interactions, and fears around sexual disinhibition. In light of existing evidence from trials that indicate poor drug adherence among research participants that may undermine interest in PrEP, future research that demonstrates how adherence to PrEP can be maintained is needed. Future PrEP research that provides evidence demonstrating the positive and wide reach of its impact on HIV services will enable countries to plan PrEP programme implementation.

PrEP: The Cost

1. Factors that influence affordability and accessibility of PrEP

Multiple factors influence affordability of PrEP, including pricing, originator vs. generic drug registration, drug quality, regulatory issues at state level and procurement and distribution of medicines. Pricing of medicines continues to be a major factor impacting access to PrEP. Registration of cheaper generic drug formulations at country level facilitates greater affordability and thus greater access; whereas, registration of drug patents, the exclusion of voluntary licenses, and research data exclusivity effectively blocks the registration of generics, and hinders drug access and affordability.

2. The status of PrEP drug patents

The patents for FTC and TDF expired in 2010 and 2017/2018, respectively. Once expired, they will be available for production in generic formulations. The combination drug TDF/FTC will only expire in 2024, which means that it cannot be generically manufactured until that time.

Globally, the vast majority of countries have not had patents filed for Tenofovir (TDF), including most notably Sub-Saharan and eastern European countries. India notably rejected the filing of a TDF patent and Indonesia granted a TDF patent which will expire in 2018.

FTC patents had either not been filed or had expired.

TDF/FTC patents have been filed in Botswana, Kenya, Malawi, Mozambique and Swaziland; patents have been granted in Indonesia and Tajikistan; and patent terms have been extended in Kazakhstan and Kyrgyzstan.

There are no major patent barriers in LINKAGES countries to access affordable versions of FTC/TDF. In most countries, the drug is already registered to treat HIV infection. There are also no major barriers to accessing TAF, once it is approved for use for PrEP.

PrEP: Concerns, Support, & the Community Perspective

Prior to the consultative meeting, a literature review was conducted to synthesize global perspectives on PrEP by a range of players, with a focus on key population perspectives. The review gathered data from various sources, including PrEP publications and reports produced by key population support networks, WHO, UNAIDS and PrEP trial findings. The review seeks to further facilitate on-going discussions among ITPC members and partners around how best to build interest in and capacity of KP networks to strengthen community-led demand for PrEP.

1. Support for PrEP

Consultations with key populations have revealed that the efficacy of TDF and TDF/FTC for preventing HIV infection is generally accepted. There is strong global attention and support paid to key populations in global PrEP policy priorities such as the UNGASS Political Declaration on HIV, as well as in current and future research and demonstration projects. The new WHO guidance that identifies risk in terms of

situation rather than targeting particular populations may help to mitigate the stigma that key populations experience when accessing HIV services. Global policy support for a comprehensive approach to HIV that includes bio-medical, behavioural and structural responses is also encouraging for key populations and their support networks. PrEP also poses the potential for more opportunities to discuss sex, sexuality and sexual and reproductive health and rights in the HIV response space. PrEP also levels the playing field in terms of the involvement of both HIV negative and positive people in HIV prevention.

2. Concerns about PrEP

There are some key issues and concerns raised by key population groups when consulted about PrEP. In general terms, PrEP is still not well known among key population communities. There are difference in knowledge levels within and between them, like the fact that the MSM and gay community likely have the highest levels of PrEP knowledge, and people in countries where trials and demonstrations have ended or are currently underway are generally more knowledgeable than people in countries where trials and demonstrations have not taken place. There is a need for clear, contextual and inclusive messaging and education about PrEP that different people can associate with.

Certain networks have raised concerns that they often feel marginalized in PrEP spaces and that their perspectives are often not heeded in PrEP dialogues. There is a need to better articulate the importance of community involvement in all processes and at all levels.

KP networks and their communities are concerned that PrEP may lead to shifts in HIV programming priorities. They fear a move away from tried and tested programmes already underway and a slow down in advocacy efforts to promote access to other services, such as harm reduction programmes which still suffers from very low global coverage in places where they are most needed. They also question the ethics of providing PrEP in contexts where there is still low coverage of ARV treatment of HIV. KP networks also raised concerns related to PrEP affordability and sustainability.

KP networks have also emphasized that HIV prevention programming must address underlying systemic and structural barriers manifested in stigma and criminalization of key populations which hinder access and sustained uptake of HIV prevention services by key populations. KP networks have continued to advocate for the decriminalisation of key populations as a necessary measure to ensure their access to HIV services. Some KP networks say that their communities have questioned the real-life feasibility of sustained adherence to PrEP medication in light of legal barriers, continued stigma and discrimination against key populations in healthcare settings.

KP groups raised concerns about drug side effects, long-term use effects and drug interactions. Female sex workers have reportedly emphasized the fact that PrEP does not protect against pregnancy and worry that if their clients know that they are using PrEP, that they may demand sex without a condom. Fear around the possibility of an increased occurrence of 'stealthing' was also mentioned. Stealthing in this context refers to the act of removing the condom during sex without the other person being aware nor consent.

PrEP: The Implementation & Practice

The following are highlights and key points presented by participants representing specific countries or key population groups. The views expressed herein are specific to their work and may not be representative of all views on the subject matter.

CASE STUDIES OF ROLL-OUT OF PrEP:

1. Oral PrEP Demonstration Projects in Swaziland

Swaziland's demonstration projects target a range of users, including but not limited to young women between 16 - 25 years of age, pregnant and lactating women and sero-discordant couples. The projects also target female sex workers, MSM and clients presenting with STIs. Inclusion criteria used is based on risk behavior. The projects aim to implement a comprehensive package of services that include bio-medical, structural and behavioural interventions. PrEP drugs which are used are FTC/TDF and 3TC/TDF, and they avail a range of service providers to prescribe PrEP and provide counselling and support. The projects are being implemented across Swaziland in several sites and plans are underway to provide training to service providers, develop IEC materials and establish a community advisory board.

In Swaziland, in partnership with LINKAGES/FHI360, the Ministry of Health is using different service modalities to introduce PrEP. In most cases, PrEP is being integrated into existing HIV-related services where it is being offered in addition to the other services being accessed. They expect that with time, service users will visit facilities for PrEP specifically.

2. PrEP Demonstration Programs in Thailand

Thailand's extensive involvement in PrEP research and implementation projects date back to clinical trials in 2010/2011. At present, Thailand is well on its way to state-funded scale up of PrEP supported by strong policy and implementation frameworks.

The National Operational Framework does not include PrEP as part of MSM and TG service packages nor is PrEP included in the Universal Healthcare Plan. However, the National AIDS Committee has endorsed PrEP as an additional prevention method and according to policy, public hospitals are required to provide PrEP on a self-pay basis and at a cost of about 20 USD per month.

With respect to community engagement, Thailand hosted the first-ever community-led consultation meeting on PrEP in 2015 facilitated by APCOM, *PrEParing Asia* and held with policymakers, healthcare providers and community advocates to discuss PrEP implementation strategies with MSM.

Thailand is extensively engaged in PrEP initiatives, ranging from clinical trials (iPrEX, 2010 and HPTN, 2011), implementation research projects (PrEP Substudy, Princess PrEP and PrEP@Piman) and PrEP service provision (PrEP30 and PrEP SCC@TropMed). In November of 2016, the Thai government initiated a state-funded PrEP implementation project (PrEP2START) that focuses on strengthening the public health system capacity towards increasing PrEP access to key populations with an eventual national scale up. Project results so far have been promising, such as in the PrEP@Piman implementation research project with MSM and TG women that have reported uptake levels of 70% and retention levels of over 85% and many projects reporting zero seroconversions.

The vast majority of PrEP projects have a strong community-led component and rely heavily on trained lay providers to provide services, including members of MSM and TG female communities who provide

a range of services throughout the HIV programming cascade. Laypersons perform clinical services including HIV testing and counselling, dispensing PrEP and PEP, syphilis screening and tuberculin skin tests. They plan to expand lay provider service provision to other areas in the future, including ARV refills, Hepatitis C screening and among other services.

There are several challenges faced in PrEP programmes in Thailand, including: resistance to HIV treatment and condom advocates and other human rights groups; inconclusive results from PrEP modelling work; low retention rates in some programs; some misunderstanding and low awareness about PrEP; still not 100% acceptability of PrEP by some clinicians and community representatives, and low PrEP uptake among certain high-risk populations, especially TG women.

3. Perspectives on PrEP in India

While there are several PrEP demonstration projects which focus on providing PrEP to sex workers in India, to date, there has been no move by the government to initiate state-funded programmes nor to establish a country plan to do so in the future. There has also been little mention of PrEP implementation by external HIV funding mechanisms.

Criminalization is seriously impeding KP access to PrEP in India. There are real concerns about prosecution and the possibility that KPs (including people who use drugs, MSM and sex workers) in India might be forced to take PrEP rather than offered it on a voluntary basis.

People who use drugs are deeply concerned that PrEP in their context threatens to replace harm reduction programming.

4. PrEP Use in the US

Since the approval of Truvada® for use by the U.S. Food & Drug Administration (FDA) in 2012, there has been a steady increase in interest in PrEP, reflected in federal and state policy and guideline development. The US National HIV/AIDS Strategy mentions PrEP in its very first objective where it describes PrEP as a 'promising strategy to complement existing prevention methods.'

This interest has also been reflected in the exponential increase in demand for PrEP (FTC/TDF) which has risen over 700% between the years 2012 and 2015¹.

Ethnic and sex-related disparities in PrEP access is likely that varying risk perceptions may be contributing, as well the fact that much of PrEP marketing depicts MSM and is not suited to all audiences in need. One of the key strategies that is needed, is to identify service providers that will offer PrEP and provide appropriate services to different potential PrEP users.

5. PrEP in Latin America and the Caribbean (LATCA)

There has been success in HIV treatment roll-out in LATCA, as most countries offer free ART and that in general there has been progress across the treatment cascade. However, HIV prevention efforts have been insufficient, due to the fact that in several countries promotion of regular HIV testing and counselling has been insufficient; many countries rely solely on condoms for HIV prevention; combination prevention models are not being sufficiently implemented; it is difficult to focus on key population needs in prevention initiatives and there are challenges with implementing new services such as PrEP.

1 Mera, R. et al. AIDS 2016. Durban, South Africa. Oral #TUAX0105LB

In terms of PrEP specifically, Brazil has announced its intention to implement PrEP; however, the region as a whole is facing implementation challenges. Concerns around fears resulting from PrEP use include behavioral disinhibition, adherence and drug resistance issues (but are receding), use of PrEP as replacement of condoms, and the cost implications of PrEP implementation. Current efforts to implement PrEP are stymied by implementation challenges such as the political justification for investment in PrEP as well as implementation questions including for whom and where PrEP should be implemented. Noted during the presentation, was a growing interest in PrEP from MSM in LATCA and highlighted the need for evidence to justify and guide implementation, as well as technical support.

6. PrEP Feasibility and Implementation in Botswana

On the heels of the WHO's 2015 PrEP recommendations, in 2016 the Botswana Ministry of Health & Wellness (MoHW) released HIV & TB Clinical Care Guidelines which recommend PrEP use for persons at high risk of HIV infection on a self-pay basis and suggest PrEP be provided by the public sector starting in 2017.

In late 2016 the Botswana MoHW with the support of UNAIDS drafted feasibility and implementation recommendations for PrEP provisions in the public sector and established a PrEP Technical Working Group (TWG) comprised of Botswana state actors, UN-partners, physicians and local civil society groups. This group has been tasked with exploring the feasibility of and making recommendations for an implementation model for a short-term PrEP program to be implemented in the private sector.

The implementation model used in Botswana is structured in a manner as to engage motivated and trained private practitioners who are identified by medical aids, community NGOs and MoHW and discussed the gradual geographical roll-out from a pilot project to full scale programming. The model also enlists local NGOs to engage in PrEP demand creation, provide routine HIV counseling and testing, manage the monitoring of implementation and provide additional health prevention services. The MoHW with the support of CDC and other technical partners will purchase PrEP drugs and provide training support for all partners.

Advantages of the model include: a decongestion of public health facilities; a reduction in stigma and discrimination in healthcare settings and de-medicalisation of prevention interventions with greater involvement of local NGOs in providing health services. Challenges for PrEP implementation include: poor baseline knowledge about PrEP generally and the need to acknowledge the reality of sexual behavioral norms and stigma of healthcare workers towards PrEP Users. Opportunities outlined include: the high levels of acceptability found among various key populations interviewed and evidence indicating that potential PrEP users would prefer to receive PrEP through the private sector channels to alleviate stigma associated with public facilities.

7. PrEP in Morocco

Five PrEP implementation studies in Morocco will begin in 2017 with an expected initial recruitment of 500 research participants. However, there are a few key challenges including observing that the Moroccan government is consulting with people who do not know how to implement PrEP and that treatment literacy and preparedness are critical. Criminalisation of key populations is also a key issue. In general, medical practitioners are overwhelmed and there is resistance to PrEP implementation. There is a need to consider implementation by private sector health practitioners because the demand for PrEP will be among MSM and gay men and they will be reluctant to an organisation that works with MSM and would prefer private sector services. PrEP implementation efforts are also moving along with very little civil society involvement.

8. PrEP in Kenya

Kenya has been involved in numerous clinical trials and demonstration studies but with varied success, and difficulties with adherence. Kenya recently launched a policy for the provision of PrEP for at-risk groups and there have been some highlights stemming from this effort. The national government has been involved from the beginning, which has strengthened national ownership of PrEP efforts. Research findings were shared widely with other stakeholders including communities representing key populations. When the PrEP policy was launched, it involved all stakeholders including the media. Other stakeholders involved included religious leaders from the Christian and Muslim communities and health care practitioners. This widespread involvement of stakeholders led to a successful launch. PrEP reporting tools have since been developed, and the development of a Training of Trainers manual for healthcare workers is underway.

PrEP: Community-Led Strategies, Solutions, and Priority Messages

Small working groups categorized by key populations tasked with generating community-led strategies, solutions and priority messages to operationalize and create improved access to PrEP by key populations and others. The following process outputs were developed:

WOMEN & YOUNG GIRLS

i. Operational solutions on HIV testing and PrEP for women and young girls are outlined in Annex 3 on Page 19.

ii. Priority Messages for PrEP for Women and Young Girls

- **Facilitate knowledge, awareness and literacy among young women and girls:** Treatment education and awareness raising about PrEP that is tailored to women and young girls is critical. Messaging should be standardized and consistent and speak to the contexts of women and girls. It is important to also identify other acceptable and appropriate channels for diverse women (including lesbian and bisexual women in non-heterosexual sexual relationships).
- **Create awareness on safety of PrEP in pregnancy and during breastfeeding:** women and girls should be fully informed about the safety of using PrEP whilst pregnant and have key evidence shared with them, for example Lynn Mofeson's study on use of tenofovir during pregnancy and 'License to Love,' study by Vernazza. At the same time, healthcare providers should also be educated on the same evidence and how to educate young girls and women. The successful use of PrEP by real-life discordant couples seeking to get pregnant can also be used to encourage uptake.
- **Cast PrEP public education audiences widely, not just for KPs and healthcare workers:** PrEP should be rebranded and marketed as an HIV prevention intervention for all people at substantial risk of HIV infection and not just KPs. Advocacy targeting governments and other stakeholders of influence is needed to promote commitment to implement PrEP at country level, and technical support provided to resolve concerns around cost-benefit of PrEP in comparison to solely prioritizing treatment programming.
- **Address Stigma and Discrimination:** 'Resilience to Stigma' initiatives can be established for women and young girls. Public education & messaging that confronts and counters societal and communal 'shaming' of women's sexuality needs to be amplified. The intersection between gender-based violence against women and girls and how it hinders their ability to access HIV prevention services must be address. Healthcare workers should be sensitized to sexual and reproductive health and rights of women and young girls to mitigate attitudes of stigma and discriminatory practices.

TRANSGENDER PEOPLE

i. Operational solutions on HIV testing and PrEP for transgender people are outlined in Annex 4 on Page 20.

ii. Priority Messages for PrEP for Transgender People

- **Train healthcare workers about trans-specific issues and healthcare:** Trans-led organisations should be involved in training healthcare workers about trans-issues and healthcare, including hormone replacement therapies and other stages of transition.
- **Design HIV programmes that meet the life circumstances of trans-people:** For instance, when designing programmes for trans-sex workers, healthcare services ought to take into consideration the fact that regular operating hours (e.g. 8 am - 5 pm) may not be suitable for them and to facilitate dialogue with trans-sex workers themselves as to the best time to reach them with services.
- Also, as confidentiality and concerns about stigma, discrimination and criminalization of trans-gender identities and/or sex work has been raised as a barrier to access and uptake of services, stakeholders need to be sensitized and trained to maintain the confidentiality of transgender individuals. Monitoring tools must be designed to protect the confidentiality of medical records as well, and transgender people must be made aware of these safeguards to protect their confidentiality.
- **Involve trans-led organisations to promote awareness about PrEP among their communities**
- **Conduct trans-specific PrEP research:** There are several PrEP studies that involve trans-communities; however, none are specific to them. They are mostly included in larger MSM studies. There is a need for trans-specific PrEP research. The HIV prevalence among transgender men also still remains a grey area that requires further research and action. Research is also needed about drug interactions between PrEP and hormonal therapy.

SEX WORKERS

i. Operational solutions on HIV testing and PrEP for sex workers are outlined in Annex 5 on Page 21.

ii. PrEP Priority Messages for Sex Workers:

- **Education is key:** treatment education customized to meet the needs of sex workers, involving sex worker-led organization. There is evidence indicating that there is high acceptability among SWs who have the right information about PrEP. However, whether knowledge alone is sufficient for them to stay on PrEP is another issue. The possibility that perhaps stigma around accessing healthcare remains a central barrier to consider.
- **Ensure sex worker led organizations are included from the very beginning:** Promoting sex worker PrEP champions is a good strategy, because then messaging is localized and other potential PrEP users in sex worker communities may be able to relate to their sex worker counterparts who are using PrEP. In many countries that were previously colonized for instance, there is still a deep historical distrust of healthcare providers by marginalized groups, related in part to racial issues. This means many sex workers and other marginalized communities will not always be so eager to believe messaging around PrEP coming solely from healthcare providers. Having PrEP users whom they can trust to share knowledge and experiences about PrEP could help mitigate this distrust of health services.
- **Provide as many options as possible within the community, as close to the end user as possible:**

Programmes that ignore the nuances in condom use, and the difficulties sex workers often face with ensuring that their clients use condoms, risk failure. In countries like Cambodia where there is a 100% Condom Use Policy, sex workers are concerned that PrEP might undermine their ability to insist on condom use with their clients, and also that they will be forced to take PrEP.

- **Engage governments on how to fund PrEP and to support the rights of sex workers leading to decriminalization**
- **Provide as many options as possible for treatment regime to follow where local communities feel safe**

Other Key Messages:

- Cultural beliefs and assumptions have a strong influence on the decision to take PrEP. For instance, in Africa and the Caribbean, the idea of taking PrEP when you are not sick does not make sense in many cultures. Prophylactic medicines are just not understood from a cultural standpoint.
- We need to find the right balance between acknowledging the efficacy of a pill (PrEP medications) and the acknowledgement that it is not a silver bullet and addressing other surrounding issues that facilitate the success of PrEP programmes.
- The ‘branding’ of PrEP needs to be community-led by advocates from within KP communities. If we want to reduce HIV- and KP-related stigma and reach KP communities, we need to also brand PrEP as something for anyone. For instance, link PrEP to the carnival culture and its events in the Caribbean.

PEOPLE WHO INJECT DRUGS (PWID)

i. Operational solutions

The unique challenges that PWID experience with regards to the widespread lack of access to harm reduction strategies and the criminalisation of drug use makes such a formulation of PrEP rollout difficult. Some key actions that need to be taken in order to facilitate PrEP programmes for PWID, are as follows:

- **Identifying and maximizing on the intersectionality that exist with other healthcare services** (e.g. harm reduction services, sexual and reproductive health services etc.), with other key populations (the fact that PWID also have other multiple identities), settings and events
- **Establish differentiated approaches for PWID in different settings** - in settings with strong harm reduction programming for PWID; settings with little or non-existent harm reduction programming and high criminalization barriers and hostilities; in settings with little or non-existent harm reduction programming but fewer criminalization barriers or hostilities
- **For all settings, identify potential synergies around assisted partner notification** where opportunities to introduce PrEP through negative sexual partners and **potential for self-testing** among PWID can be maximized.
- In all settings, **identify links to ART services**
- **Ensure PrEP is an available choice for PWID** and that the “social marketing” and service provision is PWID inclusive and free at point of contact
- **Prioritize harm reduction (NSP and OST) advocacy over PrEP advocacy** – especially in settings that are particularly hostile to PWID. Where harm reduction programmes are adequately in place, capitalize on existing harm reduction services when introducing PrEP
- **Prioritise research and feasibility studies in different settings**, for example **PrEP in prisons** for PWID.

MEN WHO HAVE SEX WITH MEN (MSM) AND OTHER GAY MEN

i. Operational solutions on HIV testing and PrEP for MSM are outlined in Annex 6 on Page 22.

ADOLESCENTS

i. Operational solutions on HIV testing and PrEP for adolescents are outlined in Annex 7 on Page 25.

ii. PrEP Priority Messages for Adolescents:

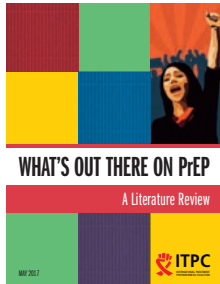
- **Youth-led (not youth-focused) PrEP programming is a pre-requisite.** Adolescents and young people should be involved in advocacy, programme development, community mobilisation and comprehensive education campaigns. This requires investing in communities, youth-led organisations and networks, social media networks, identifying groups that are best placed to deliver services, rather than just organisations that are serving youth.
- **Youth Championing:** enable platforms for both HIV positive and negative youth to share their experiences about taking ARVs for treatment and for PrEP.
- **Represent adolescent perspectives** and advocate for policy makers to view adolescents as a special population (i.e. age cohort 19-25 years) and not to be grouped together with older adults (as was done during the dapivirine ring trials).
- **Disseminate information/data about PrEP to adolescents** in global communities
- **Promote youth-friendly services:** in most cases non-government and community-based service delivery and private practitioners.

PrEP: The Way Forward for Communities

The principal outcome of the meeting was the generation of evidence-based innovative community-led demand creation solutions and strategies to operationalize and create better access to PrEP among key populations. The information shared and solutions formulated at the meeting will subsequently be used to inform the development of three key resources:

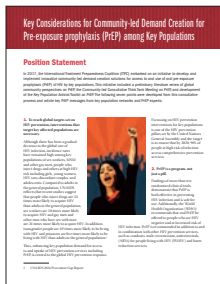
- **Policy statement:** ITPC will produce a brief policy statement informed by the think tank that articulates key messages on PrEP for key populations and sets out the key strategies and solutions, that are key to the successful roll-out of PrEP globally to key populations.
- **Toolkit for Community-led demand creation for PrEP among key populations:** ITPC, with technical advice and inputs provided by a technical working group of global partners (including participants from the think tank), will develop a participatory community-based advocacy-oriented toolkit for a wide audience including KP networks and other PrEP advocates. The toolkit is intended to educate participants about the science of PrEP, global guidelines on PrEP and current roll-out models and to equip them with skills and resources to develop their own localized PrEP advocacy plans.
- **PrEP Training Workshops:** ITPC will thereafter conduct a series of workshops to pilot the toolkit in four countries (Mexico, Vietnam, Swaziland and India) and also build KP capacity to engage in community-led demand creation for PrEP among key populations.

Annexes



ANNEX 1

What's Out There on PrEP A Literature Review



ANNEX 2

Position Statement: Key considerations for Community-led demand creation for Pre-exposure prophylaxis (PrEP) among Key Populations

