END OF GRANT EVALUATION of Unitaid's investments in PrEP

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EURO HEALTH GROUP

G:ENESIS UNLOCKING VALUE

Acronyms

ART	Antiretroviral Therapy
ARV	Antiretroviral
ABYM	Adolescent boys and young men
AGYW	Adolescent Girls and Young Women
CS	Civil Society
CSO	Civil Society Organisation
DAC	Development Assistance Committee
EA	Evaluation Approach
DREAMS	Partnership to reduce HIV and AIDS in adolescent girls and young women (PEPFAR)
EAB	External Advisory Board
ED	Event driven (ED PrEP)
EQ	Evaluation Question
FGD	Focus Group Discussion
HIV	Human Immunodeficiency Virus
HIVST	HIV self-testing
IEC	Information, education communication
ImPrEP	Preparedness for the Rollout of Effective HIV Prevention among Key Affected Populations in Brazil, Peru and Mexico (Main Grantee: Fiotec)
KI	Key Informant
KII	Key Informant Interview
KP	Key Population
KPI	Key performance indicator
LAC	Latin America and the Caribbean
LGBTQIA	Lesbian, Gay, Bisexual, Transgender, Intersex, Queer and/or Questioning, and Asexual and/or Ally
LMIC	Low and middle-income country
MoH	Ministry of Health
MPP	Medicines Patent Pool (founded by Unitaid)
MSM	Men who have sex with men

MTV Shuga	A Multi-channel campaign focusing on positive sexual health messaging for young people
MyPrEP	Website to inform users and providers about PrEP
NAFTA	North American Free Trade Agreement
NIMART	Nurse Initiated Management of Anti-Retroviral Therapy
NCE	No Cost Extension
(N)DoH	(National) Department of Health
NGO	Non-governmental organisations
OECD	Organisation for Economic Co-operation and Development
PHC	Primary healthcare
PrEP	Pre-Exposure Prophylaxis
PrEP1519	Unitaid funded PrEP adolescent and young MSM and TGW demonstration project in Brazil (Grantee: Fiotec)
Project PrEP	Integrating PrEP into Comprehensive Services for Adolescent Girls and Young Women in South Africa (Grantee: Wits-RHI)
SA	South Africa
SRH	Sexual and Reproductive Health
STAR	Self-Testing Africa Initiative
STI	Sexually Transmitted Infection
SW	Sex Worker
TDF/FTC	Tenofovir/emtricitabine
TGW	Transgender Women
ToC	Theory of Change
UMIC	Upper middle income country
UNAIDS	United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
VfM	Value for Money
WHO	World Health Organisation
WG	Working Group
WS	Workstream

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1 Background on PrEP Introduction

The incidence of HIV has declined since 2010, but not enough to meet the target of a 75% reduction

Globally, the number of **new HIV infections have declined by 31%** between 2010 and 2020.[1] However, this decline has fallen short of the 75% target for 2020 set by the United Nations General Assembly in 2016, with two regions (EECA and MENA) reporting an increase between 2010 and 2020.

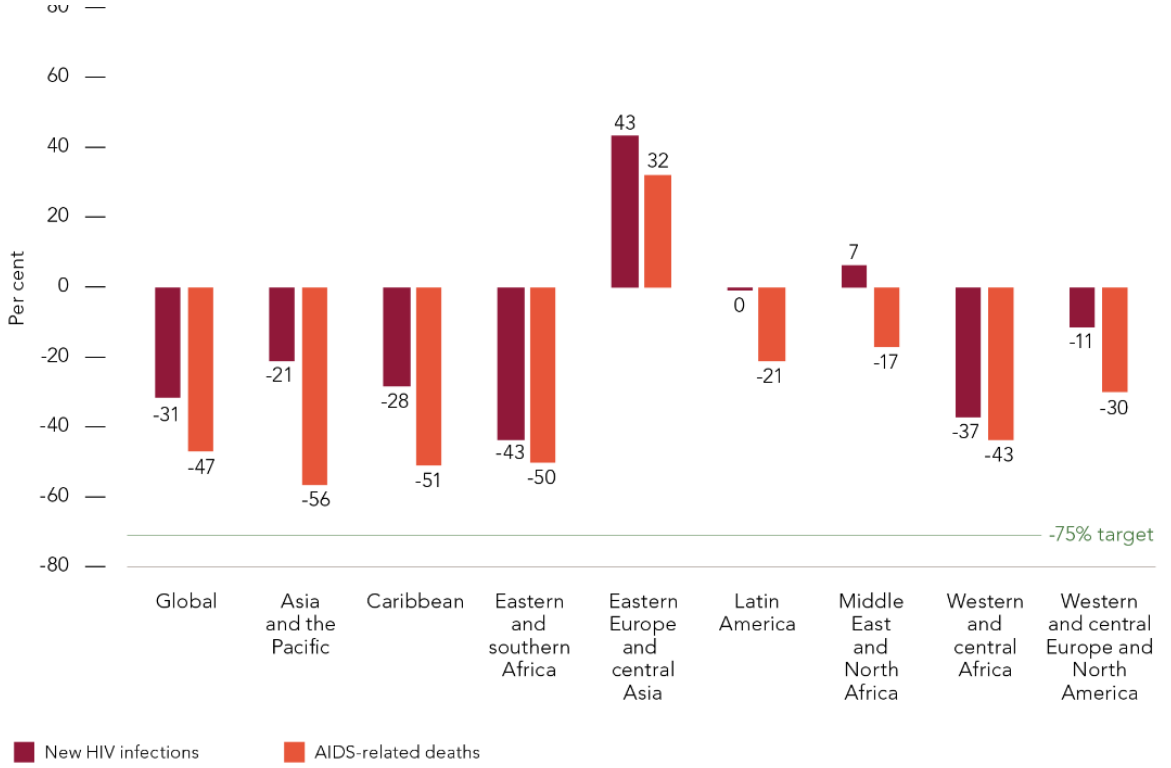
Despite this decline, HIV infections among transgender women (TGW), gay men and other men who have sex with men (MSM) has remained either unchanged or increased between 2010-2019.[2]

In 2020, key populations including MSM, transgender people, and their sexual partners accounted for 65% of global HIV infections, while adolescent girls and young women (AGYW) in sub-Saharan Africa accounted for 63% of new infections.[3]

The risk of acquiring HIV has been estimated at 34 times higher for TGWs, 25 times higher for gay and other MSM, and at least 5,000 young women aged 15-24 years acquire HIV every week.[4]

Social and structural factors including stigma, discrimination and criminalization, contribute to a lack of access to health services and perpetuates HIV infection.[5]

Figure 1: Change in new HIV infections and AIDS-related deaths by region/global – 2010-2020



Source: UNAIDS epidemiological estimates, 2021 (https://aidsinfo.unaids.org/).

[1] UNAIDS DATA (2021) - UNAIDS Data ; [2]UNAIDS (2020) New HIV infections among gay men and other men who have sex with men increasing; [3]UNAIDS Fact sheet – World Aids Day 2021, [4] ibid; [5]https://www.usaid.gov/global-health/health-areas/hiv-and-aids/technical-areas/key-populations

In 2015 PrEP was recommended by the WHO for people at substantial risk of HIV infection

In 2015, the World Health Organization (WHO) recommended oral Pre-Exposure Prophylaxis (PrEP) as part of a comprehensive HIV prevention package that should be offered to populations at substantial risk of HIV infection.[6] This is because, tenofovir disoproxil fumarate (TDF)-based oral PrEP has been shown to be highly effective at preventing HIV infections when used correctly.[7]

Specifically, the trials found that, when used correctly and consistently, PrEP provided 90% protection against HIV infections from sexual intercourse.

Since, at the time, PrEP was a new HIV prevention intervention, WHO called for countries to undertake demonstration projects to ascertain the most appropriate groups and the best delivery approaches.[8]

As of 2020, 130 countries reported adopting WHO's recommendations on oral PrEP in their national guidelines and over 940,000 people across 83 countries have received oral PrEP at least once in 2020.[9]

PrEP has also been highlighted in the UN 2025 targets under the goal "95% of people at risk of HIV infection use appropriate, prioritized, person-centred and effective combination prevention options by 2025".[10]

Figure 2: PrEP recommendations adoption over time by region

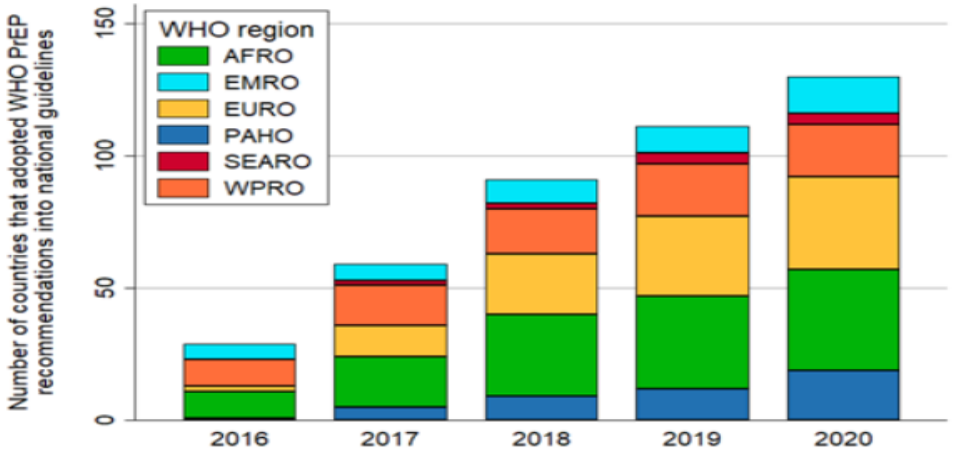
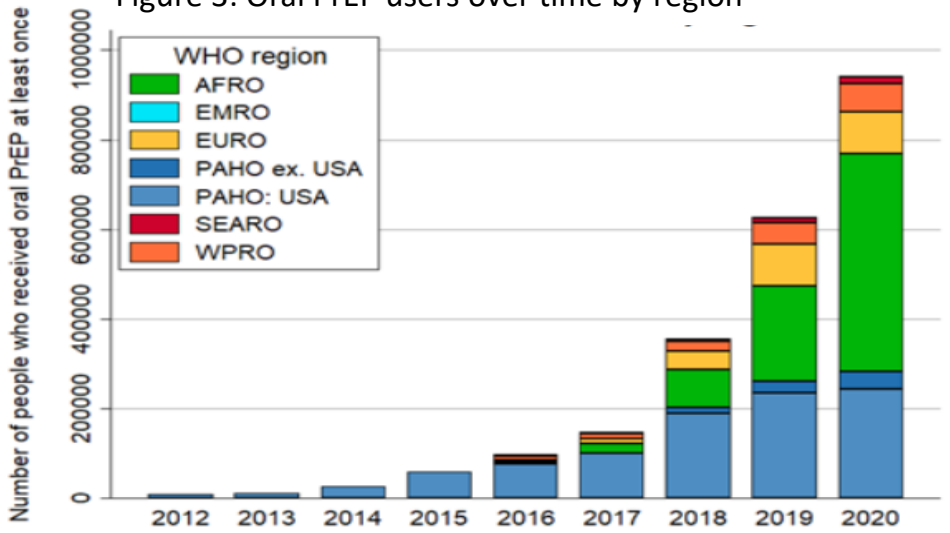


Figure 3: Oral PrEP users over time by region



[6] WHO (2022) - https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis; [7] Fonner VA, Dalglish SL, Kennedy CE, Baggaley R, O'Reilly KR, Koechlin FM, Rodolph M, Hodges-Mameletzis I, Grant RM. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. AIDS. 2016 Jul 31;30(12):1973-83. doi: 10.1097/QAD.0000000000001145. PMID: 27149090; PMCID: PMC4949005; [8] Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects; [9] https://www.who.int/groups/global-prep-network/global-state-of-prep [10] https://aidstargets2025.unaids.org/

Unitaid PrEP evolution

- In 2014, Unitaid conducted a Landscape Analysis[11] that showed evidence of reduction of HIV acquisition through use of daily oral PrEP. It pointed out the need to identify optimal delivery methods and to expand the knowledge base on clinical and real-world implications of PrEP.
- The analysis raised concerns around 1) affordability of PrEP, especially in the low- and middle-income countries (LMIC) and 2) effective delivery approaches for PrEP.
- In 2015, Unitaid announced an Area for Intervention (AfI) in PrEP to reach and generate demand for PrEP in high-risk populations.

The AfI for PrEP highlighted the need for projects that would provide real-world evidence on implementation of PrEP and identify factors needed for PrEP scale-up.

To that extent, Unitaid approved two grants to Fundação para o Desenvolvimento Científico e Tecnológico em Saúde (Fiotec) and WITS RHI; the projects under the grants include:

- 2017 – "Preparedness for the rollout of effective HIV prevention among key affected populations in Brazil, Mexico and Peru" (ImPrEP) - implemented by Fiotec.
  - 2018 - Adolescent MSM/TGW in Brazil (PrEP1519) – a sub-project under the Fiotec grant.
- 2018 - "Integrating PrEP into comprehensive services for adolescent girls and young women in South Africa" – implemented by Wits Reproductive Health and HIV Institute (Wits RHI).

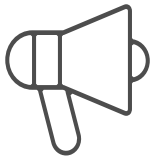
[11] http://unitaid.org/assets/UNITAID-HIV_Preventives_Landscape-2nd_edition.pdf

Expected outcome of Unitaid projects: contribute to increased PrEP uptake among high-risk populations

Sub-outcome: address supply and delivery, affordability, and demand and adoption

- **Supply and delivery** of PrEP is essential to ensure that the product is readily available to populations at greatest HIV risk and thus at most need. To address this access barrier, supply chain systems, including quantification, procurement, storage, and distribution, need to function effectively to ensure that products reach end users in a reliable and timely way. Additionally, ensuring that adequate and sustainable supply exists to meet global need is critical in addition to determining what differentiated service delivery modalities work best to reach different populations.

- **Affordability** refers to ensuring that products are available at the lowest price, sustainable for suppliers, and not unreasonable for governments, donors and patients, with a view to increasing access for the underserved.



- **Demand and adoption** activities are the drivers for raising awareness and generating demand for PrEP services among target populations. The involvement of civil society (CS) and non-governmental organisations (NGOs) in project activities and in the exchange of best practices could play a pivotal role in overcoming the stigma associated with antiretrovirals. It is vital for countries, programmes, and end users to introduce and adopt the most cost-effective products within their local context.[12] It is also critical to ensure adoption of policies, strategies and guidelines at global and country level to facilitate equitable access.

[12] Unitaid Results Framework 2021 – relevant for all three areas

2 Overall Evaluation Design

Evaluation objectives and scope

Objectives

- The overall objective is to consolidate knowledge on good practices and provide Unitaid with an assessment of the overall success of the projects as measured against the OECD DAC criteria including relevance, coherence, efficiency, effectiveness, impact, sustainability and lessons learned from the HIV PrEP grants. The findings are intended to inform future Unitaid investments including, where possible, course correction for ongoing implementation.

Scope

- The evaluation covers two projects namely PrEP implementation by Fiotec (July 2017 to December 2021 including ImPrEP and PrEP 1519) and by Wits RHI (January 2018 to December 2021); dates include no cost extension periods.
- The evaluation has briefly reviewed the extent to which the MTV Staying Alive Foundation (SAF) project, implemented from April 2018 to June 2022, contributed to the successes of PrEP implementation in South Africa.
- The WHO enabler grant for PrEP is not in scope, but WHO's contributions to PrEP, including in the Asia and Pacific Region, and to the projects have been considered.

Evaluation implementation period

- January to December 2022

Fiotec and Wits RHI project overviews

The Implementation PrEP Project (ImPrEP) | 2017 - 2021

Preparedness for the rollout of effective HIV prevention among key affected populations in Brazil, Mexico and Peru

The purpose of the project was to:

1. Generate evidence on the feasibility, acceptability and cost-effectiveness of PrEP among key populations (MSM and TGW)
2. Contribute to increased PrEP uptake among MSM and TGW

Consortium: UNFPA, Universidad Peruana Cayetano Heredia (UPCH)

Funding: US$ 26.4 million

PrEP1519 (sub-project)

Enabling Scale-up of PrEP and linkage to testing among sexually active adolescent MSM, TGW and their sexual partners with substantial HIV risk in Brazil

The purpose of the sub-project was to:

1. Evaluate and generate evidence on the effectiveness of PrEP use among adolescent MSM and TGW aged 15–19
2. Create demand for PrEP for adolescents

Project PrEP | 2018 - 2021

Integrating PrEP into comprehensive services for AGYW in South Africa

The purpose of the project was to:

1. Increase accessibility of PrEP for the eligible AGYW population (15-24) in project implementation areas
2. Demonstrate effective delivery models and appropriate use of PrEP amongst adolescents
3. Generate and disseminate evidence on the use of PrEP in real life settings

Funding: US$ 10.7 million

See Annex B for additional project background information

Overall evaluation framework – structured around the OECD-DAC evaluation criteria

Relevance

1. To what extent did the objectives and design of the projects respond to the needs of targeted beneficiaries and those most disadvantaged among those beneficiaries – was the choice of project countries the right ones to have a regional domino effect?
2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context?

Coherence

3. How well does the intervention align internally with other Unitaid interventions and externally with priorities/needs identified by partners/ the global disease response?

Efficiency

4. How cost-efficient and cost-effective was implementation (consider both allocative efficiency and technical efficiency)?
5. What was the strength of collaboration between projects and national authorities in project planning, implementation and assessment to promote integration into existing health systems?

Effectiveness: Demand and adoption, affordability, supply and delivery

6. To what extent were the access barriers addressed by the two projects at national, regional and global levels: affordability (Fiotec); demand and adoption (Fiotec/Wits); supply and delivery (Wits)?
7. How effective are the delivery models in demand and retention and what best practices can be learned from the process?

Sustainability, Scalability & Impact

8. How successful was the implementation approach in setting up conditions for promoting policy adoption and financial support in project and non-project countries?
9. To what extent did the impact of the projects address equity concerns and what are the strategic benefits and positive externalities?
10. To what extent did PrEP grants contribute to enabling country (political and financial commitments – national) and global environment for scale up?
11. What measures have been taken to ensure that the benefits will continue beyond the life of the two grant investments?

The main evaluation questions (EQs) have been grouped around the five OECD-DAC criteria seen to the left. Findings on lessons learned from the PrEP grants and how the projects have managed risk have been woven into the five criteria.

Methods and Limitations

66 interviews in total

Key informant interviews at global, regional, and country level using a semi-structured questionnaire to gain a wide range of perspectives and insights.

24 internal consultations

Fiotec and Wits RHI grantees and sub-grantees (20); and Unitaid (4).

42 external consultations

Including civil society, ministries of health (MoH) and other government stakeholders, WHO/PAHO, UNAIDS, Abia (Brazil), International Treatment Preparedness Coalition – LAC, Medicines Patent Pool, The Global Fund, and PEPFAR.

Countries studied

Four country case studies were undertaken in Brazil, Mexico, Peru and South Africa.

Key Informants included: MoH and other government stakeholders, donors, grant implementers and sub-grantees, technical partners (UNAIDS, UNFPA, PAHO, WHO) and civil society (CS).

277 Documents reviewed

Document review at global, regional and country level – grant documents and related materials, Unitaid strategy docs, docs from other key stakeholders (UNAIDS, WHO, etc.).

Analytical framework

The case studies and the document review served as an analytical framework with the documents providing another point of triangulation with interviewee responses.

Limitations

- Direct beneficiaries were not engaged in the evaluation. However, CSOs representing groups of beneficiaries were interviewed and their perspectives included in the analysis.
- Studies on cost effectiveness conducted by Fiotec were not available at the time of this evaluation as these had been submitted for publication. Therefore, adequate insight into cost-effectiveness of PrEP in these settings could not be included and the focus remained on perception of government, partners and national stakeholders as to cost-effectiveness of the projects. Wits RHI did not conduct cost effectiveness studies.
- The Fiotec project recognized affordability as one of the key market barriers in addition to regulatory and supply barriers and had proposed to deliver impact and value for money by addressing these barriers for increased accessibility (Fiotec – PrEP Project Plan 29 May 2017). However, limited activities were planned by the project to address affordability. Therefore, the evaluation is based on the extent to which these (limited) activities were implemented and the ability of governments to procure PrEP commodities (Tenofovir/emtricitabine (TDF/FTC) through domestic and donor financing as a proxy for affordability with the underlying assumption that governments can provide these therapies at an affordable cost to the end clients.
- Possible respondent bias given many key informants were grant implementers was a perceived limitation however the evaluation team analyzed evidence from informants triangulated with the results of the document review and with non-grant implementers as a mitigation measure.

See Annex D for a complete list of stakeholders interviewed

Strength of Evidence

Assessing the strength of evidence requires considering the underlying "quality" of the evidence as well as the triangulation/ "quantity" of evidence. We applied the robustness rating shown below to our findings, which we have effectively used across many complex evaluations.

Strong 	Evidence comprises multiple data sources, both internal (e.g., Unitaid Secretariat and Board) and external (good triangulation from at least two difference sources, e.g., document review and KIIs or multiple KIIs of different stakeholder categories), which are generally of good quality.
Moderate	Evidence comprises multiple data sources (good triangulation) of lesser quality, or the finding is supported by fewer data sources (limited triangulation, e.g., only documents of KIIs of one stakeholder category) of decent quality.
Limited 	Evidence comprises few data sources across limited stakeholder groups (limited triangulation) and is perception-based, or generally based on data sources that are viewed as being of lesser quality.
Poor 	Evidence comprises very limited evidence (single source) or incomplete or unreliable evidence. Additional evidence should be sought.

3 Main Findings

EQ1. To what extent did the objectives and design of the projects respond to the needs of targeted beneficiaries and those most disadvantaged among those beneficiaries - was the choice of project countries the right ones to have a regional domino effect?

Finding 1.1: *The PrEP portfolio was sound in its design and fit for purpose with regard to responding to needs of vulnerable populations (MSM, TGW, AGYW) and increasing demand for PrEP grounded in evidence-based research generated from implementation science.*

The design of the Unitaid implementation science demonstration projects addressed the issues identified in the landscape analysis (2014) and aimed at generating evidence on implementation of oral PrEP in real-world settings for AGYW in South Africa, and MSM/TGW in Latin America and Caribbean (LAC) countries. In line with the Unitaid PrEP theory of change (ToC), the projects were structured to address policy, capacity, demand and evidence, which speak to the issue of generating real world evidence through demonstration of proven approaches.

The portfolio specifically targeted the above mentioned vulnerable key populations thereby engraining equity within the design. This is particularly true when considering the limited options available to these key populations and their lack of access to tailored services with the public health system. This often results in stigma and discrimination when seeking services in addition to access barriers to services.

The barriers experienced by these key populations, according to the literature and informants, are similar to those witnessed in low and lower-middle income countries (LMICs) globally implying that lessons learned from these upper-middle income country (UMIC) demonstration projects may be applicable in the LMICs.

However, further assessment of the feasibility and the limits to the applicability of lessons learned and possibilities for a regional domino effect in the context of LMICs is warranted (some examples of success are provided in finding 6.2). This is particularly warranted taking into consideration the Landscape Analysis which highlighted that, while studies have shown that PrEP may be cost-effective in some settings, this did not mean that it was affordable, especially in LMICs, and that PrEP did not result in cost savings.

Finding 1.2: *The design of the projects, covering a wide range of activities, were comprehensive and achieved stated objectives. However, defining success of policy generation/adaption would have been useful at project inception.*

Design of the projects focused on influencing policy, generating willingness and demand among vulnerable populations including for provision of PrEP among the healthcare providers. The design also targeted developing institutional and technical capacity to deliver PrEP and disseminating learning and evidence to achieve project objectives. These elements were appropriate, and all objectives were met by both grantees.

Additionally, the projects were designed to engage civil society and peer educators to create awareness and generate demand; proven methods for increasing uptake (refer to Finding 6.5 for details on demand creation and responsiveness to the needs of vulnerable populations). Projects were also meant to establish platforms to engage with key populations, which they did successfully.

With respect to policy development, the Logframe indicator on policy is limited to reporting on the number of policies and does not focus on content, scope and changes to policies (potentially measured through a set of codes which would indicate the nature of the policy change sought and the contribution of Unitaid to the process) which would provide a more meaningful way of reporting upon upstream policy work.

Finding 1.3: *Support from WHO in the design phase, through Unitaid's WHO enabler grant for PrEP, along with direct support from Unitaid, was significant and cited by key informants as critical to ensuring the scientific soundness and integrity of the overall design.*

Unitaid served a critical role in connecting the grantees with WHO in order to capitalize on the enabling services. According to the literature and informants, the involvement of WHO in the design of the grants included extensive discussions at country and regional level to ensure that activities were relevant, in line with global standards, deliverable, flexible, targeting the appropriate key populations and addressing community awareness and demand creation.

WHO was also seen as serving a critical role in bringing together the implementers in Brazil who represented different implementing institutions. They fostered discussions not only between the two implementers but with the sub-grantees in Peru and Mexico around design of the project in the initial stages and eventually cross fertilization discussions with Wits RHI.

The role of reviewing protocol designs, undertaken by WHO, was to ensure that they were scientifically sound. WHO HQ also served a critical role in shepherding the research protocols – sent for ethical review approval at country level – through the WHO ERC. In the case of Brazil, WHO helped to establish an agreement, which was supported by Unitaid, to speed up the research approval processes by submitting approval to WHO simultaneously with country submission.

Finding 1.4: *The rational for the choice of countries was clearly articulated and appropriate.*

The selection of countries was based in part on high HIV incidence rates and levels of stigmatization taking into consideration contextual and structural issues to access services confronted by MSM, TGW and AGYW.

In South Africa, at the time of project start-up, gaps in evidence existed relating to how to reach and generate demand for PrEP among AGYW which the project design addressed. Project PrEP envisioned initiation of AGYW on PrEP in the context of comprehensive prevention strategies, working closely with the South African Government's HIV programme targeting this group. Project PrEP implementation sites selected were classified high priority areas by NDoH due to high rates of HIV, teenage pregnancy rates, sexually transmitted infections (STI), and gender-based violence (GBV). These were areas where AGYW were considered at very high risk.

Landscape Analysis - The landscape analysis noted that demonstration projects had been slow to get underway in LMICs leading to a request to expand in settings such as South Africa. This request was based on conditions including relatively inexpensive drug costs, identification of high-risk target populations and models which showed cost-effectiveness of the interventions, yet questions persisted over how best to focus programmes and how best to deliver the interventions.

Finding 1.5: *Design of support to the Asia Pacific region, under the WHO enabling grant implemented through a unique collaboration of Unitaid, WHO, and UNAIDS focusing on utilization of evidence from the Unitaid PrEP portfolio (research results, protocols, tools) generated interest in PrEP programming and improved planning and coordination of the collaborating agencies. Future in person exchanges of experience from existing grantees could have an even greater impact.*

Unitaid, in its efforts to contribute to the operational feasibility of delivering PrEP in real-life resource-limited settings, in part through dissemination of lessons learned from the Wits RHI and Fiotec grants, fielded a Regional Advisor PrEP for the Asia Pacific Region. The Advisor, reporting to both the regional director of UNAIDS and WHO HQ is based in Bangkok and serves 18 countries. This "jointness" of a WHO/UNAIDS Advisor was considered important as the agencies have different functions at country level (WHO normative and UNAIDS focused on education, advocacy, influencing, implementation, etc.) therefore the Advisor could tap into the comparative advantage of both agencies depending upon the audience or technical issue at hand. The Advisor has been able to access the leadership of WHO at the global level, UNAIDS at the regional level and use her influence at country level – "the "dynamics were massive" (quote from informant). It was noted that without the Unitaid funding the position of the Regional Advisor would not have come to fruition.

Unitaid's influence comes into play in the operational regional (Asia Pacific) meetings where they were more involved through WHO than UNAIDS. That said, Unitaid is considered an equal partner at the regional meetings and seen as "being behind the agenda". The tripartite collaboration comprises a group of likeminded experts who are on the same wavelength.

Unitaid has also contributed to the funding of a discrete choice experiment survey in the region, the biggest of its kind, targeting MSM and TGW, the results of which will be used for advocacy, better product availability and service delivery in the targeted countries. According to an informant "Unitaid's convening power made this possible". It was also noted that Unitaid is one of the few funders in the Asia Pacific region.

According to informants, and the documentation reviewed, the Regional Advisor has provided a significant contribution in support of scale up in the Asia Pacific region where an increase in the number of countries now using PrEP was notable (albeit slow and advancement varied depending on the country).

Specific areas where learnings from the Fiotec and Wits RHI grants were of relevance for the Asia Pacific region include the work on young key populations looking at demand generation and the use of chatbots which influenced the approach adapted in Thailand. Specific project documentation was also cited as influencing the discussion around PrEP in Myanmar as an example. Overall, the webinars and case studies which the Unitaid grantees engaged in were useful, and the information shared throughout the region. Lessons learned from the use of peer educators in the projects was of particular note as this type of demand generation and support to adherence is encouraged in Asia Pacific programming.

It was noted by informants that the work of Brazil was particularly relevant in the Asia and Pacific region as the experience is seen as more similar to that of Asia as opposed to the experiences in Africa. However, the sharing of protocols from both grantees was considered beneficial to the kick-start of PrEP in the region.

In addition to sharing of tools, protocols, guidelines, and results, the grantees have participated in webinars and regional Asia Pacific meetings to share lessons learned. Both Wits RHI and Fiotec have participated in webinars over the years, most recently focusing on CAB-LA including a presentation on the experience of Wits RHI. Although the virtual learning experiences were positive, site visits or project walk throughs were considered by informants as having the potential of greater influence on PrEP is Asia Pacific as “the value of bringing someone to a meeting is invaluable” as stated by one informant.

Yet another positive outcome of the sharing of information and technical exchanges between the Asia Pacific region and Brazil and South Africa is the soon to be published special issue in a peer reviewed journal (Journal of Adolescent Health) aimed at showcasing the work of the two Unitaid grants moving beyond the “headline figures”. The special issue will showcase the different facets of the projects to tell the story about PrEP. The list of proposed articles, and responsible authors can be seen to the right. The Regional Advisor for Asia Pacific will be a main editor along with representatives of WHO HQ.

Finally, it was expressed by informants that the overall design of WHO and UNAIDS co-sharing Advisors was seen as a “no brainer to continue this”. In fact, the same approach is proposed going forward in Asia with funding from the Global Fund (not for PrEP specifically) and a PrEP Advisor in Africa (funding yet to be secured) along with a joint funded position at the global level (funded by the Gates Foundation) as the design makes sense.[13]

Table 1: Proposed articles for the special issues – Journal of Adolescent Health

Theme	Manuscript Type	Lead Project
Lessons learned in providing Pre-Exposure Prophylaxis (PrEP) for HIV for young people at scale	Editorial	Guest Editors
Implementing differentiated and integrated PrEP services for adolescent key populations: what works and what next?	Viewpoint	BR and SA
Available evidence for implementation of new modalities of PrEP to adolescents, young adults, and key populations	Commentary	Unitaid
Violence, discrimination and high levels of symptoms of depression among adolescent men who have sex with men in Brazil	Research Article	Brazil
Sexual risk compensation during the first year of PrEP use among adolescents' men who have sex with men and transgender women in the PrEP1519 cohort	Research Article	Brazil
Where evidence creation, ethics and the law collide: including minor adolescent men who have sex with men and transgender women in a PrEP demonstration study in Brazil	Research Article	Brazil
Oral PrEP discontinuation in a large cohort of adolescent MSM and TGW in Brazil: a longitudinal analysis	Research Article	Brazil
Financial cost of a PrEP program among adolescent men who have sex with men and transgender women in Brazil	Research Article	Brazil
Barriers, challenges and strategies for youth engagement for PrEP among adolescents in Brazil and South Africa	Research Article	SA and BR
Description of the implementing differentiated and integrated PrEP services for AGYW: what works and what next?	Research Article	South Africa
Title: Eita! Reaching communities and young people to drive demand for oral PrEP in South Africa.	Research Article	South Africa
HIV pre-exposure prophylaxis use among adolescent girls and young women accessing routine sexual and reproductive health services in South Africa	Research Article	South Africa
Mental health needs of adolescent and youth PrEP users in South Africa: Implications for sexual and reproductive health programming	Research Article	South Africa
Implementing an etiological approach to STI management amongst PrEP users, lessons learned and future directions.	Research Article	South Africa

[13] This information was provided by one informant and could not be corroborated with any documentary evidence.

EQ2. Have design and implementation approaches been appropriately adapted/course-corrected to respond to any changes in context?

Finding 2.1: *The PrEP portfolio generally demonstrated flexibility and agility to course correct based on contextual issues arising during implementation.*

The portfolio was responsive to contextual factors that were not envisioned during the initial design phase. Adaptations comprised inclusion of nurse-initiated and -managed antiretroviral therapy (NIMART) to enhance the service provision channels for PrEP, introduction of anal swabs for detection of gonorrhoea and chlamydia among MSM/TGW in Brazil, inclusion of adolescent boys and young men (ABYM) in response to rising demand for PrEP in South Africa and dropping viral load screening for PrEP users which was also adapted by government (Brazil). Wits RHI also bought (freight) containers, converted to youth friendly services provision sites, to ensure space for the target populations within the clinic grounds.

The adaptation of NIMART was based on results demonstrating that rigid clinical monitoring of PrEP users was not necessary thereby addressing what was perceived as a need for only doctors to cover the demands of PrEP provision. In Brazil, the project assisted in the negotiations with regional nursing commissions/regulatory bodies for nurses through supporting the head of the HIV programme with critical documentation to present the case for “de-medicalizing” the MoH policy.

During project implementation, Fiotec investigated awareness of ED-PrEP among MSM/TGW. It was found that approximately 30% of participants knew about ED-PrEP and 20% were interested in switching with more than 85% of those interested wanting to switch because of convenience, among other reasons. Provision of ED-PrEP may be a viable option in addition to daily oral PrEP to enhance PrEP use.

Finding 2.2: *The PrEP portfolio adapted implementation in response to the Covid-19 pandemic providing services using new technologies and outreach techniques.*

Overall, the portfolio adapted in a timely and efficient manner to the Covid-19 pandemic including establishing telehealth, digital platforms (mobile applications, PrEP delivery by courier and online peer support groups), and decentralized models of awareness and demand generation early in the pandemic. Generally, the projects switched from face-to-face contact to primarily mobile and online based demand creation methods, many of which were successful for follow-ups and led to good PrEP continuation rates in LAC.

Since the project introduced the My Journey mobile app In South Africa further digital platforms (B-Wise and MyPrEP) and applications were developed and highly regarded. The project has helped to mainstream the platforms into the National Department of Health (NDoH) fostering sustainability beyond the scope of the project. Anecdotal evidence points to the cost effectives of the digital platforms in terms of reach and linkage to services. However, the success of these platforms in engaging and retaining AGYW on PrEP, and the sustainability of these digital platforms has not been evaluated.

Other adaptations due to the Covid-19 pandemic include:

- **Fiotec:** ImPrEP study: Brazil continued with modification; Peru suspended however continued after initial disruptions; and Mexico was ongoing. Incidence sub-study postponed however continued after initial disruptions; the PrEP 1519 study continued with modifications including PrEP dispensation for up to four months with clinical monitoring through telemedicine; and reducing time in clinics (less tests): counseling by phone, WhatsApp or social networks.
- **Wits RHI:** Enrolment in fixed facilities only; all community activities and mobile van services suspended with the exception of services provided rom the mobile clinic whilst parked on the boundary of fixed facilities including to assist in SRH service provision; PrEP dispensation for up to four months rather than three; and PPE made available by Wits at facilities.

EQ3. How well does the intervention align internally with other Unitaid interventions and externally with priorities/needs identified by partners/the global disease response?

Finding 3.1: *Strong country level synergy and integration within the national health system was evident. As were ties to civil society which was well thought through in the design and geared toward testing of various models of PrEP provision for vulnerable and key populations.*

Both projects were well integrated into the national health systems and supported by the governments through provision of health personnel, procurement of medicines and available infrastructure for provision of PrEP as part of the larger health services provision. This integration was grounded in ensuring sustainability (demonstrating how to deliver/better deliver PrEP) of existing government-provided services and efforts. From the design of the projects, the notion of strengthening and transference of skills to government systems and staff was considered essential. Additionally, integration fostered a high degree of ownership by the government, especially in Brazil and SA. This ownership of PrEP was seen as part of a bigger package integrated within government comprehensive HIV prevention efforts rather than verticalized approaches.

Fiotec adopted a multi-level engagement approach with civil society (most peer educators were also seen as part of CS). Annual project meetings with CS were held to build project momentum, disseminate knowledge on PrEP, foster advocacy activities and ensure CS contributed toward demand creation. In Peru, CS community mobilizers served a critical role in project implementation engaging in outreach and targeted educational and information activities. The components of demand creation under PrEP1519 (through social media and other networks), and peer-counselors were the main cost categories for PrEP scale-up in the national health system. Wits RHI also implemented a multi-pronged CS[14] engagement strategy.

The project built the capacity of community-based organization (CBO) members to engage in PrEP awareness raising and follow-up in addition to seeking out and applying for alternative funding to ensure sustainability of their efforts.

In addition, WITS RHI actively participated in the PrEP technical working group in South Africa presenting numerous times to the forum on project progress and learnings. Their role on this working group was commended from a policy perspective including their work with the government during the initiation of the project while it was stated by informants that “operationally it would have been interesting to have them closer” and more involved in all technical discussions.

Finding 3.2: *Alignment and linkages to other prevention services (e.g., sexual and reproductive health (SRH) – including screening and treatment for STIs, gonorrhea, chlamydia, etc.) under both grants was strong.*

Strong collaboration with CBOs (see previous finding) resulting in increased skills and awareness at the community level were noted and fostered expansion into provision of and linkages to comprehensive SRH services. Under ImPrEP specific studies into STIs contributed to integrating diagnosis and treatment at sites in line with prevention combination services and led to the development of the STI policy in Brazil. Combining STI (as well as gonorrhea and chlamydia) screening with PrEP services was reported to “have taken away the myth that using PrEP increases STIs”. The project also contributed to the PAHO/WHO STI databank to further research into STIs in the Americas and beyond.

Although the results of a cost effectiveness study are pending, it was expressed by informants that STI and PrEP combination prevention will most likely demonstrate cost effectiveness and even more so taking into consideration point of care diagnostics with immediate treatment for syphilis. Under PrEP 1519 every STI case identified was treated immediately which has led to discussions with the AIDS programme around the importance of point of care diagnostics and treatment (syndromic approach and rapid test).

In South Africa the linkage of STIs as the “lesser cousin” to PrEP was seen as critical as STIs represent a significant risk factor for HIV and the prevalence in young people, not to mention other targeted candidates for PrEP (including MSM and TGW), is high.

[14] Wits RHI defined CS as a group of actors including non-government and non-private sector such as non-governmental organisations, community groups and networks, faith-based organizations, labour unions, indigenous groups, and patient groups.

Finding 3.3: *The projects actively participated in global forums, workshops, dissemination events, webinars and conferences both to guarantee dissemination of the implementation research results and to ensure coherence and alignment with, while at the same time fostering and feeding into the global PrEP response and related guidance and policies.*

Implementation science research was conducted covering several critical aspects related to PrEP implementation and roll out in project countries. Taking into consideration the publications and presentations, a high-level analysis of broad research categories was undertaken to highlight the emphasis of research published/disseminated.

Based on the extensive research the projects represent scientifically sound responses to the WHO's call for PrEP demonstration projects for key populations as mentioned earlier. This was meant to be achieved through complementarity with efforts to expand access to PrEP including in LMICs (as per Unitaid evaluation framework guidance, Nov 2020) both within and outside the regions. Although specifically pinpointing contribution to expansion in other countries is challenging it is evident at the global level.

The large array of publications produced under the PrEP 1519 as shown in Figure 4 (also Annex G). These range from willingness to take PrEP including acceptability research among young MSM, effects of Covid-19 on the sexual and mental health of youth and continuation of services during the pandemic, demand creation studies for PrEP, peer navigation in ensuring linkages, etc. PrEP1519 published on several issues the largest focused on PrEP among adolescents MSM and TGW, followed by PrEP and barriers to PrEP and HIV prevention/combination prevention. This was followed by issues related to measuring success for oral daily PrEP among MSM and TGW and responses to the Covid-19 pandemic, awareness, preferences and barriers for PrEP.

ImPrEP published and disseminated a large volume of relevant research covering a wide array of important topics, see Figure 5 (also Annex G). The most researched and published topic related to the main purpose of the project, namely demonstration and experience of PrEP implementation. This research was used to help improve effectiveness of implementation including but not limited to demonstrating how PrEP can be integrated in SRH services and rolled out on a large scale. The adoption of digital technologies introduced by the project and taken up by government also demonstrated that project inputs and learning were adopted. See below and Annex F for examples.

Fiotec consortium members presented abstracts at annual global AIDS conferences (Amsterdam, South Africa, Canada, etc.), Global PrEP Network meetings, and through WHO satellite sessions and webinars – often together with Wits RHI. Satellite sessions have focused on topics ranging from creating demand for adolescents and young adults to digital innovations used to link young people to services including artificial intelligence and online tools.

Figure 4: PrEP1519 published research

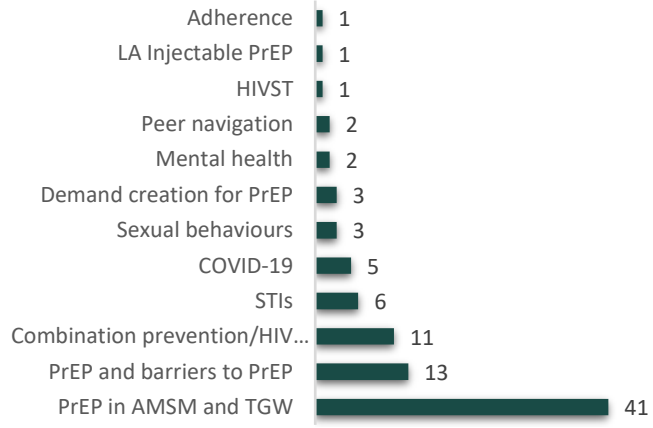
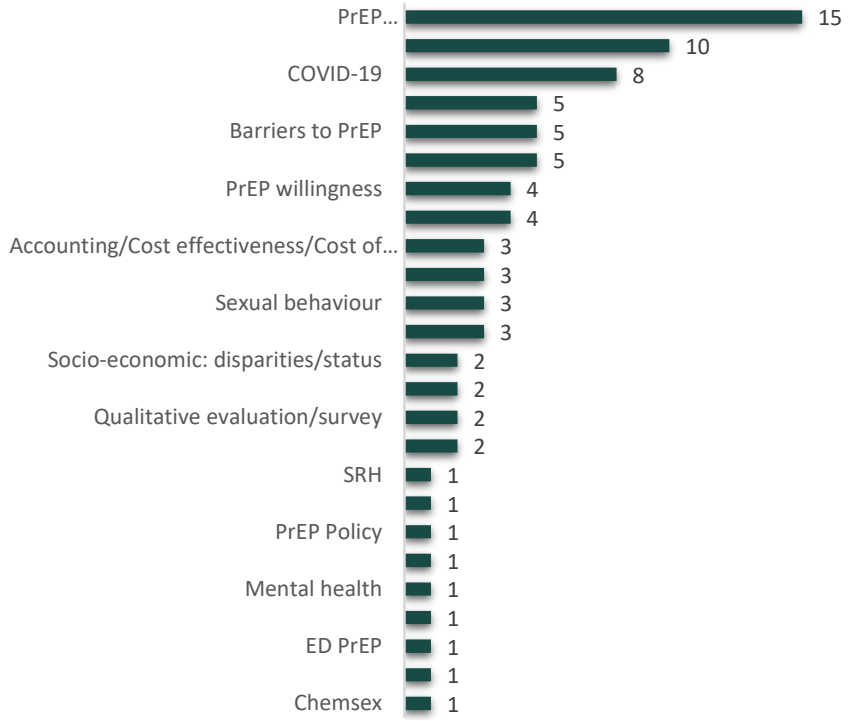


Figure 5: ImPrEP published research

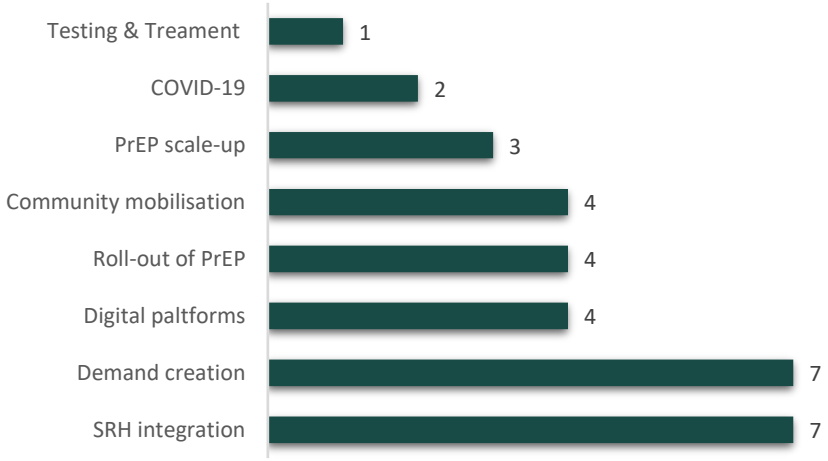


Wits RHI disseminated learning and insight with other countries through numerous dissemination platforms including international conferences, webinars, abstracts, in addition to south-to-south collaboration with Brazil. Their efforts extended to dissemination through other grants and learning networks including the PrEP Learning Network Webinar developed under OPTIONS (a USAID funded project covering three sub-Saharan African countries).[15]

Most research published by Project PrEP was on PrEP integration into SRH services and demand creation followed by PrEP roll-out, digital platforms and community mobilisation. PrEP Scale-up and Covid-19 were also included in the research. This research was used to help improve effectiveness of implementation including but not limited to demonstrating how PrEP can be integrated in SRH services and rolled out on a large scale. The adoption of digital technologies introduced by the project and taken up by government also demonstrated that project inputs and learning were adopted.

Additionally, MTV SAF (a reputable foundation focusing on demand creation) partook in dissemination efforts including hosting a webinar to share results from an evaluation of their demand creation efforts. The information was also shared at the International Workshop on HIV & Adolescents and several papers were produced for peer reviewed journals.

Figure 6: Project PrEP published research



Both projects aligned with and influenced the global response through their contribution to production of critical guidance for PrEP implementation and through their roles on committees designated to produce such guidance. The projects contributed to the design of the WHO implementation tool for PrEP of HIV Infection, Module 13 Integrating STI Services[16] (providing case studies on different aspects of STI service integration highlighting barriers, facilitators and lessons learned). They also provided case studies for the Differentiated and simplified PrEP for HIV prevention guidance: update to WHO implementation guidance.[17] They contributed to the Consolidated HIV strategic information guidelines,[18] adolescent PrEP implementation models in the implementation brief, community delivery guidance, events driven PrEP research (trials and results form 1519), etc. The projects were lauded for their critical contribution to the research and production of data/evidence around creatinine screening in PrEP users which was used to influence global policy change. It was also cited that data generated from both projects on the number of PrEP users per year, monitored since 2017, was used by WHO in annual meetings with manufactures to make the case to reduce PrEP drug pricing.

In addition to publishing results and contributing to critical policy and guideline documents, members of the grantee teams served critical roles in influential committees designed to produce global guidance around the efficacy of PrEP. For example, WITS RHI served as a co-chair for the WHO guideline development on strategic information for HIV prevention, was a member of the STI management guidelines development group and asked to present at various development group meetings.

However, of note is that the Wits RHI project was expected to be closely aligned with She Conquers (national campaign that aims to improve the lives of AGYW in South Africa) yet reference to the campaign in project reporting was minimal. However, informants cited that the project was able to make use of and adapt information, education communication materials such as PrEP/HIV testing posters with input and feedback from the She Conquers Brand Council (a group of 27 nationally representative young people).

Overall, the alignment and concerted efforts to help define priorities/needs identified by partners at the global and regional level are tangible. However, the evaluation observes that while the key and highly relevant research themes have been covered in detail and results were used to inform implementation, some themes could have been explored more including PrEP financial sustainability and scale up aspects.

[15] USAID OPTIONS consortium; [16] PrEP implementation tool; [17] Differentiated PrEP Guidance; [18] HIV SI guidelines;

Finding 3.4: *The PrEP portfolio was internally well aligned with Unitaid priority projects for HIV prevention and testing in addition to within the grants.*

Synergies in design and approaches exist between the Wits RHI and MTV (demand creation for PrEP in targeted communities and HIVST – see finding 3.5) and STAR for HIVST (including provision of test kits) although to a lesser extent.

Fiotec assumed responsibility for management of PrEP1519 sub-project of the ImPrEP grant, thereby ensuring synergies with ongoing MSM and TGW targeted activities, with the aim to inform the longer term roll out of PrEP for the adolescent population in Brazil (and beyond). It was implemented in public health facilities in Belo Horizonte, Salvador and São Paulo providing customized new services and outreach programs for <18yrs adolescent's key populations (AKP) - PrEP is now available for AKP in Brazil, approved by ANVISA (the national regulatory agency) for prescription based on body weight >35Kg. It may be noted that PrEP1519 enabled clients to self-enroll in a PrEP arm or a non-PrEP arm to receive other HIV combination prevention methods. Evidence and learning from both informed government PrEP policies for development of Adolescent and key population PrEP guidelines in Brazil.

Additionally, there was cross project alignment fostered through exchange of protocols, tools, plans, research findings and joint research efforts, etc. (see finding 3.6)

Finding 3.5 *PrEP demand creation for AGYW in South Africa through MTV was both innovative and appropriate for responding to the target populations needs and supporting the goals of Unitaid's AfIs as well as government priorities. However, it was recognized that measuring demand generated was challenging.*

Partnering with MTV, which had strong brand recognition in South Africa, was considered highly strategic to reaching the underserved AGYW with appropriate messaging aimed at increasing awareness of and demand for PrEP. Wits RHI capitalized on the popular Shuga Down South and Down South 2 (DS2) television series working with MTV, along with support from Unitaid and WHO, in reviewing content of potential messaging, to incorporate PrEP messages into the programming.

Collaboration on script development (among Wits RHI, Unitaid, WHO and MTV) was noted by informants as critical to ensuring messaging around oral PrEP was accurate. MTV reached AGYW through digital, social media, television and radio which reached beyond AGYW eventually resulting in the addition of ABYM in the Wits RHI target group.

A positive working relationship between Wits RHI and MTV was noted and the support of Unitaid recognized as can be seen in the following quote: "They (Unitaid) trust us in the creative process and their voice in the ethical expertise and communication with other partners and their market expertise is really valuable."

The design and contribution of MTV efforts in the PrEP space has been further recognised by partners. Their work extended beyond Unitaid funded grants generating interest from Global Fund (who piloted messaging in schools) and PEPFAR.

Overall, the MTV work helped to "demystify" PrEP although recognizing that introducing young girls into existing messaging was challenging. The design also extended to introduction of family planning methods. Overall, MTV contributed to demand generation according to informants, through creating awareness and interest amongst audiences where a knowledge gap about products existed, although quantifying results is challenging.

However, it was noted that the right design is not always enough to contribute to results. Success relies on priorities of the country and timing. Demand cannot be created for something that is not a country priority, and timing of demand creation for a product is critical. This will be particularly relevant when considering the design of the next generation of grants and new PrEP products coming on the market.

Finding 3.6 *The conceptual coherence of Unitaid investments through Fiotec and Wits RHI grants have further fostered internal coherence based on engagement, collaboration and information exchange.*

Both grants focused on key populations with the most similarity between PrEP 1519 (adolescent focus) in Brazil and Project PrEP (AGYW focus) in South Africa. Based on informants from country and global level a strong partnership was established between Wits RHI and the PrEP 1519 team for the exchange of implementation science results including lessons learned and best practices to further ensure coherence of the Unitaid PrEP portfolio.

Examples of coherence and alignment across the two projects, fostered through information exchange facilitated by both Unitaid and WHO, include Wits RHI taking inspiration from the Facebook and WhatsApp chatbot (Amanda Selfie) developed under PrEP 1519. A similar chatbot (Sister Unathi – available on the MyPrEP Facebook page and the NDoH B-Wise website), was developed in South Africa to reach AGYW and further demand creation efforts. Brazil was inspired by the showcasing of PrEP Champions in South Africa where young people were ready to speak up about PrEP and HIV prevention along with other adolescent issues. In addition, Wits RHI shared their roadmap for PrEP and their client facing tool with PrEP 1519 both of which have been adapted for the Brazilian context.

Grantees also cited the challenges of working in somewhat conservative settings where they struggle with the impact of religious organizations and worried parents who value the misconceptions that society holds. The projects exchanged information so that both can learn to stay relevant, innovative and find solutions in their implementation models.

Lessons learned continue to date with discussions around how to analyze data with respect to the new CAB-LA protocol (for phase 2 of the PrEP projects). This includes reportedly extensive exchanges of information on the implementation science framework and supply chain plan (with new products not in the government chain this needs consideration) which Wits RHI shared with Brazil. These exchanges were made possible through various satellites that were conducted with the support of WHO in addition to Unitaid PrEP portfolio project meetings (including ad-hoc project to project online/remote discussions) where data and experiences were discussed, in part, to ensure alignment and coherence of ideas and to learn lessons.

Finding 3.7: *Coordination and governance mechanisms designed to raise awareness and align efforts regionally were not fully exploited resulting in missed opportunities.*

The Fiotec project actively engaged countries in the region to foster PrEP adoption in close collaboration with PAHO in part through consortium meetings and in the case of Mexico a project steering committee. Despite this, informants reported that governance of the three countries was not undertaken as a joint effort.

Additionally, global stakeholders did not reference the External Advisory Board (EAB) while others acknowledge that the weak role of EAB and consortium mechanism presented a missed opportunity to:

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- Establish an overarching governance mechanism along with key global/regional players to recognize and address regional implementation and management challenges
- Improve project visibility by engaging with global partners
- Enhance accountability and garnering of support from Unitaid (gaps experienced by implementers and national stakeholders)
- Improve upon and share more widely project related documentation

EQ4. How cost-efficient and cost-effective was implementation (consider both allocative efficiency and technical efficiency)?

Finding 4.1: *Lengthy ethical approval processes were underestimated, resulting in subsequent delays in start-up of activities. This, coupled with delays associated with the Covid-19 pandemic, were factors in the issuance of no-cost extensions. Despite this, milestones were largely met by the end of 2021.*

Ethical approvals of the project protocols had to be obtained from both local and international ethical review boards before initiation of project activities. This process was time consuming, cited by respondents as taking up to seven months, thereby delaying project start-up. However, it is difficult to say if this affected overall implementation efficiency due in part to the impact of the Covid-19 pandemic and the subsequent adaptions to implementation.

Fiotec: Delayed project start up was attributed in part to ensuring ethical approval both by WHO and local ethical review boards for various protocols in addition to drug importation barriers encountered in Mexico. Consequently, implementation was delayed in Brazil for dried blood spot collection, storage, national and international shipment and payment of drug level measurement; similar situations were observed in Mexico and Peru. Initial procurement of test kits for chlamydia and gonorrhea were also delayed thereby affecting early enrollment in the project activities. The project responded by speeding up the implementation process to compensate for the delays. To address importation barriers in Mexico, UNFPA (sub-contracted to lead project implementation) was tasked with assisting with the process.

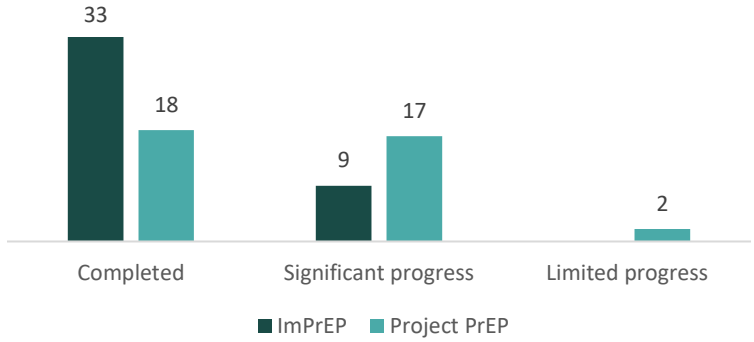
Wits RHI: Implementation start-up delays were experienced due to the approval process/time associated with identification of sites at the provincial and district level. The process entailed engaging in several meetings with the NDOH (together with other related government departments) to secure buy-in.

No-Cost Extensions (NCEs): Unitaid, allowing the projects to adapt to the delayed start up and effects of the Covid-19 pandemic, approved no-cost extensions to the two grantees thereby permitting them flexibility within the grant budgets and procurement of critically needed commodities to ensure continuous engagement with the target populations (e.g. PPE for health health care staff and peer educators). These NCEs[19] facilitated in ensuring the projects achieved their objectives (e.g., at the time of issuance Fiotec had not meet enrollment targets in addition to delayed or incomplete sub-studies) and to engage further in new activities (e.g., foundational analytic work for introduction of new (long-acting) PrEP products) under both projects.

Milestone analysis: Covid-19 had a significant restrictive impact on implementation due in part to curtailed movement. However, the projects responded well to these restrictions (see finding 4.2 for more detail) addressing the delays and bottlenecks and eventually project milestones were largely achieved over the life of implementation (end of 2021) as can be seen in the figure below.

Of note is the high proportion of Wits RHI milestones reported as achieving “significant progress” all of which are reported to as “an ongoing process” so interpretation should be done carefully. These ongoing processes include research into CAB-LA and STIs including further data collection and analysis, participation in conferences, and in relation to “new” activities. In addition, “limited progress” milestones reflect activities that will be included in a costed extension. Therefore, despite the figure showing fewer “completed” than “significant progress” milestones the justification is clear. For Fiotec some research activities are in the data analysis and reporting phase hence categorized as “significant progress”.

Figure 7: Milestone achievement for ImPrEP and Project PrEP



[19] Fiotec – Original project dates: 1 Jul 2017 - 30 Jun 2020; NCEs: 1st: 30 Jun 2020 - 30 Jun 2021; 2nd : 30 Jun 2021 - 31 Dec 2021; Wits RHI – Original project dates: 30 Jun 2021 - 31 Dec 2021; NCEs - 1st:31 Dec 2020 to 30 Sept 2021; : 30 Sep 2021 to 31 Dec 2021

Finding 4.2: *Except for the initial slow start both projects responded well and enhanced implementation speed despite Covid-19 slow down.*

The figures below, and as discussed under 4.1, who that initial delays due to approval processes (Fiotec) and lengthy discussions around site approval (Wits RHI) resulted in low expenditure rates in 2017 and 2018 respectively, as highlighted in the figures below. Fiotec was relatively slow to build implementation momentum however in 2019 they had expended 41% of the projected budget while Wits RHI expended 38% (at year two of four).

Both projects coped well with the Covid-19 pandemic and maintained project spending during 2020. As restrictions associated with the pandemic eased the projects re-engaged in traditional face-to-face engagement through peer educators with potential clients and communities. In addition, promotional activities through CS were ramped up and mobile/digital platforms were brought to scale, all of which contributed to positive results (reflected most notably in the Wits RHI project - see Figure 9). These efforts led to a jump in expenditures in end 2020 and 2021.

The budgets were deemed appropriate across cost categories and outputs resulting in overall positive results for both grants.

Further expenditure analysis is presented in Supplementary Annex B.

Figure 8: Fiotec actual expenditure as a percentage of the GAD budget (2017-2021)

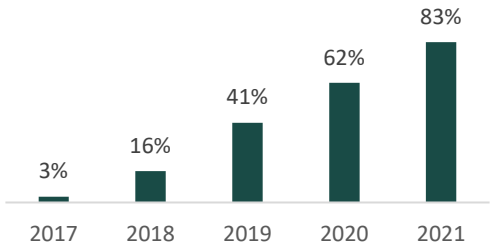
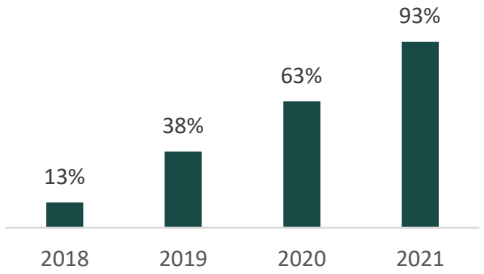


Figure 9: Wits RHI actual expenditure as a percentage of the GAD budget (2018-2021)



Finding 4.3: *Mobile technology products for demand generation activities and follow-up, designed and implemented under the projects, have been widely adopted by government demonstrating steps toward sustainability.*

As per Finding 2.2, mobile phone-based products for demand creation and follow-up, created under the projects have been institutionalized by government fostering sustainability of the successful products and adoption/reach beyond the project catchment areas.

Finding 4.4: *The Unitaid projects demonstrated that involving the community in PrEP programming, through employing direct project hires (peer educators and payment to CS organizations) , contributed to demand creation and service provision in line with the "nothing for them without them" community –based programming mantra. However, in the absence of a government sustainability plan/action for the positions concerns exits around longer -term sustainability of such efforts.*

As referred to earlier, the projects engaged peer educators and paid for CS organizations to conduct various community-based activities, which enabled fast-track achievement of project objectives. Unitaid initially expressed concerns about the need to engage additional human resources. However, justification for the approach was accepted in view of the delays and need to catch-up on demand creation and enrollment on PrEP. This represented a welcome flexibility and willingness to adjust to new contexts by Unitaid and eventually proved effective.

Due to the undeniable value offered by such a task-specific cadre (peer educators and CS organizations) continuation is warranted. However, it is likely that in the short to medium term, maintaining this approach will remain contingent upon donor funding as domestic funding does not cover this cadre in South Africa and not in full in Brazil although some peer educators are being included in the MoH human resource budgets. That said, in South Africa, the government is considering a community engagement strategy/process for coordinating efforts across partners.

Both projects are integrated within the national health system, however the implications (both financial and human resource) for scale-up were not fully explored or addressed during the design phase. Future Unitaid PrEP portfolio planning and design efforts could consider a focus on generating evidence of human capacity and resource needs for scale-up taking into consideration community-based efforts. This could help ensure the continuation of efforts by peer educators and CS in a sustainable manner.

Finding 4.5: *Unitaid management was highly regarded for their technical prowess and supportive and flexible responses grounded in a willingness to change what was perceived as cumbersome processes to foster greater efficiency in implementation.*

Unitaid was lauded by some informants for their technical strengths and leadership in the PrEP landscape and their ability and availability to interact with grantees on a continuous basis. They were also praised for their role in the regional technical meetings (including in Asia Pacific) and seen as a critical presence at the table. Unitaid's efforts at ensuring that WHO had the means to provide support to the grantees was crucial for guaranteeing the scientific rigor of the projects and the coming together of grantees to exchange best practices and share lessons learned. As previously mentioned, the role of Unitaid in securing a regional PrEP advisor in the Asia Pacific region contributed to the roll out of PrEP in a number of countries.

However, grantees cited various challenges, which affected the efficiency of grant management and implementation. Processes, particularly reporting and monitoring including relevant templates (both programmatic and financial), during the initial years of implementation, were seen as extremely lengthy, tedious, difficult to understand/follow. The processes were seen as bureaucratic with a high level of rigidness, making adaptation challenging. It was understood that "templates and M&E processes are important, but it was a big burden on the researchers". That said, this rigidness in the beginning was considered understandable to a degree according to informants, given that the grantees were new to Unitaid and in recognition that building trust and confidence takes time.

Grantees acknowledged that Unitaid acted upon the challenges and in subsequent years simplified the processes to make things more efficient for the grantees, including more simplified reporting. Informants also cited the "collegiate" approach of Unitaid as a "flexible donor" and the respectfulness brought to conversations. An example of the flexible nature of Unitaid was their immediate response to provide personal protective equipment during the Covid-19 pandemic, which was not included in the budgets.

EQ5. Strength of collaboration between projects and national authorities in project planning, implementation and assessment to promote integration into existing health systems?

Finding 5.1: *Integration of the projects into government systems and national HIV programmes has fostered ownership, influenced adoption of PrEP as part of national HIV prevention polices, guidelines and implementation and resulted in efficiency gains.*

By design, integrating the projects into the government systems, helped to ensure programmatic efficiencies with regard to planning of service delivery activities, thus avoiding duplication of efforts. Across all four project countries, ministries were engaged with project implementation and eager to learn and adapt approaches to integrate PrEP into the national HIV prevention policy.

Ultimately, both projects provided services through public health facilities, utilizing government infrastructure and resources and built capacity of government personnel for PrEP planning and service delivery.

Efficiency gains were realized through the sharing of all tools, guidelines, media materials, etc. in an integrated approach rather than a vertical programme. Engaging with civil society and peer educators on both projects allowed the projects to reach key populations in a manner not possible through "traditional" health care professional responses However, integration of these critical cadres into full government responses in the future poses challenges; less so in Brazil where the movement has assumed the costs to a certain degree, but in South Africa where they have yet to be included in the government workforce (see finding 4.4).

Evidence generated by the projects was used by governments for PrEP planning and programming while project results have been used to update the national guidelines on PrEP in Brazil.

In addition to programmatic efficiencies realized, the purchase of commodities by the governments of South Africa and Brazil, led to further efficiencies utilizing one procurement system. This was originally not envisioned for Project PrEP in South Africa but was agreed upon through discussions with the NDoH.

In LAC the project worked with PAHO, and their task force established for drug pricing, to ensure that pricing agreements were undertaken on a regional basis employing a transparent and efficient approach for all countries concerned. This approach was considered more efficient as countries are regulated by different strategies and norms with respect to drug pricing and what is available for purchasing (including the use of generics). Therefore, the attempts of PAHO to affect overall pricing were welcome.

In Mexico, involvement of the city AIDS council led to development of a policy, however political will and resources for implementation are pending.

In Peru, key informants reported that government engagement and integration was weak (referring to lack of policy adoption associated with Covid-19).[20] Despite pending policy approval in Peru, the project is credited with providing the evidence needed to roll out PrEP, as "the government will not start financing a new strategy when there is no proof of concept; very difficult to get money without proof". The project, working with the government, has managed to secure approval for the primary track for PrEP in the country. Based on what is considered rigorous data produced from the implementation science project (ImPrEP), the Global Fund has begun roll out of PrEP in three regions in Peru with intentions to go to scale in another 15 regions.

[20] Government was pre-occupied with Covid-19 measures to the detriment of PrEP implementation

EQ6. To what extent were the access barriers addressed by the projects at national, regional and global levels?
EQ7. How effective are the delivery models in demand and retention and what best practices can be learned from the process?

DEMAND & ADOPTION

Finding 6.1: *The PrEP portfolio has influenced the policy environment for PrEP across all four countries to varying degrees in part through strong partnerships and government and civil society engagement.*

As of February 2022, three of the four implementing countries have included or adopted PrEP within national policy frameworks. Although Peru has yet to adopt a comprehensive PrEP policy (the current policy covers pregnant women and serodiscordant couples only) there is a conducive policy environment within the ministry of health.

The support and influence of the PrEP portfolio on national PrEP guidelines and protocols is evident and well recognized/documented. Proposed service delivery models (including training curriculum, monitoring and evaluation tools, outreach models, etc.) improved demand and adoption in the targeted countries. One government informant responded that "the project was used as a guide by the government for implementation of PrEP and for refining PrEP policy" .

Finding 6.2: *The expected catalytic role of the PrEP portfolio to influence uptake is not widely evident in Southern Africa, except for interest from Mozambique, however in LAC the demand by countries for technical assistance and guidance was more evident and well responded to by Fiotec.*

Although activities under the PrEP portfolio have been published widely and disseminated valuable experience and evidence at different fora, the influence beyond LAC, Mozambique and Asia Pacific (see finding 1.5 and 4.5) at present is limited.

Global informants expressed that Unitaid Interventions have been catalytic in providing guidance on PrEP introduction and scale-up in the four targeted countries and in Asia Pacific. This was fostered in part through the development by Fiotec of a learning platform focusing on technical visits, exchange of information, document sharing, and technical assistance for countries in LAC, Mozambique and South Africa. This platform, led by Fiotec, demonstrates the catalytic role of the project.

Evidence also points to Fiotec's proactive support to other countries in establishing PrEP, including assisting with the PrEP policy in Chile. The support also included sharing protocols with other countries, conducting workshops on PrEP implementation in various countries, enabling active engagement of representatives of non-project countries in regional meetings and hosting technical visits to help develop deeper understanding of PrEP implementation. The Global Fund is exploring a "twinning" type arrangement between Mozambique and Brazil/Fiotec to continue the ongoing collaboration and scale-up what has already been achieved during the life of the Unitaid projects (initial visit by the ImPrEP PI in 2018 and visit by technical staff from the Mozambique MoH to ImPrEP sites in Rio de Janeiro in 2018).

Fiotec has also undertaken tailored workshops for different countries (Guatemala, Costa Rica, El Salvador, Honduras, Colombia, Dominican Republic and Cuba in 2018) as part of the annual Unitaid meetings focusing on PrEP implementation where all three ImPrEP countries presented their programmes. It is reported that Chile, Panama, Argentina, Uruguay and Paraguay are also actively engaging with ImPrEP on different discussions, including during a field visit to ImPrEP sites in Sao Paulo where they were familiarized with the study protocols. In 2019 Fiotec engaged with MoH representatives from Ecuador and Bolivia, together with representatives of UNAIDS from Panama and Peru, where different approaches to PrEP provision were discussed along with the lessons learned. This effort culminated in an offer by Fiotec for provision of technical assistance to the countries.

In Mozambique both Project PrEP and PrEP 1519 provided technical support and advice as well as exchange visits to the country. Wits RHI used their technical expertise and experience in developing B-Wise to provide TA to Mozambique for a similar website (Vibrações) targeting young people. Mozambique actively showed interested in the

project and requested Wits RHI to share their experiences and tools related to media, content, innovations, management of websites etc. The request initiated from the Catholic University and the youth coalition in Mozambique.

In addition, the Global Fund is currently working on organizing a site visit for the principal recipients in Mozambique to visit Wits RHI to learn from the policy work carried out under the project, both from a development and on the ground implementation perspective. Furthermore, Wits RHI has hosted several visits to different sites by Boston Consulting Group who were assisting the Gates Foundation to develop their AGYW strategy.

The evidence base developed by the projects, including as part of the above-mentioned platform, present an opportunity for a more aggressive knowledge dissemination strategy to catalyze the lessons learned for policy and programme changes in other countries.

Finding 6.3: *Project PrEP has contributed to the successful adoption and expansion of PrEP by the NDoH in South Africa.*

Based on the Wits RHI project model, the government expanded PrEP delivery to more than 2,000 health facilities. The project leveraged the NDoH's sexual and reproductive health school services to recruit and increase linkages from schools to PrEP clinics. Close collaboration with government also resulted in the adoption of MyPrEP.co.za (refer to finding 2.2) developed under the project. As one national informant stated: "Project PrEP was a critical support in launching PrEP in public health facilities in South Africa."

Table 2: Number and percentage of primary health care facilities implementing PrEP[21]

Province	No. PHC facilities total	No. PHC facilities implementing PrEP	% PHC Facility Implementing PrEP
EC	767	507	66%
FS	225	211	94%
GP	370	349	94%
KZN	625	607	97%
LP	482	89	18%
MP	292	280	96%
NC	159	23	14%
NW	310	139	45%
WC	235	19	8%
Total	3,465	2,224	64%

Finding 6.4 (responding to question 7): *The PrEP projects were effective in creating demand and demonstrating best practices for implementation with MTV demand creation activities positively associated with PrEP awareness and use.*

The projects were able to provide ongoing evidence to government for shaping policies, strategies and guidelines. For example, the national health system in South Africa adopted the digital platforms (i.e., MyPrEP, B-Wise), creating awareness and demand for PrEP among target populations; however, the overall effect has yet to be evaluated. In LAC, Fiotec transferred the telemedicine model to the MoH which is now being used successfully.

Both projects significantly exceeded their targets for enrolment, which demonstrates effective methods employed for reaching the target populations. However, disaggregated data (e.g., by educational level, socio-economic status, living status, relationship status, sexual partner's HIV status, etc.) on persons reached was not available.

In 2020 the London School of Hygiene and Tropical Medicine (LSHTM) undertook an evaluation of the MTV activities (both the Shuga Down South and the Down South 2 series (DS2) series), which demonstrated the effectiveness of demand generation and the critical role the media played in influencing awareness and uptake of PrEP.[22] Both mini-series addressed topics such as PrEP, HIVST, STIs, contraception, etc. with DS2 including PrEP and disseminated messages not only through television but also radio and other multi-media activities.

The quantitative research results (from a web-based survey) of the LSHTM evaluation showed that one-third of respondents were aware of PrEP with rates higher among those exposed to DS2 (52% versus 27%) and overall demand for PrEP (willingness to take PrEP every day) was high. While qualitative research "identified mechanisms by which DS2 increased awareness, confidence and motivation to use HIVST and PrEP, but had less influence on service access" with some respondents learning about PrEP and the related resources for the first time, while for others it enhanced their knowledge. That said, some respondents stated that their confidence in service availability was limited by the fact that PrEP was not always available at delivery sites.

[21] National Department of Health Working Group: Long-Acting Biomedical Products for HIV Prevention Oral PrEP update March 2022. [22] Birdthistle et al. (2021) Effects of a multimedia campaign on HIV-self testing and PrEP outcomes among young people in South Africa: A mixed-methods impact evaluation of 'MTV Shuga Down South'; first published as 10.1136/bmjgh-2021-007641 on 1 April 2022

Overall, the evaluation found that as new technologies are introduced for PrEP there is a critical need for "immersive" demand campaigns to help widen knowledge about the HIV prevention choices available to targeted groups. A positive causal impact of the demand generation work carried out by MTV on prevention outcomes among young people was also noted.

Finding 6.5 (responding to question 7): *Despite increased demand, overall success remains to be evaluated and the effect on retention rates is variable yet not the only measure of success.*

In LAC, positive retention (continuation) rates (78% Brazil, 70% Mexico, 48% Peru) for MSM and TGW have largely been attributed to efforts of peer educators. However, in South Africa, client retention for AGYW was poor with a significant drop from 17% at the one month visit to 9% at the four-month visit. (see graph on the following slide).

Reasons/causes for low retention/continuation rates vary, and include:

- **Individual ideational factors** – concern about stigma, misinformation about the product, difficulties with maintaining confidentiality, lack of ongoing risk perception, partner or parental disapproval of PrEP use, cycling on and off or discontinuing PrEP according to their perceived risk level (which could also represent a good outcome/reason if they are lowering their risk-taking behaviour due to other preventive activities promoted by the project).
- **Relationship factors** – disclosure, changes in relationship status
- **Product factors** – side-effects of the drugs, difficulty with daily pill use
- **Access barriers** – unpredictability of mobile sites, inability to access clinics easily, transient (e.g., during school holidays to other provinces) or permanent move away from a PrEP site.

Additional barriers are elaborated in the **Power PrEP user Journey - Power PrEP User Journey.**

One measure employed by Wits RHI to combat low retention was the appointment of designated staff to implement a telephonic follow-up initiative designed to alert clients of their appointments and provide information on the mobile van schedules.

As a result, the project saw an increase in the number of clients returning for their 4-month visit from 920 before the initiative was implemented to 2,058 as of end December 2021 (note that absolute numbers presented as denominators were not made available to the evaluation team therefore percentages could not be calculated).

Figure 10 presents the total number of people screened under the Wits RHI project resulting in an overall retention rate of 9%. It should be noted that continuation rates for PrEP have historically been low, and Project PrEP was no exception. This did vary between the sites and was a particular problem at the mobile van sites (see supplementary Annex A2 for retention variation by site).

Figure 10: Wits RHI PrEP cascade among AGYW in South Africa

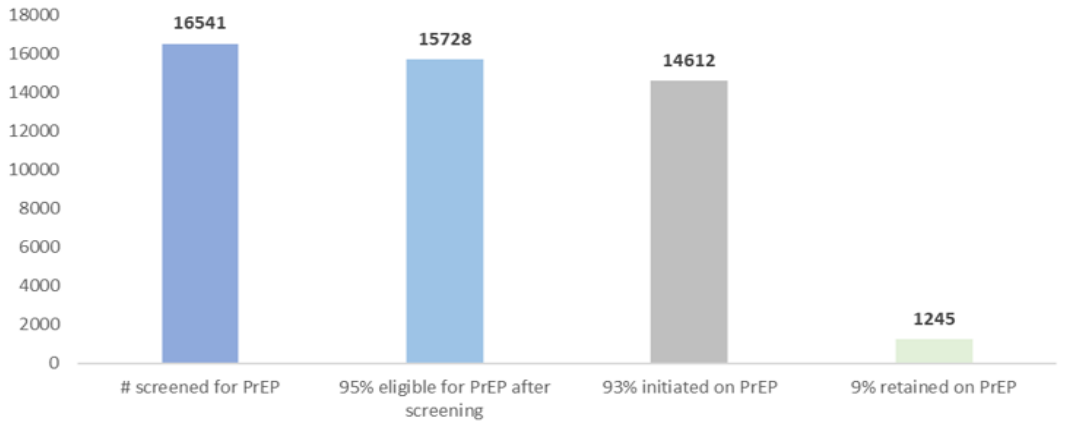
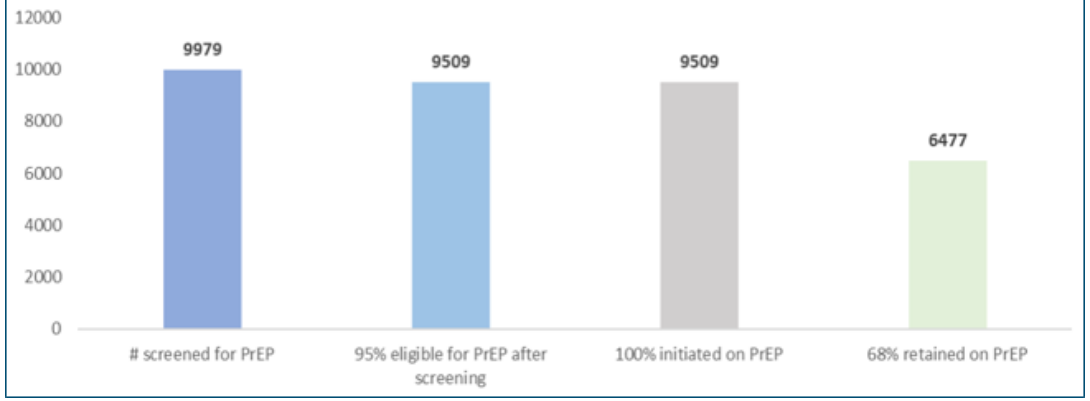


Figure 11 presents the total number of individuals screened for PrEP (9,979) under the Fiotec project. Eligible for PrEP: 3,928 in Brazil; 3,288 in Mexico; 2,293 in Peru (all eligible were initiated). Retention rates: Brazil 3,053 (78%); Mexico 2,315 (70%); Peru 1,109 (48%) – overall 68%.

Figure 11: Fiotec PrEP cascade among MSM and TGW in LAC



However, caution is advised when looking at retention in isolation. The measurement was initially used when PrEP was thought of in the same way as HIV treatment, however this has evolved over time. PrEP use is understood to be much more dynamic than treatment, with people starting/stopping/re-starting frequently (some of the reasons for that are seen on the slide before). Therefore, a low "retention" should not necessarily be singled out as a negative issue, but it is rather, to some degree expected with PrEP use.

AFFORDABILITY

Finding 6.6: *PrEP is perceived to be affordable in the project countries based on a combination of domestic and donor funding however future PrEP options need to be further assessed with regard to pricing and affordability.*

While affordability has many aspects including from the perspective of private market and private clients, Unitaid's interest is focused on the ability of governments to finance PrEP (not an end user focus). To that extent the supply of oral PrEP for the Unitaid interventions benefitted from project integration within the government health systems in Brazil and South Africa.

PrEP grants in Brazil and South Africa included elements of sustainability from project onset, in part due to their advanced maturity of PrEP initiation. Full integration for procurement and supply under the Wits RHI project is expected within a 6-month period. However, pricing of TDF/FTC in the LAC (UMICs) remains an area needing further work as prices are high compared to South Africa where several generics exist, and regulation is more stringent.[24] Additionally with the potential introduction of CAB-LA affordability issues should be considered during design phase and interventions planned to address price reduction of what is considered by many respondents as an expensive option for PrEP particularly for already constrained HIV funding environments.

Regulatory environment aspects:

- From a regulatory perspective, South Africa had a proactive approach for registered formulations since December.[25] Meanwhile, national regulatory authorities in Brazil and Mexico requested and were granted approval of TDF/FTC for oral PrEP specifically for the Fiotec project (see Annex C, final two columns). In addition, after the introduction of PrEP, there was an accepted off-label use in Mexico. Overall regulatory challenges seem to be primarily linked to the introduction of PrEP in countries (see Annex C final two columns).
- No structured information on pricing and regulatory status was found in the Fiotec reporting system although this was implied as a secondary objective of the project. As per information in the annex C, coverage of MoH PrEP programmes and private sector pricing in LAC should be monitored as a proxy indicator of affordability.

[24] Although the FIOTEC project plan acknowledges issues around pricing, affordability and direct activities to reduce price this was not of significant focus, rather price reduction was envisioned as an indirect influence of demand generated.;
[25] In December 2015, the Medicines Control Council (MCC, now SAHPRA) approved the use of TDF/FTC combinations to include PrEP and "requested the applicants to implement a risk management plan, which requires applicants to provide prescribers with a detailed information pack, to gather data on adverse effects, and to report these to the MCC at 6-monthly intervals."; MCC Press Release.

- ABIA was contracted by Fiotec in 2018 to conduct a landscape analysis of prices, regulatory and patent status in four LAC countries to be presented at a workshop and at the IAS conference in Mexico. No follow-up work was performed. This evaluation did not find other reference material or entities monitoring affordability at public and/or private sector level in LAC countries.
- Informants stated strong coordination was established between PAHO and the ImPrEP consortium (including through enabling funds) including for the conduct of support activities to countries in the LAC region to incorporate/scale-up PrEP into their national policies. This included ensuring buy-in of governments for continued provision of PrEP commodities.
- Ongoing procurement of PrEP drugs through a combination of domestic and donor funding in LAC demonstrates continued affordability for governments. However, without focused and concerted attention to regulate and lower PrEP prices, reliance on domestic funding alone for PrEP in the medium- to long-term will not be possible.

Finding 6.7: *Fiotec's planned Working Group on Drug Licensing and Pricing of TDF/FTC did not come to fruition; however, through collaboration with PAHO, consensus was built, and country led processes encouraged to lead legislative and price reduction efforts.*

Fiotec plans included establishing a Working Group (WG) on Drug Licensing and Pricing. However, the WG was not pursued as Fiotec considered that most market challenges were overcome in the first two years of the project. Rather, the project management reported pricing and regulatory aspects jointly with policy aspects in its annual meetings, which were open to other LAC countries and to civil society representatives working on technical aspects and advocacy for PrEP.

Fiotec presented a report on PrEP drug prices and registration status in selected LAC countries followed by review of implications of country specific implementing partner agreements and international policies. In 2019 it was agreed (by the ImPrEP Consortium with members of the Advisory Board, Unitaid and PAHO) that PAHO would coordinate and support activities for LAC countries to incorporate/scale-up PrEP into national policies together with the project. Reportedly informal agreements with PAHO were made for achieving higher buy-in from national governments based on legal and international agreements signed by each country. It was also agreed that drug price reductions and generic drug purchases must respect specific national agreements/legislations and efforts must be country led.

Role and use of PAHO Strategic Fund

Since 2014, the PAHO Strategic Fund has supported the supply of ARVs for 25 countries in the region. TDF/FTC and TDF/3TC were initially supplied to 11 countries for antiretroviral treatment in its generic version (WHO prequalified). No price differentiation based on country income was evident. Since the entry of fixed-dose combination drugs of TLE, TEE, TLD, the formulation TNF/FTC TNF/ 3TC has been used for alternative treatment schemes for PrEP, but the breakdown of the real usage is still under analysis by PAHO.

Eligibility: All 34 PAHO member states and their corresponding public health agencies like social securities etc.. can procure through PAHO Strategic Fund. Constraints may lie at the country level.

The impact of the Fiotec project on PrEP expansion in LAC cannot be determined looking at the PAHO Strategic Fund procurement data. The data sets available from the Fund do not capture increased procurement of oral PrEP following initiation of Fiotec activities (currently no disaggregated data on TDF/FTC for ART or PrEP exist).

However, informants cited activities targeting price reduction conducted through alignment with the PAHO Strategic Fund "resulting in price reduction for Peru and other LAC countries" as a sign of positive collaboration between the ImPrEP consortium and PAHO.

Overview of PrEP procurement issues in LAC

Several factors influence the capacity of governments to procure oral PrEP at affordable prices, following the adoption of PrEP policies and implementation plans. These include free trade agreements, patent status/patent rejection, regulatory status/approaches, civil society advocacy, etc. Challenges to PrEP implementation, in relation to addressing procurement issues under the Fiotec project, include:

- In Brazil, Unitaid funded and contributed to patent opposition to the TDF/FTC combination (other funding streams) and at global level, the Medicines Patents and Licenses Database, which includes patent status information (MPP funding stream), see Annex C.
- All LAC countries achieved a decrease in prices of TDF/FTC during project implementation for project procurement (Mexico) and/or MoH procurement (Brazil). See Annex C.
- Mexico, as a UMIC, faced more difficulties in decreasing prices. North American Free Trade Agreement (NAFTA) enforced patents and procurement procedures prices were high even with one generic version registered (circumvent valid patent: different salt of tenofovir), the potential for more generic competition exists. In addition, access to the PAHO strategic fund was blocked due to requested prepayment modalities not foreseen in national procurement procedures and NAFTA's restriction on use of generic medicines (re-negotiated in 2019). Patent status and related monopoly of Gilead's Truvada impacted access to oral PrEP at the start of the project in Mexico.
- Private sector retail prices of both originator and generic TDF/FTC formulations remain very high in all LAC countries outside. This impacts the key populations outside the reach and coverage of the MoH PrEP programmes (out of pocket/ social insurance schemes). See Annex C.

SUPPLY AND DELIVERY

Finding 6.8: *The projects benefitted from integration into the national health systems which ensured smooth availability of oral PrEP to target populations.*

Working from within the national health systems in all project countries was advantageous from a supply perspective as government assumed responsibility for provision of oral PrEP. This included purchasing PrEP using domestic funding in Brazil, South Africa and Peru and eventually in Mexico. As mentioned in finding 6.5, the supply set-up for PrEP within the government systems was facilitated by the projects leading to no notable structural supply related challenges once adequate demand was present and capacity of health personnel developed. Delivery models are covered under demand and adoption.

EQ8. How successful was the implementation approach in setting up conditions for promoting policy adoption and financial support in project and non-project countries?

Finding 8.1: *The projects influenced PrEP policy in project countries and/or provided insights into implementation within the health system with demonstrated financial support from host governments.*

Refer to finding 5.1 and 6.1 for the policy influence related to project implementation.

The commitment of government to engage in and contribute to the cost of PrEP delivery in project countries was evident. Under the Fiotec project the government covered costs of all health facility infrastructure, procurement of PrEP drugs and related supply chain and logistics expenses in addition to STI and HIV rapid tests, viral load testing, office supplies, personnel, and other support services.

Similarly, support from government under the Wits RHI project included investment in scaling-up PrEP to over 2,000 health facilities based on the project model and implementation experience. The DOH also provided the project with commodities including for treatment of clients accessing SRH services (e.g. primary health care supplies and drugs, ART and STI drugs and related lab supplies, HIV test kits, etc.). However, continued financial support of peer educators and CS for demand creation remains a challenge.

With regards to setting up conditions for promoting PrEP policy in non-project countries, as noted in Finding 6.2, Fiotec proactively supported non-project countries to establish PrEP. For example, networking with Latin American and African countries (Mozambique, Chile, Argentina), began as early as 2017/18 in addition to international agencies such as UNAIDS, CDC, National Institute of Health, ANRS, WHO/PAHO. ImPrEP has been involved in the PrEP Regional Task Force, led by PAHO aimed at streamlining PrEP adoption and scale up in the region and globally. ImPrEP was also actively engaged with other countries and disseminated evidence on PrEP implementation. In addition, PrEP1519 collaborated with Wits sharing tools, guidelines, innovative ideas, etc.

EQ9. To what extent did the impact of the projects address equity concerns and what are the strategic benefits and positive externalities?

Finding 9.1: *The Unitaid grants demonstrated contribution to providing more equitable access to PrEP services and information through targeting previously unserved vulnerable and high-risk populations who had limited access to PrEP.*

As previously stated under the relevance section, access to services for key populations were scaled up. In all four countries, more clients (AGYW, MSM, TGW and adolescents) were initiated on PrEP than initially planned and services extended to other vulnerable groups including ABYM in South Africa[26]. Civil society, through strengthening demand and delivery, played a critical role in this success (with less-than-optimal engagement noted in Peru).

Effective models of service provision employed within the national health systems contributed to scale-up during the life of the project in South Africa. The role of peer educators as mediators with healthcare providers, sensitizing them to the needs and issues of target populations, served as a two-way bridge between the health services and clients ultimately contributing to increased service uptake.

In addition, PrEP focused scripting for AGYW in the work of MTV pointed to the need to address vulnerable populations with specific messaging, noting that reaching adolescent girls is extremely challenging. The mass media demand creation platform established by MTV reached beyond the targeted AGYW to all young people with critical messages on PrEP. The added benefit of the reach of their efforts was applying a “family” focus to help foster discussions within the household between children and parents. Finally, MTV products were distributed at no costs and with no restrictions on rights to broadcasting.

[26] In South Africa sites were selected based on their high HIV prevalence and high rates of teenage pregnancy, sexually transmitted infections (STIs), and gender-based violence (GBV. Data from Wits RHI shows that 14% of the AGYW clients who tested for HIV were testing for the first time. Additionally, of all the AGYW clients that were provided with contraceptives, 43% were being provided for the first time indicating they were reaching new, potentially underserved clients.

Finding 9.2: *The Unitaid PrEP portfolio contributed to ensuring access to and integration of other critical services as part of a comprehensive prevention package.*

A focus of both projects was to ensure access to comprehensive HIV prevention services for the targeted population including access to sexual and reproductive rights services. In South Africa this included establishing a standardized package of services which was designed with the NDoH and the support of WHO.

The demand creation activities of MTV in South Africa covered contraceptive options and safe abortion, and Wits RHI focused on screening for and treating STIs, gender-based violence screening and provision of contraception to key populations. This integration of services was said to be "easy to do" through the use of mobile clinics where all services were in one location but more challenging in facilities in part due to the physical layout and the patient-to-nurse ratio. Data reported by Wits RHI shows improved contraceptive uptake at PrEP initiation by 12.2% to 74.5%.

Training of health care workers to expand PrEP services in Brazil covered specific aspects of HIV testing, HIV post-exposure prophylaxis (PEP), clinical management, management of STI prevention health services, to name a few.

As mentioned under finding 3.2 both projects helped, through the evidence generated during the piloting of the implementation science projects, in the development of the WHO implementation tool for PrEP of HIV Infection, Module 13 Integrating STI Services (**PrEP implementation tool**).

EQ10. To what extent did PrEP grants contribute to enabling country (political and financial commitments - national) and global environment for scale up?

Finding 10.1: *PrEP grants directly influenced country conditions for scale-up by working from within the MoH/DoH structure and setting the scene for other funding possibilities, however not necessarily on a national level.*

Political will and financial support for scale-up

In 2017, with existing PrEP policies in South Africa and Brazil, and interest in Mexico and Peru, PrEP grants were firmly grounded in national health agendas and systems. However, it should be noted that the existing momentum in the countries for PrEP was not necessarily targeted toward the key populations of MSM, TGW and AGYW. Through ongoing support to government, PrEP policies in South Africa and Brazil were advanced for these key populations, adoption in Mexico ensued and foundational work undertaken in Peru. Algorithms, protocols, guidelines and evidence for PrEP delivery were developed (in close cooperation and consultation with the government) and capacity building of government health staff (doctors, nurses and allied staff) undertaken. In addition, national health systems adopted the successful project-specific digital platforms for demand, delivery and follow-up.

As noted in Finding 8.1 governments provided financial resources for PrEP, thereby pointing toward sustainability of activities, however not guaranteed for the peer educators and civil society/community-based efforts. Integration of PrEP in SRH and primary health care in South Africa and LAC are strong features facilitating sustainability.

As noted in finding 5.1, the ImPrEP demonstration project in Peru set the scene for introduction of PrEP in the country. The quality of the research, according to informants, and the ability of the team to translate results into advocacy with government, resulted in the Global Fund entering into PrEP implementation. It was thought that without ImPrEP, the introduction of PrEP in the country would have been delayed by at least 1-2 years.

Albeit the policy agenda has moved forward in project countries, the issues of financial sustainability and scaling up to cover national needs remains a question. This may pose a risk to further implementation of PrEP for MSM, TGW and AGYW in the targeted countries and beyond.

Programmatic capability to scale-up
Brazil and South Africa have clearly demonstrated their programmatic ability to implement PrEP for key populations in targeted settings. Both countries have improved their programmatic capability to take over key piloted activities/interventions (e.g., B-Wise website in South Africa for demand creation, assuming contracting of some peer educators in Brazil) reflecting on their readiness to scale. The products produced under the projects including guidelines, policies, demand generation media tools, operational tools (e.g., M&E tools) not to mention national experience of implementation by health care professional, peer educators and civil society are also a signal of the countries readiness to scale.

Civil society and demand by peers for services
The engagement of civil society and peer educators from the onset of the projects was considered by informants as crucial for PrEP demand generation, scale-up and advancements in retention.

Finding 10.2: Unitaid's PrEP portfolio has influenced scale up of PrEP in the Asia Pacific region and globally and has show broad policy effect which has contributed to driving adoption.

As discussed under finding 1.5, the Unitaid PrEP projects influenced the introduction and scale-up of PrEP in the Asia Pacific region. This was greatly facilitated through the PrEP Regional Advisor partially funded by Unitaid but with a mandate to report to WHO and UNAIDS. It was expressed by informants that positioning of this role, coupled with the technical input of Unitaid and access to the protocols, guidance, tools, etc.. produced under the Unitaid PrEP portfolio helped bolster interest and action in the different countries in the Asia Pacific region.[27]

The model of a jointly funded WHO/UNAIDS technical position to advance PrEP is due to be initiated at the global level (funded by Gates Foundation) and in Africa (funding pending) based on the learning in Asia Pacific (according to one informant).

At a global level the contribution of the projects, through their extensive research and implementation of innovative measures to address the needs of target populations, has contributed to global level guidance, policies, strategies, etc. (refer to finding 3.3 for more examples).

EQ11. What measures have been taken to ensure that the benefits will continue beyond the life of the two grant investments?

Finding 11.1: *National scale-up of oral PrEP for key populations and creating a conducive PrEP policy and implementation environment demonstrate high likelihood of interventions continuing beyond the life of the projects. Engaging the private sector in the response may further these benefits.*

As discussed, including in finding 5.1, scale-up of PrEP by the South African government to more than 2,000 health facilities as an integrated intervention in primary healthcare and SRH services is a testament to the success of Wits RHI project in ensuring that benefits will continue beyond the life of the project.

The three Latin American countries are at different stages of maturity for provision of PrEP. The projects' influence on the policy environment through approaches noted under finding 10.1 have brought the national health systems closer to ensuring that PrEP will continue to be provided as part of an integrated combination prevention approach. Evidence of government support to the project, through infrastructure and financial support, points to positive interest and commitment.

[27] The PrEP Regional Advisor works with 18 countries in the Asia Pacific region.

It was expressed by key informants that for both Wits RHI and Fiotec projects, development of capacity within the government and of the civil society for supply, demand and management of PrEP will continue beyond the life of the grants, positively contributing to the longevity of benefits.

The private sector plays an important role in health care service provision in the targeted countries. Future engagement with private sector (e.g., facilities, pharmacies, medical aid schemes, manufactures, etc.) for generating the requisite implementation evidence may further improve the efficiency and effectiveness, along with ability to scale up PrEP interventions. In South Africa, the opportunity is ripe, according to informants VIIV Healthcare[27] has provided a grant to Wits RHI to conduct peer education for CAB-LA uptake based on content developed with Unitaid on oral PrEP. Additionally, Gilead has provided a grant for peer education targeting MSM.

In addition, the Wits RHI project is working with private sector pharmacies in each of their clusters as a point (physical space) where individuals can access services or simply pick up medicine with some clusters further along than others.

It was mentioned by informants that the role of the private sector is discussed in the TWG in South Africa, however "no clear answers exist". It has been suggested that Wits RHI could reach out to private sector providing them with current knowledge of PrEP. Discussions in other countries include engaging "vibrant small scale private sector providers" to ensure that individuals are getting high quality prevention services at facilities. Unitaid could consider if there is scope for gathering evidence around the benefit of the private sector in working with the government while at the same time ensuring that the de-medicalization of PrEP is front and centre. This may represent another area of operational research for Unitaid around ensuring easier access (e.g., in line with the work to ensure that nurses were able to prescribe necessary medication). Tapping into corporate social responsibility initiatives for larger companies in the UMIC settings could be another feasible way of engaging private sector, as a strong interest in keeping employees healthy should exist.

Finding 11.2: *Research undertaken by Fiotec demonstrates that given certain qualifications PrEP is a cost-effective and efficient intervention for demonstrating impact on reducing HIV incidence.*

PrEP is a costly intervention, however if taken up by those at highest risk it will become more cost-effective and cost-saving in future years.[28] Fiotec commissioned a series of research studies, including modelling studies, to assess the cost effectiveness and efficiency of PrEP. One study, Modeling PrEP impact and cost-effectiveness,[29] demonstrated that PrEP is cost-effective for MSM and TGW if incidence is above 3% and if it is provided at scale. However, this depends on effective use of PrEP. This was corroborated by another study which observed that NGO PrEP drug costs were higher than government costs by at least 15% as were personnel costs by at least 23%.[30] Furthermore, research demonstrated that 20% PrEP coverage among MSM and TGW is needed to reduce HIV incidence and make the intervention cost-effective as per established thresholds.[31] Overall, the studies demonstrate the cost effectiveness and efficiency of PrEP within a combination prevention strategy, with the potential for reducing more than 50% incidence of HIV acquisition.[32]

Finding 11.3: *Based on real-world implementation science projects, provision of PrEP services was considered by governments to outweigh its cost. However, design of the projects could benefit from early interaction with government, including ministries of finance, to determine their needs including for scale-up.*

Key informants from government expressed that the benefit of implementing these projects outweighed the cost. This is based on the learning and evidence on provision of oral daily PrEP for key and vulnerable populations as part of larger healthcare delivery systems. This was expressed by various informants and highlighted strongly in the case of Peru, where it was mentioned that government is unlikely to approve a policy/policy change without strong national level evidence, which was provided by ImPrEP.

[28] VIIV Healthcare is an independent, global specialist HIV company committed to delivering innovative new medicines for the care and treatment of people living with HIV and AIDS [29] Borques A et al (2021) Modeling PrEP impact and cost-effectiveness based on the ImPrEP demonstration project. CROI 2021.; [30] Cerecero-Gaercia D et al (2021) Assessing the cost of PrEP delivery in Mexico: results from the ImPrEP study. IAS 2021 poster presentation; [31] Borquez A et al (2021) Importance of accounting for ART costs saved in the long term when estimating HIV pre-exposure prophylaxis (PrEP) cost-effectiveness: a modeling study informed by the ImPrEP demonstration project. Virtual poster presentation at IAS 2021; [32] Bórquez et al (2019). The impact & cost-effectiveness of combined HIV prevention scenarios among TGW sex-workers in Lima, Peru: a mathematical modelling study. Lancet Public Health.

The importance of youth engagement and peer driven platforms has emerged as a best practice in sub-Saharan Africa, demonstrated as effective for demand creation, youth engagement and linkages to care. This was also seen within the Wits RHI project implementation. With regard to implementation in South Africa it is pertinent to note that PEPFAR has very limited funds for demand creation/communication and expressed the desire to understand how Unitaid anticipated and closed this gap with respect to demand for PrEP under Project PrEP.

The implementation models developed by the projects that effectively link supply and demand efforts have the potential to serve as an example of leveraging a relatively small investment (Unitaid) to change the approach of a major contributor to PrEP implementation and uptake (PEPFAR).

However, concerns were expressed around engagement costs of peer educators and CS organizations for demand activities (one of the largest project costs) which reflects that government respondents did not have a clear strategy to fund the demand creation activities through these modalities.

This speaks to the expressed need, according to informants, to better understand the context and the exact needs of a country that a pilot/demonstration study can address from the design phase. Exact needs for evidence may include number of sites, quality and rigor of the evidence to be produced to roll out at scale, requirements of MoF to fund at scale, etc.. This would imply including the MoH and the MoF when engaging in budgeting around incorporating new interventions. This could help to tailor the pilot studies to ensure they are economically sound to addresses the need for scale up. It is important to acknowledge that a critical part of piloting, along with generating the evidence, is convincing the national stakeholders of the usefulness of the evidence which requires combining piloting with a level of inclusiveness at the design stage and advocacy throughout implementation for broader roll out.

4 Conclusions

Overall Conclusion:

The Unitaid PrEP portfolio has successfully demonstrated the feasibility of implementing PrEP programmes for key vulnerable populations in the targeted countries while at the same time generating significant learnings disseminated through various channels. Contribution to policies, strategies and guidelines have also helped influence the global environment for scale up of PrEP. However, barriers to widespread PrEP including political, contextual and financial challenges remain.

Areas of success:

1. The PrEP portfolio has generated an evidence base for successfully addressing the needs of underserved populations contributing to advancing equity in access to oral daily PrEP as a viable choice through diversified channels and delivery models. It has generated operational evidence to contribute to scale-up in targeted countries and to raising awareness around PrEP in some neighbouring countries in LAC and Africa and in the Asia Pacific region. Globally, the projects contributed to WHO-generated policy, guidelines and protocol development/updates through research generated, development of case studies and collaboration on WHO development committees.
2. Demand generation activities, and their adaptation over time, have significantly contributed to awareness raising, uptake of services and future sustainability of interventions. These activities which targeted key populations and communities included a mix of media channels (television, radio, printed materials), digital platforms (Facebook, WhatsApp, Instagram), websites, mobile van services, youth friendly spaces, etc. Many of the activities have been absorbed into the government systems.
3. The integration of PrEP provision within a comprehensive HIV prevention package ensures access to critical sexual and reproductive health services for key populations. This integration was evident both in demand generation and awareness raising activities as well as service provision.
4. Collaboration with WHO on the design and implementation of the projects ensured a level of rigor and scientific soundness in protocol development and presented additional opportunities for dissemination of research (e.g. webinars, satellites) to further promote PrEP as a cost-effective preventive intervention.
5. Engagement of peer educators and civil society has demonstrated models for reaching key populations generating first time interest in PrEP as a prevention method.
6. Embedding the projects within the government services delivery systems helped guarantee buy-in and further sustainability of the project activities while at the same time presenting cost-efficiency gains. This also facilitated the scale-up of PrEP in all countries.
7. Coordination and integration with the Unitaid PrEP portfolio fostered sharing of protocols, tools, guidelines, plans and innovate ideas resulting in cross-fertilization of best practices and lessons learnt within the portfolio. These lessons were also shared with numerous countries in LAC and resulted in exchange visits and TA to Mozambique. Portfolio level efficiency gains were witnessed through the simplification of reporting enacted by Unitaid during implementation.

Conclusions

Areas that need improvement

1. Delays in implementation associated with securing ethical approval of protocols slowed the pace of implementation during project start-up. Despite this the projects reached their targets however roll-out and scale-up may have happened on a larger scale without the delays.

2. Although MTV engaged in demand generating activities, clearly showing positive results, availability of supplies presented challenges.

3. The private sector plays a critical role in health care service provision including for commodities in the targeted countries. However, engagement with the private sector was limited. Further engagement is warranted to advance efficiency and effectiveness along with scale-up of PrEP interventions.

4. Both supply and demand challenges remain in targeting key populations due to continued stigma and discrimination as well as lack of perceived risk.

5. The projects have engaged in extensive global dissemination events and activities. However, a more tailored/personal country approach to sharing of project models with other funders, like PEPFAR, Global Fund and the Gates Foundation (through their funded projects), was not always evident and points to a missed opportunity.

6. Measuring the “harder stuff” - success of demand generation and success of PrEP - remains a challenge not only in the project countries but globally. Strategies to ensure that young people most at risk of HIV have access to PrEP when they are at risk and ways to measure the effectiveness of use are critical.

7. The lack of attention to comprehensive community response strategies which consider both human resources and financial implications, challenges the sustainability and scale-up of critical community-focused and peer educator activities.

8. Despite project management functions being performed through a regional consortium of stakeholders in LAC a functional high level steering mechanism was not established. This is seen as a missed opportunity and leaves room for improvement related to governance, accountability, transparency, informed decision making, advocacy to regional and global stakeholders and wider support - all of which affect efficiency of project implementation.

9. Despite integration within the government health systems extending this collaboration with other ministries was not fully evident (e.g. ministry of gender/women for gender-based violence, ministry of education for SRH education) yet could help further tailor the implementation science to what is needed in the countries. Additionally, involvement of the ministry of finance in the design stage and in ongoing analysis of implications of PrEP could help with future planning exercises and strategizing sustainability of interventions.

10. Although evidence points to the general success of demand creation activities, more evidence is needed on the cost-effectiveness of digital demand-creation channels for PrEP.

5 Recommendations

Recommendations

Recommendation 1: Unitaid should build on the success and the momentum generated for PrEP by focusing on concrete areas to further equitable access to oral PrEP, the dapivirine ring and CAB-LA for key populations both in the existing project countries but also beyond. The evaluation has highlighted progress and successes at catalyzing country and global enabling environments for PrEP scale-up during the first five years of the Unitaid PrEP portfolio implementation. Continued support under the portfolio in the following areas would further capitalize on those successes and enhance the overall effectiveness and value for money of the grants while maximizing on the catalytic nature and effect of Unitaid's investments in PrEP.

- **For non project countries, Unitaid should consider a more targeted approach to supporting dissemination of evidence** generated along with best practices and lessons learnt from country implementation through concrete efforts to link with large scale funders of HIV interventions at country level. This could take on the form of more face-to-face information exchanges with funders and their implementing partners including study exchanges or “twinning” opportunities to intimately engage them in the functioning of their PrEP models thereby further facilitating access to best practices produced under the projects. The interactions could take place around key planning activities (e.g., Country Operation Plan preparation for PEPFAR, Funding Request development for the Global Fund). There is interest in such a model particularly South Africa and this momentum should be harnessed. *(responsible: Unitaid and grantees).*

- **In line with supporting dissemination, as a matter of urgency Unitaid should work with existing structures for further dissemination of results both in the target countries and the regions.** Unitaid should continue leveraging existing global partnership such as with AVAC – global entity that works to accelerate the development and global delivery of HIV prevention options as part of a comprehensive and integrated response to fight HIV in countries where HIV prevention research is conducted - or a similar structure. In addition, Unitaid should explore partnership with the South South Learning Network which currently engages 15 African countries with PrEP being one of their focus areas. Working with these structures to ensure both identification of new models for PrEP delivery and new avenues for dissemination of lessons learned/best practices by Unitaid grantees and those engaged in similar activities can influence PrEP adoption and avoid duplication of efforts. This collaboration also affords the opportunity to identify areas where research/information gaps exist tapping into countries beyond those targeted by Unitaid to help tailor further research and information sharing.

Recommendations

- **Advocate early and more actively with governments** for PrEP scale-up through existing information sharing channels. This will be particularly relevant when introducing CAB-LA which is a high-cost ticket item for HIV prevention. As a first step, Unitaid should consider closer involvement of the MoF from the design phase for the new projects to ensure a better understanding of the exact needs and priorities of the country which will have an influence on the associated costs of PrEP scale-up. This could help to tailor the implementation studies to generate evidence that is more useful for convincing stakeholders of the value, effectiveness and feasibility of different models for provision of PrEP. *(responsible: Unitaid and grantees).*
  - **Specifically, for the ongoing projects Unitaid should conduct analysis of government fiscal and capacity space** for strategies that are tested/implemented outside of routine government structures such as project demand creation activities through peer educators and CSOs, together with CSO demand-side efforts as a "package". Effort should be placed on determining how CSO demand-side work, which have demonstrated to be catalytic and impactful results, can be shown to be cost-efficient and more palatable to national governments. This will in turn allow development of approaches that speak to governments' (current and planned) ability to incorporate these cadres and activities into government systems to guarantee their sustainability and scalability. *(responsible: Unitaid and grantees).*

- **Advance efforts to clearly align with other funders on measurement of success for PrEP (performance measures)**. Currently successful use of PrEP is measured differently across the PrEP portfolio and funders both at the country level and global level. However, there is consensus among stakeholders that measuring PrEP initiation is insufficient to determine successful uptake of PrEP services.
  - Specifically, Unitaid should engage with PEPFAR, Global Fund, Gates and other funders at the country level to both align priorities when it comes to implementation of PrEP for targeted groups as well as strategies being used to measure aspects of PrEP use/success. They should foster discussion on establishing an agreed set of metrics to allow rational assessment of PrEP success in line with the latest Strategic Information Guidelines for PrEP and the soon to be updated (2023) WHO implementation tool for PrEP. This engagement should also be done in coordination with the MoH, national AIDS councils and other critical national stakeholders to ensure that measurements are harmonized within the countries. *(responsible: Unitaid together with WHO and support of grantees).*

Recommendations

- **Conduct a cost benefit analysis with a focus on CAB LA and the vaginal ring including demand generation aspects. This study will help ensure that the catalytic nature of MTV demand generation investments are capitalized.** Recognizing that CAB LA is a high-ticket item Unitaid should conduct a cost analysis study to ensure that a balance exists between these priorities, availability of commodities and demand creation. This analysis should also focus on timing for demand creation. The analysis could also focus on generating evidence on demand creation for a range of prevention products, and how to help clients chose between them to ensure effectiveness and sustainability of the methods. *(responsible: Unitaid for assessing the priorities either through a continued grant to MTV or an external evaluation; continued demand generation through Unitaid costed extension to MTV).*

- **Partner with WHO/UNAIDS on regional PrEP Advisor role to catalyze interest and action in LAC and Southern Africa.** Recognizing the unique set-up of the WHO/UNAIDS PrEP Advisor in Asia Pacific and the catalytic results achieved in the region through this dedicated work of engaging countries, both UMIC and LMIC, in PrEP introduction and scale up Unitaid, WHO and UNAIDS should consider this role in other regions. The PrEP advisory role should be seen as catalytic, in line with the experience in Asia Pacific, where a multiplier effect was evident (interest generated and action taken to introduce PrEP in different countries) and helped leverage support from wider resources.
  - Concretely this would entail funding of the position and negotiating with WHO/UNAIDS on the roles and responsibilities, and measurement indicators, of the advisor based on lessons learnt from the Asia Pacific experience. This would foster interest in, and contribute to, regional uptake of PrEP activities. This is in line with the objectives of the grants yet something that has yet to be concretely demonstrated. *(responsible: Unitaid continued support to the enabling grant channeling co-financing for an Africa Regional Advisor and working with WHO and UNAIDS).*

- **Generate evidence on the effectiveness of the digital platforms**, to ascertain whether they address the right target groups, respond to the right issues building on lessons learned and are cost effective. Recognizing the expansion of digital platforms as a catalytic means of reaching target groups in larger numbers and influencing uptake of PrEP Unitaid should commission a study on the cost-effectiveness of the platforms and dissemination the results within the countries and beyond through various channels to help influence future programming of governments and funders. *(responsible: grantees under the cost extensions or Unitaid through and independent evaluation).*

Recommendations

Recommendation 2: Partner with other PrEP funders to test the efficacy of the Fiotec and Wits RHI community-based/peer driven efforts and systems (or other efforts and systems) as well as the new products in resource-constrained settings combined with appropriate demand generation to garner trust in PrEP including for the latest products (CAB LA and the vaginal ring). This is in line with meeting Strategic Objective 1 of the Unitaid 2023-2027 strategy through ensuring that efforts focus on the "nothing for them without them" community-based mantra. Unitaid should aim to test responses that are grounded in, and driven by, community-led approaches to identify the needs and help shape demand generation responses with a focus on the most vulnerable and marginalized populations. This effort should be undertaken in coordination with major funders of HIV prevention services (e.g., Global Fund, PEPFAR, Gates Foundation) to agree on where unique evidence gaps exist specific to these settings and how to prioritize the game changers or most catalytic aspects of community-based responses as well as identification of the target countries. The work could be facilitated, in South Africa for example, through a Southern African Regional WHO/UNAIDS PrEP Advisor similar to the Asia Pacific region. (responsible: Unitaid)

This response should be considerate of recommendation 1, bullet 2 and the related sub-bullet which focus on enhancing sustainability through working with governments and partners to ensure both political and financial support exists including for cadres of community responders.

Recommendations

Recommendation 3: Unitaid should consider generating evidence on the role of the private sector in the implementation science projects implemented by Wits RHI and Fiotec and their potential to contribute to PrEP for key populations. Private sector models could be designed and tested with an eye on promotion of comprehensive HIV prevention packages including commodities while at the same time exploring the overall benefit of the private sector working with the government. This may include:

- Supporting a private sector model for engaging and expanding cadres of peer educators and CS organizations that would help address concerns about sustainability and scalability. A public-private partnership approach (e.g., with the MoH, MoF and private sector) may allow government to have more control and to continue to work with civil society through national programmes without additional administrative and management responsibility.
- Engaging more concretely private health care facilities and pharmacies in the demonstration projects to ensure that people are getting high quality prevention services at these facilities.
- Exploring engagement with larger companies, tapping into their corporate social responsibility obligations, around the establishment of channels for introducing and ensuring access to PrEP for their key and vulnerable populations.

All options could be explored through targeted research under the costed extensions. *(responsible: grantees for research implementation).*

Recommendations

Recommendation 4: Establish an overarching/high level steering/governance mechanism to allow provision of critical guidance, networking opportunities and a measurement of transparency and accountability in addition to garnering support for interventions and dissemination of knowledge. The governance mechanism for the Unitaid PrEP projects needs to be strengthened and the role of platforms such as external advisory boards (EABs) and steering committees elevated not only to influence grant implementation but to foster regional awareness and uptake of PrEP. Suggested steps to strengthen the EAB include:

- Assign the EAB a role in linking the projects to other similar or related initiatives in the region and globally – fostering direct transferability of project knowledge products to other countries
- Ensure the EAB serves as 'external eyes' to projects offering valuable critique and guidance including more transparency and accountability
- Encourage the EAB to foster higher regional/global visibility of lessons learned with key stakeholders
- Guarantee alignment of the Unitaid grants with other funders of PrEP scale-up, such as PEPFAR/USAID, the Global Fund and the Gates Foundation while at the same time encouraging their involvement in the EAB.

(responsible: these steps should be engaged in as a joint effort between the grantees and Unitaid).

Recommendation 5: Extend the period of the grants to afford adequate time to undertake what is often in-depth and complex implementation science research. Generating quality evidence requires time and thoughtful and well-planned dissemination of results. It was found that of those milestones not reached under the grants it was due to continued gathering and analysis of data and planning of dissemination events. Therefore, extending the grants, coupled with proper planning from the onset, would help maximise the impact and influence from Unitaid grants on introduction within the regions.

Recommendations

Recommendation 6: Ensure that new insights into longer-acting PrEP options generated under the Unitaid PrEP portfolio are fed into the Coalition to Accelerate Access to Long-Acting PrEP and insights from the Coalition are fed into grant implementation. Evaluators note that Unitaid is already one of the conveners of the Coalition and encourages this sharing of information from the Unitaid PrEP portfolio to focus on informing rapid policy and guideline development in high priority countries and supporting adoption of these longer-acting products. Sharing of Unitaid PrEP portfolio information at coalition/coalition working group meetings should be led by the Secretariat and include active participation of the Unitaid grantees together with representatives of the Ministry of Health or other relevant government entities. Concurrently, the Secretariat should hold joint information sharing meetings with the grantees following coalition/coalition working group meetings to discuss critical information on advancements and/or setbacks for longer-acting PrEP options and potential consequences and possibilities for adaptation to grant implementation.

6 Annexes

Annex A: HIV PrEP Portfolio Theory of Change

Theory of Change: Enabling Scale-Up of Pre-Exposure Prophylaxis (PrEP) and Linkage to HIV Test				
Problem	**Public Health Need**	▪ The HIV response faced limited success in reducing new HIV infection, partly due to limited uptake of HIV prevention services. Key populations (KP) constitute small proportions of the general population but contributes higher proportion (62% in 2019) of new adult HIV infections globally. Target to reduce new infections to under 500,000 by 2020 (or by 75% between 2010 and 2020 among KP) was not met. ▪ In sub-Saharan Africa, adolescent girls and young women (aged 15 – 24 years) represent only 10% of the population but accounted for 25% of HIV infections in 2020 while in Latin America the annual new infections did not achieve any reduction in the last decade.		
	Access Barriers	Limited uptake largely due to barriers below: ▪ **Affordability:** Higher drug prices due to limited supply base in particular Latin America region; ▪ **Demand & Adoption:** Lack of country level guidance on distribution including for new PrEP methods as well as low awareness; ▪ **Supply & Delivery:** Limited evidence around the strategies for effective delivery and use in real life situation		
Pathway to Impact	**Input**	**Outputs**	**Outcomes**	**Impact**
	▪ Unitaid funding ▪ Leveraged funds from other donors and governments	1. **Enabling Environment:** Promote in country buy-in, capacity, demand creation and supportive environment for introduction of PrEP, other sexual health & prevention services e.g. HIV self-testing (HIVST) and Hepatitis C self-testing (HCVST) 2. **Effective Delivery:** Delivery models supporting PrEP choices and switching (oral, cabotegravir long-acting, dapivirine ring), other sexual health and prevention services and appropriate integration (e.g. with family planning) are developed and tested through comprehensive HIV and sexual health services 3. **Evidence Generation:** Acceptability, feasibility and effectiveness is provided to support policy, guidelines and scale up for PrEP, other sexual health and prevention services	**Improved access to and uptake of PrEP and other comprehensive prevention services (e.g., HIVST, HCVST, etc..)** ▪ Evidence available on acceptability, feasibility and effectiveness of existing and upcoming tools to inform global and national guidance ▪ Strengthened national level policies, guidance and strategies accessible to sub-national levels ▪ Delivery models integrated within existing systems to support cost-effective delivery ▪ Increased demand to support price reduction and increase affordability	**Public Health Impact** ▪ Reduced new infection, morbidity and mortality among PLHIV; ▪ Accelerate progress towards achieving global target **Economic Impact** ▪ Increased economic impact **Equitable access to diagnosis and treatment**
Key Risks	▪ **Strategic:** Evidence of real-life use fails to demonstrate added value ▪ **Implementation:** Challenges in the supply chain and shortages of drugs resulting in stockouts ▪ **Scalability & Transition:** Lack of sustainable funding, lack of political commitment, competing priorities between prevent and treatment interventions			

Annex B: Project background information
The ImPrEP Project was implemented in 14 sites across 11 cities in Brazil

The **HIV epidemic** in Brazil is the largest in Latin America. The population is estimated at over 2 million people and almost 60% are aged between 15-54 years. **HIV incidence** increased by 21% over the last decade. In 2018, about 53 000 people became newly infected with HIV. Even with coverage of antiretroviral treatment, new HIV infections are estimated at 48 000 each year. Populations at highest risk of HIV include transgender people (30%) and MSM (18.3%).[25]

Early efforts by the MoH to implement PrEP in high prevalence locations demonstrated awareness and willingness to initiate in Rio de Janeiro and Sao Paulo among the more educated population. As of March 2022, The Global PrEP Use Landscape estimated the cumulative PrEP initiation at 57 597.

[25] UNAIDS (2020) Global PrEP tracker https://www.prepwatch.org/resource/global-prep-tracker/,

Annex B: Project background information

PrEP1519 was implemented among 15-19 years old 1,790 MSM/TGW in Brazil

The PrEP1519 is a component of the ImPrEP grant. Its ultimate goal is to inform the longer term roll out of PrEP for the adolescent MSM/TGW population in Brazil (and beyond).

PrEP1519 is the first PrEP demonstration cohort study among 15 to 19 years old MSM and TGW in Latin America. The project has two main goals:

1) to evaluate the effectiveness of PrEP use and
2) to reduce the incidence of HIV among this population.

PrEP1519 has been implemented in public health sector facilities in three large and diverse state capital cities: Belo Horizonte, Salvador and São Paulo.

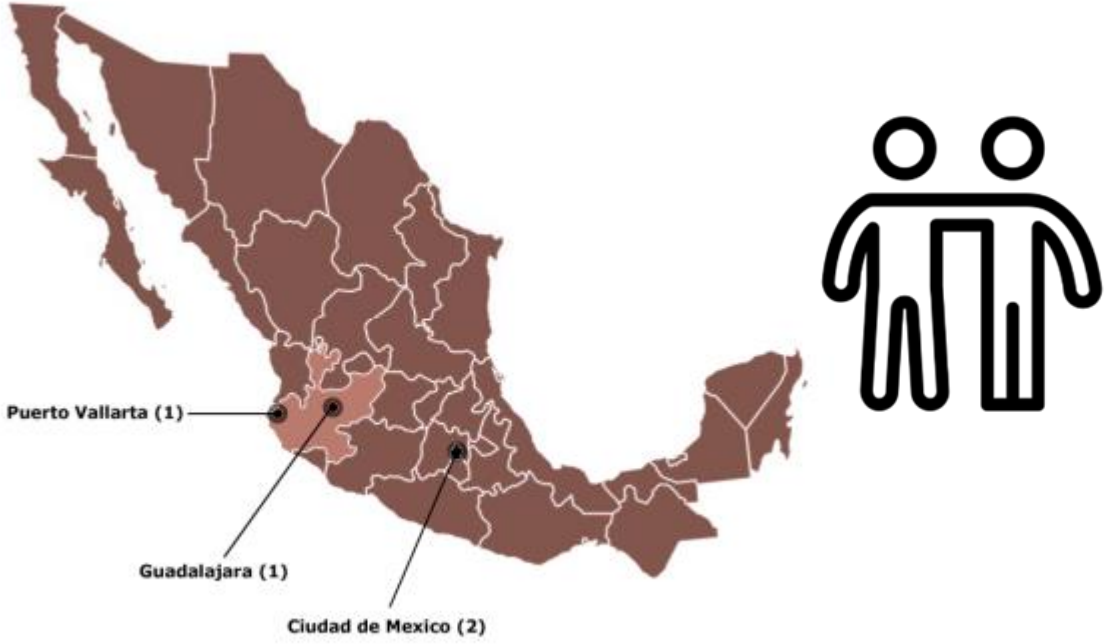
Participants were recruited by demand creation strategies conducted by the PrEP1519 team, including activities developed by peer-educators and the health team in schools, health centres, community centres, youth gathering/venues, hook-up apps, and online networks. A total of 5 PrEP clinics in 3 cities in Brazil (3 in São Paulo, 1 in Salvador and 1 in Belo Horizonte) enrolled 1131 AMSM and ATGW aged 15-19 years in PrEP and 232 in other combination prevention.

Preliminary results from PrEP1519 showed a retention rate after 1-year follow-up of 56.5%, and an adherence level capable of protecting against HIV around 57% among MSM and ATGW enrolled in PrEP. The reasons observed for not continuing on PrEP go beyond risk perception and are related to challenges with daily use, greater social vulnerability and incompatibility between daily life and the demands of the PrEP1519 follow-up.[26]

[26] StatsSA Mid-year population estimate 2021, Global PrEP tracker https://www.prepwatch.org/resource/global-prep-tracker/

Annex B: Project background information

The ImPrEP Project was implemented in 4 sites across 3 cities in Mexico



There are about 200 000 people living with HIV in Mexico. The number of people **newly infected with HIV increased by almost 30%** between 2010 and 2020, from 16 000 to 20 000. HIV prevention programmes have targeted key populations including sex workers, MSM and drug injectors as the drivers of the epidemic.[27]

The number of **PrEP** users increased from 1120 in 2018 to 2454 in 2019. Since then, PrEP uptake has been on a slow decline, estimated at 2143 in 2020 and declining further in the second half of 2020. As of March 2022, the Global PrEP Use Landscape estimated the cumulative PrEP initiation to be 3 402. Under the ImPrEP demonstration project, those accessing PrEP were largely MSM (97.1%) aged between 25 – 34 years.[28]

[27,28] UNAIDS (2020)

Annex B: Project background information

The ImPrEP Project was implemented in 10 sites across 6 cities in Peru

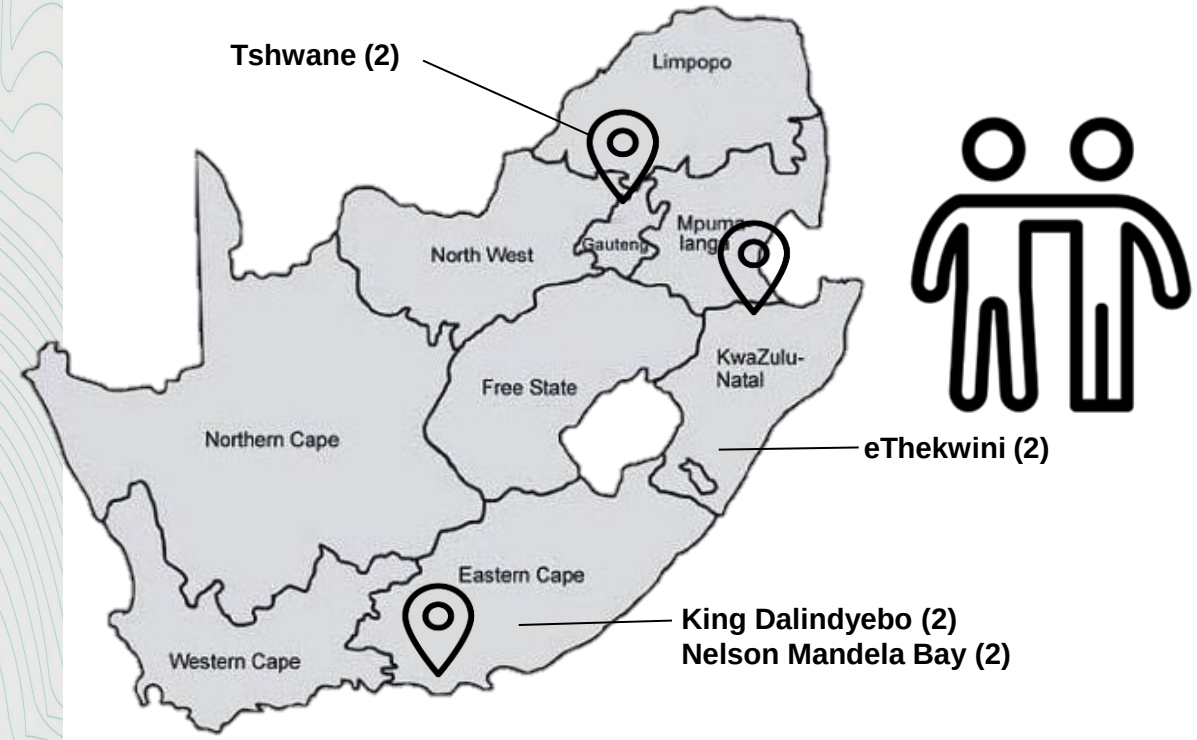
Over 70 000 people in Peru are living with HIV. The HIV prevalence has increased by 24% since 2010.[29] The epidemic is locally concentrated among MSM and transgender people with 60% of all new infections occurring among these groups.[30] Guidelines for the prevention, treatment and control of HIV are in place, however, there is persistent discrimination against people infect with HIV.[31]

Despite the availability of PrEP, mainly through ImPrEP demonstration projects, PrEP use remains suboptimal. The Global PrEP Use landscape estimated the cumulative PrEP initiation in Peru to be 2931 as of March 2022.[32]

[23,31,32] UNAIDS (2020); [30]. Tattsbridge, J., Wiskin, C., de Wildt, G. *et al.* HIV understanding, experiences and perceptions of HIV-positive men who have sex with men in Amazonian Peru: a qualitative study. *BMC Public Health* **20,** 728 (2020). https://doi.org/10.1186/s12889-020-08745-y, Global PrEP tracker https://www.prepwatch.org/resource/global-prep-tracker/

Annex B: Project background information

Project PrEP was implemented in 8 sites across 3 provinces in South Africa



South Africa houses one of the largest HIV epidemics globally. As of 2021, about 8,2 million people were living with HIV.[33] Adolescent girls and young women (15 – 24 years old) carry a disproportionate burden of HIV, with one third of all new HIV infections in the country being among them.

In 2016, South Africa became the first country in the region to approve PrEP. South Africa's PrEP roll out strategy was initially a phased approach focusing on target populations. However, PrEP is now available to all individuals at primary health care facilities and through demonstration projects and observational studies as part of the 2019 National Roll-out of PrEP. Over 2000 PHC facilities have been trained to provide PrEP across the country. As of March 2022, the Global PrEP Use Landscape estimated the cumulative PrEP initiation in South Africa to be 415 658.

[33] StatsSA Mid-year population estimate 2021, Global PrEP tracker https://www.prepwatch.org/resource/global-prep-tracker/

Annex C: Table of prices and regulatory status of TDF/FTC medicines in the PrEP covered projects

Country	Price (2017) & supply arrangements	Expected price	Achieved price (2022)	Regulatory status for TDF/FTC indicated for PrEP (2017)	Regulatory status (2022)*
Brazil	Gilead retail price: 1440 USD ppy Gilead offer to MoH: ≤300 USD ppy Supply: Ministry of Health	67 USD ppy *(« assuming Gilead appeal on the patent rejection is not successful")	MoH PrEP price: 156 USD ppy (TDF/FTC generic version manufactured in Brazil) Retail price: 780 USD ppy (generic version Blanver) Gilead retail price: 3567 USD ppy	Gilead registration application under fast-track consideration (ANVISA granted approval for use in the MOH & Fiotec PrEP projects)	Gilead's Truvada (TDF/FTC) registered for PrEP (approved in May 2017) 2 generic versions of TDF/FTC approved for PrEP (version manufactured in Brazil approved in 2018)
Mexico	Gilead retail price: 6000 USD ppy Gilead MoH price (ART): 1260 USD ppy Supply: Gilead donation for Y1-2 project (2600 users) Price reduction strategies (introduction of generics after patent expiry)	180 USD ppy («after patent expiries in Jan 2018 »)	2022 MOH PrEP bid price: 360 USD ppy (tenofovir/FTC generic version) Retail price: 880-1080 USD ppy (generic version) Supply: Ministry of Health	Gilead registration application under review (COFEPRIS granted approval for use of Truvada in PrEP demonstration projects)	Gilead's Truvada (TDF/FTC) not registered for PrEP, used off label for PrEP One generic version (Sandoz) of tenofovir/FTC approved for PrEP in 2018 (used off label for treatment)
Peru	Gilead retail price: 1440 USD ppy Mylan retail price: 500 USD ppy Supply: Project managed for the only registered generic (Mylan 300 USD ppy for the project duration) (around 2000 patients)	75 USD ppy (PAHO price)	2022 MOH PrEP price (via PAHO): 75 USD ppy (Mylan generic version) Gilead retail price: 1440 USD ppy Mylan generic version retail price: 500 USD ppy Supply: Ministry of Health via PAHO Strategic Fund (as of June 2022)	3 TDF/FCT approved formulations (originator plus 2 generic versions) Truvada approved for PrEP after the end of Gilead's iPrEx clinical trial.°	TDF/FCT approved formulations: Gilead's and 4 generic versions (Mylan, Emcure, Hethero, Laboratorio AC) All registered TDF/FTC formulations in Peru seem to have been approved for PrEP (documents not available)
South Africa	67 USD ppy (generic version government price for the Unitaid project) Supply: Project funded and procured at DoH prices with DoH awarded tender suppliers, Integrated in the DoH supply management at facility level	Starting government achieved price already aligned with lowest international prices	2021 (until April) MOH price (accessed by Wits): 48,24 USD ppy Gilead retail price: 576-756 USD ppy* Generic versions retail prices: 268-498 USD ppy* Supply: Full integration with DoH PSM in the Wits PrEP project provinces (ongoing, expected to be finalized in 6-month period)	In December 2015, the Medicines Control Council (MCC, now SAHPRA) approved the use of TDF/FTC combinations to include PrEP indication, "requested the applicants to implement a risk management plan, which requires applicants to provide prescribers with a detailed information pack, to gather data on adverse effects, and to report these to the MCC at 6-monthly intervals."	Gilead's Truvada (TDF/FTC) approved for PrEP Over 15 generic versions of TDF/FTC generic versions approved (including for PrEP)

Annex C: Table of Patent status (current) for TDF/FTC and TDF/3TC for Brazil, Mexico, Peru, South Africa *(Source: MedsPaL, MPP)*

Country	Patent status summary
Brazil	The patents on TDF and FTC compounds and FDCs have been rejected in Brazil. The patent opposition on TDF/FTC in early 2017 in Brazil has been achieved with the support of other Unitaid-funded projects on IP and Access to Medicines (ITPC/ABIA). Synergic effect.
Mexico	The patents on the TDF and FTC compounds have expired, while the patent on the TDF/FCT combination will expire as of January 2024.
Peru	No patent application has been filed concerning TDF, FTC or their combination.
South Africa	The patents on FTC and 3TC compounds and synthesis have expired, no patent application has been filed for the TDF compound. The patent application on the TDF/FTC combination has been withdrawn.

- The MedsPaL database reported original patent for TDF/FTC combination included a claim for HIV treatment and prevention. This patent due to expire in 2024 where it has been granted in several countries has been withdrawn or rejected.
- Latin American countries not included in the MPP license for TDF.
- The MPP provided the reference to a PCT application, which could include TDF/FTC combination for HIV prevention filed by the US government, Department of Health. It is unlikely that this patent application will block any oral PrEP access.
- Generic competition was already possible also in Europe, where the TDF/FTC patent is still enforced until 2024, by marketing a combination with another salt of tenofovir disoproxil. These combinations were approved as bioequivalent generic versions by EMA since 2016. (Manufacturers: Mylan, Sanofi, KrKa).
- The MPP often provide and help other organizations including other Unitaid grantees to interpret patent data information also in light of MPP specialized staff. For PrEP, MPP is acquainted with a number of PrEP actors. (**synergic effect)**
- After patent rejection in Brazil to which ITPC/ABIA contributed, a PPP between Fiocruz and a pharmaceutical company manufactured a TDF/FTC generic version, which was procured by the government at affordable price. (**synergic effect)**

Annex D: Stakeholders Interviewed

Name	Organization	Position	Stakeholder Group
Brazil			
Marcelo Araujo de Freitas	PAHO - Brazil Office	Advisor on HIV, STI and Viral Hepatitis	National Stakeholder
Carlos Passarelli	UNAIDS - Brazil Office	Senior Advisor Access to Medicines	National Stakeholder
Veriano Terto Jr.	ABIA - Brazilian AIDS Association	Director	National Stakeholder
Keila Simpson	ANTRA - National TGW Association	President	National Stakeholder
Marcus Vinícius Lacerda	Fundação de Medicina Tropical Heitor Vieira Dourado - Manaus/AM	ImPrEP Site PI	Implementing Partner
José Valdez Ramalho Madruga	CRT - SP (São Paulo)	ImPrEP Site PI	Implementing Partner
Josué Lima	CRT - Campinas	ImPrEP Site PI	Implementing Partner
Beatriz Grinzstejn	INI- Fiocruz	ImPrEP PI in Brazil	Implementing Partner
Alexandre Grangeiro	University of São Paulo	PrEP 1519 project	Implementing Partner
Gerson Fernando Mendes Pereira	National AIDS Department	Director	National Stakeholder
Cristina Pimenta	Brazilian MoH -Department of Chronic Conditions Diseases and Sexually Transmitted Infections of the Ministry of Health	Research Director and IMPREP Project Director	Implementing Partner
Prof Ines Dourado	Federal University of Bahia	PrEP 1519 Project Lead	Implementing Partner

Annex D: Stakeholders Interviewed (cont.)

Name	Organization	Position	Stakeholder Group
Mexico			
Andrea Gonzalez	Mexico City AIDS Programme	Executive Director	National Stakeholder
H. Rodrigo Moheno	Fundación Mexico Vivo	General Secretary	National Stakeholder
Victor Dante Galicia	CHECCOS	Director	National Stakeholder
Hamid Vega	Center for Research in Global Mental Health, National Psychiatric Institute	Medical doctor/ researcher	National Stakeholder
Francisco Arjona	SETAC	Director	National Stakeholder
Hilda Peñaloza	Inspira Cambio	Director	National Stakeholder
Althse De La Torre	Censida	General Director	National Stakeholder
Alanna Armitage	UNFPA Mexico	UNFPA representative	Implementing partner
Peru			
Patricia Bracamonte	UNAIDS Lima	M&E Officer	National Stakeholder
Ricardo Chuquimia	Abbott/USAID	Technical Officer	National Stakeholder
Kelika A. Konda	Universidad Peruana Caetano Heredia - UPCH	Epidemiologist	Implementing Partner
Carlos Cáceres	Universidad Peruana Caetano Heredia	Professor of Public Health	Implementing Partner
Juan Vicente Guanira	INMENSA	Executive Director	National Stakeholder

Annex D: Stakeholders Interviewed (cont.)

Name	Organization	Position	Stakeholder Group
South Africa			
Hasina Subedar	National Department of Health	Technical Advisor - HIV Prevention including PrEP	National Stakeholder
Thato Chidarikire	National Department of Health	Director: HIV Prevention	National Stakeholder
Nonceba Mofu	Department of Health (Ikamvelihle Clinic)	Facility Manager: Ikamvelihle clinic	National Stakeholder
Sinead Delany-Moretlwe	Wits RHI	Director: Research at WRHI and HPTN 084 protocol chair	Implementing partner
Ali Feizzadeh	UNAIDS	Senior Strategic Information Adviser	National Stakeholder
Amanda Khoza	Wits RHI	AGYW representative/ambassador	Implementing Partner
Liyema Nqadolo	Wits RHI	AGYW representative/ambassador	Implementing Partner
Liesl Page-Shipp	Bill and Melinda Gates Foundation	TB and HIV Senior Programme Officer	National Stakeholder
Mopho Radebe	WHO South Africa	Technical Officer	National Stakeholder
Yvonne Diogo	MTV South Africa	Country Director at MTV Staying Alive Foundation	Implementing Partner
Vusile Butler	Wits RHI	Technical Head: Programme Implementation	Implementing Partner
Saiqa Mullick	Wits RHI	Project PrEP PI	Implementing Partner
Catherine Martine	Wits RHI	Senior Techncial Speicalist	Implementing Partner
Elmari Briedenhann	Wits RHI	Senior Programme Manager Design4Health Team	Implementing Partner

Annex D: Stakeholders Interviewed (cont.)

Name	Organization	Position	Stakeholder Group
Market & Regulation			
Marcos Benedetti	Fiotec	ImPrEP Project Manager	Implementing Partner
Steven Diaz	UNFPA Mexico	HIV Consultant	National Stakeholder
Hamid Vega	National Psychiatry Institute, MoH, Mexico	Researcher	National Stakeholder
Carlos F. Caceres	Cayetano Herredia University, Peru	Professor of Public Health	National Stakeholder
Maserame Mojapele	Wits South Africa	PrEP Programme Manager	Implementing Partner
Esteban Burrone	Medicines Patent Pool	Policy Director	National Stakeholder
Veriano Terto Jr	ABIA, Brazil	Director	National Stakeholder
Felide de Carvalho Felipe	ABIA, Brazil	Advisor for Intellectual Property Rights and Patents	National Stakeholder
Alma de Leon	International Treatment Preparedness Coalition Latin America and The Caribbean (ITPC LATCA)	Regional Director	Regional Stakeholder
Christopher Lim	PAHO Strategic Fund/ARV procurement	Senior Advisor *(via email)*	National Stakeholder
Andy Gray	Division of Pharmacy, University of Kwazulu Natal, South Africa	Senior lecturer *(via email)*	National Stakeholder
Giovanni Ravasi	Former PAHO; now WHO Europe	former Senior Advisor	National Stakeholder

Annex D: Stakeholders Interviewed (cont.)

Name	Organization	Position	Stakeholder Group
Global/Regional			
Michelle Rodolph	WHO	Technical Officer, Global HIV, Hepatitis and STIs Programmes, WHO	Global Stakeholder
Maeve Brito de Mello	WHO/ PAHO	Advisor HIV/STI Prevention	Global Stakeholder
Heather-Marie Schmidt	WHO and UNAIDS Regional Office for Asia and the Pacific , Thailand	Regional Advisor PrEP	Global Stakeholder
Rachel Baggaley	WHO	Team Leader, Testing, Prevention and Populations in the Global HIV, Hepatis and STI Programme	Global Stakeholder
Shona Dalal	WHO	Epidemiologist, PrEP and HIV Prevention for Adolescents and Young Adults	Global Stakeholder
Eammon Murphy	UNAIDS	Actin Deputy Executive Director AI Programmes	Global Stakeholder
Obinna Onyekwena	The Global Fund	HIV Disease Advisor	Global Stakeholder
Vincent Wong	USAID/PEPFAR	Branch Chief - Behavioural and Structural Interventions, Office of HIV/AIDS	Global Stakeholder
Robin Schaeffer	WHO	PrEP scale-up lead, Global HIV, Hepatitis and STIs Programmes,	Global Stakeholder
Sarah Klucking	U. S. Department of State, Office of the Global AIDS Coordinator	Sr. Technical Advisor and Acting Director, Office of Research and Scient	Global Stakeholder
Esther Braud	USAID/PEPFAR	Senior Behavioral and Structural Interventions Advisor, OHA/PCT	Global Stakeholder
Sara Piot	MTV Staying Alive Foundation	Managing Director and Depty Exectuvie Director	Global Stakeholder
Maxim Berdnikov	Global Fund	Senior Fund Portfolio Manager High Impact Africa 2 Department	Global Stakeholder
Alwin De Greeff	Global Fund	Fund Portfolio Manager LAC	Global Stakeholder
Unitaid			
Heather Ingold	Unitaid	Programme Manager	Internal Stakeholder
Ombeni Mwerinde	Unitaid	M&E Manager	Internal Stakeholder
Mailys Bobin	Unitaid	Grant Finance Officer	Internal Stakeholder
Irina Fomenko	Unitaid	Grant Finance Officer	Internal Stakeholder

Annex E: List of Documents Reviewed

Name	
Fiotec annual and semi-annual reports incl. financial and other background documents, 2018-2020	34 docs
Fiotec disbursement memos and grant brief overviews	33 docs
Wits RHI annual and semi-annual reports incl. financial and other background documents, 2018-2020	66 docs
Wits disbursement memos and grant brief overviews	26 docs
Grant agreement documents	45 docs
MTV various	50 docs
Fiotec 2020 Scalability Reporting Matrix	3 docs
Wits 2020 Demand Creation Activities Report	2 docs
Fiotec 2021 SAR Flash Report	1 doc
Fiotec kick-off meeting presentation	1 doc
Wits 2021, SAR Flash Report	1 doc
Wits kick-off meeting presentation	1 doc
Unitaid, HIV Preventives Technology and Market Landscape 2nd Edition, 2014	1 doc
ABIA presentation at the IAS meeting in 2018, in Mexico City, in the satellite symposium “PrEP implementation for MSM and Trans Women in Latin America – early lessons from the ImPrEP initiative: reaching, engaging and retaining”	1 doc
ABIA, Informe sobre la accesibilidad de tenofovir 300 mg/emtricitabile 200 mg en los paises Peru, México, y Colombia, 2018	1 doc
SAHPRA press release Medicines Control Council approves fixed-dose combination of tenofovir disoproxyl fumarate and emtricitabine for pre-exposure prophylaxis of HIV, 3 December 2015	1 doc
MedsPaL (the Medicines Patent Pool database): TDF/FTC and TDF/3TC patent status in Brazil, Mexico, Peru, South Africa. Sourced on 9th March 2022	1 doc
Unitaid-WHO-UNAIDS, Building Capacity for the Roll-out of PrEP and HIV Testing Innovations in Asia and Pacific, Bangkok October 2018, Meeting report	1 doc

Annex E: List of Documents Reviewed (cont.)

Name	
Fiotec-PrEP Procurement Report, June 2021	1 doc
WHO, PrEP Demonstration Projects: A framework for country level protocol development, April 2013	1 doc
AVERT, Global HIV and AIDS Statistics, 2020	1 doc
ImPrEP Final Report 2017 - 2021	1 doc
Interagency Guidelines for medicine donations, 3rd edition, WHO, Geneva	1 doc
MSF, Untangling the web of antiretroviral price reductions, 2020	1 doc
PAHP, HIV epidemic and response in Latin America and the Caribbean, November 2021	1 doc
Unitaid-WHO-UNAIDS, PrEP innovation and implementation in Asia and the Pacific: Virtual regional discussion, 15-16 December 2020, Meeting Report	1 doc
ABIA, Summary Patent and regulation meeting ABIA, (08/05/year?) PAHO, HIV epidemic and response in Latin America and the Caribbean, November 2021	Web page
DIGEMID database for registered formulation of TDF/FTC (accessed on 24th March 2022): https://www.digemid.minsa.gob.pe/productosfarmaceuticos/principal/pages/default.aspx	Web page
SAPHRA database for registered formulation of TDF/FTC (accessed on 24th March 2022): https://www.sahpra.org.za/registered-health-products/	Web page
ANVISA database for registered formulation of TDF/FTC (accessed on 24th March 2022): https://consultas.anvisa.gov.br/#/medicamentos/q/?substancia=23992	Web page

Annex F: Wits RHI selected list of publications

1. International conferences, webinar presentations, abstracts etc..

Below is a list of all dissemination activities that the project was directly responsible. The list includes conference and webinar presentations as well abstracts:

1. Cox L, Martin C, Butler V, Naidoo N, Mullick S. Providing STI care in the context of PrEP provision in South Africa. Oral presentation at the International Aids Society 2021. (July 2021)
2. Mullick S. HIV combination prevention and new PrEP modalities for youth, key and vulnerable populations: lessons learned from South Africa, perspectives and challenges post-Covid-19 pandemic. Oral presentation at the International Aids Society 2021. (July 2021)
3. Kutywayo A, Butler V, Cox L, Martin C, Naidoo N, Mullick S. Gender-based violence, mental health and PrEP psychosocial support to AGYW in PrEP clinics in South Africa. Oral presentation at the International Aids Society 2021. (July 2021)
4. Pillay D, Plourde K, Morales G, Briedenhann E, Vundamina N, Smith BA, Mullick S. Being a part of the conversation: capacitating youth to participate in HIV prevention conversations using a digital citizen engagement platform in South Africa. Oral Presentation at HIV R4P 2021 (Feb 2021)
5. Mullick S. Programmatic requirements for providing large scale access to PrEP as well as Barriers and facilitators to Oral PrEP update, Retention and consistent use during the era of Covid-19. Oral Presentation at HIV R4P 2021 (Feb 2021)
6. Mullick S. South African perspective: Programmatic requirements for providing large scale access to PrEP as well as barriers and facilitators to oral PrEP uptake, retention, and consistent use during the era of Covid-19. Oral presentation at HIV R4P Virtual Conference. (3 Feb 2021)
7. Greener L, Briedenhann E, Sheobalak N, Butler V, Mullick S. How have digital health technologies helped oral PrEP delivery for key and vulnerable populations during the Covid-19 pandemic and beyond? Pre-recorded Satellite session at HIV R4P 2021 (Feb 2021)
8. Briedenhann E, Sheobalak N, Rosenberg P, Subedar H, Mullick S. It takes a village…ISof tactics to successfully drive demand creation for HIV prevention. Poster presentation at Interest 2020 Conference, 1-4 December 2020
9. Kwatsha K, Briedenhann E, Sheobalak N, Mullick S. I am the generation that will end HIV: documenting my PrEP journey through a daily video diary. Poster presentation at Interest 2020 Conference, 1-4 December 2020
10. Briedenhann E, Sheobalak N, Rosenberg P, Subedar H, Mullick S. It takes a village… of tactics to successfully drive demand creation for HIV prevention. Poster presentation at IAS 2020 Conference, 6-10 July 2020
11. Mullick S. Rethinking unmet healthcare needs among adolescents and youth: The need for integrated SRH and HIV prevention services. Oral presentation at International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA) 2-7 December Kigali, Rwanda
12. Sheobalak N, Briedenhann E, Mullick S. Break through the clutter - Using digital media tools to influence and engage adolescents on oral PrEP in South Africa. Poster presentation at International workshop on HIV and Adolescents, 2-4 October 2019
13. Rosenberg P, Briedenhann E, Mullick S. Nothing about us without us - Continuous & meaningful youth engagement built into demand creation for PrEP rollout to youth in South Africa. Poster presentation at International workshop on HIV and Adolescents, 2-4 October 2019
14. Makamu T, Rambally-Greener L, Lelaka MC, London V, Butler V, Mullick S. Health care provider's and adolescent girls and young women perspectives on how to engage youth for effective roll out of PrEP in South Africa. Poster presentation at International workshop on HIV and Adolescents, 2-4 October 2019
15. Briedenhann E, Rambally-Greener L, Rosenberg P, Sheobalak N, Subedar H, Mullick S. Holistic demand creation and community mobilisation for PrEP integration into comprehensive sexual reproductive and health (SRH) services for adolescent girls and young women (AGYW) supporting South African National PrEP programme. Poster presentation at International AIDS Society, 21-24 July 2019, Mexico City
16. Briedenhann E, Rambally-Greener L, Rosenberg P, Sheobalak N, Subedar H, Mullick S. Youth driven demand creation and community mobilisation to promote the use of PrEP, HIV, sexual and reproductive health services among adolescent girls and young women in South Africa. Poster presentation at International AIDS Society, 21-24 July 2019, Mexico City
17. Mullick S, Butler V, Greener L, Briedenhann E. Reaching young people where they are: Creating demand and providing PrEP services for young people. Non-Commercial Satellite
18. Briedenhann E, Rambally-Greener L, Rosenberg P, Sheobalak N, Subedar H, Mullick S. Holistic demand creation and community mobilisation for PrEP integration into comprehensive sexual reproductive and health (SRH) services for adolescent girls and young women (AGYW) supporting South African National PrEP programme. Poster presentation at INTEREST 14-17 May 2019, Accra, Ghana
19. Briedenhann E, Rambally-Greener L, Rosenberg P, Sheobalak N, Subedar H, Mullick S. Youth driven demand creation and community mobilisation to promote the use of PrEP, HIV, sexual and reproductive health services among adolescent girls and young women in South Africa. Poster presentation at INTEREST 14-17 May 2019, Accra, Ghana
20. Mullick S, Butler V, Greener L, Briedenhann E. Enhancing access to information and the provision of HIV prevention, testing and treatment services through scalable technologies and innovations among adolescents and young people. Satellite Session at SA AIDS Conference 11-14 June 2019

Annex F: Wits RHI selected list of publications

2. South to South Collaboration: Annual SA and Brazil Unitaid funded PrEP implementer disseminations

Additionally, Project PrEP and Brazil PrEP implementing partners hosted annual meetings to share learnings and lessons from each of their projects. A list of all Project PrEP presentations shared at these meetings is shown below:

Conference/Event Title	Date	Topic	Type
2019			
Project PrEP1519 ImPrEP and Project PrEP meeting as well as Unitaid and WHO visit to PrEP1519 sites	9-Oct-19	Developing an investment / impact case for oral PrEP – discussion points	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	10-Oct-19	Integrating PrEP into Comprehensive Services for Adolescent Girls and Young Women (AGYW) in South Africa	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	10-Oct-19	STIs: Frequency of occurrence among adolescents and possible treatment protocols	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	11-Oct-19	Demand Creation: Having fun and getting results	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	11-Oct-19	PrEP continuation and adherence: Main challenges, lessons learned and support tools	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	11-Oct-19	Project PrEP:Publications and Conferences	Presentation and discussion
2020			
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	28-Oct-20	Project PrEP:Routine monitoring data, national scale up and supporting the introduction of new technologies	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	28-Oct-20	Project PrEP:Connecting with the community through Peers and CBOs	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	28-Oct-20	Project PrEP:STI management	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	29-Oct-20	PrEP scalabity, transition, and creation of the necessary conditions for PrEP scale-up among adolescent KPs	Presentation and discussion
2021			
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	12-Dec-21	Achievements and lessons learned providing oral PrEP to AGYW 15 to 24 years	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	13-Dec-21	Site based best practices: Mthatha and eThekwini clusters	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	13-Dec-21	Integration of PrEP and SRH services	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	13-Dec-21	Innovative approaches to measure the impact of demand creation and social mobilisation on behaviour change: Best practices @ Project PrEP's Mthatha sites – A snapshot in time	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	14-Dec-21	Project PrEP South Africa Costed extension plans	Presentation and discussion
Project PrEP1519, ImPrEP and Project PrEP meeting - including Unitaid and WHO	14-Dec-21	JAH Supplement: Overview of planned papers	Presentation and discussion

Annex F: Wits RHI selected list of publications

3. Project PrEP learning and insights included in disseminations through other grants and learning networks

Additionally, the Project PrEP PI and other key project staff had further opportunities to share specific project lessons and insights on various other dissemination platforms. Platforms such as the PrEP Learning Network Webinar (that has an average reach of between 35 to 50 countries from Africa, Asia, South America, North America, and Europe per webinar) made possible by the USAID funded OPTIONS grant. This 5-year grant initially focused its work on 3 sub-Saharan countries, but from 2021 transitioned into a larger grant mechanism called MOSAIC that now focuses on 16 sub-Saharan countries (7 of those being core countries). The list below shows presentations, posters and abstracts shared through OPTIONS project platforms that had specific learnings and insights from Project PrEP:

Conference/Event Title	Date	Topic	Type
Faculty of Health Sciences Biennial Research Day and Postgraduate Expo	6-Sep-18	Insight-driven adaptation of PrEP communications materials for new key audiences: the South Africa experience	Poster
IAS 2019	21-24 Jul-19	Healthcare Providers' Attitudes and Experiences Delivering Oral PrEP to Adolescent Girls and Young Women: Implementation Research to Inform PrEP Rollout in Kenya, South Africa, and Zimbabwe	Mini Oral
INTEREST	14-17 May-19	Service provider insights: Implications for national training and support for PrEP provision in South Africa	Poster
International Workshop on HIV Adolescence 2019	2-4 Oct-19	Speak my language! Using digital media to reach and engage adolescents on oral PrEP	Oral
International Workshop on HIV Adolescence 2021	2-4 Oct-21	Mapping the Knowledge and Gaps in the Adolescent Girls and Young Women focused oral PrEP Implementation Projects and Trials in South Africa	Poster
Aids 2020	6-10 Jul-20	#IYKWIM… What AGYW really think about PrEP, HIV services and how we talk to them	Poster
YTH Live	2-3 Aug-20	LIGHTING STORY PrEP4Youth: Tackling stigma, side effects, and more through empowerment	Oral
OPTIONS PrEP Learning Network Webinar	23-Jul-20	PrEP4Youth Video: Addressing the Elephant in the Room: Stigma and PrEP Rollout	Presentation
OPTIONS PrEP Learning Network Webinar	25-Jun-20	Online training: The clinical management of oral PrEP, SA	Presentation
OPTIONS PrEP Learning Network Webinar	23-Apr-20	PrEP Delivery in the Context of Covid-19	Presentation

4. Disseminations on Cross Cutting Platforms -the Project PrEP PI and other key project staff had further opportunities to share project lessons and insights on various other cross cutting platforms. The list below shows presentations shared on these platforms.

Conference/Event Title	Date	Topic	Type
WHO STI and PrEP Think Tank Meeting	14-15 Mar-19	Integrating PrEP into Comprehensive Services for Adolescent Girls and Young Women (AGYW) in	Presentation
Stepped care core group meeting (SA)	28-Jan-20	Rethinking unmet healthcare needs among adolescents and youth: Reaching young people and	Presentation
WHO Global PrEP Network webinar on STIs and PrEP	21-Sep-21	Integration of STI management into PrEP programmes: A South African experience	Presentation
Unicef and Partners Webinar	23-Nov-21	Achieving more for Young Women and Girls Achieving more for Young Women and Girls: Sharin	Presentation
Digital Health Conference	6-Dec-21	Stepping up for Sexual Health! Supporting self-care and linkage to care with integrated online se	Presentation
ICASA	21-Dec	UNAIDS – WHO – PrEP non-abstract driven plenary session; PrEP in Africa: Success and challeng	Session co-chair (Project PrEP PI)

Annex G: Fiotec selected list of publications

PUBLISHED PAPERS

- Zucchi EM, Couto MT, Castellanos M, Dumont-Pena E, Ferraz D, Félix Pinheiro T, Grangeiro A, da Silva LAV, Dourado I, Pedrana L, Santos FSR, Magno L. Acceptability of daily pre-exposure prophylaxis among adolescent men who have sex with men, travestis and transgender women in Brazil: A qualitative study. PLoS One. 2021 May 4;16(5):e0249293. doi: 10.1371/journal.pone.0249293. PMID: 33945527; PMCID: PMC8096080.
- Ferraz D, Dourado I, Zucchi EM, Mabire X, Magno L, Grangeiro AD, Couto MT, Ferguson L, Westin M, Alves Dos Santos L, Préau M. Effects of the Covid-19 pandemic on the sexual and mental health of adolescent and adult men who have sex with men and transgender women participating in two PrEP cohort studies in Brazil: COBra study protocol. BMJ Open. 2021 Apr 1;11(4):e045258. doi: 10.1136/bmjopen-2020-045258. PMID: 33795308; PMCID: PMC8024057.
- Dourado I, Magno L, Soares F, Massa P, Nunn A, Dalal S, Grangeiro A; Brazilian PrEP1519 Study Group. Adapting to the Covid-19 Pandemic: Continuing HIV Prevention Services for Adolescents Through Telemonitoring, Brazil. AIDS Behav. 2020 Jul;24(7):1994-1999. doi: 10.1007/s10461-020-02927-w. PMID: 32440973; PMCID: PMC7241065.
- Factors Associated With Willingness to Use Pre-Exposure Prophylaxis in Brazil, Mexico, and Peru: Web-Based Survey Among Men Who Have Sex With Men. Torres TS, Konda KA, Vega-Ramirez EH, Elorreaga OA, Diaz-Sosa D, Hoagland B, Diaz S, Pimenta C, Benedetti M, Lopez-Gatell H, Robles-Garcia R, Grinsztejn B, Caceres C, Veloso VG, ImPrEP Study Group. JMIR Public Health Surveill 2019;5(2):e13771. https://doi.org/10.2196/13771
- How heterogeneous are MSM from Brazilian cities? An analysis of sexual behavior and perceived risk and a description of trends in awareness and willingness to use pre-exposure prophylaxis. Thiago S Torres, Luana MS Marins, Valdilea G Veloso, Beatriz Grinsztejn, Paula M Luz. BMC Infectious Diseases 2019 Dec 19;19(1):1067. https://doi.org/10.1186/s12879-019-4704-x
- Telemedicine as a tool for PrEP delivery during the COVID-19 pandemic in a large HIV prevention service in Rio de Janeiro-Brazil. Hoagland B, Torres TS, Bezerra DRB, Geraldo K, Pimenta C, Veloso VG, Grinsztejn B. Braz J Infect Dis. 2020 Jul-Aug;24(4):360-364. Epub 2020 May 31. PMID: 32504552 https://doi.org/10.1016/j.bjid.2020.05.004
- Impact of COVID-19 Pandemic on Sexual Minority Populations in Brazil: An Analysis of Social/Racial Disparities in Maintaining Social Distancing and a Description of Sexual Behavior. Torres TS, Hoagland B, Bezerra DRB, Garner A, Jalil EM, Coelho LE, Benedetti M, Pimenta C, Grinsztejn B, Veloso VG.AIDS Behav. 2020 Jul 31:1-12. Online ahead of print. PMID: 3273781 doi: https://doi.org/10.1007/s10461-020-02984-1.
- High acceptability of PrEP teleconsultation and HIV self-test among PrEP users during the COVID-19 pandemic in Brazil. Brenda Hoagland, Thiago S. Torres, Daniel R.B. Bezerra, Marcos Benedetti, Cristina Pimenta, Valdilea G. Veloso, Beatriz Grinsztejn. Braz J Infect Dis. 2020. Online ahead of print https://doi.org/10.1016/j.bjid.2020.11.002 .
- High-Risk Sexual Behavior, Binge Drinking and Use of Stimulants are Key Experiences on the Pathway to High Perceived HIV Risk Among Men Who Have Sex with Men in Brazil. Paula Luz, Thiago S. Torres, Celline C. Almeida-Brasil; Luana M. S. Marins; Valdilea G. Veloso; Beatriz Grinsztejn; Joseph Cox; Erica E. M. Moodie. AIDS and Behavior. Published online 17 September 2020. https://doi.org/10.1007/s10461-020-03035-5
- Barreiras e facilitadores do acesso de populações vulneráveis à PrEP no Brasil: estudo qualitativo ImPrEP Stakeholders. Maria Cristina Pimenta de Oliveira, Bruno Kauss, Marcos Renato Benedetti, Ívia Maksud, Alcinda Maria Godoi, Ximena Pamela Bermúdez, Brenda Hoagland, Thiago S. Torres, Beatriz Grinsztejn, Valdiléa G. Veloso. Cadernos de Saúde Pública. 2022; 38(1):e00290620 http://dx.doi.org/10.1590/0102-311X00290620.
- Are men who have sex with men at higher risk for HIV in Latin America more aware of PrEP? Ryan D. Assaf; Kelika A. Konda, Thiago S. Torres, E. Hamid Vega-Ramirez, Oliver A. Elorreaga, Dulce Diaz-Sosa, Steven D. Diaz, Cristina Pimenta, Rebeca Robles, Maria Elena Medina-Mora, Beatriz Grinsztejn, Carlos Caceres, Valdilea G. Veloso. PLoS ONE 16(8): e0255557. August 13, 2021 https://doi.org/10.1371/journal.pone.0255557
- Low socioeconomic status is associated with self-reported HIV positive status among young MSM in Brazil and Peru. Thiago S. Torres, Lara E. Coelho, Kelika A. Konda, E. Hamid Vega-Ramirez, Oliver A. Elorreaga, Dulce Diaz-Sosa, Brenda Hoagland, Cristina Pimenta, Marcos Benedetti, Beatriz Grinsztejn, Carlos F. Caceres and Valdilea G. Veloso. BMC Infectious Diseases (2021) 21:726. Published online 31 July 2021. https://doi.org/10.1186/s12879-021-06455-3 .
- Preferences for pre- exposure prophylaxis (PrEP) among men who have sex with men and transgender women at risk of HIV infection: a multicentre protocol for a discrete choice experiment in Brazil Claudia Cristina de Aguiar Pereira, Thiago Silva Torres, Paula Mendes Luz, Brenda Hoagland, Alessandro Farias, Jose David Urbaez Brito, Marcus Vinícius Guimarães Lacerda, Daila Alena Raenck da Silva, Marcos Benedetti, Maria Cristina Pimenta, Beatriz Grinsztejn, Valdilea Gonçalves Veloso.. BMJ Open 2021; 11:e049011. http://dx.doi.org/10.1136/bmjopen-2021-049011

Annex G: Fiotec selected list of publications

PUBLISHED PAPERS

- High rates of sexualized drug use or chemsex among Braziliantransgender women and young sexual and gender minorities. Emilia M. Jalil, Thiago S. Torres, Claudia Pereira, Alessandro Farias, Jose D. U. Brito, Marcus Lacerda, Daila A. R. da Silva, Nickols Wallys, Gabriela Ribeiro, Joyce Gomes, Thiffany Odara, Ludymilla Santiago, Sophie Nouveau, Marcos Benedetti, Cristina Pimenta, Brenda Hoagland, Beatriz Grinsztejn and Valdilea G. Veloso. International Journal of Environmental Research and Public Health, 2022, 19,1704. (https://www.mdpi.com/journal/ijerph/sections/public_health) https://doi.org/10.3390/ijerph19031704
- Awareness, knowledge, and attitudes related to HIV pre-exposure prophylaxis and other prevention strategies among physicians from Brazil and Mexico: cross-sectional web-based survey. Vega-Ramirez H, Torres TS, Guillen-Diaz C, Pimenta C, Diaz-Sosa D, Konda KA, da Cunha ARC, Robles-Garcia R, Benedetti M, Hoagland B, Bezerra DRB, Caceres CF, Grinsztejn B, Veloso VG; ImPrEP Study Group. BMC Health Serv Res. 2022 Apr 22;22(1):532. doi: 10.1186/s12913-022-07900-y. PMID: 35459177; PMCID: PMC9027096.
- Awareness, willingness, and barriers to HIV Self-testing (HIVST) among Men who Have Sex with Men (MSM) in Brazil, Mexico, and Peru: A web-based cross-sectional study. Oliver A. Elorreaga, Thiago S. Torres, E. Hamid Vega-Ramirez, Kelika A. Konda, Brenda Hoagland, Marcos Benedetti, Cristina Pimenta, Dulce Diaz-Sosa, Rebeca Robles-Garcia, Beatriz Grinsztejn, Carlos F. Caceres, Valdilea G. Veloso. PLOS Global Public Health 2(7): e0000678. https://doi.org/10.1371/journal.pgph.0000678
- HIV Risk Perception and Pre-exposure Prophylaxis (PrEP) Awareness among Transgender Women from Mexico. Centli Guillen-Diaz-Barriga; Dulce Diaz-Sosa; Thiago S. Torres; Kelika A. Konda; Rebeca Robles-Garcia; Brenda Hoagland; Marcos Benedetti; Cristina Pimenta; Beatriz Grinsztejn; Carlos F. Caceres; Valdilea G. Veloso; Hamid Vega-Ramirez. AIDS and Behavior (published online Sept 22). https://doi.org/10.1007/s10461-022-03836-w
- Factors associated with long-term pre-exposure prophylaxis (PrEP) engagement and PrEP adherence among transgender women (TGW) in Brazil, Mexico and Peru: Results from the ImPrEP study. Konda, Kelika; Torres, Thiago; Mariño, Gabriela; Ramos, Alejandra; Ismerio, Ronaldo; Leite, Iuri; Cunha, Marcelo; Jalil, Emilia; Hoagland, Brenda; Guanira, Juan; Benedetti, Marcos; Pimenta, Cristina; Vermandere, Heleen; Bautista-Arredondo, Sergio; Vega-Ramirez, Hamid; Veloso, Valdilea; Cáceres, Carlos; Grinsztejn, Beatriz. Journal of the International AIDS Society. Volume25, IssueS5. Supplement: Improving the HIV response for transgender populations: evidence to inform action. Guest Editors: Tonia Poteat, Nittaya Phanuphak, Beatriz Grinsztejn, Sari L. Reisner. October 2022. e25974. https://doi.org/10.1002/jia2.25974

ACCEPTED PAPERS

- Dourado I, Sousa LMS, Greco DB, Zucchi EM, Ferraz DAS, Westin MR, Grangeiro A. Interdisciplinarity in HIV prevention research: the experience of the PrEP1519 study protocol among adolescent MSM and TGW in Brazil. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Silva LAV, Brasil SA, Duarte FM, Cunha LA, Castellanos MEP. Between risk and pleasure: reflections on HIV prevention and care in the current context of PrEP use by men who have sex with men. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Pena D, Westin MR, Duarte MJ, Greco M, Silva AP, Martinez YF, Tupinambás U. When prevention is the best remedy: meanings of HIV pre-exposure prophylaxis (PrEP) among gay adolescents, transgender women and transvestites in Belo Horizonte. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Westin MR, Martinez YF, Silva AP, Greco M, Marques LM, Barreto G, Alves MP, Mancuzzo A, Tupinambás U. Prevalence of syphilis and sexual behavior and practices among MSM and TGW adolescents in a Brazilian multi-center cohort for daily use of PrEP. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Santos LA, Unsain RF, Brasil SA, Silva LAV, Duarte FM, Couto MT. PrEP experiences of adolescent gay and bisexual men: an intersectional analysis. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Sousa LMS, Medeiros DS, Soares F, Grangeiro A, Caires P, Fonseca T, Westin MR, Dourado MIC. HIV prevalence and care continuum among adolescent men who have sex with men in Salvador, Brazil: a baseline study of the PrEP1519 cohort. [Accepted for publication in a supplement of the Reports in Public Health 2022].
- Martins GB, Pinheiro TF, Ferraz DAS, Grangeiro A, Zucchi EM. Use of HIV prevention methods and contexts of the sexual practices of adolescent gay and bisexual men, travestites and transgender women in São Paulo, Brazil.

Annex G: Fiotec selected list of publications

ARTICLES UNDER DEVELOPMENT AND/OR SUBMITTED FOR JOURNAL PUBLICATION

- Valdiléa Gonçalves Veloso; Carlos F. Cáceres; Brenda Hoagland; Ronaldo I. Moreira; Hamid Vega-Ramírez; Kelika A. Konda; Iuri C. Leite; Sergio Bautista-Arredondo; Marcus Vinícius Lacerda; José Valdez Madruga; Alessandro Farias; Josué N. Lima; Ronaldo Zonta; Lilian Lauria; Cesar Vidal Osco Tamayo; Hector Javier Salvatierra Flores; Yovanna Margot Cabrera Santa Cruz; Ricardo Martín Moreno Aguayo; Marcelo Cunha; Júlio Moreira; Alessandra Ramos Makkeda; Steven Díaz; Juan V. Guanira; Heleen Vermandere; Marcos Benedetti; Heather L. Ingold; M. Cristina Pimenta; Thiago S. Torres; Beatriz Grinsztejn. Same-day oral pre-exposure prophylaxis (PrEP) implementation, PrEP adherence and engagement among cisgender gay, bisexual and other men who have sex with men and transgender women in Brazil, Mexico and Peru: the ImPrEP study. The Lancet HIV (submitted and accepted for publication.)
- Claudia Cristina de Aguiar Pereira; Thiago Silva Torres; Paula Mendes Luz; Brenda Hoagland; Alessandro Farias; José David Urbaez Brito; Marcus Vinícius Guimarães Lacerda; Dalia Alena Raenck Silva; Marcos Benedetti; Maria Cristina Pimenta; Beatriz Grinsztejn; Valdilea Gonçalves Veloso. Preferences for pre-exposure prophylaxis (PrEP) among sexual and gender minorities at risk of HIV infection: a discrete choice experiment in Brazil. The Lancet Regional Health – Americas (submitted, under review).
- Thiago S Torres, Alessandro R Nascimento, Lara E Coelho, Kelika A Konda, E Hamid Vega-Ramirez, Oliver A Elorreaga, Dulce Diaz-Sosa, Brenda Hoagland, Juan V. Guanira, Cristina Pimenta, Marcos Benedetti, Beatriz Grinsztejn, Carlos F. Caceres, Valdilea G. Veloso. PrEP preferences among gay, bisexual and other men who have sex with men (MSM) from Latin America: long-acting injectable as the most preferred PrEP modality. (under finalization for submission)
- Maria Cristina Pimenta de Oliveira, Bruno Kauss, Marcos Renato Benedetti, Ívia Maksud, Alcinda Maria Godoi, Ximena Pamela Bermúdez, Brenda Hoagland, Thiago S. Torres, Beatriz Grinsztejn, Valdiléa G. Veloso. “Experiences of gays, men who have sex with other men, transgender women and travestis (transvestites), with HIV Pre-Exposure Prophylaxis (PrEP) in Brazil – a qualitative study.” (submitted to the journal – Culture, Health and Sexuality)
- Ximena Pamela Bermúdez, Maria Cristina Pimenta de Oliveira, Alcinda Maria Godoi, Bruno Kauss, Marcos Renato Benedetti, Ívia Maksud, Brenda Hoagland, Thiago S. Torres, Beatriz Grinsztejn, Valdiléa G. Veloso. “Living a policy: methodological notes on the implementation of PrEP strategy in Brazil” (Currently under finalization to be submitted for journal review)
- Paula M. Luz; Vijeta Deshpande; Pooyan Kazemian; Justine A. Scott; Fatma M. Shebl; Cristina Pimenta, Madeline Stern, Gerson Pereira, Claudio J. Struchiner, Beatriz Grinsztejn, Valdilea G. Veloso, A. David Paltiel, Kenneth A. Freedberg, “Transmission impact of pre-exposure prophylaxis uptake among gay, bisexual and other men who have sex with men in urban centers in Brazil” (submitted for publication at JIAS, under review).

CONFERENCE ABSTRACTS

- MAGNO L, SOARES F, EUSTORGIO FILHO M, GRANGEIRO A, FERRAZ D, ZUCCHI EM, MASSA P, ESCUDER M, DOURADO I. Effectiveness of strategies for generating demand for PrEP and combination prevention among adolescent´s men who have sexwith men and transgender women in Brazil Type: Research. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- MAGNO L, MEDEIROS D, SOARES F, SANTOS CJM, DUARTE FM, GRANGEIRO A, DOURADO I. Demand creation and HIV self-testing delivery during Covid-19 contingency measures of physical distancing among adolescents key population enrolled in PrEP in Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021. v. 24. p. e25755.
- DUARTE FM, CASTELLANOS ME, SILVA LAV, BRASIL S, SILVA L, PEDRANA L, OLIVEIRA R, MAGNO L, DOURADO I. 'I had condomless sex, but I'm calm because I use PrEP': experiences of adolescent’s men who have sex with men and transgender women with daily oral PrEP in Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- PEDRANA L, MAGNO L, SILVA LAV, CASTELLANOS ME, BRASIL S, OLIVEIRA R, DUARTE FM, GRANGEIRO A, ZUCCHI EM, FERRAZ D, DOURADO I. Zero knowledge and high acceptability of long-acting injectable PrEP among adolescents men who have sex with men and transgender women in Northeast Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- SOARES F, MAGNO L, EUSTORGIO FILHO M, DUARTE FM, CAIRES P, GRANGEIRO A, MASSA P, GRECO D, TUPINAMBAS U, DOURADO I. Factors associated with PrEP uptake among adolescent´s men who have sex with men and transgender women in Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- SALGADO VJ, OLIVEIRA CM, MARQUES LM, CAMPOS GB, SILVA AMB, BRITO HIL, MAGNO L, MEDEIROS D, SOARES F, DOURADO I. Bacterial STI rates by pharyngeal, urethral and rectal sites among adolescents men who have sex with men in Northeast Brazil: the importance of comprehensive sample collection sites. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- OLIVEIRA CM, SALGADO VJ, MARQUES LM, CAMPOS GB, MAGNO L, SILVA AMB, BRITO HIL, MEDEIROS D, SOARES F, NASCIMENTO PR, FONSECA T, WESTIN M, DOURADO I. High prevalence of bacterial sexually transmitted infections among Brazilian adolescents men who have sex with men in Northeast Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.

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CONFERENCE ABSTRACTS

- BRASIL S, ZUCCHI EM, SILVA LAV, FERRAZ D, DUARTE FM, MASSA P, MAGNO L, BILLAND J, CASTELLANOS ME, GRANGEIRO A, PEDRANA L, OLIVEIRA R, SILVA L, DOURADO I. 'Reaching adolescents where they are: Innovative recruitment strategies for PrEP enrolment of adolescent´s key population in Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. 11th IAS Conference on HIV Science, 2021.
- DOURADO I, MAGNO L, GRECO D, ZUCCHI EM, FERRAZ D, GRANGEIRO A. Construindo laços: a interdisciplinaridade na coorte PrEP15 19 com adolescentes gays e mulheres trans. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia, 2021. v. 2.
- SANTOS CJM, MAGNO L, CAIRES P, SOARES F, DOURADO I. Adaptação de serviço de prevenção ao HIV e outras IST para adolescentes durante a pandemia da Covid-19. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 2.
- ZEBALLOS, D. ; PEREIRA, M. ; MAGNO, L ; DOURADO, I. . Revisão sistemática de adesão à profilaxia-pré exposição (PrEP) entre adolescentes e jovens.. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia, 2021. v. 1.
- CAIRES P, MAGNO L, SOARES F, DOURADO I, FONSECA T. Diagnóstico e busca ativa para tratamento de IST em populações-chave em salvador. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 2.
- FONSECA T, MAGNO L, CAIRES P, SOARES F, DOURADO I. Navegação por pares: estratégia de adesão à profilaxia pré-exposição entre adolescentes. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 1.
- MEDEIROS D, MAGNO L, EUSTORGIO FILHO M, GRANGEIRO A, GRECO D, DOURADO I. Fatores associados a sintomas depressivos entre adolescentes gays e mulheres trans. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 2.
- MAGNO L, MEDEIROS D, SOARES F, GRANGEIRO A, CAIRES P, FONSECA T, WESTIN M, DOURADO I. Prevalência de HIV entre adolescentes homens que fazem sexo com homens em Salvador, Brasil. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 1.
- ZEBALLOS D, PEREIRA M, MAGNO L, DOURADO I. Revisão sistemática: adesão à profilaxia pré-exposição ao HIV entre adolescentes e jovens. In: 11º Congresso Brasileiro de Epidemiologia, 2021, Fortaleza. Anais do 11º Congresso Brasileiro de Epidemiologia. Campinas: Galoá, 2021. v. 2.
- GRANGEIRO A, MAGNO L, FERRAZ D, ESCUDER M, ZUCCHI EM, KOYAMA M, MASSA P, SOARES F, SANTOS LA, WESTIN MR, PREAU M, MABIRE X, DOURADO I. High risk sexual behavior, access to HIV prevention services and HIV incidence during the Covid-19 pandemic among men who have sex with men and transgender women in Brazil. In: 11th IAS Conference on HIV Science, 2021, Berlim. Abstracts of the 11th IAS Conference on HIV Science, 18-21 July 2021, 2021. p. 358.

AIDS 2018, 2020, 2022

- V. G. Veloso, C. Caceres, E.H. Vega-Ramirez, M. C. Pimenta de Oliveira. Workshop entitled “PrEP demonstration projects in middle-income countries: Preparation and implementation. The ImPrEP project in Brazil, Mexico and Peru.”
- K. Konda, T.S. Torres, H. Vega-Ramirez, O. Elorreaga, C. Guillén-Díaz-Barriga, D. Diaz, B.Hoagland, J.V. Guanira, M. Benedetti, C. Pimenta, H. Vermandere, S. Bautista-Arredondo, V.G.Veloso, B. Grinsztejn, C.F. Caceres, for the ImPrEP Study Group. Awareness of U=U among sexual and gender minorities in Brazil, Mexico, and Peru:Differences according to self-reported HIV status. Presented as a poster
- K. Konda, B. Hoagland, K. Campos, N. Fernandes, G. Calvo, C. Pimenta, M. Benedetti, T.S.Torres, C. Rocha, J.R. Grangeiro, E. Bastos, S. Nazer, R. Ismerio Moreira, M.T.L. de Vasconcellos, L.A.Camacho, C. Palombo, C.F. Caceres, B. Grinzstejn, V.G. Veloso, for the ImPrEP study. HIV Self-Testing to Increase Combination Prevention Demand Among Men who have Sexwith Men (MSM) and Transgender Women (TGW): A Randomized Clinical Trial and Sub-Studyof the ImPrEP Project. Presented as a poster
- K. Konda, O. Elorreaga, T.S. Torres, H. Vega-Ramirez, C. Guillén-Díaz-Barriga, D. Diaz, B.Hoagland, J.V. Guanira, M. Benedetti, S. Bautista-Arredondo, V.G. Veloso, C.F. Caceres, B.Grinsztejn, for the ImPrEP Study Group. Profiles of Pre-Exposure Prophylaxis (PrEP) Modality Preferences among Brazilian, Mexican,and Peruvian Sexual and Gender Minorities (SGM). Presented as a poster
- M. Benedetti; X.P. Bermúdez, A. Godoi, I. Maksud, B. Kauss, T. S. Torres, B. Hogland, B. Grinsztejn, V. G. Veloso, M.C. Pimenta, ImPrEP Study Group. Qualitative study on PrEP implementation among Men Who Have Sex with Men and Transgender Women in Brazil: the user’s perspectives. Presented as a poster

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CONFERENCE ABSTRACTS
AIDS 2018, 2020, 2022

- T.S.Torres, E. M. Jalil, C.C. d.A. Pereira, D. R. B. Bezerra, A. Farias, J.D. Brito, M. Lacerda. D. Silva, G. Ribeiro, M. Rebouças, V. Casaroto, A. Barbosa, J. Cunha, J. Pimenta, M. Benedetti, C. Pimenta, B. Hoagland, B. Grinsztejn, V. G. Veloso, ImPrEP DCE Study Group. Comparing the characteristics of Brazilian gay, bisexual and other cisgender men who have sex with men (MSM) according to recruitment strategy: online approach as na useful tool during COVID-19 pandemic. Presented as a poster
- V. G Veloso; E. H. Vega-Ramírez; B. Hoagland; K. A. Konda; S. Bautista- Arredondo; J. V. Guanira; T. Torres; C. Pimenta; H Vermandere; A. Farias; Lacerda MVG; M. Benedetti; S. Diaz; P.M Luz; I. C. Leite; R. I. Moreira; J. Moreira J; B. Grinsztejn; C. Cáceres, for the ImPrEP Study Team. *Factors associated with early continuation (EC) of Pre-exposure prophylaxis (PrEP) among young MSM (YMSM) in Brazil, Peru and Mexico: the ImPrEP Study*. Oral presentation at the session "Next Steps in PrEP", available at http://programme.aids2020.org/Programme/Session/58
- Diego Cerecero-García, Heleen Vermandere, José Gomez-Castro, Luis Alberto Moreno-Aguilar, Arantxa Colchero-Aragonés, Gisela Martínez-Silva, Araczy Martínez-Dávalos, Ivonne Huerta-Icelo, Sergio Bautista-Arredondo. *Awareness, willingness to use, and willingness to pay for different PrEP schemes among MSM in Mexico*. Presented as virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/8906
- J.V. Guanira, K.A. Konda, A. Ramos, R. Ismerio Moreira, I. Leite, B. Hoagland, M. Benedetti, G. Mariño, M. Vinicius Lacerda, B. Grinsztejn, E.H. Vega-Ramirez, C.F. Caceres, V. Veloso, ImPrEP Study Group. *Early Engagement on PrEP among Transgender Women in Latin America: The ImPrEP Experience.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/5358
- Carlos Cáceres; Kelika Konda; Gino Calvo, Juan Vicente Guanira; Hamid Vega-Ramírez; Carlos Benítes; Valdiléa Veloso, ImPrEP Study Group. *PrEP Roll-out in Latin America Should Aim to Increase Awareness among Eligible Individuals to Prevent Refusal, and Provide Support to New Users to Prevent Early Discontinuation.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/8838
- Thiago S. Torres, Brenda Hoagland, Daniel RB Bezerra, Alex Garner, Kim Geraldo, Lucilene Freitas, Sandra W. Cardoso, Emilia Jalil, Lara E. Coelho, Marcos Benedetti, Cristina Pimenta, Beatriz Grinsztejn, Valdilea G. Veloso. *Social and racial disparities are associated with unattainability of maintaining social distancing during the COVID-19 pandemic among men who have sex with men and transgender/non-binary populations in Brazil*. Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/11253
- Thiago S. Torres, Brenda Hoagland, Daniel RB Bezerra, Alex Garner, Kim Geraldo, Lucilene Freitas, Sandra W. Cardoso, Emilia Jalil, Lara E. Coelho, Marcos Benedetti, Cristina Pimenta, Beatriz Grinsztejn, Valdilea Veloso. *Sexual behavior and PrEP use among sexual minorities during COVID-19 pandemic in Brazil*. Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/11282
- Diego Cerecero-Garcia, Heleen Vermandere, José Gómez-Castro, José Arturo Sánchez-Ochoa, Araczy Martínez-Dávalos, Ivonne Huerta-Icelo, Ietza Bojorquez, Sergio Bautista-Arredondo. *Assessing the prevalence of depressive symptoms among PrEP users during the COVID-19 outbreak in Mexico. A Latent Class Analysis.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/11595
- T.S. Torres, L.E. Coelho, K.A. Konda, E.H. Vega-Ramirez, O.A. Elorreaga, D. Diaz-Sosa, B. Hoagland, J.V. Guanira, C. Pimenta, M. Benedetti, B. Grinsztejn, C. Caceres, V. Veloso, ImPrEP Study Team. *MSM at high HIV risk in Latin America prefer long-acting PrEP***.** Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/2779
- Satellite Symposium entitled "Moving forward PrEP programming for MSM and Trans Women in Latin America: lessons learnt from the ImPrEP Project". Presentations by: Giovanni Ravasi - *Update on PrEP implementation in Latin America,* Valdilea Veloso – *Lessons from ImPrEP project in Brazil,* Carlos Cáceres - *Lessons from ImPrEP project in Peru,* Sérgio Bautista-Arredondo - *Lessons from ImPrEP project in Mexico*
- Thiago Torres, Hamid Vega-Ramirez, Kelika Konda, Oliver Elorreaga, Centli Guillén-Díaz-Barriga, Dulce Diaz, Brenda Hoagland, Juan V. Guanira, Marcos Benedetti, Cristina Pimenta, Heleen Vermandere, Sergio Bautista-Arredondo, Valdilea G. Veloso, Carlos F. Caceres, Beatriz Grinsztejn, for the ImPrEP Study Group. Changes in Awareness and Willingness to use pre-exposure prophylaxis (PrEP) among men who have sex with men (MSM) in Latin America between 2018 and 2021: Results from the ImPrEP project. Presented as a poster
- Heleen Vermandere, Gisela Martínez-Silva, Santiago Aguilera-Mijares, Araczy Martínez-Dávalos, Sergio Bautista-Arredondo. An evaluation of the HIV risk screening and enrollment process in Mexico's pre-exposure prophylaxis demonstration project— the ImPrEP study. Presented as a poster
- Santiago Aguilera-Mijares, Araczy Martínez-Dávalos, Sergio Bautista-Arredondo, Heleen Vermandere. The PrEP care continuum among men who have sex with men and transwomen: ImPrEP Mexico. Presented as a poster
- Cruz Bañares A., Rojas A., Martínez-Dávalos A., Aguilera-Mijares S., Bautista-Arredondo S., Vermandere H. PrEP and telemedicine in times of COVID-19: experiences of health professionals in Mexico. Presented as a poster

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CONFERENCE ABSTRACTS

AIDS 2018, 2020, 2022

- O.A. Elorreaga, K.A. Konda, J. Guanira, G.M. Calvo, S.K. Vargas, A. Borquez, C.F. Caceres, for the ImPrEP Study Group. Sexual behavior and HIV prevalence among Venezuelans immigrants in Peru: a study among men who have sex with men (MSM) and transgender women (TGW) screened for preexposure prophylaxis (PrEP). Presented as a poster
- J. P. Jirón Sosa, K. A. Konda, C. Sandoval, C. F. Cáceres. Health care providers' perspectives on PrEP Adherence among MSM and TGW in Peru: a qualitative study of the ImPrEP demonstration study.). Presented as a poster
- O.A. Elorreaga, K.A. Konda, K.E. Campos, G.M. Calvo, T.S. Torres, C.F. Caceres, for the ImPrEP Study Group. Which are the most valued pre-exposure prophylaxis (PrEP) attributes? A discrete choice experiment among men who have sex with men (MSM) and transgender women (TW) in Peru. Presented as a poster
- Satellite Symposium entitled "Evidence for PrEP implementation in Latin America: ImPrEP project results". Presentations by: Gerson Pereira – Opening remarks, Valdiléa Veloso - PrEP Outcomes among MSM and Transgender women in Brazil - Results and lessons learned from the ImPrEP study, Hmaid Vega-Ramírez - The ImPrEP outcome in Mexico: Implementing PrEP in public health and community services. Carlos Cáceres - Focusing on PrEP discontinuation among those most vulnerable to HIV in Peru: Challenges Ahead for Latin America. Hortencia Peralta - The situation of PrEP in the LAC Region: Implementation, Challenges and Opportunities. Beatriz Grinsztejn - The way forward – ImPrEP CAB LA

CROI 2019, 2020, 2021, 2022

- Ryan D. Assaf, Kelika A. Konda, Thiago S. Torres, E. Hamid Vega-Ramirez, Oliver A. Elorreaga-Reyes, Dulce Diaz-Sosa, Steven D. Diaz, Cristina Pimenta, Hugo López-Gatell, Rebeca Robles-Garcia, Beatriz Grinsztejn, Carlos Caceres, Valdilea Veloso. *Association of Higher Risk and PrEP Awareness among MSM in Brazil, Mexico, and Peru*. Abstract # 975 (available at https://www.croiconference.org/sessions/association-higher-risk-and-prep-awareness-among-msm-brazil-mexico-and-peru)
- Vincent B. Ofori, Ryan D. Assaf, Kelika A. Konda, Thiago S. Torres, E. Hamid Vega-Ramirez, Oliver A. Elorreaga-Reyes, Dulce Diaz-Sosa, Steven D. Diaz, Cristina Pimenta, Hugo López-Gatell, Rebeca Robles-Garcia, Beatriz Grinsztejn, Carlos Caceres, Valdilea Veloso. *PrEP-related Barriers among Men Who Have Sex With Men in Brazil, Mexico & Peru.* Abstract # 976. (available at https://www.croiconference.org/sessions/prep-related-barriers-among-men-who-have-sex-men-brazil-mexico-peru)
- Thiago S. Torres, Kelika A. Konda, E. Hamid Vega-Ramirez, Oliver A. Elorreaga-Reyes, Dulce Diaz-Sosa, Cristina Pimenta, Brenda Hoagland, Hugo López-Gatell, Rebeca Robles-Garcia, Steven D. Diaz, Beatriz Grinsztejn, Carlos Caceres, Valdilea Veloso. Willingness to use HIV Self-testing among MSM in Brazil, Mexico and Peru. Abstract # 936 (Available at: https://www.croiconference.org/sessions/willingness-use-hiv-self-testing-among-msm-brazil-mexico-and-peru)
- Thiago S Torres**,** Lara E Coelho, Kelika A Konda, E Hamid Vega-Ramirez, Oliver A Elorreaga, Dulce Diaz-Sosa, Brenda Hoagland, Cristina Pimenta, Marcos Benedetti, Beatriz Grinsztejn, Carlos Caceres, Valdilea Veloso, for the ImPrEP Study Group. *Socioeconomic Disparities Are Associated with HIV in Young MSM in Latin America*. Poster # 1569 CROI 2020
- Paula M. LUZ, Vijeta DESHPANDE, Pooyan KAZEMIAN, Justine A. SCOTT, Fatma M. SHEBL, Cristina PIMENTA, Madeline STERN, Gerson PEREIRA, Claudio J. STRUCHINER, Beatriz GRINSZTEJN, Valdilea G. VELOSO, Kenneth A. FREEDBERG, A. David PALTIEL. *Transmission impact of PrEP uptake in urban centers in Brazil: a modeling study*. Oral presentation at CROI 2021.
- Annick Borquez, Kelika Konda, Oliver Elorreaga, Ximena Gutierrez, Juan Guanira, Sonia Flores, Gino Calvo, Carlos Cáceres. *Modeling PrEP impact and cost-effectiveness based on the ImPrEP demonstration project.* Oral presentation at CROI 2021.
- Valdiléa G. Veloso, Ronaldo I. Moreira, Kelika. A. Konda, Brenda Hoagland, Hamid Vega-Ramírez, Iuri C. Leite, Juan V. Guanira, Sergio Bautista-Arredondo, Hellen Vermandere, Marcos R Benedetti, M. Cristina Pimenta, Thiago S. Torres, Beatriz Grinsztejn, Carlos F. Cáceres, for ImPrEP Study Group. PrEP long-term engagement among MSMand TGW in Latin America – the ImPrEP Study. Presented as a poster
- Hamid Vega-Ramírez, Centil Guillén Díaz-Barriga, Dulce Díaz, Kelika A. Konda, Thiago S. Torres, Oliver A. Elorreaga, Brenda Hoagland, Juan V. Guanira, Marcos R Benedetti, Sergio Bautista-Arredondo, Beatriz Grinsztejn, Carlos Cáceres, Valdilea Veloso, for ImPrEP Study Group. Mental Health and PrEP Adherence among MSM/non-cisgender people from Latin America. Presented as a poster

Annex G: Fiotec selected list of publications

IAS 2019, 2021

- C.F. Caceres, K. Konda, G. Calvo, J.V. Guanira, X. Salazar, A. Nunez-Curto, S. Vargas, E. Lugo, X. Gutierrez, B. Huaman, ImPrEP Study Group. *Challenges and barriers to PrEP implementation in public health facilities in Latin America: Initial lessons from the ImPrEP demonstration project in Peru.* Poster # TUPEC416 (available at http://programme.ias2019.org/Abstract/Abstract/3048)
- E.H. Vega-Ramirez, T.S. Torres, K.A. Konda, D. Diaz-Sosa, R. Robles, O.A. Elorreaga-Reyes, B. Hoagland, S. Diaz, C. Pimenta, M. Benedetti, H. Lopez-Gatell Ramírez, B. Grinsztejn, C.F. Caceres, V.G. Veloso, on behalf of ImPrEP Study Team. *Factors associated with perceived and current HIV risk among men who have sex with men in Brazil, Mexico and Peru*. Poster # WEPED845 (available at http://programme.ias2019.org/Abstract/Abstract/1793)
- T.S. Torres, K.A. Konda, E.H. Vega-Ramirez, O.A. Elorreaga Reyes, D. Diaz-Sosa, B. Hoagland, S. Diaz, C. Pimenta, M. Benedetti, H. Lopez-Gatell, J.V. Guanira, R. Robles-Garcia, B. Grinsztejn, C.F. Caceres, V.G. Veloso, ImPrEP Study Team. *Characteristics of younger MSM and association of age with PrEP awareness and willingness in Brazil, Mexico and Peru*. Poster # TUPEC490 (available at http://programme.ias2019.org/Abstract/Abstract/978)
- V. G Veloso; E.H. Vega-Ramírez; B. Hoagland; K. A. Konda; S. Bautista-Arredondo; J. V. Guanira; R. Leyva-Flores; C. Pimenta; M. Benedetti; P. Luz; I. C. Leite; R. I. Moreira; B. Grinsztejn; C. Cáceres. *Safety, early continuation and adherence of same day PrEP initiation among MSM and TGW in Brazil, Mexico and Peru: the ImPrEP Study.* Oral presentation at the session Hot off the press: What's new in HIV prevention. (abstract and slides available at http://programme.ias2019.org/Programme/Session/167)
- J.V. Guanira , B. Hoagland , G.M. Calvo , S. Díaz , K. Konda , B. Grinsztejn , E.H. Vega, C.F. Caceres , V.G. Veloso , ImPrEP Study Team. *Acute HIV infection among individuals who start PrEP: The ImPrEP experience, a demonstration project in the context of combination prevention in Brazil, Mexico and Peru*. Oral presentation at the session Interrupting transmission using new testing tools. (abstract and slides available at http://programme.ias2019.org/Programme/Session/81)
- Pimenta, C.; Bermúdez, P.; Benedetti, M.; Godoi, A.; Veloso, V.; Grinzstejn, B.; Masksud, I. *Qualitative Evaluation of PrEP implementation in Brazil -ImPrEP Stakeholders Study*. Oral presentation at the session Stop worrying about the definition and get to work! Implementation science for policy and programme application at scale. (abstract and slides available at http://programme.ias2019.org/Programme/Session/146)
- Satellite Symposium entitled "PrEP implementation for MSM and Trans Women in Latin America – early lessons from the ImPrEP initiative: reaching, engaging and retaining". Presentations by: Mauricio Cysne – Welcoming remarks, Valdiléa Veloso - *PrEP Implementation for MSM and TRANS Women in Latin America – early lessons from the ImPrEP initiative: reaching, engaging, and retaining,* Carlos Cáceres - *Challenges for Improving Access to All: The ImPrEP Experience,* Hamid Vega-Ramírez – *Challenges for PrEP continuation,* Alessandra Ramos - *Community Engagement – Perspectives on reaching, enrolling and retaining Brazil - Peru – México,* Felipe de Carvalho – *Science, Activism and Sexual Rights: Why it is important to challenge the patent monopoly over the drug Truvada*?
- C.F. Caceres, K.A. Konda, R. Moreira, I. Leite, M. Cunha, B. Hoagland, J.V. Guanira, H. Vermandere, H. Vega, B. Grinsztejn, C. Pimenta, V. Veloso, ImPrEP Study Group. *Early Predictors of Seroconversion Among Enrollees in a PrEP Program in Brazil, Mexico and Peru – The ImPrEP Demonstration Study.* Oral presentation at the session "Proof in the pudding: PrEP outcomes in diverse settings", available at https://conference.ias2021.org/media-690-early-predictors-of-seroconversion-among-enrolees-in-a-prep-program-in-brazil--mexico-and-
- B. Hoagland, T. Torres, K.A. Konda, E.H. Vega-Ramirez, J.V. Guanira, H. Vermandere, R.I. Moreira, I.C. Leite, M. Derrico, C. Pimenta, M. Benedetti, S. Bautista, B. Grinsztejn C. Caceres, V.G. Veloso, ImPrEP Study Group. *Awareness of ED-PrEP and interest in switching from daily oral PrEP to ED-PrEP in Brazil, Peru and Mexico – The ImPrEP study.* Presented as a virtual poster, available at https://conference.ias2021.org/media-446-awareness-of-ed-prep-and-interest-in-switching-from-daily-oral-prep-to-ed-prep-in-brazil--
- E. Jalil, T. Torres, C. Pereira, A. Farias, J. Brito, M. Lacerda, D. Silva, T. Andrade, L. Lannoy, M. Valoes, N. Wallys, J. Gomes, T. Odara, L. Santiago, S. Nouveau, L. Monteiro, M. Benedetti, C. Pimenta, B. Hoagland, B. Grinsztejn, V. Veloso. *High Rates of Sexualized Drug Use among Brazilian Transwomen*. Presented as a virtual poster, available at https://conference.ias2021.org/media-494-high-rates-of-sexualized-drug-use-among-brazilian-transwomen
- T.S. Torres, B. Hoagland, K.A. Konda, E.H. Vega-Ramirez, J.V. Guanira, H. Vermandere, R.I. Moreira, I.C. Leite, C. Pimenta, M. Benedetti, S. Bautista, B. Grinsztejn, C. Caceres, V.G. Veloso, ImPrEP Study Group. *Impact of COVID-19 pandemic and pandemic response on cisgender men who have sex with men (MSM) and transwomen in a PrEP cohort from Brazil, Peru and Mexico - ImPrEP study.* Presented as a virtual poster, available at https://conference.ias2021.org/media-492-impact-of-covid-19-pandemic-and-pandemic-response-on-cisgender-men-who-have-sex-with-men-m
- Diego Cerecero-García, José Gomez-Castro, Heleen Vermandere, Sergio Bautista-Arredondo. *Assessing the cost of PrEP delivery in Mexico: results from the ImPrEP study*. Presented as a virtual poster, available at https://conference.ias2021.org/media-461-assessing-the-cost-of-prep-delivery-in-mexico-results-from-the-imprep-study

Annex G: Fiotec selected list of publications

IAS 2019, 2021

- E.H. Vega-Ramirez, T.S. Torres, C. Guillen-Diaz-Barriga, C. Pimenta, D. Diaz-Sosa, R. Robles-Garcia, K.A. Konda, B. Hoagland, M. Benedetti, S. Diaz , H. Vermandere, S. Bautista-Arredondo, J.V. Guanira, R.I. Moreira, B. Grinsztejn, C. Caceres, V.G. Veloso, ImPrEP Study Group. *Awareness, beliefs, and barriers to prescribing PrEP among physicians in Brazil and Mexico – ImPrEP Study*. Presented as a virtual poster, available at https://conference.ias2021.org/media-704-awareness--beliefs--and-barriers-to-prescribing-prep-among-physicians-in-brazil-and-mexico
- Annick Borquez, Kelika A. Konda, Oliver A. Elorreaga, Ximena Gutierrez, Juan V. Guanira, Sonia Flores, Gino M. Calvo, Carlos F. Cáceres. *Importance of accounting for ART costs saved in the long term when estimating HIV pre-exposure prophylaxis (PrEP) cost-effectiveness: a modeling study informed by the ImPrEP demonstration project*. Presented as a virtual poster, available at https://conference.ias2021.org/media-764-importance-of-accounting-for-art-costs-saved-in-the-long-term-when-estimating-hiv-pre-expo
- J.P. Girón, K. Konda, C. Sandoval, G. Calvo, C. Caceres and the ImPrEP Study Group. *Understanding barriers and challenges to PrEP adherence: experiences of PrEP discontinuation among MSM and transwomen in Peru - The ImPrEP Demonstration Study*. Presented as a virtual poster, available at https://conference.ias2021.org/media-401-understanding-barriers-and-challenges-to-prep-adherence-experiences-of-prep-discontinuatio
- Satellite Symposium entitled "PrEP implementation in Latin America - Results of the ImPrEP Project". Presentations by Valdiléa Veloso - *ImPrEP project overview and selected results.* Brenda Hoagland - *Challenges and facilitators for PrEP implementation in public health services in Brazil under Covid-19 pandemic.* Kelika A. Konda - *The impact of the COVID restrictions on the ImPrEP Cohort in Peru.* Hamid Vega-Ramírez - *From enrolment to adherence and retention in PrEP services: Experiences of ImPrEP in Mexico.* Rachel Baggaley –*Commentaries.* Available at https://conference.ias2021.org/media-1080-sa04---strengthening-hiv-prevention-through-same-day-prep-access-in-latin-america-findings

AIDS 2020

- V. G Veloso; E. H. Vega-Ramírez; B. Hoagland; K. A. Konda; S. Bautista- Arredondo; J. V. Guanira; T. Torres; C. Pimenta; H Vermandere; A. Farias; Lacerda MVG; M. Benedetti; S. Diaz; P.M Luz; I. C. Leite; R. I. Moreira; J. Moreira J; B. Grinsztejn; C. Cáceres, for the ImPrEP Study Team. *Factors associated with early continuation (EC) of Pre-exposure prophylaxis (PrEP) among young MSM (YMSM) in Brazil, Peru and Mexico: the ImPrEP Study*. Oral presentation at the session "Next Steps in PrEP", available at http://programme.aids2020.org/Programme/Session/58
- Diego Cerecero-García, Heleen Vermandere, José Gomez-Castro, Luis Alberto Moreno-Aguilar, Arantxa Colchero-Aragonés, Gisela Martínez-Silva, Araczy Martínez-Dávalos, Ivonne Huerta-Icelo, Sergio Bautista-Arredondo. *Awareness, willingness to use, and willingness to pay for different PrEP schemes among MSM in Mexico*. Presented as virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/8906
- J.V. Guanira, K.A. Konda, A. Ramos, R. Ismerio Moreira, I. Leite, B. Hoagland, M. Benedetti, G. Mariño, M. Vinicius Lacerda, B. Grinsztejn, E.H. Vega-Ramirez, C.F. Caceres, V. Veloso, ImPrEP Study Group. *Early Engagement on PrEP among Transgender Women in Latin America: The ImPrEP Experience.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/5358
- Carlos Cáceres; Kelika Konda; Gino Calvo, Juan Vicente Guanira; Hamid Vega-Ramírez; Carlos Benítes; Valdiléa Veloso, ImPrEP Study Group. *PrEP Roll-out in Latin America Should Aim to Increase Awareness among Eligible Individuals to Prevent Refusal, and Provide Support to New Users to Prevent Early Discontinuation.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/8838
- Thiago S. Torres, Brenda Hoagland, Daniel RB Bezerra, Alex Garner, Kim Geraldo, Lucilene Freitas, Sandra W. Cardoso, Emilia Jalil, Lara E. Coelho, Marcos Benedetti, Cristina Pimenta, Beatriz Grinsztejn, Valdilea G. Veloso. *Social and racial disparities are associated with unattainability of maintaining social distancing during the COVID-19 pandemic among men who have sex with men and transgender/non-binary populations in Brazil*. Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/11253
- Diego Cerecero-Garcia, Heleen Vermandere, José Gómez-Castro, José Arturo Sánchez-Ochoa, Araczy Martínez-Dávalos, Ivonne Huerta-Icelo, Ietza Bojorquez, Sergio Bautista-Arredondo. *Assessing the prevalence of depressive symptoms among PrEP users during the COVID-19 outbreak in Mexico. A Latent Class Analysis.* Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/11595
- T.S. Torres, L.E. Coelho, K.A. Konda, E.H. Vega-Ramirez, O.A. Elorreaga, D. Diaz-Sosa, B. Hoagland, J.V. Guanira, C. Pimenta, M. Benedetti, B. Grinsztejn, C. Caceres, V. Veloso, ImPrEP Study Team. *MSM at high HIV risk in Latin America prefer long-acting PrEP***.** Presented as a virtual poster, available at http://programme.aids2020.org/Abstract/Abstract/2779
- Satellite Symposium entitled "Moving forward PrEP programming for MSM and Trans Women in Latin America: lessons learnt from the ImPrEP Project". Presentations by: Giovanni Ravasi - *Update on PrEP implementation in Latin America,* Valdilea Veloso – *Lessons from ImPrEP project in Brazil,* Carlos Cáceres - *Lessons from ImPrEP project in Peru,* Sérgio Bautista-Arredondo - *Lessons from ImPrEP project in Mexico*

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- **HIV Research for Prevention (HIV R4P) – January 2021 -** B. Hoagland, T.S. Torres, D.R.B. Bezerra, A. Garner, K. Geraldo, L. Freitas, C. Jalil, E. Carvalheira, A. Nabor, E. Bastos, D. Waite, J.R. Grangeiro, T. Santos, L. Monteiro, J. Freitas, C. Souza, M. Benedetti, C. Pimenta, B. Grinsztejn, V. Veloso. *Acceptability of telemedicine and HIV self-test among PrEP users during the COVID-19 pandemic in Brazil*. Oral presentation # OA13.03 (available at https://programme.hivr4p.org/Abstract/Abstract/1039)
- **International Health Economics Association – 2021 Conference (July 12-15, 2021) -** Jose Gomez Castro, Diego Cerecero Garcia, Heleen M. Vermandere, Sergio Bautista-Arredondo. *Impact of Covid-19 In PrEP Use: An Online Survey with Men Who Have Sex with Men and Transwomen.* Oral presentation
- **18th European AIDS Conference -** Torres, T.S., Pereira, C.C.A., Luz, P.M., Hoagland, B. Farias, A. Brito, J.D.U., Lacerda, M.V.G., Silva, D.A.R., Benedetti, M. Pimenta, M.C., Andrade, T., Lannoy, L. Santos, M., Casaroto, V., Grinsztejn, B. Veloso, V.G. Preferences for pre-exposure prophylaxis (PrEP) among sexual and gender minorities (SGM) in Brazil: results from a multicenter discrete choice experiment. Presented as e-poster at the 18th European AIDS Conference (https://eacs2021.abstractserver.com/program/#/details/presentations/446)
- **First Latin America Academy Meeting of the EuroQol Research Group (Trinidad and Tobago, 12 and 13 July 2022) -** Claudia Cristina de Aguiar Pereira, Ph.D., MS **-** Escola Nacional de Saúde Pública Sérgio Arouca – ENSP/FIOCRUZ; Thiago Silva Torres, Ph.D. **-** Instituto Nacional de Infectologia Evandro Chagas – INI/FIOCRUZ; Paula Mendes Luz, MD, PhD **-** Instituto Nacional de Infectologia Evandro Chagas; Brenda Hoagland, MD, PhD - Instituto Nacional de Infectologia Evandro Chagas – INI/FIOCRUZ; Marcos Benedetti, MSc - Instituto Nacional de Infectologia Evandro Chagas – INI/FIOCRUZ; Maria Cristina Pimenta, PhD - Ministério da Saúde do Brasil; Beatriz Grinsztejn, MD, PhD - Instituto Nacional de Infectologia Evandro Chagas – INI/FIOCRUZ; Valdilea Gonçalves Veloso, MD, PhD - Instituto Nacional de Infectologia Evandro Chagas – INI/FIOCRUZ. Quality of life among sexual and gender minorities in Brazil as measured by the EQ-5D-3L. Presented as a poster