The International AIDS Society in partnership with Fundación Huésped

Educational Fund Meeting Outcome Report
3-4 November, Buenos Aires, Argentina

Challenges for PrEP Implementation in Argentina
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This report was developed in collaboration with Fundación Huésped. The views expressed in the report do not necessarily reflect the views of the International AIDS Society.
2. Acknowledgements

Fundación Huésped and the International AIDS Society (IAS) wish to acknowledge all stakeholders for their contributions towards making the IAS Educational Fund meeting *Challenges for PrEP Implementation in Argentina* a success. In particular, they would like to recognize the commitment and participation of the local, regional, national and international HIV scientists and researchers, policymakers, programme implementers, community representatives who were able to attend. They would also like to extend their appreciation to ViiV Healthcare for their continued support.
## 3. List of abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immunodeficiency syndrome</td>
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<tr>
<td>AIDS 2018 CLPC</td>
<td>22nd International AIDS Conference Community and Leadership Programme Committee</td>
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<td>ANMAT</td>
<td>Drug, Food and Technology Administration</td>
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<td>ART</td>
<td>Antiretroviral therapy</td>
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<td>ARV</td>
<td>Antiretroviral (drug)</td>
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<td>CDC</td>
<td>United States Centers for Disease Control and Prevention</td>
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<tr>
<td>FALGBT</td>
<td>Federación Argentina Lesbianas, Gays, Bisexuales y Trans (Argentinean Federation of Lesbians, Gays, Bisexuals and Trans)</td>
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<tr>
<td>FTC</td>
<td>Emtricitabine</td>
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<td>FTC-TP</td>
<td>Emtricitabine-triphosphate</td>
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<td>FUNCEI</td>
<td>Centre for the Study of Infectious Disease Foundation (Fundación Centro de Estudios Infectólogos)</td>
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<td>GNP+</td>
<td>Global Network of People Living with HIV</td>
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<td>HBV</td>
<td>Hepatitis B virus</td>
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<td>HCV</td>
<td>Hepatitis C virus</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>IAS</td>
<td>International AIDS Society</td>
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<td>KPs</td>
<td>Key populations</td>
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<td>LA</td>
<td>Latin America</td>
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<td>LAC</td>
<td>Latin America and Caribbean</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<td>MSM</td>
<td>Men who have sex with men</td>
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<td>NGO</td>
<td>Non-Governmental Organization</td>
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<td>PAHO SF</td>
<td>Pan-American Health Organization Strategic Fund</td>
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<td>PEP</td>
<td>Post-exposure prophylaxis</td>
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<tr>
<td>PEPFAR</td>
<td>US President’s Emergency Plan for AIDS Relief</td>
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<td>PLHIV</td>
<td>People living with HIV</td>
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<td>PrEP</td>
<td>Pre-exposure prophylaxis</td>
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<td>PWID</td>
<td>People who inject drugs</td>
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<td>RAJAP</td>
<td>Red Argentina de Jóvenes y Adolescentes Positivos (Argentinean Network of HIV-positive Youth and Adolescents)</td>
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<td>Acronym</td>
<td>Description</td>
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<tr>
<td>STIs</td>
<td>Sexually transmitted infections</td>
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<td>SWs</td>
<td>Sex workers</td>
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<tr>
<td>TDF</td>
<td>Tenofovir disoproxil fumarate</td>
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<td>TDF/ FTC</td>
<td>Tenofovir disoproxil fumarate / emtricitabine</td>
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<td>TGW</td>
<td>Transgender women</td>
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<td>TNF</td>
<td>Tenofovir / emtricitabine</td>
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<td>TNF-DP</td>
<td>Tenofovir diphosphate</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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4. Executive summary

On 3 and 4 November 2017, Fundación Huésped in partnership with the International AIDS Society (IAS), held a workshop with the theme Challenges for PrEP Implementation in Argentina. The meeting hosted one of the first open and multi stakeholder debates on PrEP implementation at the national level.

Day 1 included presentations and discussions on key messages from IAS 2017 including relevant PrEP messages, advances on combination prevention in Argentina, and evidence of the effectiveness of PrEP implementation. In addition, the programme included a panel discussion to address challenges, actions and potential solutions for PrEP implementation across the country.

Day 2 featured a presentation on the advances of PrEP implementation in Latin America, and working group discussions on issues related to PrEP implementation in Argentina. Discussions were conducted based on the WHO Recommendation Guidelines for PrEP and included the following topics:


**Group 2 - Clinical assistance:** eligibility for PrEP; characteristics of PrEP provision centres; PrEP prescription models; initial assessment of eligible candidates; schedule of follow-up visits; and management of seroconversion.

**Group 3 - Human rights and community:** recommendations for PrEP advocacy strategy; challenges of the regulatory situation in Argentina; main stakeholders to be included in PrEP; PrEP communication and information strategy; and PrEP counselling strategy.

**Key recommendations:**

- Define the regulatory status of PrEP, and advocate for TNF/FTC as a prevention drug by the ANMAT to avoid prescribing off label.
- Promote a rights based approach to PrEP implementation in Argentina and build consensus among stakeholders.
- Hold a demonstration study and share the preliminary results in order to proceed with an implementation study
- Adopt PrEP Public Health Policy based on the results studies conducted at national, regional and international levels.
- Design a PrEP public response, including PrEP as part of combination HIV prevention approaches at country level.
- Define the strategic framework for PrEP implementation, including specific information about the modality of intervention at field level such as distribution and characteristics of PrEP provision and follow-up screening centres, trainings modules and guidelines for PrEP prescription.
5. Background and context

At the end of 2016 in Latin America (LA), there were an estimated 1.8 million [1.4 million-2.1 million] people living with HIV, an estimated 97,000 [79,000-120,000] new HIV infections, and an estimated 36,000 [28,000-45,000] AIDS-related deaths. Approximately 58% [42-72] of people living with HIV have access to antiretroviral therapy, although variation between and within countries exists.

Overall, the region has a concentrated epidemic as demonstrated by the prevalence found among key populations at risk of HIV exposure, including transgender women, gay men and other men who have sex with men, male and female sex workers and people who inject drugs. Regarding the HIV testing and treatment cascade, LA is far from achieving the 90-90-90 goals. Concerning the use of condoms, data shows that in LA use is around 60% overall.

In 2012, the Americas region launched an initiative for the elimination of congenital syphilis and HIV mother to child transmission. Consequently, Cuba became the first country in the world to achieve elimination certification, while another five countries from the Caribbean have provided the necessary documentation for certification.

PAHO’s Strategic Fund is a mechanism of pooled procurement for supplies for diagnosis, prevention and ART, which has enabled countries to improve access and extend coverage with convenient pricing and high quality standards.

In 2016, there were an estimated 120,000 people living with HIV in Argentina. Approximately, 70% knew their HIV status, and 81% of those who knew their status received ART. Late HIV diagnosis was estimated to be around 27%. Argentina has a concentrated epidemic as demonstrated by prevalence found in key populations at risk of HIV exposure including transgender (34%), MSM (12-15%), PWID (4-7%) and SWs (2-5%). The main mode of transmission was associated with unprotected sex in approximately 90% of cases. The national survey on sexual and reproductive health showed low rates in condom use, 30% for women and 50% for men.

Concerning PrEP implementation status in Argentina, TNF/FTC is not registered as a prevention drug by the regulatory body for drug, food and technology administration at the national level in Argentina. This situation forces off-label prescription – PrEP only exists “in the wild” – meaning that PrEP is used without any monitoring or specific health care; this is an issue that demands reflection.

Given the epidemiological situation in Argentina, combined HIV prevention approaches that include PrEP as a key component, pose a very real opportunity to strengthen the country’s HIV response.
6. Meeting report

6.1. Friday, 3 November 2017 / Day 1

Date, time: Friday, 3 November 2017, 15.00-18.00
Chair: Dr Pedro Cahn (Fundación Huésped)
Co-Chairs: Mr Javier Hourcade Bellocq (GNP+, AIDS2018 CLPC, PAHO & WHO TAC)
Dr Horacio Salomon (IAS)
Attendance: 46 participants
Opening remarks: Dr Horacio Salomon (IAS)
Dr Pedro Cahn (Fundación Huésped)

Dr Horacio Salomon, IAS Governing Council member for Argentina, welcomed participants to the workshop. The IAS Educational Fund programme started in 2016. In addition to supporting attendance and access to information shared during the IAS conferences, the programme includes regional meetings to provide access to the latest science to healthcare workers, advocates, and policymakers and opportunities to question how that information impacts local epidemics. In this instance, the workshop is planned to address “Challenges for PrEP implementation in Argentina”.

Dr Pedro Cahn, former President of the IAS, expressed his satisfaction to be working again with the IAS on such as relevant theme, and to convene a debate in order to identify advantages and potential obstacles of prevention policies through an open dialogue to advance knowledge sharing.

Plenary presentations:

6.1.1 Combination Prevention: Integrated Programmes
Dr Adriana Duran (Coordination of Sexual Health, HIV and STIs, Ministry of Health City of Buenos Aires)

Dr Duran shared her thoughts on strategies for the implementation of combination HIV prevention approaches in Buenos Aires, through a public health perspective. The strategies were categorized into three groups related to biomedical interventions, practice, and legal frameworks. She highlighted well-known interventions at the national level, such as male condom promotion implementation, confidential and free access to HIV testing, and access to ART for mother to child prevention and PEP since 1996.

The legal framework has enabled programme and policy implementation since 1990, as well as the progressive reduction of stigma and discrimination targeted at vulnerable groups of sexually diverse populations. Dr Duran highlighted the innovative fusion of HIV/STI/viral hepatitis with sexual and reproductive health programmes which has been done since 2016.
Concerning access to condoms, the reduction in the distribution among health care services, community points, organizations and sexually diverse networks due to the reduction in the demand was noted. Moreover, the national survey on sexual and reproductive health showed low rates in condom use, 30% for women and 50% for men. The increased number of cases and rates of syphilis in the general population and congenital syphilis, in residents of the city of Buenos Aires, were noted. The survey results are far away from achieving PAHO/UNICEF proposed targets for congenital syphilis.

In 2012, the diagnostic algorithm changed with the incorporation of an innovative screening strategy in public places and with the introduction of a rapid test for screening and viral load confirmation, conducted in 30 health care services, hospitals and NGOs. This innovative strategy facilitated early and timely HIV diagnosis among men. Since the beginning of rapid test implementation, HIV prevalence has increased in the screening centres. Regarding the MSM population, the screening was conducted in collaboration with NEXO NGO and the results showed a reduction in prevalence and a decrease in the percentage of late diagnostics. These results could be associated with the impact of the policy.

Concerning access to treatment, currently 14,000 PLHIV receive ART and 71% have undetectable viral load and around 70% uptake ARV every month.

To conclude, Dr Duran shared the following programmatic recommendations:

- Strengthen condom promotion and counselling strategies
- Generate condom demand in the community through mass campaigns
- Implement rapid test screening and treatment for syphilis at the first point of care
- Promote early diagnosis of heterosexual men
- Implement ART adherence strategies
- Implement methods in order to differentiate new diagnoses and new infections

6.1.2. Prevention properly understood
Javier Hourcade Bellocq (GNP+, AIDS2018 CLPC, PAHO & WHO TAC)

Javier Hourcade highlighted some key messages from the IAS conference in Paris that support PrEP implementation:

- Reduction in new HIV infections due to PrEP implementation
- High acceptability of PrEP intervention (surveys showed 95-96% of acceptability where treatment is free and 60% if the individual has to pay)
- Reduction in condom use requires adding other prevention methods
- No evidence of increased risk of STI transmission (i.e. in Argentina syphilis rates had increased before the introduction of PrEP)
- Risk compensation? Being a PrEP user does not imply an increased number of sexual partners
- Costs related to PrEP are crucial for several countries. Currently, prices of PAHO SF are affordable for Argentina and other countries in LAC region, with a cost of US$ 6 plus a 15% transaction fee.
• Dose based on events: it is not necessary to take PrEP every day and this simplifies adherence
• WHO directives for implementation: the PrEP tool contains modules for a range of stakeholders to support them in the consideration, planning, introduction and implementation of oral PrEP. All modules make reference to the evidence-informed 2015 WHO Recommendation on PrEP. Other modes of administration are currently available for PrEP and these alternatives are mainly targeted at increasing adherence, i.e. injectable integrase inhibitors.

The context in which PrEP emerged includes:

• Limited communication, information and education related to HIV and prevention campaigns
• Lack of interest in receiving information through preventative messages, well documented on several studies among vulnerable populations
• Limited coverage of NGOs since the peers that are reached are those closer to the organization; the so-called “low ceiling”

Consequently, a new working paradigm of combination prevention appeared. Some myths associated with PrEP were addressed:

• PrEP communication strategies do not exclude condom use; on the contrary they promote both, PrEP and condom use.
• PrEP is only a component of combination prevention. In addition, PrEP is not for all, not forever, not for every day and it is voluntary; that is why it cannot be considered a prescriptive medication strategy for life.
• There is currently a debate around implementing PrEP while being far from the expected goals to achieve universal treatment coverage; nevertheless, it is necessary to reduce new infections in order to achieve universal coverage. PrEP costs will be affordable for countries without free trade agreements such as Argentina.
• Regarding access to health care services, the PrEP strategy revitalizes services with the introduction of regular visits as part of the strategy.
• In addition, the right of each individual to remain HIV-negative should be considered.

The restrictions on PrEP implementation included: lack of awareness, conservative views, prejudices and resistance to change.

Ten countries will start with PrEP programs in Latin America next year, and it is still necessary in Argentina to discuss its mode of implementation.

Concerning PrEP accessibility in Argentina in the future, it is expected to be provided at the level of health sub-systems for people who cannot afford to purchase it. Currently, access is limited to individuals who can afford to purchase it. It should be necessary to establish PrEP as a public health policy. The debate about a potential mode of implementation financed by the public sector is starting at the national level. In addition, the private health sector should be included in the discussions in order to be supportive of PrEP implementation, although PrEP cost and affordability could be identified as a challenge for this sector.
Concerns brought up by participants during discussions relating to PrEP and combination prevention in Argentina included:

- Access to PrEP through the informal market, without any regular follow-up with health care services including regular screenings for HIV and STIs. Consequently, PLHIV with unknown HIV status could be receiving PrEP.
- STIs could potentially increase with PrEP implementation. Although, STIs have increased substantially without PrEP.
- The pending ANMAT regulatory approval to enable PrEP prescription in order to reduce the risk of taking PrEP without the adequate health care follow-up and controls
- The lack of prevention campaigns to promote condom use
- The affordability of PrEP for the different health sub-systems in Argentina.

6.1.3. Pre-Exposure Prophylaxis: An HIV Prevention Strategy

Dr Pep Coll (IrsiCaixa Research Institute, Fundación de lucha contra el Sida, BCN Checkpoint)

Dr Coll presented scientific evidence from PrEP studies in order to demonstrate the strategy’s effectiveness.

In addition to TNF/FTC, several administration modes are currently available for PrEP, which are aimed at targeting increased adherence, such as injectable integrase inhibitors, rings containing contraceptive and PrEP, and broadly neutralizing antibodies among others.

PrEP demonstrated effectiveness in most of the studies, except in the implementation studies carried out among young African women (FEM-PREP and VOICE) and the reasons might be associated with adherence. MSM, transgender people, PWID, and women were among the population groups involved in the PrEP studies. Several studies, demonstrated a correlation between evidence and efficacy (Partners PrEP, iPrEx, among others). Two European studies were presented in detail. The first one, the British study “PROUD”, analyzed systematic PrEP with TNF/FTC in two groups: immediately and delayed twelve months. The follow-up Committee recommended offering TNF/FTC before the end of the study as preliminary results demonstrated an 86% reduction in HIV incidence. High PrEP efficacy was also demonstrated in the double-blind French study, IPERGAY. The study participants were advised to take a double dose of TNF/FTC 2 to 24 hours prior to having sex without condom, followed by repeated doses 24 and 48 hours after the first dose. The follow-up committee also recommended opening the double-blind study and offering TNF/FTC to all participants. The effectiveness in HIV incidence reduction was 86%, and 97% in the opened phase. Moreover, in the Kaiser permanent study, between April 2012 and February 2017, no new infections were observed with more than 5,000 people per year under follow-up receiving TNF/FTC.

Regarding effectiveness, with more than 100,000 people currently receiving PrEP, only three cases of HIV resistance have been documented. Two of them were adherent, but the infection was associated with a multi-resistant virus; and the other case, found in Amsterdam, was associated with risky sexual behaviour (unprotected sex was reported in 3 partners per day).
Concerning PrEP’s safety, the evidence showed most side effects were gastrointestinal (such as emesis, diarrhoea and weight loss); renal toxicity and bone demineralization (mean 1%) in general were mild and reversible side effects. The Kaiser permanent study demonstrated less frequency in renal toxicity with a baselines glomerular filtration rate of 90 ml/min; not a single study showed renal toxicity grade 3 or 4. The impact of PrEP on other STIs:

- The iPrEx study showed that increased condom use was documented as well as a reduction in the number of partners
- The PROUD study revealed that more frequent STIs were not statistically significant.
- A study in Seattle among MSM receiving PrEP documented an increased number of *Chlamydia* and *Gonococcus* infections
- Additionally, a Fenway Institute study demonstrated an increase in STIs of 25% among people receiving PrEP

Concluding remarks:

- STIs rates were elevated among PrEP beneficiaries, but it was not clear if these were related.
- STIs rates were increasing before PrEP was introduced.
- STIs rates will decrease with the regular follow-up screening of PrEP programmes.
- HCV only increased among HIV negative MSM.

Finally, the cost effectiveness was demonstrated when PrEP is used among people with an increased risk of HIV exposure.

6.1.4. Discussion
Moderator: Dr Pedro Cahn (Fundación Huésped)

The increased number of STIs could be related to active screening and syphilis. Unprotected oral sex should be taken into account as another mode of transmission.
6.1.5. Panel discussion
Chair: Javier Hourcade Bellocq (GNP+, AIDS2018 CLPC, PAHO & WHO TAC)

Panel discussion (from left to right): Dr Sergio Maulen, Esteban Paulon, Matías Muñoz, Dr Omar Sued, Dr Valdilea Veloso

Panellist 1: Dr Valdilea Veloso, Fio Cruz Institute, Brazil

“Even if STIs increase with PrEP, I prefer people having an STI as it is not necessary to treat them for life.”

Dr Valdilea Veloso (Fio Cruz Institute)

“From the experience in Brazil, some people have requested PrEP and when they were informed about PrEP they decided not to use it, but the benefit is related to the information they received to protect themselves.”

Dr Valdilea Veloso (Fio Cruz Institute)

Key issues highlighted:

- The current concern is the increased number of new HIV infections related to sexual intercourse.
- Evidence shows that new HIV infections have decreased in places where PrEP has been implemented.
- Inequity in access to health care can decrease with PrEP implementation, considering that people with an increased risk of HIV exposure need to be reached.
- PrEP is a component of a package of prevention measures; people not only receive information about how to use PrEP, but also information to improve their lives.
- In addition, with the introduction of PrEP interventions people are more motivated to talk about prevention.
Panellist 2: Mr. Esteban Paulon (President of Argentinean Federation of Lesbians, Gays, Bisexual and Transgender, FALGBT)

“My major concern is related to the possibility of ensuring equity access to PrEP provided by the State at national level.”
Mr. Esteban Paulon (FALGBT)

Key issues highlighted:
- Each individual should have the possibility of selecting the most suitable prevention method.
- A comprehensive sexual education approach is necessary.
- Different components of the combination prevention strategy (condoms, testing among others) should not be mutually exclusive.

Panellist 3: Dr Omar Sued (Director of Clinical Research, Fundación Huésped)

“We have to reflect if people with an increased risk of HIV exposure have all the prevention measures and technologies currently available to protect themselves.”
Dr Omar Sued (Fundación Huésped)

Main points highlighted:
Despite the fact that Argentina has universal ART coverage and condom availability, new infections remain the same and are mainly distributed among young gay people with a low rate of condom usage. Currently there is no specific response for this population. In addition, available evidence has demonstrated the effectiveness of PrEP. All these reasons strongly support the need for PrEP implementation in Argentina.

Panellist 4: Mr Matias Muñoz (Argentinean Network of Positive Youth and Adolescents RAJAP)

“It is necessary to increase early and timely diagnostic of PLHIV and above everything, strengthen ART access and adherence that associated with combination HIV prevention approaches will have an impact on HIV transmission reduction.”
Mr Matias Muñoz (RAJAP)

Main points highlighted:
- Sex education is available but not properly implemented in Argentina. It should be considered an enabling component that could substantially contribute to strengthening prevention.
The data presented on PrEP acceptability, within the key messages from IAS 2017, is not exclusively assessing acceptability among PrEP beneficiaries.

- PrEP implementation will generate less condom use, within a context of condom use reduction, as well as a potential increase of STIs.
- Concerning intermittent PrEP, it is difficult to plan sexual intercourse 48 hours in advance.

Panellist 5: Dr Sergio Maulen (Director, HIV/AIDS/STIs Hepatitis, Tuberculosis and Lepra Program, Ministry of Health, Argentina)

“It is necessary to think in a comprehensive public response, including PrEP as part of combination HIV prevention approaches. It is essential to define the place and implementation modality for PrEP in a federal country such as Argentina, with a heterogeneous quality in the health care response and diagnostic accessibility hindering even more the implementation. Therefore, it is critically important to define how the strategy could be implemented in order to guarantee access to HIV/STIs diagnostic, treatment and follow-up, as well as quality counselling. We should think about PrEP in a meeting targeted on addressing sexual and reproductive Health, HIV/STI prevention access for people with an increased risk of HIV exposure.”

Dr Sergio Maulen (Ministry of Health, Argentina)

Panel discussion with participants:

Main topics highlighted:

- Concerning a reduction in condom use, it is necessary to improve condom promotion efforts among health care services that could have been affected by workload issues and previous obstacles to condom provision.
- Concerning PrEP costs, prices of generic drugs and/or PAHO SF are affordable in Argentina that is why the major concern is related to the mode of implementation at a national level. In addition, it is estimated that population beneficiaries are mainly covered by social work programmes instead of the public system.
- Concerns about the increased risk of HIV transmission in the presence of other STIs, taking into account the increased number of STIs identified on PrEP implementation studies.

“We indeed are seeing a lot of detection bias, because those infections were already among us, but we were not detecting them. When the PrEP programmes started people were being seen more frequently and STIs were being tested every three months so we are not seeing more STIs, they were already there contributing to increasing HIV acquisition and transmission. In addition, those STIs are treatable and so it is not the case of preferring to have STIs rather than HIV, it is just because STIs are treatable. If individuals are linked to a sexual health programme they will be treated for those STIs and in the longer term new HIV infections will be prevented” Dr Beatriz Grinsztejn"
Concerning acceptability, three studies were conducted in Argentina, one among MSM, the second study focused on PrEP acceptability among MSM (less than 26 years old) and the third one among transgender people. The rates of acceptability were 80%, 77% and 90% respectively.

The National AIDS Programme conducted trainings related to PrEP to build capacity on this issue and invited ANMAT representatives to raise awareness considering the urgent need of ARV approval for PrEP prescription. A PrEP debate is planned with the Advisory Committee.

Main challenges:

- Limited availability for STI screening every three months within the national context of Argentina.
- Achieving adequate design and organization of PrEP implementation to prevent poor practice.
- Achieving multi-stakeholder commitment: the need to have political decision making as well as multi-stakeholder engagement in an open dialogue was stressed in order to find a way forward to design a policy that will include a PrEP component.

Recommendations:

- Agreement on the need for consensus among stakeholders regarding a broad rights-based approach to PrEP implementation in Argentina.
- Consider PrEP as an opportunity to reduce new HIV infections within the prevention strategy targeted on the achievement of 90-90-90 cascade, since PrEP is expected to be a short-term treatment and not a treatment for life. In addition, intermittent PrEP could be taken two hours before the exposure and not necessarily 48 hours in advance.
- Consider alternatives and/or modalities for PrEP implementation in Argentina, such as one implementation study or four pilot projects.

6.2 Saturday, 4 November 2017 / Day 2

Date, time: Saturday, 4 November 2017, 9.00-13.00

Chair: Dr Pedro Cahn (Fundación Huésped)

Co-Chairs: Mr. Javier Hourcade Bellocq (GNP+, AIDS2018 CLPC, PAHO & WHO TAC)
Dr Horacio Salomon (IAS)

Attendance: 32
6.2.1 PrEP implementation in Latin America  
Dr Beatriz Grinsztejn (Fio Cruz Institute)

Dr Grinsztejn opened her presentation with remarks on the advances in PrEP implementation in Latin America. Some data on HIV epidemiology from the LAC Region showed that the reduction of new HIV infections in Latin America is considerably far from the expected target to achieve the 90-90-90 goal. With regard to the distribution of new HIV infections and changes per country in LA, there were increases in several countries and it was shown that new infections are mostly related to several KPs: MSM, SWs, PWID, trans women, clients of SWs and partners of KPs. Overall, the region has a concentrated epidemic according to the prevalence found in these KPs. Additionally, new HIV infections related to sexual intercourse are increasing through time among men, particularly young men. Regarding HIV testing and the treatment cascade, LA is far from achieving the 90-90-90 targets. Condom use is at around 60% in LA so it is necessary to rethink HIV prevention and other interventions to improve the HIV epidemic in the region, within the context of combination prevention. Focusing on PrEP, after iPrEX and other studies with other populations, the WHO issued PrEP guidelines to focus interventions on populations where high HIV incidence exists. This is a strong recommendation targeted at people with substantial risk of HIV infection and always as part of a package containing several other approaches within the combination prevention framework.

Concerning the regulatory status of TNF and FTC globally, TNF/FTC is already registered as a prevention drug in several countries, including some in LAC. It is important to remember that LA, specifically Peru and Brazil, participated in the iPrEX and iPrEX OLE studies that were seminal for PrEP implementation among MSM. Since their commencement, the region has participated in PrEP studies. Regarding the status of PrEP as a public health policy in LA, discussions are advancing in the Bahamas and Barbados, and in Brazil PrEP was recently established as a public health policy (1 December 2017). Implementation for sero-discordant couples is being discussed by the Ministries of Health in Costa Rica, St. Lucia, Suriname, Grenada and Guatemala. There are nine demonstration projects ongoing from the UNITAID, PEPFAR, Global Fund, or different MOH in countries such as Brazil, Mexico, Peru, Chile, Guatemala, Haiti, Jamaica, Paraguay, and the Dominican Republic. Initiatives are also being started by civil society in several countries such as Guatemala, Paraguay, Dominican Republic, and Ecuador (still in the planning stage).

PrEP on demand (meaning that individuals have the choice to purchase it) exists in countries such as Argentina, Barbados, Chile, Peru and Brazil. PrEP “in the wild”, as it is called in the literature, is also being used, meaning that there is no monitoring or specific health care around its consumption, and this needs to be addressed.

The MOH in Brazil has funded three demonstration projects since 2013: PrEP Brazil (FIOCRUZ) dedicated to MSM and transgender women; PrEParadas (FIOCRUZ), an ongoing project targeted only at trans population; and another project “Combina” championed by the University of São Paulo.
Two further implementation projects are also co-funded by the MOH in partnership with UNITAD. One project targets adults and the other targets young adults and adolescents. The objective is to extend the evidence by including different populations and a large diversity in the context of a public health system. The demonstration studies have taken place in twelve cities: Manaus, Fortaleza, Recife, Salvador, Brasilia, Belo Horizonte, Rio de Janeiro, D. Caxias, Niterói, São Paulo, Santos, Campinas, Ribeirão Preto, Curitiba, Florianópolis and Porto Alegre.

In the beginning, when PrEP came to Brazil and during all the studies in the pre-screening stage, there were questions about awareness and willingness, not only for PrEP but also for other modes of prevention. Out of 1,200 individuals, condom use was known by almost everyone, PrEP around 60%, and PEP (post-exposure prophylaxis) by 68%. With regards to different prevention modalities, 82% showed an interest in using PrEP and around 77% showed interest in using condoms. This data was published in 2016.

The factors absolutely related with PrEP awareness included level of schooling, risk perception (measured by the use of HIV testing in the 12 last months) and age.

In another project on PrEP, transgender women (n=345) were asked about their level of awareness and willingness to use it. The results showed that although few had heard about PrEP, a large majority wanted to use it. Most of the women met the CDC criteria for PrEP use.

In the study from Argentina, it was shown as well that although many of the participants did not know about PrEP, when the benefits were explained most of them were willing to use it. Educational level and discrimination by healthcare workers are important factors that must be taken into account when PrEP is discussed as a public health policy.

Regarding PrEP in Brazil, a study resulted in the implementation of PrEP as a public health policy. It was a demonstration study, for which planning was started once WHO released the first guidelines in 2012 saying that countries should develop demonstration studies according to the profile of their epidemics. Planning began in 2012 and enrolment in 2014. The study was funded with national resources and medication was donated by Gilead. The study was performed in Rio de Janeiro, São Paulo, and Manaus in the Amazonas. The initial analysis included 450 eligible individuals from Rio de Janeiro and São Paulo, and was targeted at MSM and transgender women older than 18 years.

An initial 1,270 participants who came for HIV testing were approached for PEP or were referred to the project. There was no active recruitment for the study. From the initial 1,270 participants, HIV prevalence was 12%, 753 pre-screenings were potentially eligible for PrEP and the study finally included 450 individuals who were interested in using PrEP (61% of PrEP uptake). Drug levels were tested at 4 weeks to measure early adherence to TNF-DP. Seventy-eight percent had more than four doses a week, implying high adherence. Ninety participants (379/424) had FTC-TP detectable levels at week 4, indicating that they had used the study drug in the last 48 hours. In the final adjusted model, schooling was the strongest predictor of early adherence.

Summary results at 48 weeks were presented at IAS 2017: 83% were retained after one year with very good engagement, and high adherence was found in 74% of the participants. Adherence was in line with early adherence in week 4 and is in line with other studies. For individuals younger than 25 years old and transgender individuals the adherence was measured at any point of the study. Among participants 18-25 years of age, adherence ≥4 doses/week decreased from 78% at week 4 to 59% at week 48. Among transgender women,
adherence ≥4 doses/week decreased from 74% at week 4 to 62% at week 48. It is necessary to work on adherence among these groups. No increase in STIs was seen, there were no levels of TNF that signified a lack of adherence. We did not see a difference in sexual partners or unprotected sex. In conclusion, the results showed high levels of retention and adherence to PrEP, corroborating PrEP’s feasibility in real-world settings of a middle-income country. Nevertheless, sexual behaviour and STI incidence remained stable over time, suggesting a lack of risk compensation in this population.

PrEParadas is an ongoing study, also sponsored by the MOH in Rio de Janeiro, targeted solely at transgender women. Its aim is to describe the use of oral PrEP with TDF/FTC, and included a sample of 120 participants. The study is focused on self-empowerment and PrEP as an instrument of self-empowerment.

PrEParadas is a study to be rolled out on effective HIV prevention among 7,500 MSM/transgender women, 3,000 of whom are in Brazil. It is an implementation project for Brazil and a demonstration project for Mexico and Peru, using daily TNF/FTC. The coordinating site will be Fiocruz Brazil. It will be funded by UNITAID in partnership with the different MOH in each of the programme countries. The project will address strategic gaps hindering scaling-up plans in these countries.

This project will serve as a catalyst for national preparedness for the rollout of integrated PrEP services in Brazil, Mexico and Peru as well as the region. Activities will include:

- A demonstration/implementation study
- A sero-incidence study
- Surveys among MSM & transgender women
- A survey among physicians
- A qualitative study with stakeholders
- Community education/mobilization
- Economic studies/mathematical modelling
- An exchange of experience between countries in the region and other developing countries - South-South collaboration

The protocol was shared with the Chilean MOH in order to conduct a similar project.

The ImPrEP study will be distributed in 33 selected cities in Brazil, Mexico and Peru. The study drug is TNF/FTC, purchased by the MOH in Brazil with discussions ongoing in Mexico and Peru about drug donation.

Through the PAHO SF, TNF/FTC can be purchased in the region for an annual cost of US$75.

Regarding the impact of PrEP in the region and cost effectiveness, a Peruvian study was published showing that PrEP can be a cost effective strategy in addition to other prevention strategies for MSM.

In Brazil, a cost effectiveness study was conducted in partnership with colleagues from Harvard that is almost approved for publication. The study showed that at US$ 22.50 per month, PrEP is a cost effective strategy. Thanks to this data, the AIDS Program was able to get PrEP validated as a public health policy as of 1 December 2017. PrEP guidelines were published in Brazil and the implementation will start in 12 cities, however the plan is to have at least one referral centre per state or region. PrEP will be delivered to target populations at high risk: MSM, transgender, SWs and sero-discordant couples.
PrEP advocacy in Guatemala started in 2014 with the community group “Collective of Friends against AIDS” (“Colectivo amigos contra el SIDA”). A small PrEP project was begun in 2015 in partnership with the MoH community initiative. The study enrolled 26 participants who purchased their own drug. A larger demonstration project with the World Bank and PEPFAR is currently planned.

Other agents are currently under development: Rilpivirine injectable, Cabotegravir injectable, rings containing contraceptive and PrEP, and broadly neutralizing antibodies. There are many participants from the LA region in this study. Peru and Brazil have several sites using VRC1 that is a broadly neutralizing antibody. Cabotegravir also has generated much interest among participants in the region with several sites in Brazil, Peru and Argentina.

6.2.2. Discussion
Moderator: Dr Pedro Cahn

Clarifications about PrEP implementation in Brazil:

- PrEP implementation became public health policy. Its purchase is at the charge of the federal government without any reimbursement by insurance systems.
- VCT centres need to have a minimum requirement for each of the units prescribing PrEP: a counsellor and a prescribing physician (in Brazil only physicians can prescribe).
- A three-day training for all units will take place in Brasilia.
- As a public health policy from 1 December 2017 PrEP is free to users: not only the drug itself but the monitoring embedded in it, including the cost of physicians, counsellors, creatinine, syphilis testing, risk management, condoms and lubricants – the whole prevention package is included.
- ARVs are not sold in Brazil for treatment. PrEP is already being sold by local representative of Gilead. It will probably come to pharmacies from December 1 and only for PrEP and with a local prescription.
- Based on a previous surveillance study PrEP demand was estimated at 7,000 units per year.

6.2.3 Group Work Session: PrEP implementation in Argentina
Moderator: Javier Hourcade Bellocq (GNP+, AIDS 2018 CLPC, PAHO & WHO TAC)

Participants were divided into three working groups to analyze issues related to PrEP implementation in Argentina, such as public policies, clinical assistance and human rights and community issues. The discussions were based on WHO Recommendation Guidelines for PrEP and for people with an increased risk of HIV exposure.
**Group Work 1: Public Policies**
Facilitator: Dr Pedro Cahn
Rapporteur: Leandro Cahn

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<thead>
<tr>
<th>Topics discussed</th>
<th>Key challenges and recommendations</th>
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<tbody>
<tr>
<td>PrEP regulatory status in Argentina: Should the lack of registration for prescription in the ANMAT be considered an obstacle for implementation?</td>
<td>PrEP regulatory status was identified as an implementation challenge since TNF/FTC is not registered as a prevention drug by the regulatory body for drug, food and technology administration at the national level in Argentina. This situation obligates off-label prescription. Advocacy efforts should be directed towards pharmaceutical companies at national level since they are expected to request ANMAT approval.</td>
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<td>Evidence currently available about PrEP: Is it enough to proceed with implementation or is it necessary to conduct studies at a national level?</td>
<td>The group agreed on the need to conduct an initial demonstration study, and then proceed with an implementation study in order to finalize implementation as a public health policy.</td>
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<td>PrEP provision centres: Public and/or private sector?</td>
<td>The highest recommendation is related to the creation and establishment of Integrated Sexual Health Care Centres. HIV voluntary testing centres could be potentially considered for the initial phase of PrEP implementation, but the selection of the most suitable ones should be based on concrete performance indicators properly defined.</td>
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<td>Guidelines: Is it necessary to develop care guidelines for HIV infections and PrEP?</td>
<td>The group agreed on the need to develop and issue concrete care guidelines for PrEP implementation</td>
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<td>PrEP implementation costs</td>
<td>PrEP should be established as public health policy and the state should finance PrEP implementation at national and sub-national levels, including all costs related to PrEP implementation: ARV drugs, STIs treatments, follow-up screening suppliers, trainings and guidelines, among others.</td>
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Group Work 2: Clinical Assistance  
Facilitator: Dr Omar Sued  
Rapporteur: Dr Gustavo Lopardo

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<thead>
<tr>
<th>Topics discussed</th>
<th>Recommendations:</th>
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| **Eligibility for PrEP** | Eligible candidates for PrEP were divided into in the following three groups:  
Group 1: MSM and transgender people who engage in sex with multiple partners or have sex under the effect of drugs, unprotected sex with a positive partner (independent of their role – insertive or receptive) or sex with a partner with unknown HIV status. The behavioural risk exposure period was not defined.  
Group 2: SWs and women with an HIV positive partner or sexual violence exposure.  
Group 3: Heterosexual men considering the epidemiological context in Argentina. |
| **PrEP provision centres** | PrEP centres should be decentralized at the national level, and include STI health care clinics, NGOs, and screening centres. Centres should be located in accessible sites for target audiences and with friendly extended hours of assistance. PrEP provision centres should include health care providers engaged with PrEP for counselling and prescription (such as gynaecologists, physicians, nurses, pharmacists, and social workers), a laboratory for HIV/STIs screening and diagnostics, and pharmacy for drug delivery. Infectious diseases experts are expected to be responsible for training health care providers. Pharmacies should have enough stock under strict control in order to prevent stock outs and for informal PrEP provision. |
| **PrEP prescription modality** | The recommended option for PrEP provision should initially be continuous. |
| **Initial assessment of eligible candidates** | The eligible criteria should include the willingness to use PrEP as prescribed. 
The initial assessment will be conducted as follows:  
Clinical assessment to identify possible acute HIV infection.  
Initial diagnostic assessment: HIV rapid testing with 4\textsuperscript{th} generation ELISA test; syphilis rapid testing; antibodies for Hepatitis B (in negative cases HBV vaccine will be prescribed); Hepatitis C antibody; serum creatinine; and pregnancy testing in women.  
The period between initial screening and PrEP prescription should be immediate in case of same-day rapid testing availability, and without rapid testing should not be delayed to more than one week. It was agreed that Creatinine results should not delay PrEP prescription since the target population are young people not expected to have renal failure (exceptions: pregnant women and people with diabetes). |
Follow-up visits
After PrEP prescription, only for one month, the first follow-up visit should be planned between 2-4 weeks, in order to assess adherence and related side effects. Follow-up visits will then be planned every three months including adherence and side effects assessment as well as HIV and Syphilis screening and PrEP provision for three months. HCV screening will be repeated annually. Despite the lack of innovative technologies for other STIs screening in Argentina, it was agreed that PrEP prescriptions should not be delayed.

Management of seroconversion
Every follow-up visit clinical assessment will be performed to detect clinical seroconversion and users will be asked about specific symptoms related to HIV acute infection such as rash among others. If PrEP user tests positive for HIV, therapy for HIV infection should be started. In case of acute infection resistance, the test will be performed before starting treatment.

Group Work 3: Human Rights and Community issues
Facilitator: Javier Hourcade Bellocq
Rapporteur: Nadia

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<tr>
<th>Topics discussed</th>
<th>Priorities and or/actions identified</th>
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| Define main stakeholders to be included in PrEP debate | The group suggested the following:  
- Key populations not formally associated with organizations: HIV-negative gay men between 14-25 years, bisexual men, transgender women, SWs  
- NGO representatives working with KPs identified.  
- Networks representatives working with KPs identified  
- Key political actors  
- ANMAT representatives  
- Health care providers including health care professionals (physicians), and lawyers  
- Representatives from sexually diverse care and assistance centres  
- Representatives from health subsystems including the private sector  
- HIV programme directors at sub-national level |
| Define PrEP consultation process | The group agreed on the need to address inter-sectoral discussions at national and sub-national level (provincial level) with HIV programme directors. They also acknowledged the need to use innovative technological tools (digital surveys) to conduct consultation processes to protect anonymity. |
| Define Communication and | The group agreed to use online communication channels to share information about PrEP, such as webpages, Facebook, Twitter. |
**Information about PrEP**

In addition, PrEP information should be replicated at field level with people at increased risk of HIV exposure to strengthen community outreach. The recommended strategy is peer-to-peer community communication.

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<th>Define PrEP Counselling Strategy</th>
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<td>Several recommendations should be considered by counsellors:</td>
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<td>- Use appropriate and understandable language when communicating with target populations</td>
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<td>- Dedicate enough time to provide counselling and follow-up visits</td>
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<td>- Develop protocols and guidelines for PrEP users in order to summarize the adequate use of PrEP</td>
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<tr>
<td>- Ensure confidentiality</td>
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<td>- Use sensitive and non-discriminatory language based on the right to use PrEP</td>
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<th>Define a PrEP advocacy Strategy</th>
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<td>A PrEP advocacy strategy should be based on the rights of having access to PrEP. The strategy should account for individuals at increased risk of HIV exposure, including those from diverse and vulnerable backgrounds.</td>
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<tr>
<th>Challenges of Regulatory status in Argentina: Lack of registration for prescription in the ANMAT</th>
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<td>Main recommendations include:</td>
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<tr>
<td>- Advocate for equity and universal access to PrEP.</td>
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<td>- Demand and claim PrEP where it is declared as a right within the context of a public health policy.</td>
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<td>- Create spaces for dialogue to create position with the participation of national programmes, provincial programmes, ANMAT.</td>
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<td>- Generate strategic information.</td>
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7 Conclusion

The IAS Educational Fund Meeting on Challenges for PrEP Implementation in Argentina was one of the first open and multi stakeholder debates on PrEP implementation at the national level. Participants identified PrEP implementation as a priority for the country and the region.

Discussions on the status of PrEP as public health policy in Latin America, are advancing in the Bahamas and Barbados. In Brazil PrEP was recently established a public health policy (the programme started 1 December 2017). PrEP is currently being discussed by Ministries of Health for implementation among sero-discordant couples in Costa Rica, St. Lucia, Suriname, Grenada and Guatemala. There are nine demonstration projects ongoing from UNITAID, PEPFAR, The Global Fund, and different Ministries of Health in Brazil, Mexico, Peru, Chile, Guatemala, Haiti, Jamaica, Paraguay, and the Dominican Republic. In addition, civil society has instigated initiatives in several countries including Guatemala, Paraguay, The Dominican Republic, and Ecuador (though this is still in the planning stage).

PrEP implementation is currently under discussion in Argentina. The National AIDS Program conducted workshops related to PrEP to build capacity on this issue and invited ANMAT representatives to raise awareness of the urgent need of approving PrEP prescriptions. Furthermore, a PrEP debate with the advisory committee of the Ministry of Health is planned.

It is time to move the debate about PrEP implementation forward. The presentations and discussions that took place during the IAS Educational Fund meeting in Buenos Aires on 3 and 4 November, on Challenges for PrEP Implementation in Argentina and the outcomes presented in this report will contribute substantially to this process.

Key Recommendations and Next Steps:

- Define the regulatory status of PrEP, and advocate for TNF/FTC as a prevention drug by the ANMAT to avoid prescribing off-label.
- Promote a rights based approach to PrEP implementation in Argentina and build consensus among stakeholders.
- Hold a demonstration study and share the preliminary results in order to proceed with an implementation study.
- Adopt PrEP Public Health Policy based on the results studies conducted at national, regional and international levels.
- Design a PrEP public response, including PrEP as part of combination HIV prevention approaches at country level.
- Define the strategic framework for PrEP implementation, including specific information about the modality of intervention at field level such as distribution and characteristics of PrEP provision and follow-up screening centres, trainings modules and guidelines for PrEP prescription.
IAS 2017 post-conference workshop:
Challenges for PrEP implementation in Argentina

PROGRAMME
3 November 2017 – 15:00-18:10

14:00 – 15:00 Registration and networking
15:00 – 15:10 Opening comments and welcome
15:10 – 15:40 Key messages from IAS 2017: Combination prevention
15:40 – 16:10 Introductory presentation on PrEP
16:10 – 16:30 Coffee break
16:30 – 18:00 Panel discussion: PrEP and targeting key populations
18:00 – 18:10 Wrap-up of day 1

4 November 2017 – 09:00-14:00

09:00 – 09:20 PrEP implementation in Latin America
09:20 – 11:00 Group work: Addressing the implementation of PrEP in Argentina
11:00 – 11:20 Coffee break
11:20 – 12:30 Presentation of group work
12:30 – 13:00 Rapporteur summary and closing remarks
13:00 – 14:00 Lunch and networking