

Availability of Oral PrEP through the National Program in Brazil

Ministry of Health of Brazil

Secretariat for Health Surveillance

Department for Surveillance, Prevention and Control of STIs,
HIV/AIDS and Viral Hepatitis

March 27th, 2018



MINISTÉRIO
DA SAÚDE



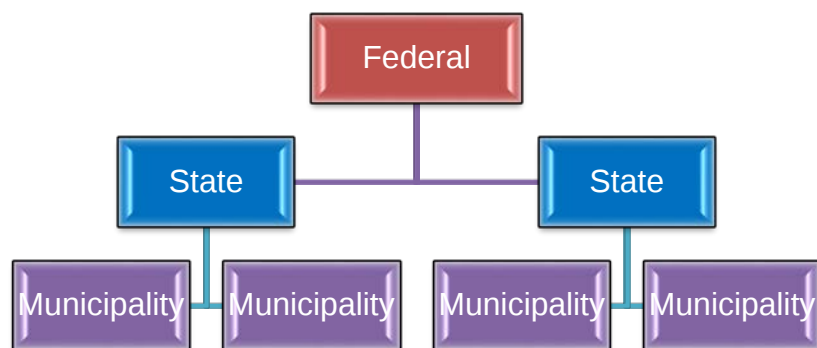
www.saude.gov.br/svs

Outline

- PrEP Implementation Studies in Brazil
- Brazilian PrEP Guideline
- Investment and TDF/FTC Procurement
- Health Workers Capacity Building
- PrEP Service Network
- Monitoring and Indicators
- Current PrEP Status

BRAZIL

Health system based on
decentralized universal
access



The federal, state and
municipal levels are
responsible for prevention,
diagnosis and treatment of
STI/HIV/AIDS and VH.



Population: 207.8 million
Area: 8,514,877 km²

Source: Instituto Brasileiro de Geografia e Estatística,

Oral PrEP global roll-out, 2018

National roll-out- Australia, Belgium, Brazil, Canada, Kenya, New Zealand, Norway, Scotland NHS, South Africa (?US)

Other implementation (e.g. demonstration projects, pharmacy access, DREAMS)



Lancet HIV 2018

Published Online

February 18, 2018

iPrEP Ya! Latin America wants PrEP, and Brazil leads the way

[http://dx.doi.org/10.1016/S2352-3018\(18\)30011-0](http://dx.doi.org/10.1016/S2352-3018(18)30011-0)



PrEP Implementation Studies in Brazil

- Since 2013, the MoH has co-financed **five PrEP demonstration projects*** to inform National PrEP policy with consistent scientific evidence, including a knowledge and willingness among MSM * * .
- A **cost-effectiveness study**, in partnership with Fiocruz and Harvard University, has showed PrEP is cost-effective in Brazil among key populations** *.

* PrEP Brazil (Fiocruz), Projeto Combina (FMUSP), “PreParadas” (Fiocruz), Projeto Horizonte (UFMG), Projeto Trans (UFBA) em: Rio de Janeiro, São Paulo, Porto Alegre, Manaus, Ribeirão Preto, Belo Horizonte, Salvador, Fortaleza e Curitiba.

* * L. Magno , I. Dourado , et al. Never heard of it, but I can think about it: knowledge and willingness to use PrEP among men who have sex with men in Northeastern Brazil. Abstract presented on the 22nd International AIDS Conference, Paris, 2017.

** * Luz, P et al. The cost-effectiveness of HIV pre-exposure prophylaxis (PrEP) in high-risk men who have sex with men (MSM) and transgendered women (TGW) in Brazil. Available at: <http://programme.aids2016.org/Abstract/Abstract/7622>

- In 2018, other **two new implementation studies**, in partnership with UNITAID and Fiocruz (**ImPrEP and PrEP Adolescents**), will start.

PrEP Brazil Demonstration Project



Retention, engagement, and adherence to pre-exposure prophylaxis for men who have sex with men and transgender women in PrEP Brasil: 48 week results of a demonstration study

*Beatriz Grinsztejn, Brenda Hoagland, Ronaldo I Moreira, Esper G Kallas, Jose V Madruga, Silvia Goulart, Iuri C Leite, Lucilene Freitas, Luana M S Martins, Thiago S Torres, Ricardo Vasconcelos, Raquel B De Boni, Peter L Anderson, Albert Liu, Paula M Luz, Valdiléa G Veloso, for the PrEP Brasil Study Team**

Summary

Background PrEP Brasil was a demonstration study to assess feasibility of daily oral tenofovir diphosphate disoproxil fumarate plus emtricitabine provided at no cost to men who have sex with men (MSM) and transgender women at high risk for HIV within the Brazilian public health system. We report week 48 pre-exposure prophylaxis (PrEP) retention, engagement, and adherence, trends in sexual behaviour, and incidence of HIV and sexually transmitted infections in this study cohort.

Lancet HIV 2018
Published Online
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See Online/Comment

- PrEP retention (48w): 83%
 - PrEP adherence: 74%
 - Mean number of sexual partners and STI decreased
 - 76% volunteers had > 12 years of schooling
- ✓ Offering PrEP at public health clinics in Brazil, free of charge at the point of care, can retain high numbers of users and achieve high levels of adherence without risk compensation.

Combine Study! PrEP Demonstration Project

Open Access

Protocol

BMJ Open Pre-exposure and postexposure prophylaxes and the combination HIV prevention methods (The Combine! Study): protocol for a pragmatic clinical trial at public healthcare clinics in Brazil

Alexandre Grangeiro,¹ Márcia Thereza Couto,¹ Maria Fernanda Peres,¹ Olinda Luiz,¹ Eliana Miura Zucchi,² Euclides Ayres de Castilho,¹ Denize Lotufo Estevam,³ Rosa Alencar,³ Karina Wolffenbüttel,³ Maria Mercedes Escuder,⁴ Gabriela Calazans,^{1,5} Dulce Ferraz,^{1,6} Érico Arruda,⁷ Maria da Gloria Corrêa,⁸ Fabiana Rezende Amaral,⁹ Juliane Cardoso Villela Santos,¹⁰ Vivian Salles Alvarez,¹ Tiago Kietzmann¹

- PrEP retention: 91,2%
- PrEP engagement: 72%
- Gay man individuals with higher educational level and reporting higher risk for HIV are more likely to initiate PrEP
- One third of participants reported the intention of not using condoms after initiating PrEP

Sources:

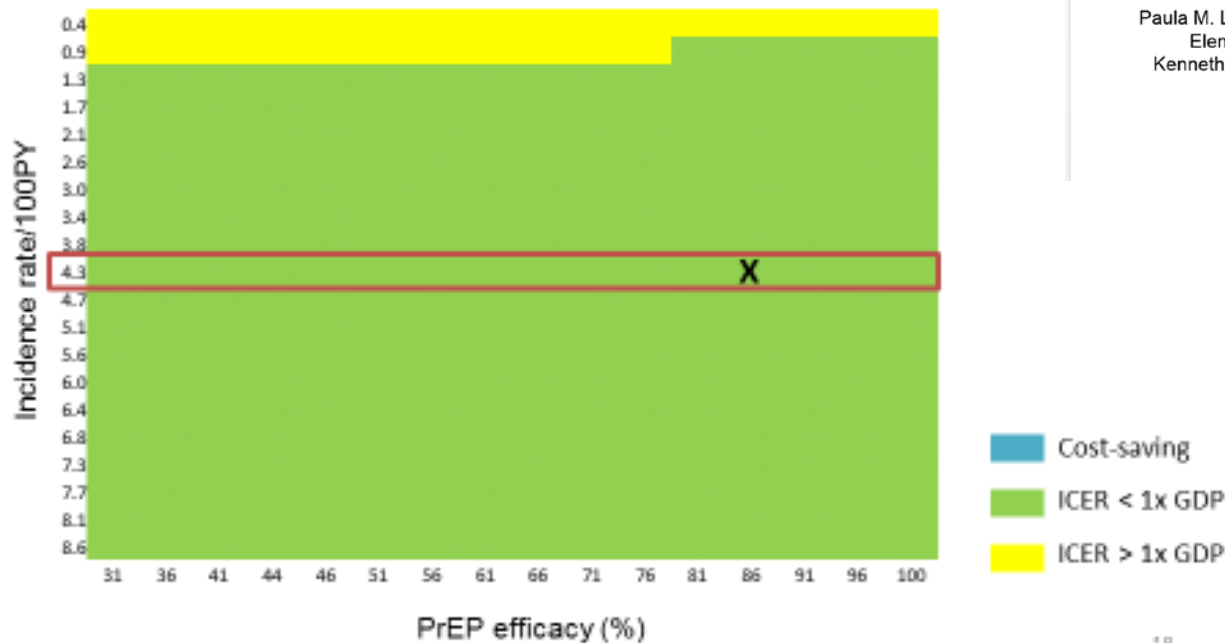
- Grangeiro A, Combine Study Midterm Report, 2018. Personal Communication.

- Grangeiro A, Couto MT, Peres MF, et al. Pre-exposure and postexposure prophylaxes and the combination HIV prevention methods (The Combine! Study): protocol for a pragmatic clinical trial at public healthcare clinics in Brazil. BMJ Open 2015;5: e009021. doi:10.1136/bmjopen-2015-009021

PrEP Cost-effectiveness study in Brazil

Sensitivity analysis Two-way

PrEP drug cost = \$25/month (\$300/year)



The cost-effectiveness of HIV pre-exposure prophylaxis in high-risk men who have sex with men and transgendered women in Brazil

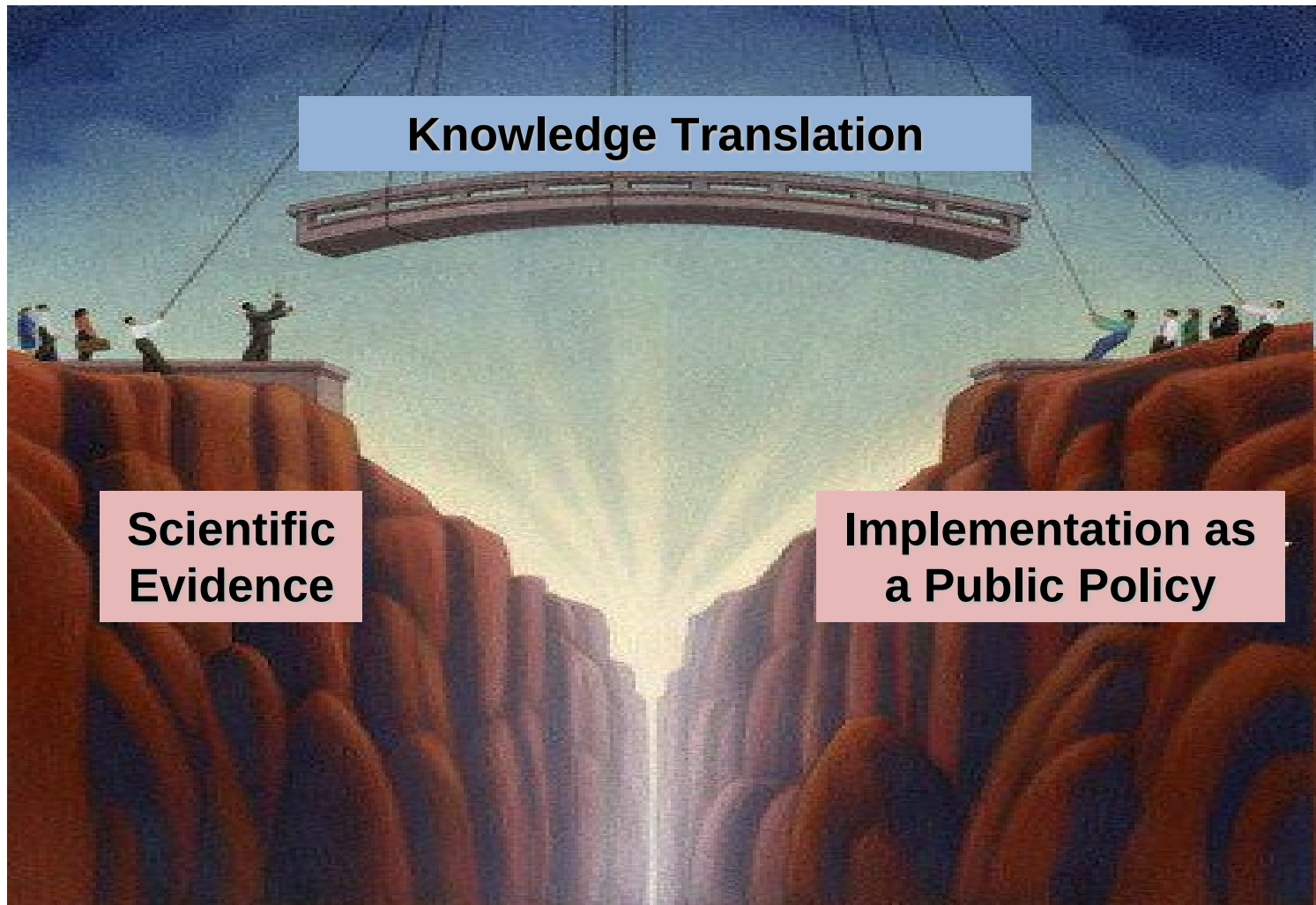
Paula M. Luz, Ben Osher, Beatriz Grinsztejn, Rachel L. MacLean, Elena Losina, Claudio J. Struchiner, Robert A. Parker, Kenneth A. Freedberg, Fabio Mesquita, Rochelle P. Walensky, Valdilea G. Veloso, A. David Paltiel

Source:

Luz, P et al. The cost-effectiveness of HIV pre-exposure prophylaxis (PrEP) in high-risk men who have sex with men (MSM) and transgendered women (TGW) in Brazil. 21st International AIDS Conference; Durban, South Africa; 18-22 July, 2016.

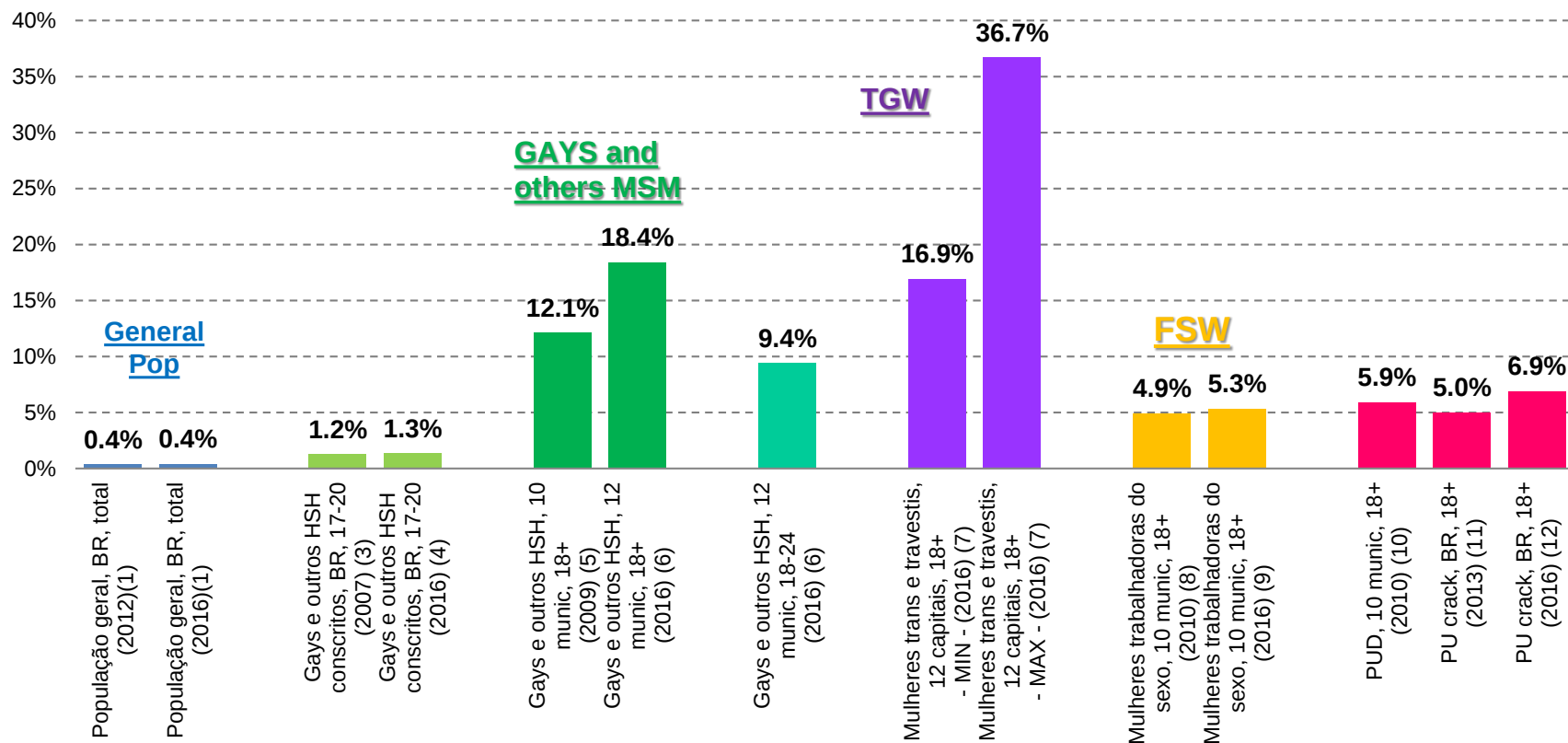
<http://programme.aids2016.org/Abstract/Abstract/7622>

Translating Evidence Into Action



Brazilian HIV Epidemic

HIV Prevalence. Brazil, 2007-16



Sources: (1) BRASIL. Ministério da Saúde. Secretaria de Vigilância em Saúde. Departamento das IST, do HIV/aids e das Hepatites Virais. Relatório de Monitoramento Clínico do HIV. Brasília, 2016; (2) Pereira et al. Transitioning from antenatal surveillance surveys to routine HIV testing: a turning point in the mother-to-child transmission prevention programme for HIV surveillance in Brazil. BMC Infect Dis. 2017 Jul 5;17(1):469; (3) Szwarcwald et al. Práticas de risco relacionadas à infecção pelo HIV entre jovens brasileiros do sexo masculino, 2007. Cad. Saúde Pública [online]. 2011, vol.27, suppl.1, pp.s19-s26; (4) Sperhake et al. Apresentação realizada no Departamento das IST, do HIV/aids e das Hepatites Virais, 2017; (5) Kerr et al. HIV among MSM in a large middle-income country. AIDS. 2013 Jan 28;27(3):427-35; (6) Kerr et al. Comportamento, atitudes, práticas e prevalência de HIV e sífilis entre homens que fazem sexo com homens (HSH) em 12 cidades brasileiras. Relatório técnico entregue ao Departamento das IST, do HIV/aids e das Hepatites Virais, 2017; (7) Bastos et al., "Pesquisa Divas: Diversidade e Valorização da Saúde. Estudo de abrangência nacional de comportamentos, atitudes, práticas e prevalência de HIV, Sífilis e Hepatites B e C entre travestis e mulheres trans", Apresentação realizada em março de 2018; (8) Damacena et al. Risk factors associated with HIV prevalence among female sex workers in 10 Brazilian cities. J Acquir Immune Defic Syndr. 2011 Aug;57 Suppl 3:S144-52; (9) Szwarcwald et al. Comportamento, atitudes, práticas e prevalência de HIV e sífilis entre mulheres profissionais do sexo em 12 cidades brasileiras. Relatório técnico entregue ao Departamento das IST, do HIV/aids e das Hepatites Virais, 2017; (10) Bastos et al. Taxas de infecção de HIV e sífilis e inventário de conhecimento, atitudes e práticas de risco relacionadas às infecções sexualmente transmissíveis entre usuários de drogas em 10 municípios brasileiros. Relatório técnico entregue ao Departamento de DST, Aids e Hepatites Virais, 2010; (11) Bastos et al. Pesquisa Nacional sobre o uso de crack: quem são os usuários de crack e/ou similares do Brasil? Quantos são nas capitais brasileiras? Rio de Janeiro; 2014. 224 p.

Combination Prevention “package”

Combination Prevention Mandala



- Condoms and Gel Lubricants
- Testing for HIV
- TasP
- PrEP
- PEP
- STI diagnoses and treatment
- PMTCT
- Harm reduction

National PrEP Guideline (PCDT PrEP)

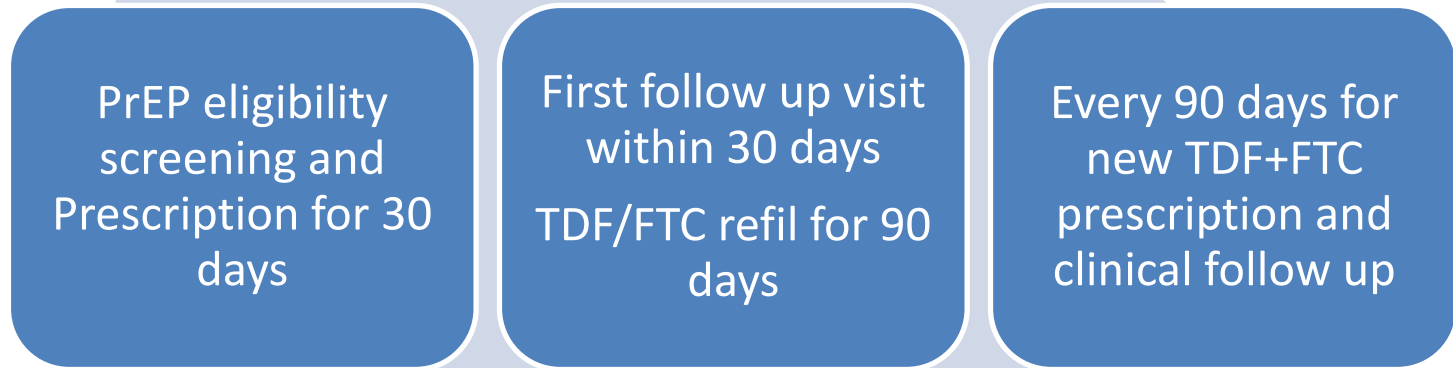
- Developed by a special committee of scientific experts and civil society.
- National Commission for Technology Incorporation (CONITEC) has **recommended the inclusion of PrEP** + ANVISA regulatory approval of TDF+FTC (Gilead) in May 2017.
- The priority target for PrEP are key populations, which concentrate the highest prevalence of HIV in the country:
 - o Gays and other MSM;
 - o Trans people;
 - o Sex workers,
 - o Serodiscordant couples



www.aids.gov.br/pcdt

- The Brazilian guideline offers **daily dosing** of TDF+FTC.

PrEP follow up - overview



Eligibility criterias:

- Key population Groups and
- Condomless anal or vaginal sex past 6 months and/or
- Repeated PEP use and/ or Repeated IST.
- HIV negative
- + Other HIV vulnerabilities (use of drugs, number of partners, etc)

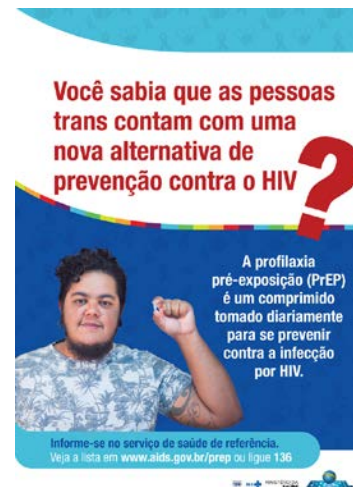
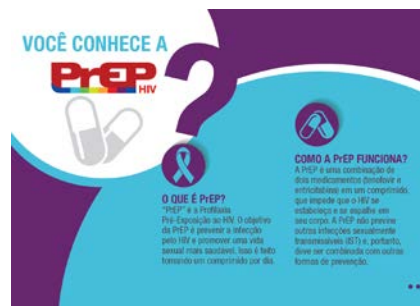
Investment and procurement of TDF+FTC

- Initial investment of USD 2.7 million to purchase 3.6 million tablets, in order to meet the demand for the **1st year**
(US\$ 0.75/unit or US\$ 22.50/bottle)
- **Generic medicines may potentially become available**
- Available at the Brazilian National Health System **free of charge** at the point of care.

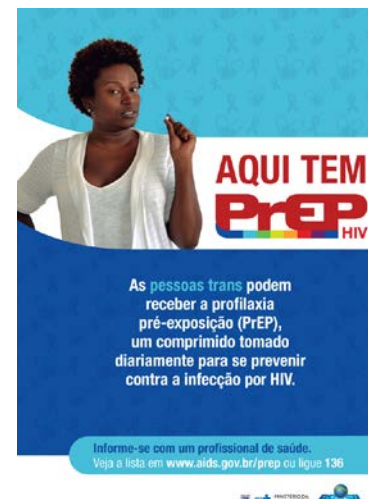
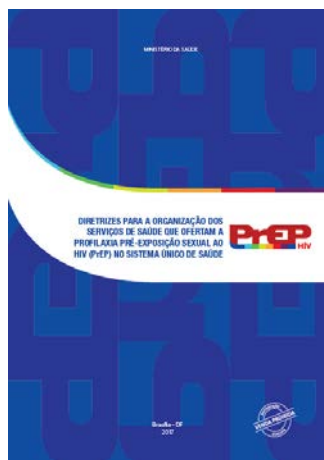


Other IEC materials

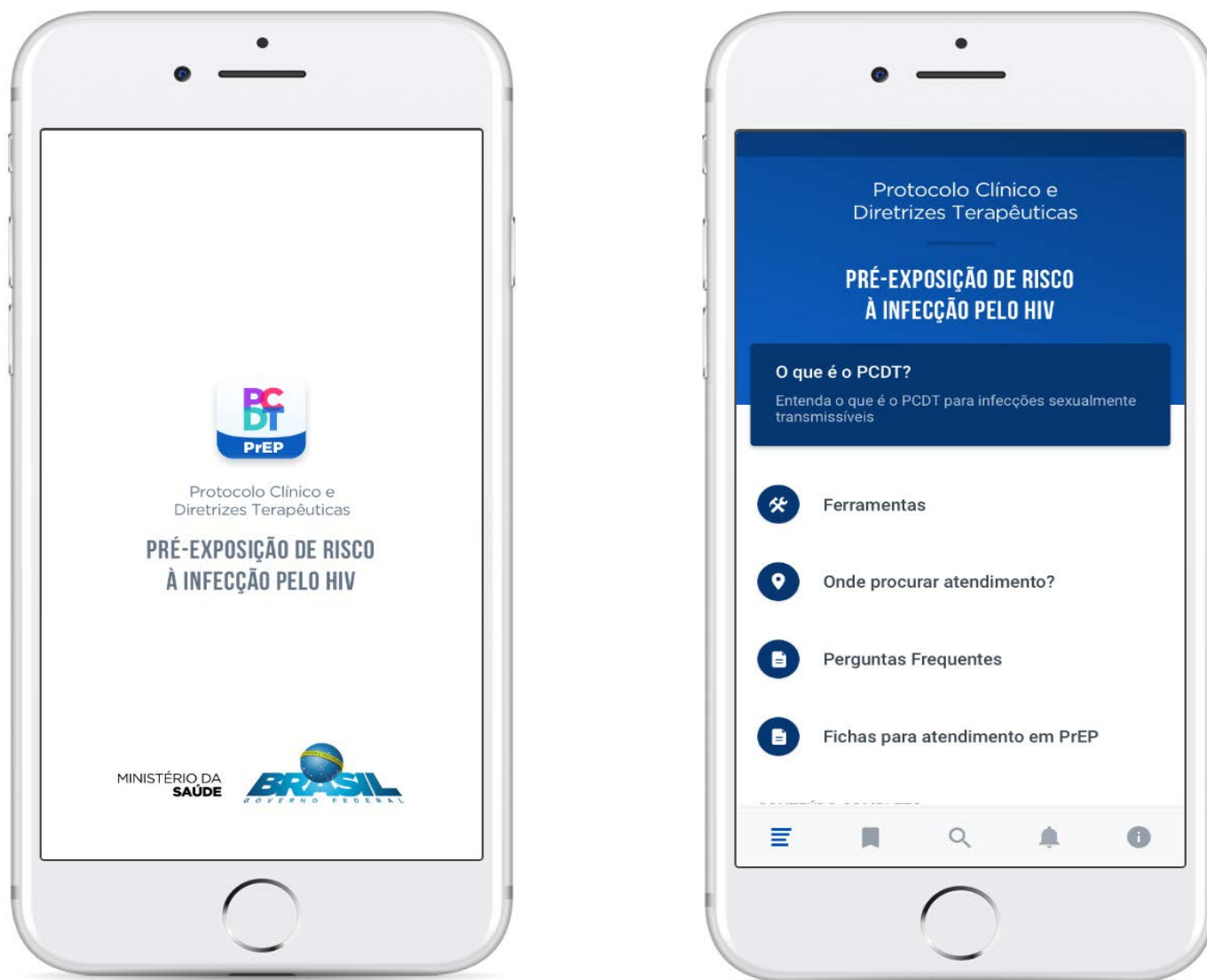
For PrEP Users



For Health Professionals



PrEP Guideline App



PrEP Capacity Building and Trainings

- Webinars for health workers
- Followed by a 2-day workshop for health workers
- Ongoing: development of PrEP e-course in partnership with CDC and ICAP.



PrEP services across the country

- **9,000 prophylaxis** for the first year(2018).
- Roll-out in two phases:
 - Started provision of PrEP through **36 sites** in 11 states, beginning on December 2017
 - Second phase will resume in March 2018 in other 16 states, including other **29 health services**.



1st Phase: 36 services in 22 municipalities/ 11 states

PrEP Monitoring System in SICLOM – National database (ARV logistic system)

SICLOM OPERACIONAL

Ministério da Saúde
Departamento de DST, AIDS e Hepatites Virais

Principal | Sair

Olá, USUÁRIO DE SUPORTE, você está logado no SERVIÇO DE ASSISTÊNCIA ESPECIALIZADA DO ACRE

Menu

- Controle de Permissões
- Cadastramento**
 - Cadastrar Usuário PrEP
- Registro de Óbitos
- Inativação de Usuário SUS
- Cadastro de Médico
- Estoque
 - Mapa
 - Entrada
 - Saída
- Dispensação
 - Farmacovigilância do Dolutegravir
 - Gerenciador de Relatórios
 - Aplicativo
- Novidades
- Alterar Estoque
- Incluir Estoque
- Cadastros duplicados
- Consulta histórico
- Consulta Paciente
- Consultar LOG
- PrEP
 - Cadastro de Usuários PrEP
 - Monitoramento
 - Dispensação PrEP
 - Relatório
 - Incluir login

Cadastramento

Consultar Usuário PrEP

Nome do Usuário PrEP: (Quanto mais caracteres forem informados, mais rápida será a pesquisa)

CPF do Usuário PrEP: (Deve ser um número válido.)

Consultar

RESULTADO DA CONSULTA

Nome do usuário PrEP	Data Nasc.	CPF	Cidade Nasc.
Usuário Teste PrEP Nome Social: Usuário Teste	01/01/1980	000.000.000-00	Brasília
Usuário Teste PrEP 2 Nome Social: Usuário Teste 2	01/01/1981	000.000.000-00	Brasília
Usuário Teste PrEP 3 Nome Social: Usuário Teste 3	01/01/1982	000.000.000-00	Brasília

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Monitoramento

Monitoramento de Usuário PrEP

Nome Social: Número de Prontuário: 123456789

Usuário Teste

Nome Civil: CNS - Cartão Nacional de Saúde: 12345678910

Usuário Teste para Cadastro de Profilaxia

Data de Nascimento: Data do 1º Atendimento: 01/01/1980 11/07/2017

1º Atendimento **Retorno 30 dias** **Acompanhamento** +

Avaliação de risco para infecção pelo HIV

Realizou cirurgia de redesignação sexual (mudança de sexo)? ☐ Sim ☐ Não

Planejamento Reprodutivo? ☐ Sim ☐ Não

Está Gestante? ☐ Sim ☐ Não

Casal Sorodiferente? ☐ Sim ☐ Não

Você teve alguma exposição de risco ao HIV nas últimas 72 horas? Se SIM, avaliar PrEP.

☐ Sim, por relação sexual desprotegida ☐ Sim, por violência sexual

☐ Sim, por compartilhamento de seringa e/ou agulha ☐ Sim, por acidente perfuro-cortante ☐ Não

Quantas vezes você usou PrEP nos últimos 12 meses? (Inserir a quantidade, inclusive se for 0)

☐ N° de vezes

Nos últimos três meses, com quantas pessoas você teve relação sexual? (Inserir a quantidade, inclusive se for 0):

☐ Homens ☐ Mulheres ☐ Homem Transsexual ☐ Mulher Transsexual ☐ Travesti

Você usou preservativo na última relação sexual?

☐ SIM ☐ NÃO

Nos últimos seis meses, você teve algum tipo das seguintes relações sexuais SEM preservativo? (pode marcar mais de uma opção)

☐ Anal Inverso ☐ Anal Receptivo ☐ Inverso Vaginal ☐ Receptivo Vaginal ☐ Oral

Nos últimos seis meses, você teve relação sexual SEM preservativo com parceiras (ou) HIV+?

☐ Sim ☐ Não ☐ Não sei ☐ Não se aplica (usou preservativo em todas as relações sexuais ou não teve relação sexual)

Nos últimos 12 meses, você aceitou dinheiro, objetos de valor, drogas, moradia ou serviços em troca de sexo?

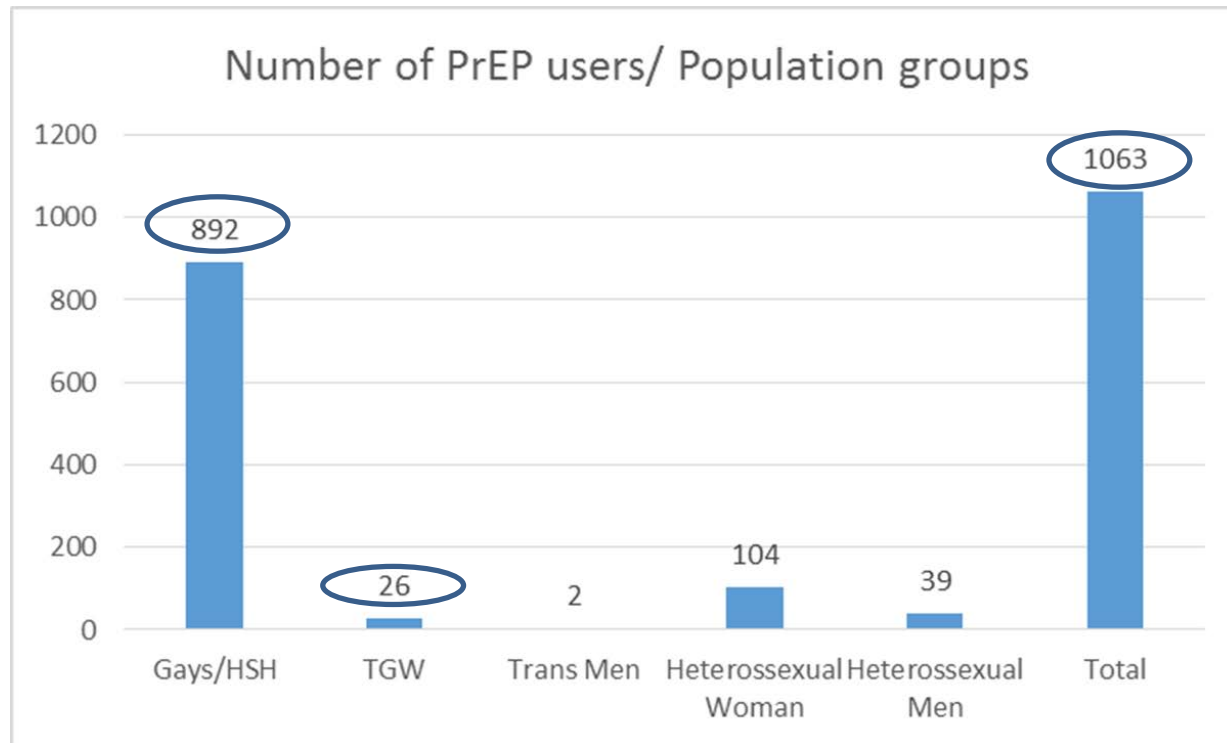
☐ SIM ☐ NÃO

- 1st round of PrEP Monitoring will happen with 90 days of implementation (March 31st)

PrEP indicators

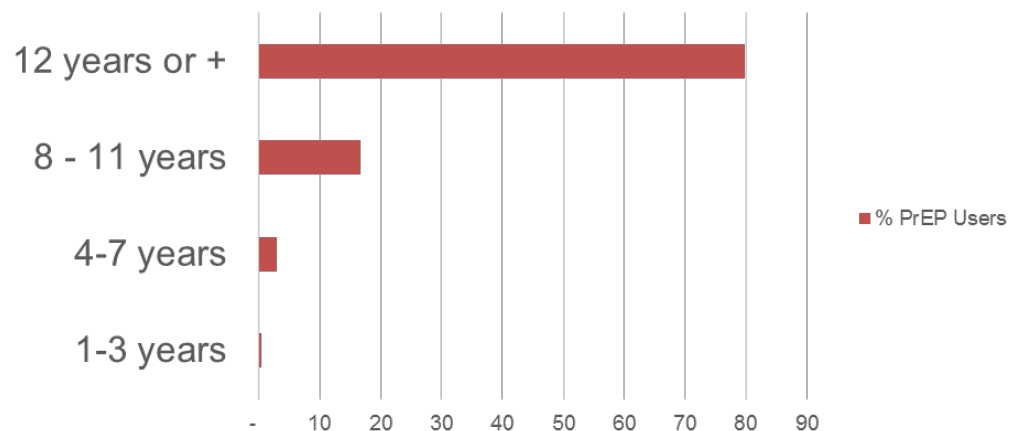
- In line with La Lupa (PAHO/WHO) and GAM (UNAIDS)
- **20 indicators** comprising the following dimensions:
 - PrEP user profile
 - Sexual practice
 - Adverse events
 - PrEP adherence
 - HIV and HCV diagnosis and seroconversion
 - PrEP interruption
 - STI occurrence
 - Health service network

Preliminary Results of PrEP implementation in Brazil (60 first days)

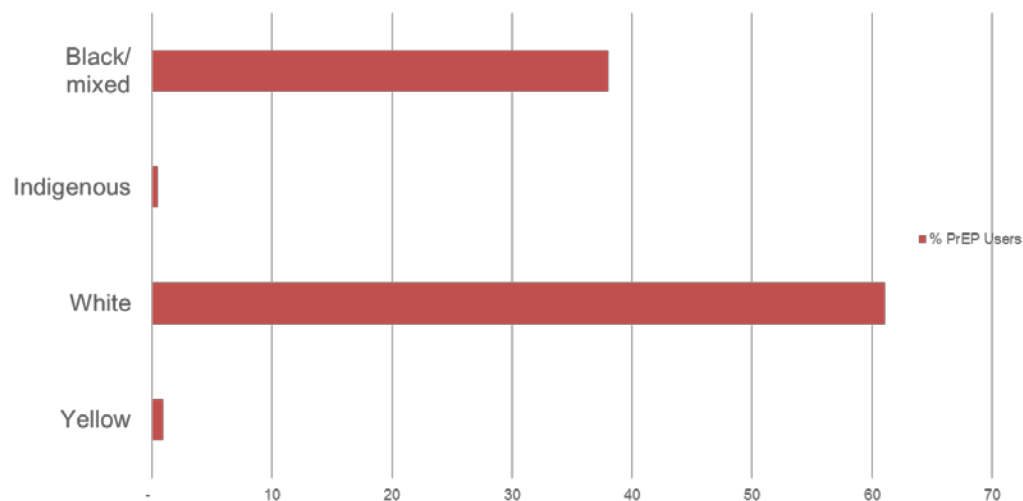


- o Around 9% of PrEP users under SUS reported Transactional Sex

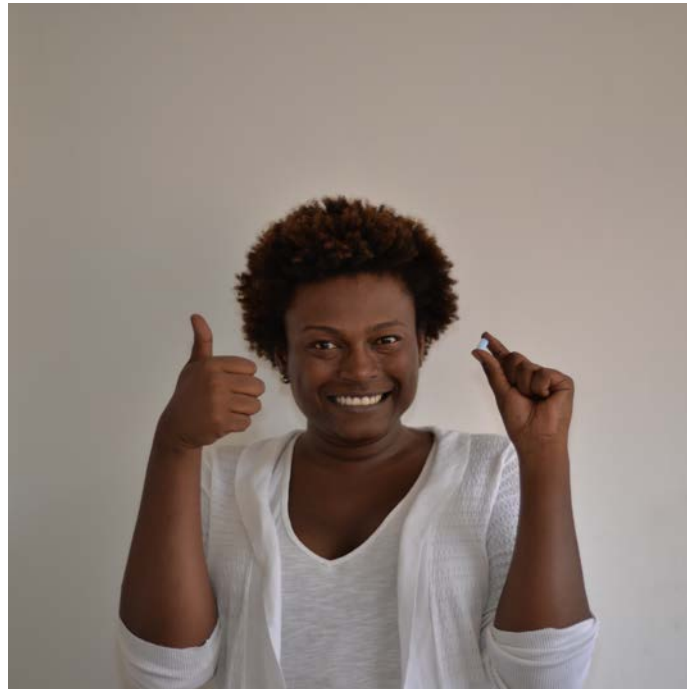
% PrEP users/ Years of Education



% PrEP Users/ Race - skin colour



Now, our challenge is to get PrEP to reach those who can most benefit from it and are at greater risk for HIV: low-income and non-white individuals from transgender, young gays and sex workers groups.



Thank you!
www.aids.gov.br/prep

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prep@aims.gov.br



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