

Ongoing and Planned PrEP Trials and Demonstration Projects, as of June 2015

Trial/Project	Sponsor/Funder	Type/Category	Location	Population	Design/Key questions	Status
Partners Demonstration Project	Led by a team of scientists from Kenya, Uganda and the US; funded by NIMH/NIH, USAID and BMGF	Demonstration Project	Kenya, Uganda	Serodiscordant couples	Evaluates HIV prevention preferences among approximately 1,000 HIV serodiscordant couples, adherence to PrEP and ART and interface of reproductive health priorities and ART-based prevention. Will implement PrEP as “bridge” to ART, providing PrEP to HIV-negative partner when HIV-positive partner is not yet on ART due to ineligibility based on country guidelines or personal decision.	**Preliminary results presented Feb 2015 show the use of PrEP reduced the risk of HIV infection by 96 percent.** Ongoing; fully enrolled. Full results expected 2016.
AMPrEP (Amsterdam PrEP)	GGD Amsterdam; Soa Aids Nederland; AIDS Fund	Demonstration Project	Netherlands	MSM, transgender people	Evaluates PrEP in 370 MSM and transgender people. Participants can choose between taking PrEP on a daily basis, or according to a fixed schedule before and after anal sex. Focuses on interest in using PrEP, compliance/adherence and cost-benefit analysis. The outcomes of the project will be used to give an opinion on the inclusion of PrEP as a standard intervention for HIV prevention in the Netherlands.	Ongoing; started June 2015. Expected completion December 2018.
PRELUDE Study	Kirby Institute; AIDS Council of New South Wales (ACON) and Positive Life New South Wales.	Demonstration Project	Australia	Men and women at high and ongoing risk of HIV	To look into how clinics can provide PrEP. It will study whether people find it easy and agreeable to take PrEP every day, why they take it, what it's like to take it, and whether it changes how they have sex. It will study how easy it is for doctors to use it with their patients, and what resources are necessary to make PrEP available.	Ongoing; started November 2014. Expected completion November 2016.
PrEPBrasil	Oswaldo Cruz Foundation; University of Sao Paulo; Centro de Referência e Treinamento DST AIDS	Demonstration Project	Brazil	MSM; transgender women	Plans to enroll 500 MSM and transgender women to assess the acceptability, feasibility and safety of daily, oral TDF/FTC as PrEP over 12 months.	Ongoing; enrollment completed end-March 2015. Expected completion end-March 2016.
Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)	NIAID	Demonstration Project	South Africa	Heterosexual adolescent men and women ages 15-19	Designed to combine different HIV prevention strategies into an optimized prevention ‘menu’ for adolescents. CHAMPS consists of three pilot projects: three pilots: MACHO interrogates adolescent men’s attitude to circumcision; Pluspills investigates PrEP; UChoose investigates preferred types of prevention utilizing contraception as the surrogate in 16-17 year old women.	Ongoing; Pluspills is expected to complete in October 2016; UChoose is expected to complete in June 2016.

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Sibanya Health Project: Comprehensive HIV Prevention Package for MSM in Southern Africa Pilot Study	Rollins School of Public Health, Johns Hopkins School of Public Health, Desmond Tutu HIV Foundation; Emory University	Demonstration Project (Pilot Study)	South Africa	MSM	To develop and evaluate a combination package of biomedical, behavioral, and community-level HIV prevention interventions and services for MSM in South Africa. The pilot study is a prospective one-year study of 200 men in Cape Town and Port Elizabeth, South Africa. The study will assess a package of HIV prevention services, including condom and condom-compatible lubricant choices, risk-reduction counseling, couples HIV testing and counseling, PrEP for eligible men, and non-occupational post-exposure prophylaxis for men with a high risk exposure. The design of a future, larger study of the HIV prevention package will be conducted at the end of the pilot study, powered to detect efficacy of the prevention package.	Ongoing; started in October 2014. Expected completion May 2016.
VicPrEP Demonstration Project	Alfred Health in conjunction with the Victorian AIDS Council/Gay Men's Health; funded by the Victorian Department of Health	Demonstration Project	Australia	Gay men, transgender people, HIV-negative partners (heterosexual serodiscordant couples), people who received non-occupational post-exposure prophylaxis (N-PEP) on more than two occasions in previous 12 months	To determine the effectiveness of PrEP in the local setting, and the factors contributing to its success. Truvada will be administered to 100 participants for up to 12 months.	Ongoing; started mid-June 2014. Expected completion July 2018.
Sisters Antiretroviral therapy Programme for Prevention of HIV –an Integrated Response (SAPPH-Ire)	Centre for Sexual Health and HIV/AIDS Research Zimbabwe; University College London; London School of Hygiene and Tropical Medicine ; RTI; DFID; UNFPA	Open Label	Zimbabwe	Female sex workers	Seeks to enhance HIV treatment and prevention among highway-based sex workers at 7 sites by increasing uptake and frequency of testing, demonstrate acceptability and feasibility of delivering PrEP, maximize retention in care, promote timely initiation of ART for those eligible, and maximize adherence to both ART and PrEP. The evaluation will be in a representative population based sample of 2800 sex workers after 18 months.	Ongoing; started July 2014 (120 enrolled on PrEP to date). Expected completion October 2015.
Gender-Specific Combination HIV Prevention for Youth in High Burden Settings (MP3-Youth)	New York University; University of Nairobi; Impact Research and Development Organization (IRDO)	Demonstration Project	Kenya	Adolescent men and women ages 15-24 (<i>Only enrolling adolescent female arms on PrEP</i>)	To evaluate the feasibility and acceptability of a gender-specific combination HIV prevention package for youth in high burden settings. The study aims to pilot a combination package of gender-specific interventions in western Kenya in a mobile health delivery format using integrated services delivery. Interventions include: Male-Specific Intervention Package (HIV counseling and testing; facilitated linkage to care for HIV-positive; condoms; VMMC); Female-Specific Intervention Package (IV counseling and testing; facilitated linkage to care for HIV-positive; contraception/family planning; PrEP; conditional cash transfer).	Ongoing; started in November 2014. Expected completion November 2016.

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Benin Demonstration Project with CHU de Québec (Canada)	Projects implemented by national partners in each country in collaboration with the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the O'Neill Institute of Georgetown University, the London School of Hygiene and Tropical Medicine (LSHTM), and Imperial College London; projects are funded by Bill & Melinda Gates Foundation	Demonstration Project	Benin	Female sex workers	To assess feasibility and usefulness of integrating TasP and PrEP to combination prevention package offered to FSWs in Benin; identify best way to successfully implement TasP and PrEP in this setting and to ensure their adoption by national policymakers as part of the HIV prevention package for FSWs.	Ongoing; early-October first participants were enrolled receiving TasP (if HIV-positive) or PrEP (if HIV-negative). Expected completion January 2017.
Senegal Demonstration Project with Reseau Africain De Recherche Sur Le Sida, University of Washington, and Westat		Demonstration Project	Senegal	Female sex workers	Two phase project including a formative research phase followed by a prospective study of PrEP with TDF/FTC to assess changes in HIV incidence and prevalence in FSW followed at IHS, and Pikine, Mbao, Rufisque and Diamniadio Health Centers over 12 months during the implementation of PrEP and compare that to detailed historical data in this population dating back to 1985.	Phase I (feasibility study) data analysis underway to inform Phase II; Phase II (demonstration project) preparation activities are ongoing, enrollment start expected end-April 2015; expected completion 15 months after Phase II start.
The TAPS Demonstration Project (Wits RHI)		Demonstration Project	South Africa	Female sex workers (18 and older)	Evaluates whether oral PrEP and immediate treatment can be rolled out within a combination prevention and care approach tailored to needs of 400 HIV-negative and 300 HIV-positive female sex workers. Study sites include Hillbrow and Pretoria	Ongoing; started April 2015. Expected completion April 2017.
LVCT Health and SWOP Kenya (IPCP-Kenya)		Demonstration Project	Kenya	Young women (15-29), female sex workers and MSM	Aims to introduce PrEP to combination prevention interventions. Feasibility study assessing consumer perceptions, cost, delivery options, potential barriers and opportunities for introduction and adherence completed. Acceptability among target populations, cost, menu of combination interventions and feasible delivery options established. Demonstration project deliver PrEP as part of combination prevention to 2,100 participants over 12 months in preliminary stages. The project will define criteria for PrEP indication among targeted populations, adherence strategies, health system requirements and model impact of PrEP in Kenya.	Planned; expected start date April 2015. Expected completion July 2016
Nigerian National Agency for the Control of AIDS		Demonstration Project	Nigeria	Serodiscordant couples	Evaluates the effectiveness of models for delivery of PrEP and TasP as combination prevention strategy for 1,200 heterosexual, serodiscordant couples. Couples will be recruited from facilities that provide prevention of vertical transmission, ART and other services. Study findings will be used to inform scale-up of PrEP and TasP as part of comprehensive national HIV-prevention package. Study sites: Plateau, Edo and Cross River State.	Planned; expected start date first half of 2015.
Durbar (DMSC) and Ashodaya Samithi		Demonstration Project and Feasibility Study	India	Female and transgender sex workers	Evaluates potential introduction of PrEP for female and transgender sex workers at Durbar Mahila Samanwaya Committee, a brothel-based project in Sonagachi, and the Ashodaya Samithi project for street-based sex workers based in Mysore. Demonstration project includes female sex workers at Durbar and Ashodaya sites; feasibility study includes female and transgender sex workers at Ashodaya.	Planned; expected start date first half of 2015. Expected completion December 2016.

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Be PrEPared - The Antwerp PrEP project	Institute of Tropical Medicine (ITM); Applied Biomedical Research (TBM) program of the Belgium Research Agency (IWT)	Demonstration Project	Belgium	MSM	To determine if PrEP is acceptable, can be taken safely and whether it can be integrated into existing prevention strategies. Provides daily, intermittent or late start PrEP, and offers participants the opportunity to different timing during the trial. Enrolling 250 MSM aged 18 and over who have a high risk of infection for 18 months, with follow-up every 3 months.	Planned; expected start date mid-2015. Expected completion mid-2017.
NZ PrEP	New Zealand AIDS Foundation; Auckland Sexual Health; Body Positive	Demonstration Project	New Zealand	People at high-risk of HIV	Currently in the planning stages. Received approval from PHARMAC and the Ministry of Health. Work underway to gain clinical and ethical approval from the District Health Boards to make PrEP available to people at high-risk of HIV, through the sexual health service.	Planned; expected start end-2015.
Anova Health Institute's Health4Men initiative	Anova Health Institute, Desmond Tutu HIV Foundation; Elton John AIDS Foundation	Demonstration Project	South Africa	MSM	To implement and review a limited rollout of PrEP among MSM in Cape Town, in partnership with the Desmond Tutu HIV Foundation.	<i>Status to come</i>
Bangkok Tenofovir Study (BTS) Follow-Up	Bangkok Metropolitan Administration, CDC, Gilead	Open label extension	Thailand	People who inject drugs	Follow-on trial of daily oral TDF in men and women who inject drugs	Ongoing; expected completion in early-2015.
The Demo Project	National Institute of Allergy and Infectious Diseases of the NIH	Demonstration Project	US (Miami, Florida; San Francisco, California; and Washington, DC)	MSM and transgender women	Enrolled 300 HIV-negative MSM and transgender women at City Clinic, while a sister project in Miami enrolled 157 participants in a PrEP regimen. Whitman Walker Clinic in Washington, DC enrolled approximately 100 participants.	Ongoing; started in October 2014. Finished last follow-up visit in January 2015.
East Bay Consortium/ CRUSH (Connecting Resources for Urban Sexual Health)	California HIV/AIDS Research Program of the University of California	Demonstration Project	US (East Bay, California)	Young MSM of color	Aims to test and link young MSM of color to sexual health services; enhance and evaluate engagement and retention strategies for HIV-positive young MSM of color; and engage and retain HIV-negative young MSM of color in sexual health services, including PrEP.	Ongoing; started in May 2013. Expected completion January 2017.
LAC PATH PrEP Demo Project	California HIV/AIDS Research Program of the University of California; LA County HIV & STD Program; Los Angeles Gay and Lesbian Center; OASIS Clinic; AIDS Project LA; UCLA	Demonstration Project	US (Los Angeles, California)	MSM	Plans to enroll 375 high-risk MSM and transgender women who will receive a customized prevention package that may include PrEP.	Ongoing; expected completion date of May 2017.

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California Collaborative Treatment Group Consortium/ ALERT (Active Linkage, Engagement and Retention to Reduce HIV)	California HIV/AIDS Research Program of the University of California, San Diego County HIV, STD, and Hepatitis Branch and the Long Beach Health and Human Services Agency	Demonstration Project	US (Long Beach, Los Angeles and San Diego, California)	MSM	Plans to enroll 400 eligible high-risk MSM, for two years who will receive daily TDF/FTC-based PrEP, into a randomized study that evaluates whether a text messaging–based adherence intervention can improve adherence to the PrEP medication.	Ongoing; expected completion date October 2015.
Sustainable Healthcenter Implementation PrEP Pilot Study (SHIPP)	CDC; CDC Foundation; Gilead Sciences	Implementation pilot study	US	MSM and heterosexual women	Evaluates real-world PrEP use in MSM, heterosexual women and men and people who inject drugs in four federally qualified health centers and primary care services, in 1,200 participants.	Ongoing; started October 2014. Expected completion May 2017.
SPARK Project NYC	HART and Callen-Lorde Community Health Center (CLCHC); funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA)	Demonstration Project	US (New York)	MSM and transgender women	Designed to evaluate a program in which PrEP is introduced, provided, and supported as part of a comprehensive prevention package. The project is also designed to identify and examine social and behavioral factors associated with disparities in access to prevention and care services among gay, bisexual, and other men who have sex with men in NYC that might direct or impact PrEP implementation programs and policies.	Ongoing; started October 2013. Expected completion of July 2017.
Project PrEPare (Adolescents 18-22)	Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN); funded by NICHD, NIDA, NIMH	Open Label Demonstration Project and Phase II Safety Study	US (Baltimore; Boston; Bronx, New York; Chicago; Washington, DC; Denver; Detroit; Houston; Los Angeles; Memphis; Miami; New Orleans; Philadelphia; Tampa)	MSM	Designed to explore the safety, acceptability and feasibility of PrEP among young men who have sex with men (YMSM) who are at risk for HIV infection. This study will take place at clinical sites across the US with about 300 HIV-uninfected YMSM.	Ongoing, started November 2012; expected completion November 2015.
Project PrEPare (Adolescents 15-17)				MSM		Ongoing; expected completion March 2016.
HPTN 073	HPTN; funded by NIAID/NIH	Open label demonstration project	US (Los Angeles, California; Washington, DC; Chapel Hill, North Carolina)	MSM	Designed to assess the initiation, acceptability, safety, and feasibility of PrEP for Black MSM (BMSM). A subset of participants will also be recruited to participate in qualitative interviews about facilitators and barriers regarding PrEP. Recruiting HIV-uninfected BMSM at risk for HIV infection in three US Cities. Enrollment will include those aged 18 and over with an effort to recruit an equal number of BMSM under age 25 and over age 25 with a total of 225 participants (75 per site).	Ongoing; started July 2013. Expected completion mid-2015.

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iPrEx OLE	Sponsored/funded by DAIDS/NIH, through a grant to the Gladstone Institutes.	Open label extension	Brazil, Peru, Ecuador, South Africa, Thailand, US	MSM and transgender women	Continuation of the iPrEx study designed to provide additional information about the safety of PrEP and the behavior of people taking PrEP over a longer term.	**Results show PrEP provides a high degree of protection against HIV infection, even for individuals who miss some daily doses; high Interest in PrEP; longer-term evidence of safety and efficacy; and no sign of increased risk behavior among PrEP users.**
CDC 494 (TDF2 Follow-Up)	Botswana Ministry of Health, CDC, Gilead	Open label extension	Botswana	Heterosexual men and women	Follow-on trial of daily oral TDF/FTC in heterosexual men and women.	Completed. Full results expected mid-2015.
PROUD (pilot trial)	Sponsored/funded by UK MRC CTU, Public Health England	Open label pilot study for Phase IV trial	UK	MSM	<i>Randomization stopped in October 2014 after an interim analysis showed that PrEP was protective against HIV. Participants in the deferred arm offered PrEP. Trial to continue for one year to look at long-term benefit and safety.</i> Enrolled 500 MSM, assessed: whether or not a large trial is feasible; the level of interest in PrEP in clinic populations; acceptability of randomization; who takes up offer of PrEP; risk behavior over; change in risk following behavioral interventions; adherence behavior over time (self-report, pill count, and real time PK in a sub-set); and facilitators and barriers to reducing risk and adhering to a daily pill.	**Results show PrEP reduced the risk of HIV infection by 86 percent for MSM when delivered in sexual health clinics in England.** Ongoing; full results expected 2016.
IPERGAY	Inserm-ANRS	III	Canada, France, Germany	MSM	<i>Randomization stopped in October 2014 after DSMB examination of data showed PrEP was protective against HIV. All trial participants offered PrEP "on demand." Trial to continue for one year to demonstrate long-term benefit and safety of "on demand" PrEP.</i> Evaluated "on demand" PrEP with Truvada versus placebo arms. The drug regimen involved taking Truvada in the 24-hour period before anticipated sex and then, if sex happened, two separate one-pill doses in the two days following sex.	**Results show PrEP reduced HIV risk among the MSM who were prescribed the study regimen by an average of 86 percent.** Ongoing; full results expected 2016.
HPTN 067 (ADAPT)	DAIDS, Gilead, HPTN, NIMH	Phase II open label	South Africa, Thailand, US	Women (South Africa); MSM and transgender women (Thailand & US)	Randomized study designed to examine the feasibility of different methods of dosing for a PrEP regimen. Three methods of delivery will be compared: daily, twice-weekly, and pre and post sex dosing.	**Preliminary results from women in Cape Town show daily dosing fostered better adherence, better coverage of potential sexual exposure, and more sustained use of PrEP by South African women.** Ongoing; full results currently being analyzed and expected mid-2015.

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HPTN 069/ACTG 5305 (NEXT-PrEP)	ACTG, HPTN, NIAID	Phase II	US (Baltimore, Boston, Chapel Hill, Cleveland, Los Angeles, New York, Newark, Philadelphia, Pittsburgh, Raleigh, San Francisco, San Juan, Seattle, Washington)	MSM and at-risk women	Designed to evaluate the safety and tolerability of four ARV regimens in preventing HIV infection in a population of men who have sex with men who may be at risk of getting HIV infection through sex. The four ARV regimens being evaluated are maraviroc (MVC), MVC plus emtricitabine (FTC), MVC plus tenofovir disoproxil fumarate (TDF), and TDF plus FTC.	Ongoing; expected completion November 2015.

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