AVAC
Global Advocacy for HIV Prevention

Ongoing and Planned PrEP Trials and Demonstration Projects, as of December 2013

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.	All four sites open and enrolling as of August 2013; results expected in 2016.
LVCT and SWOP	Implemented by national partners in each country in collaboration with the World Health Organization, UNAIDS, O'Neill Institute of Georgetown University, London School of Hygiene and Tropical Medicine, Imperial College London; funded by Bill & Melinda Gates Foundation	Demonstration Project	Kenya	Young women, female sex workers and MSM	Aims to introduce PrEP into combination prevention interventions targeting young women, female sex workers and MSM. Formative research underway to assess consumer perceptions and identify potential barriers and opportunities related to introduction. Outcomes include criteria for PrEP indication among young women and a menu of interventions for target populations, including PrEP and feasible delivery options.	Formative research in planning phase; feasibility study report results likely in December 2013.
Nigerian National Agency for the Control of AIDS		Demonstration Project	Nigeria	Serodiscordant couples	Evaluates the effectiveness of various models for the delivery of PrEP and TasP as part of a 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 sites include Plateau, Edo and Cross River State. Study findings will be used to inform the scale-up of PrEP and TasP as part of a comprehensive national HIV-prevention package.	Formative discussions underway. No start date for demonstration project.
Wits Reproductive Health and HIV Institute		Demonstration Project	South Africa	Female sex workers	Aims to assess whether oral PrEP and TasP can be rolled out within a combination prevention and care approach tailored to the needs of 605, both HIV-positive and negative, female sex workers age 18 and older. Study sites include Hillbrow and Waterval Boven.	Expected start date of February 2014, with expected completion September 2016.
Durbar (DMSC) and Ashodaya Samithi		Demonstration Project	India	Female and transgender sex workers	Aims to assess the potential introduction of PrEP among female and transgender sex workers. The project includes sex workers part of the Durbar Mahila Samanwaya Committee (DMSC), a brothel-based sex work project in Sonagachi, and also the Ashodaya Samithi project, a CBO for street-based sex workers based in Mysore.	Feasibility study underway from May to September 2013, with results expected in October 2013.
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	Aims to enroll 300 HIV-negative MSM and transgender women at City Clinic, while a sister project in Miami will enroll 200 participants in a PrEP regimen. Whitman Walker Clinic in Washington, DC, will also be a site, aiming to enroll approximately 100 participants.	Started October 2012. Expected completion by August 2014.
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.	Started in December 2012.

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DemoPrEP	University of Sao Paulo; Centro de Referência e Treinamento DST AIDS; Oswaldo Cruz Foundation	Demonstration Project	Brazil	MSM; transgender women	Plans to enroll 400 MSM and transgender women to assess the acceptability, feasibility and safety of daily, oral TDF/FTC as PrEP over 12 months.	Planned to start in January 2014. Expected completion date of January 2016.
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.	Started in May 2013. Expected completion date of May 2017.
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.	Started in January 2013. Results expected October 2015.
CDC Foundation Demonstration Project	Funding pending	Demonstration Project	US	MSM and heterosexual women	Proposed to evaluate real-world PrEP use in MSM and heterosexual women at risk of HIV infection in health clinic settings, potentially in 1,200 participants.	Start date pending funding.
Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)	NIAID	Demonstration Project	South Africa	Heterosexual men and women	Designed to combine different HIV prevention strategies into an optimized prevention ´menu´ for adolescents, from which young women and men at risk of HIV infection may choose a particular combination of strategies to meet their specific needs and circumstances, including PrEP, microbicides, HIV Counseling and Testing (HCT) and circumcision.	Started in July 2011; results expected June 2015.
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.	Started in October 2013.

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Victorian PrEP Demonstration Project	Monash University and Alfred Health at the Victorian AIDS Council/Gay Men's Health; funded by the Victorian Government	Demonstration Project	Australia	At-risk population	To determine the effectiveness of PrEP in the local setting and the factors contributing to its success. Truvada will be administered to half the cohort for up to 12 months. The other participants will elect not to use Truvada, but agree to provide relevant information through regular on-line surveys.	Planned and funded; to run for three years.
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.	Started in November 2012; results expected November 2015.
Project PrEPare *(Adolescents 15-17)*				MSM		Estimated start date 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. The study will recruit 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).	Enrolling as of July 2013; results expected June 2015.
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	Expected start date in mid- to late-2013, with expected completion in late-2014.
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	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.	Fully enrolled and complete; results expected late-2013.
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.	Started in November 2012; results expected in late-2013.
PROUD *(pilot trial)*	Sponsored/funded by UK MRC CTU, Public Health England	Open label pilot study for Phase IV trial	UK	MSM	Enrolling 500 MSM, aims to assess: 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 time (self-report, STIs); change in risk following behavioral interventions; adherence behavior over time (self-report, pill count, and real time PK in a sub-set); facilitators and barriers to reducing risk and adhering to a daily pill.	Started in November 2012; results expected November 2015.
IPERGAY	Inserm-ANRS	III	Canada, France,	MSM	Designed to evaluate a strategy for the prevention of HIV infection	Started in Canada and

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			Germany		including "on demand" antiretroviral pre-exposure with Truvada versus placebo, associated with overall prevention (counseling, condoms, STD screening, HBV and HAV vaccinations and post-exposure treatment of HIV infection) in MSM, exposed to the risk of HIV infection.	France; start pending in Germany; results expected December 2016.
HPTN 067 (ADAPT)	DAIDS, Gilead, HPTN, NIMH	Phase II open label	South Africa, Thailand, US	MSM	Designed to examine the feasibility of different methods of dosing for a PrEP regimen. Three methods of delivery will be compared: daily, time-based, and event-based.	Started in August 2011; results expected late-2013.
HPTN 069/ACTG 5305 (NEXT-PrEP)	ACTG, HPTN, NIAID	Phase II	US (Baltimore, Boston, Chapel Hill, Cleveland, Los Angeles, New York, Newark, Philadlphia, 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.	Started in February 2012; results expected December 2014.
ATN 110	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	Phase II (and Open Label Demonstration Project)	US (Los Angeles, Denver, Miami, Tampa, Chicago, New Orleans, Baltimore, Boston, Detroit, Philadelphia, Memphis, Houston)	YMSM	Enrolled 200 HIV-uninfected YMSM at high risk of acquiring HIV infection, ages 18-22 years. Subjects complete the behavioral intervention, Many Men, Many Voices (3MV) and Personalized Cognitive Counseling (PCC), offered at their respective site and then are provided with open label TDF/FTC as PrEP. Those subjects who meet specific bone or renal criteria will be followed in the Extension Phase. The primary objectives of the study are to provide additional safety data regarding TDF/FTC use as PrEP in YMSM, to examine acceptability, patterns of use, rates of adherence, measure levels of drug exposure and patterns of risk behavior when YMSM are provided open label TDF/FTC. The study will also examine information regarding safety and efficacy of PrEP from prior studies.	Enrollment completed. Started in November 2012; results expected November 2015.
ATN 113	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	Phase II (and Open Label Demonstration Project)	US (Los Angeles; Denver; Chicago; New Orleans; Boston; Philadelphia)	YMSM	Enrolling 100 HIV-uninfected YMSM at high risk of acquiring HIV infection, between the ages of 15-17. Subjects will first complete the behavioral intervention (3MV and PCC) offered at their respective site and will then be provided with open label TDF/FTC as PrEP. Those subjects who meet specific bone or renal criteria will be followed for an additional 48 weeks in the Extension Phase. The aims of the study are to obtain additional data on the safety of TDF/FTC and to evaluate acceptability, patterns of use, rates of adherence, and measured levels of drug exposure when YMSM are provided with open label TDF/FTC and information regarding safety and efficacy of PrEP from prior studies. The study will also examine patterns of sexual risk behavior among high-risk HIV-1 uninfected YMSM in the US who are provided with open label PrEP. The study will also explore the feasibility and acceptability of implementing two different types of efficacious risk reduction interventions prior to the provision of PrEP - 3MV and PCC.	Currently enrolling. Started in March 2013; results expected March 2016.