

Ongoing and Planned PrEP Open Label, Demonstration and Implementation Projects, as of April 2018							AVAC Global Advocacy for HIV Prevention	
Trial/Project	Sponsor/Funder	Type/Category	Location	Population	Design/Key questions	Status	Status Details	
3Ps for Prevention Study (Perception, Partners, Pills)	DTHF; University of Washington; funded by NIH/DAIDS and BMGF	Demonstration Project	South Africa	Adolescent girls and young women ages 16-25	Demonstration project in Masiphumilele (Cape Town) assessing uptake to oral PrEP and effect of conditional incentives based on drug levels on adherence to oral PrEP. Through BMGF supplemental funding, PrEP demand creation campaign is being developed with McCann South Africa and PrEP uptake will be enumerated.	Ongoing	Ongoing; started February 2017.	
Anova Health Institute's Health4Men Initiative	Anova Health Institute, Desmond Tutu HIV Foundation; Elton John AIDS Foundation	Demonstration Project	South Africa	MSM	Limited rollout of PrEP among 300 MSM at two sites. Primary research question: Can primary health care nurses provide PrEP to MSM at a primary health care level?	Completed	Completed; ended December 2017.	
CAPRISA 082: Prospective Study of HIV Risk Factors and Prevention Choices in Young Women in KwaZulu-Natal, South Africa	USAID; CAPRISA	Observational study	South Africa	Adolescent girls and young women aged 18-24; women 25-30	Observational study looking at: 1) demographics, 2) HIV risk perception and behavioural assessment, 3) acceptability assessment of expanded HIV prevention options. Data on PrEP uptake, adverse events, usage, barriers, PrEP cycling, adherence by pill count and drug levels will be collected.	Completed	Completed; study closed February 2018.	
CAPRISA 084: A demonstration project of daily oral PrEP as part of sexual reproductive health services for young women at high risk of acquiring HIV in KwaZulu-Natal	USAID; CAPRISA	Demonstration Project	South Africa	Adolescent girls and young women aged 18-24; women 25-31	This PrEP demonstration project will identify in two high HIV burden districts in KwaZulu-Natal: who is likely to use PrEP; how PrEP will be used (understanding pill taking practices); barriers to consistent adherence; how PrEP will change current behavioral practices for HIV prevention (risk compensation); and what support and training is required for service providers.	Ongoing	Ongoing; started in June 2016.	
Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)	NIAID	Demonstration Project	South Africa	AGYW, Adolescent Men	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.	Completed	Completed; still providing PrEP.	
Church of Scotland Hospital PrEP Project	Church of Scotland Hospital	Demonstration Project	South Africa	Adolescent girls	Aims to recruit pregnant teenagers at their first ANC visit and enroll them into comprehensive support program, including PrEP, with the aim of improving outcomes for the mothers and babies. Central focus will be assisting young mothers to return to school, prevent acquisition of HIV and postponing further pregnancies. Other adherence strategies will be investigated as well.	Planned	Planned.	
DREAMS	PEPFAR, BMGF, Nike Foundation	Implementation Project	Kenya, South Africa, Swaziland, Uganda, Lesotho, Tanzania, Zambia, Zimbabwe	AGYW	Partnership to reduce HIV infections among AGYW; extends beyond health sector to address poverty, gender inequality, sexual violence, lack of education; PrEP implementation component included.	Ongoing	Ongoing.	
EMPOWER (Enhancing Methods of Prevention and Options for Women Exposed to Risk) Consortium	Wits RHI, LSHTM; USAID	Demonstration Project	South Africa; Tanzania	Adolescent girls and young women aged 16-24 years	An initiative of STRIVE, a research consortium investigating the social norms and inequalities that drive HIV, that integrates violence prevention and combination prevention, including PrEP. Aims to assess whether it is feasible, acceptable, and safe to offer oral PrEP as part of a combination prevention package that addresses gender-based violence (GBV) and HIV.	Ongoing	Ongoing.	
HPTN 082: Evaluation of daily oral PrEP as a primary prevention strategy for young African women: A Vanguard Study	Wits RHI, HPTN; DAIDS, NIAID, NIMH	Demonstration Project	South Africa; Zimbabwe	Young women (16-25 years)	The goal of this study is to evaluate whether HIV-uninfected sub-Saharan African women ages 16-25 who are at high risk for HIV infection will initiate PrEP and achieve sufficient adherence using scalable adherence support interventions to achieve HIV prevention benefits from this promising biomedical prevention intervention.	Ongoing	Ongoing; started June 2016. Expected completion October 2018.	
IMPAACT 2009 (DAIDS ID 30020): Feasibility, Acceptability and Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy and Breast Feeding in Adolescents and Young Women	International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network	Observational study	Zimbabwe, South Africa, Malawi, Uganda	Adolescent girls and young women aged 16-24 years	Parallel, observational cohort study of HIV-uninfected pregnant adolescents and young women (aged 16-24). The study is designed to characterize adherence over time among women who initiate once daily oral PrEP during pregnancy and continue in the first 6 months following delivery, and to compare pregnancy outcomes among women who take PrEP and women who decline PrEP during the antenatal period.	Planned	Planned; Expected start early-2018.	
MSF AGYW PrEP Demo Program	MSF	Open Label Study	South Africa	AGYW	Clinic-based SRH club for delivery of PrEP to young women in Khayelitsha.	Ongoing	Ongoing; started June 2017.	
MTN-034/IPM 045	MTN; IPM; NIH	Phase IIa, Open Label	South Africa; Kenya; Zimbabwe	Adolescent girls and young women aged 16-17 years	Enrolling approximately 300 healthy, HIV-uninfected adolescent females between the ages of 16 - 17 years old (inclusive). Participants will be randomized to product sequence and will use a silicone elastomer vaginal matrix ring (VR) containing 25 mg of dapivirine (DPV) to be replaced each month for a total period of 6 months of use, as well as take oral emtricitabine/tenofovir (FTC/TDF) tablets daily for a 6 month product use period. The primary purpose of this trial is to collect safety and adherence data over the course of study product use. The study will also examine the acceptability of the study products. It is anticipated that this study will take approximately 12 months at each site to enroll the target sample size. Each participant will be followed for approximately 49 weeks.	Planned	Planning underway, expected start early 2018.	

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PEPFAR	PEPFAR	Implementation Project	South Africa, China, Laos, Thailand, Botswana, Cote d'Ivoire, DRC, Dominican Republic, Ethiopia, Haiti, Kenya, Lesotho, Mozambique, Namibia, Swaziland, Uganda, Ukraine, Vietnam, Tanzania, Zambia, Zimbabwe	At risk individuals	Provides PrEP to adults and adolescents at risk of HIV infection.	Ongoing	Ongoing.
<b>POWER: Prevention Options for Women Evaluation Research</b>	University of Washington ICRC, Carnegie Mellon University, DTHF, Harvard U., KEMRI, Massachusetts General Hospital, RTI, Wits RHI; USAID	Demonstration Project	South Africa; Kenya	Adolescent girls and young women aged 16-24; women 25-29	Assesses women's preferences for using microbicides and PrEP through demonstration projects with strategic pilots of delivery strategies, first with oral PrEP. Project will characterize choice, uptake, early adherence and identify cost-effective delivery models, including assessment of repeat HIV testing, decision-making within partnerships, and the interface with reproductive health services.	Ongoing	Ongoing; started July 2015, PrEP delivery cohort to begin late-2016. Expected completion June 2020.
<b>Right to Care (DREAMS)</b>	PEPFAR, BMGF, Nike Foundation	Demonstration Project	South Africa	Adolescent girls and young women	Proposed demonstration project under the DREAMS partnership, to reduce HIV infections among adolescent girls and young women—which includes efforts to address poverty, gender inequality, sexual violence, lack of education and PrEP.	Planned	Planned.
<b>Sibanye Health Project</b>	NIH	Demonstration Project	South Africa	MSM, Men, Transgender Women	A comprehensive HIV Prevention Package for MSM in Southern Africa.	Completed	Completed; no longer providing PrEP to former participants.
<b>The TAPS Demonstration Project</b>	BMGF	Demonstration Project	South Africa	FSW	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.	Completed	Completed; no longer providing PrEP to former participants.
<b>ECHO</b>	FHI 360	Open Label Study	South Africa, Kenya, Swaziland, Zambia	Women, AGYW	The ECHO Study will compare three highly effective, reversible methods of contraception (including a non-hormonal method) to evaluate whether there is a link between use of any of these methods and increased risk of acquiring HIV infection. A randomized clinical trial among about 7,800 women in four countries, ECHO will deliver evidence to support and guide individual, policy and programmatic decisions on contraception for women at risk of acquiring HIV infection.	Ongoing	Ongoing; expected end June 2019.