Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence

Presented by Robert M Grant (United States).

R.M. Grant[1,2,3], P.L. Anderson[4], V. McMahan[1], A. Liu[2,5], K.R. Amico[6], M. Mehrotra[1], C. Mosquera[7], M. Casapia[8], O. Montoya[9], S. Buchbinder[2,5], V.G. Veloso[10], K. Mayer[11], S. Chariyalertsak[12], L.G. Bekker[13], S. Hosek[14], E.G. Kallas[15], M. Schechter[16], D. Glidden[2], for the iPrEx study team

[1]Gladstone Institutes, San Francisco, United States, [2]University of California, San Francisco, United States, [3]San Francisco AIDS Foundation, San Francisco, United States, [4]University of Colorado, Denver, United States, [5]San Francisco Department of Public Health, San Francisco, United States, [6]University of Connecticut, Storr, United States, [7]INMENSA, Lima, Peru, [8]ACSA, Iquitos, Peru, [9]Equidad, Guayaquil, Ecuador, [10]FIOCRUZ, Rio de Janeiro, Brazil, [11]Fenway Health, Boston, United States, [12]Research Institute for Health Sciences, Chiang Mai University, Chiang Mai, Thailand, [13]Desmond Tutu Health Foundation, Cape Town, South Africa, [14]Stroger Hospital of Cook County/The CORE Center, Chicago, United States, [15]University of Sao Paulo, Sao Paulo, Brazil, [16]Praca Onze, Rio de Janeiro, Brazil

Background: The impact of HIV PrEP depends on drug uptake, adherence, sexual practices, and interactions between these factors.
Methods: Participants in randomized placebo-controlled iPrEx, ATN 089, or US PrEP Safety trials were enrolled in a 72-week open label extension (iPrEx OLE). The study provided services regardless of choice to receive oral FTC/TDF PrEP. Tenofovir-diphosphate (TFV-DP) was quantified in dried blood spots (DBS) among seroconverters and a random sample of site and visit matched seronegatives.
Results: 1603 HIV-uninfected persons enrolled, of whom 76% opted to receive PrEP. Non-condom receptive anal intercourse (ncRAI) was associated with PrEP uptake (P=0.001). The reasons for not requesting PrEP included concern about side effects (49%), the inconvenience of a daily pill (24%), and preference for other prevention methods (14%). Among those starting PrEP, HIV incidence was 1.83/100PY which was 49% (95% CI: -1 to 74%) lower than among those who did not choose PrEP after adjusting for sexual behavior, 53% (95% CI: 26 to 70%) lower than in the placebo arm of the randomized phase (3.93/100PY), and 51% (95% CI: 23% to 69%) lower than during the gap between the randomized phase and OLE (3.81/100PY). Incidence was lower among those with higher drug exposure.

TFV-DP in DBS (fmol/punch)	Est. dosing	% of follow-up	HIV incidence	95% CI
<2.5	None	26%	4.7/100 PY	2.8 to 7.2
2.5 to < 350	<2 tablets/wk	27%	2.2/100 PY	1.1 to 4.1
>=350 to < 700	2 to 3 tablets/wk	12%	0.6/100 PY	0.0 to 2.5
>=700 to 1249	4 to 6 tablets/wk	22%	0 /100 PY	0.0 to 0.6
>=1250	Daily	5%	0 /100 PY	0.0 to 1.1

[HIV Incidence According to TFV-DP in DBS]

Effective PrEP use (≥4 tablets/week) was associated with older age, more schooling, ncRAI, more sexual partners, and syphilis or herpes. The proportion reporting ncRAI decreased from 33% to 25% among PrEP recipients (P < 0.01) and from 27% to 20% among non-recipients (P< 0.01).
Conclusions: PrEP was preferentially requested by those reporting higher risk sexual practices; risk declined in the cohort, regardless of PrEP receipt. The impact of oral PrEP may be increased by these synergies and limited by non-adherence. DBS drug concentrations are convenient and strong correlates of PrEP protection.