HIV Pre-Exposure Prophylaxis in an Urban VA Infectious Disease Clinic Setting

Swalpa Udit* MD PhD, Reginald Hilarie* RN MSN, William Hua PhD, and Harry Lampiris MD
Department of Medicine, San Francisco VA Health Care System and University of California San Francisco, San Francisco, CA

Background

- Once daily dosing of oral Tenofovir/Emtricitabine (Truvada), known as pre-exposure prophylaxis (PrEP) has been demonstrated to be highly effective in prevention of human immunodeficiency virus (HIV) infection in multiple trials.
- As PrEP expands into wider clinical applications, questions remain about its use outside of the research context.

Initial Visit

- Discuss interest in PrEP, indications, and side effects.
- Complete risk reduction counseling. Patient with option to see in-clinic psychologist for any behavioral health concerns.
- Baseline labs: HIV Ab, other STI screening (RPR; urine, pharyngeal, and rectal GC/CT), Hep B screening, and Creatinine.
- Prescribe 30 day supply.

One Month

- Evaluate for side effects, adherence, and interest in continuing.
- If patient tolerating PrEP and interested in continuing, prescribe 90 day supply, renewable only with repeat HIV testing.

Three Months

- Laboratory evaluation: HIV Ab, RPR, GC/CT (urine, pharyngeal, and rectal), Creatinine. Consider LFTs and Hepatitis C screening.
- Evaluate for continued indication, side effects, and adherence, and reinforce importance of continued safer sex practices.

Methods

Subjects:

- All outpatients (n = 80) evaluated for initiation of PrEP in the San Francisco VA Infectious Disease Clinic between February 2014 and March 2016.

Methods:

- As part of the PrEP program, patients were screened for HIV infection, contraindications to the use of Tenofovir/Emtricitabine, and indications for PrEP during an in-person intake visit.
- Safety assessments and HIV/STI screening were repeated at one month after initiation and then every 3 months. Data on demographics; indications; reported side effects and adherence; and testing for HIV, other STIs, and Creatinine was collected via retrospective chart review. Compliance was also assessed based on completion of required visits and testing.
- We present descriptive statistics about demographic, indications, HIV and other STIs, and compliance data. The institutional review board at UCSF approved this study.

Referrals for PrEP Evaluation

- Over the course of the study period, 80 individuals were referred for evaluation of PrEP.
- Of these, **91% (73) were started on PrEP**. Reasons for not starting PrEP included low risk for HIV, concern about potential side effects, and ineligibility due to other medical conditions.

Characteristics of the Participants

	Percentage of Individuals
Age	
< 30	14.1%
30 – 39	35.2%
40 – 49	18.3%
50 – 65	16.9%
> 65	15.5%
Gender	
Male	96.3%
Female	1.3%
Transgender	2.5%
Sexual Orientation	
Gay and Bisexual Males	94.4%
Heterosexual Males	1.4%
Bisexual Females	1.4%
Transgender with Male Partners	2.8%

Indications for PrEP

Indication	Percentage of Individuals
Unprotected Anal Intercourse	69.9%
Multiple Sexual Partners	45.2%
Serodiscordant Partners	34.2%
Prior Post-Exposure Prophylaxis Use	11.0%
Prior Bacterial STI	27.4%
Intravenous Drug Use	1.4%

Most participants had multiple indications.

HIV Prevention

- There were **no diagnoses of HIV** during the **59 person-years** of follow-up.
- Data from the delayed treatment arm of the PROUD study would predict an incidence of HIV infection as high as **8.9 per 100 person-years** in a high risk population in the absence of effective prophylaxis.

Incidence of Other STIs

	Percentage of Individuals
At Least One STI	25.0%
Multiple STIs	6.7%

n = 60 patients with at least 3 months of follow-up
Average follow-up of 11 months

Other STIs

	Percentage of STI Cases
Chlamydia (CT)	48.1%
Gonorrhea (GC)	40.7%
Syphilis	3.7%
Other	7.4%

Sites of GC/CT

Site	Percentage of Cases
Rectal	45.5%
Pharyngeal	36.4%
Urethral	4.5%
Infection at Multiple Sites	13.6%

Compliance

	Percentage of Individuals
No Missed Doses	66.7%
1-2 Missed Doses/ Month	6.3%
> 2 Missed Doses/ Month	7.9%
Self-discontinuation*	11.1%
Discontinuation due to Noncompliance (Missed Visits/STI screening)	7.9%

*Reasons patients cited for discontinuation included entering into monogamous relationship, pill fatigue, and side effects.

Side Effects

Side Effect	Percentage of Individuals
None	74.5%
Startup Syndrome	14.5%
Fatigue/Myalgias	5.5%
Acute Kidney Injury	3.6%
Increased LFTs	1.8%

Limitations

- Lack of a control group limits ability to attribute effects to PrEP use.
- All data was collected for clinical and not research purposes, introducing variation in assessment by individual providers.
- Adherence to PrEP is self-reported.

Conclusions

- Despite high rates of bacterial STIs, there were no new HIV infections among our PrEP cohort.
- High rates of bacterial STIs raise concern about behavioral modification in patients on PrEP.
- The incidence of bone and renal toxicity was low in this relatively high risk population due to age and comorbidities.
- Overall, there is high interest in PrEP, with most users tolerating therapy well with good compliance.