Background

Truvada (TVD) used for HIV Pre-Exposure Prophylaxis (PrEP) was approved by the FDA in July 2012 to reduce the risk of sexually acquired HIV in high-risk adults. From Gardner’s HSV cascade, approximately 20% of people diagnosed with HIV are unaware of their status and may be correlated to 54% of new infections. In addition, only 40% of people diagnosed are treated and only 20% of all HIV infected individuals have HIV RNA < 50 copies/ml. The people who are not virally suppressed comprise approximately 60% of new infections. HPTN 052 have shown that “treatment as Prevention” strategy have shown to decrease the transmission of HIV in serodiscordant couples. PrEP has been shown to be safe and efficacious in numerous clinical trials in MSM, young heterosexual adults and IDU, however, longitudinal “real world” data is lacking. We describe an approach to implementation of PrEP over a two and half year period, and report on patient health outcomes.

Methods

High-risk evaluation & reduction: The PrEP Specialist, or a Community Health Initiatives (CHI) tester meets with the PrEP patient at each visit to conduct a high-risk evaluation, HIV rapid test, and risk-reduction counseling. The high-risk evaluation involves discussing the patient’s current sexual behaviors including; number of sexual partners, HIV status of current partners, the type of sex they engage in, and frequency of condom use. After the risk-assessment, the tester works with the patient to create a risk reduction plan. The plan is specific to each patient’s needs. Examples include; improving PrEP adherence, increasing condom use, decreasing number of partners, or engaging in alternative lower-risk sexual practices.

HIV testing: PrEP patients will receive a 3rd generation rapid HIV test and a test for syphilis and every three months to confirm negative status. If a patient reports a high-risk encounter within the three month window period, the tester will report to the provider who will determine if a 4th generation or HIV RNA test is necessary.

Medication education: At baseline visits, PrEP patients will meet with the PrEP Specialist or Clinical Pharmacist to review medication information. The patient is counseled on the importance of adherence. Staff reiterates the CDC recommendation that Truvada takes 21 days to reach an appropriate level of concentration in the blood that is highest protection against HIV. Possible and common side effects are discussed and recommendations to side effects are given. The pharmacist or PrEP Specialist also discusses the importance of completing lab work at each visit.

Description of PrEP Program: At baseline visits the PrEP Specialist or Clinical Pharmacist will emphasize the need for follow up every three months and the procedures to be conducted at each follow up. Every three months the patient will receive HIV rapid testing and creatinine monitoring. The patient will receive STI testing at each visit. In addition, the provider recommends Hepatitis C testing annually. The PrEP Specialist will also follow up patients two weeks after the initial visit to review lab results, conduct treatment adherence counseling, and evaluate for side effects.

Medical provider role: Every visit the provider will confirm program eligibility and discuss clinical data with the provider will also summarize adherence and risk reduction provided by the PrEP Specialist or CHI tester and perform a physical exam with Provider notes stated above.

PrEP Specialist Role: In addition to HIV testing, risk evaluation and reduction, and medical follow up, the PrEP Specialist works with PrEP patients on non-medical concerns such as financial obstacles. Truvada and other PrEP list will apply to appropriate medication assistance programs based on patient’s income and insurance status. If uninsured, the PrEP Specialist will link the patient to an insurance company that will find the most appropriate plan for the cost of PrEP. Patients who are relocating can also be directed to PrEP providers in their area.

Results

All 119 patients from August 1st 2012 to April 1st 2015 evaluated for PrEP had a high risk; defined as having unprotected sex and at least one of the following: casual partners of people of unknown HIV status, have multiple sexual partners, are in a sero-discordant relationship, a recent sexually transmitted infection (STI), and/or are engaged in transactional sex. Eight of the 119 declined PrEP. Of the 111 who started PrEP 13 discontinued during the reported time period. The 98 individuals who started PrEP remained HIV negative while on treatment. 7.4% of PrEP patients self-reported having an STI in the last six months prior to intake. Between the initial visit and six months, 3.0% of the PrEP patients reported having been diagnosed with an STI.

According to data collected by routine risk assessments number of sexual partners decreased from 4.1 partners at the initial assessment to 3.3 partners at the six month follow up assessment. In-depth interviews were also conducted with 10% PrEP patients. In these interviews, patients reported no change in sexual behaviors and that peace of mind as well as staying HIV negative were the most positive outcomes from their experience on PrEP.

Conclusion

To date, in our medium-sized city community clinic, utilizing a team approach, all 98 patients remained HIV negative while on treatment, had an adherence rate of >90%, had no increase in STI rate, and had no change in their sexual routines.

Discussion

Early drug utilization analysis (Mera RM et al.) of PrEP in the US revealed that when compared to HIV – positive patients, HIV infected person receiving PrEP were more likely to be < (P < 0.01) female, < 25 years of age, treated by a non-ID physician and are from the South US. Our experience is different in that our demographics include 87.8% Male, ages 21 – 65, and treated by HIV specialist. We are planning to expand our success in other sub population who are also at high risk including, but not limited to injection drug users and adolescent population. In addition, we also plan to provide tele-PrEP consultations to underserved areas.

References:
