

**Agenda Item Number:**

**ORANGE COUNTY BOARD OF HEALTH  
AGENDA ITEM SUMMARY**

**Meeting Date:** August 27, 2014

**Agenda Item Subject:** Pre-Exposure HIV Prophylaxis Recommendation

**Attachment(s):** PrEP White Paper

**Staff or Board Member Reporting:** Andrea Mulholland, Family Nurse Practitioner II

**Purpose:**     Action  
                   Information only  
                   Information with possible action

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**Summary Information:**

Despite a decrease in the incidence in new HIV infections amongst heterosexuals and people who use IV drugs, the rate of new HIV infections continues to increase in men that have sex with men (MSM).

“Daily oral PrEP (pre-exposure prophylaxis) with the fixed dose combination tenofovir disoproxil fumarate (TDF) 300mg and emtricitabine (FTC) 200mg has been shown to be safe and effective in reducing the risk of sexual HIV acquisition.” (CDC, 2014)

Target Population: Serodiscordant couples; MSM engaging in high risk sexual behaviors or diagnosed with a STI within the last six months; Heterosexually active men and women who do not use condoms frequently; People who use IV drugs who report to share needles.

Prescribing Information: Truvada (tenofovir disoproxil fumarate (TDF) 300mg and emtricitabine (FTC) 200mg, once daily tablet.

Prior to initiation of PrEP: Assess client’s motivation and willingness to adhere to once daily medication, return for follow-up tests and counseling. Lab tests (initially & every 3 months) renal function tests \$12.00; Hepatitis B test: \$13.00; HIV test: Minimal cost as sent to NC State Lab for Public Health; Pregnancy test: Done in house.

Cost of Truvada: OCHD Medical Director, Dr. Julie Monaco, able to call in prescription to UNC Hospital Pharmacy, where a one month supply of medication is \$4.00 via the patient assistance program.

Side effects: Nausea, gas/bloating, and headache.

Barriers: Access to medication, motivation & willingness to take daily medication, return to clinic for appropriate counseling & lab tests, non-adherence.

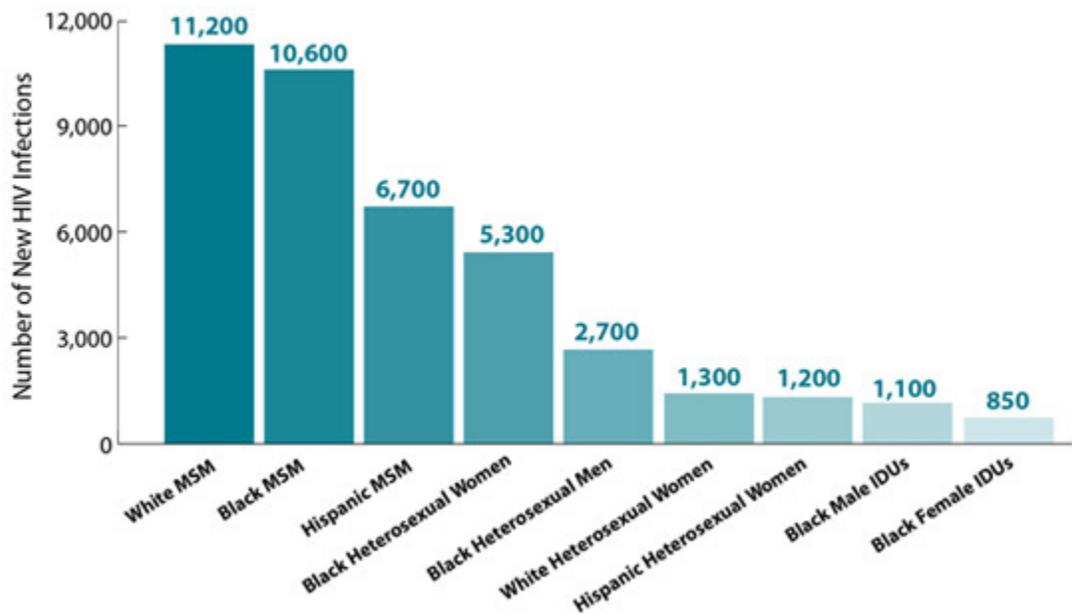
Staff recommends that the BOH approve this recommendation to expand services to include prescribing TDF and FTC as HIV pre-exposure prophylaxis.

- Recommended Action:**
- Approve
  - Approve & forward to Board of Commissioners for action
  - Approve & forward to \_\_\_\_\_
  - Accept as information
  - Revise & schedule for future action
  - Other (detail):

PrEP White Paper

According to the CDC, around 50,000 people in the US are infected each year with HIV. Data from 2008-2010 indicate that the incidence of new HIV infections has decreased or stabilized in heterosexuals and people who use IV drugs. However, the rate has increased among Men who have Sex with Men (MSM), particularly in young African American MSM. This information highlights the need for additional measures to prevent new HIV infections, particularly in young MSMs of all races and amongst African-Americans.

**Figure 1: Estimated New HIV Infections in the United States, 2010, for the Most Affected Subpopulations**



Source: <http://www.cdc.gov/hiv/statistics/surveillance/incidence/>

Chart review from Patagonia reviewing male STD visits from April – June, 2014 at Hillsborough and Chapel Hill reveal a total of 121 screens, 31 (HB) & 90 (CH). The following numbers represent the percentage of male clients who were MSMs within the STD Clinic.

HB: 1/31: MSM 3%

CH: 15/90: MSM 17%

3 new HIV infections were detected in CH cohort between this timeframe: 1 heterosexual Latino male, 2 homosexual AA males. These findings coincide with epidemiological trends seen at the national level.

In July, 2012, Truvada (tenofovir + emtricitabine) a once daily medication, was approved by the FDA, as part of a comprehensive strategy to prevent sexually acquired HIV infections in high risk people. Given guidance from the U.S. Public Health Service in 2014 and the recent trends seen at the OCHD, I feel this is a medication we should be offering to a select group of clients who present for STD screens.

Those considered high risk are:

- Serodiscordant couples
- MSM engaging in high risk sexual behaviors or diagnosed with a STI within the last six months
- Heterosexually active men and women who do not use condoms frequently
- People who use IV drugs who report to share needles

Clients eligible for Truvada need to be highly motivated to take the medication on a daily basis. In addition, blood tests for HIV, Hepatitis B, renal function tests and if indicated, pregnancy tests, need to be done prior to initiation of PrEP. Lastly, clients need to present to clinic every three months for repeat blood tests, counseling on HIV/STI prevention, preconceptual counseling, and review of medication adherence.

Out of pocket costs for a month supply of Truvada can range between \$1300-\$1400/month. OCHD medical director, Julie Monaco, has offered to call prescriptions into the UNC Hospital Pharmacy, where the medication can be obtained at a reasonable cost, which is \$4 for a one month supply. Costs to the OCHD are as follows: Hepatitis B test: \$13.00, BUN/Creatinine: \$12.00, HIV test: minimal as run at State Lab, and pregnancy tests: minimal as done in house. Reports of abnormal bone density have been reported amongst mothers taking Truvada during pregnancy. Therefore, pregnancy status should be assessed prior to initiation of the medication. In general, Truvada is well tolerated. Common side effects include nausea, gas/bloating, and headache.

Studies such as iPrEx and the US MSM Safety Trial examined the effectiveness and safety of Truvada in MSM. Overall, there were minimal adverse effects in the trial participants and high medication adherence correlated to high PrEP efficacy. Similar results were seen with heterosexual subjects in trials like partners PrEP trial, TDF2 trial, VOICE, FEM-PrEP, and the West African trial (Phase 2 Trial of PrEP with tenofovir among Women in Ghana, Cameroon, and Nigeria).

I do not estimate large number of our clients utilizing this medication. However, given the recent trends seen at OCHD, the need for additional HIV/STI preventative strategies, and guidance from the CDC and U.S. Public Health Service, I strongly feel that this is a medication the OCHD can offer to selected clients.

Reference:

US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States-2014 Clinical Practice Guideline (2014). Available at: <http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>