

AIDS ACTION BALTIMORE
PREP UP

Town Hall Meeting
Lynda Dee

March 9, 2016

PrEP UP Town Hall Meeting

- **Pre-Exposure Prophylaxis - PrEP works if you take it**
 - **MSM Data**
 - **Dosing**
 - **Behavioral Issues/Adherence**
 - **Resistance/HIV & STI Testing**
 - **Toxicity/Side Effects**
 - **Future Directions**

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- **PrEP MSM Reduced Risk of HIV & Dosing**
- **IPIRGAY OLE: 92%, PROUD 86%**
- **Demo Project: DC 88%, Miami 65%, SF 90%**
- **HTPN 076: ADAPT: Harlem, NYC and Bangkok:**
 - **Three Dosing Strategies:**
 - **Daily Dosing**
 - **Twice Weekly + post sex doses-time driven**
 - **Pre and Post sex doses-event driven**

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- Dosing Recommendations: CDC Guidelines - Daily
- IPREX OLE: 4x per week for 92% reduced risk of HIV
- **New Dosing Data: Not from a clinical trial**
 - UNC mucosal tissue PK + mathematical modeling study
 - Truvada levels are **10 times higher in colorectal vs vaginal tissue**
 - **2/3** doses of Truvada per week **are 75-95% effective in men**
 - **6/7** doses of Truvada per week **are necessary in women**

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- **HPTN 067-ADAPT MSM DOSING STUDY: Harlem & Bangkok**
 - **Daily** Truvada is most effective to prevent HIV infection, sex act coverage and best promoted adherence
 - Post-sex dose was the most frequently missed dose
 - Stigma related impediments were frequent at the Harlem site
 - Harlem participants were perceived as HIV+ and promiscuous
 - Partner disclosure fostered adherence in Bangkok
 - Both underscore the need for community education
 - Dosing preferences varied at the Bangkok site; doses adapted to participant preference may be the most powerful adherence tool

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- **MSM Behavioral Issues**
 - **Will people use condoms if they are using PrEP?**
 - Yes and No
 - PrEP adherence is better without condom use
 - **Will people have more sexual partners if they are using PrEP?**
 - No: The same or less sexual partners during studies
 - **Will recreational drug use affect PrEP adherence?**
 - Yes and No

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- **MSM Adherence**
 - **What are the best ways to foster adherence?**
 - **Daily dosing (ADAPT Study)**
 - **Stable living arrangements (DEMO Project Study)**
 - **Condomless insertive anal sex (ADAPT and DEMO)**
 - **Will all MSM populations take their medication as required?**
 - **UK, Canada, Harlem, Bangkok, DC, Miami,**
 - **SF only 7% black and 2% transgender**
 - **Will real life adherence be the same as during study participation???**

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- **New IPREX OLE Data in Trans Women**
 - **339** trans women in the study, **not 29**
 - Lower Truvada blood levels, half that of MSM
 - Less likely to take Truvada consistently
 - Higher rates of sex work, condomless receptive anal sex and STIs
 - No correlation of taking Truvada with condomless anal sex
 - Same reduced risk of HIV if they took Truvada 4x per week
 - Less bone mineral density loss. Is this from feminizing hormones?
 - Well tolerated, same side effect profile as those on placebo

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- **PrEP is effective in trans women**
- **But they have more barriers to PrEP use**
 - Institutional barriers and lack of legal protections
 - Lack of food and housing
 - Housing, income and employment discrimination
 - **Feminizing hormones are a priority**
- **Solutions:**
 - **Studies designed specifically for trans women**
 - **Trans-specific clinics, services and programs**
 - **Not lumped in with MSM studies or programs**
 - **Integration of PrEP clinics and hormone clinics**
 - **Prevention tools they can control**

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- **Resistance and HIV Testing**
 - **Will PrEP users who become HIV+ develop resistance to Truvada?**
 - Minimal resistance so far for people taking insufficient Truvada who become infected, but still keep taking Truvada
 - **One case of multi-drug resistant HIV transmitted from a partner**
 - **Thousands of people in trials have been protected by Truvada**
 - **CDC Guidelines still recommend condom use**
 - **Truvada is only 92% effective, not 100%**
 - **What is your level of risk comfort**
 - **How frequently should people be tested for HIV? Every 3 months**
 - **How frequently should people be tested for STIs?**
 - **CDC Guidelines: Every 6 months**
 - **Demo Project: Guidelines should be changed to every 3 months**
 - **Many rectal infections with no symptoms diagnosed by routine exams because no symptoms were being experienced**

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- **Side Effects and Toxicity**
 - Demo Project shows no serious side effects
 - ADAPT Study shows similar side effects in daily and intermittent dosing
- **New Side Effect Information: Bone Loss & Kidney Toxicity**
 - Loss of bone mineral density (BMD) (2-6%) reversed when Truvada stopped
 - High dose calcium that includes Vit D or Vit D alone may prevent related bone loss
- **Kidney Toxicity: New Monitoring Recommendation**
 - CrCl - Creatinine Clearance: Measure of waste products in kidneys
 - Elevated levels suggest improper kidney functioning
 - Normal levels in men: **97-137** ml per min and **88-128** in women
 - GFR - Glomerular filtration rate and eGFR - Estimated GFR
 - Calculated by age, gender, ethnicity and creatinine blood levels

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- **Kidney Recommendation: Additional Monitoring**
 - Partners PrEP: No proximal tubulopathy thru 24 months
 - US Demo Project
 - PrEP associated with modest eGFR decline after week 12
 - No further clinically relevant decline after week 48
 - **IPREX OLE: Additional monitoring or kidney consultation**
 - **New onset eGFR ≤ 70 , and**
 - **Baseline eGFR ≤ 90 , especially in patients over 40**

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- **Future Directions: TAF**
 - **TAF/FTC is replacing TDF/FTC (Truvada) for HIV TX**
 - **TAF containing regimens have the same efficacy**
 - **TAF has a better kidney & BMD side effect profiles**
 - **Side effect profiles maintained in longer term trials**
 - **TAF PrEP study successfully completed in animals**
 - **CDC TAF/FTC trials are in the works**

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- **Future Directions: HPTN069/ACTG5305 Maraviroc (MRV)**
 - MRV used for HIV TX; has **better kidney side effect profile**
 - **MRV alone or MRV/FTC** (Truvada = TDF/FTC = kidney and BMD issues)
 - Almost 400 high risk individuals with 22% having over 100 STIs
 - **Adverse events are the same in both arms**, BMD yet to be reported
 - Not enough people in the study to definitively say one arm is better
 - 4 HIV infections in the MRV alone arm (3/4 had low drug levels)
 - 1 HIV infection in the MRV/FTC arm (No drug levels found)
 - Explant studies showed **MRV alone offered less protection**

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- **Future Directions: Cabotegravir (CTG) - ÉCLAIR Study**
 - Long Acting (LA) formulation every 12 weeks
 - Study suggests that every 8 weeks is better
 - Intramuscular (IM) injections were well tolerated
 - Mild to moderate injection site reactions (ISRs)
 - No study discontinuations; no kidney or BMD issues
 - 85-95% satisfied with CTG and would continue LA IM
- **Future Directions: MK-8591- 6 months to 1 year**

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- **Next Town Hall Meeting**
 - **Wednesday, May 25, 2016**
- **Time**
 - **6:30 to 8:00 PM**
- **Place**
 - **First and Franklin Presbyterian**

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• THANK YOU

- Ashley Queen**
- Richard Pazornick**
- First and Franklin Presbyterian Church**
- Center for AIDS Research & REACH HIV**
Joyce Jones, MD
- PrEP UP: Falina Chanel, Alvin Moody,**
Jeffrey Grabelle, Phillip Lovett