AIDS ACTION BALTIMORE
PREP UP

Town Hall Meeting
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September 27, 2017
PrEP UP Town Hall Meeting

• IAS & CDC HIV Statistics
• IAS: PrEP Usage Update
• IAS: Long-Term PROUD Results
• IAS: Ipergay “On Demand” PrEP Results
• IAS: New Drugs for PrEP
• IAS: Why Some People Don’t Use PrEP
• IAS: PreP Adherence Measurements
• IAS: Generic PrEP Usage Report
• IAS: HIV Transmission in Undetectable Couples
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• CDC HIV Transmission Statistics
  • 1 in 49 in Maryland
  • 1 in 20 in Black Men in the US
  • 1 in 2 in Black MSM in the US
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• Increases in HIV Transmission

<table>
<thead>
<tr>
<th>Table 1. HIV diagnoses by year of diagnosis, United States, 2008–2014.</th>
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</thead>
<tbody>
<tr>
<td>2008  2009  2010  2011  2012  2013  2014  EAPC  P</td>
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<tr>
<td>---------------------------------------------------------------</td>
</tr>
<tr>
<td>All MSM</td>
</tr>
<tr>
<td>Black Hispanic/ Latino</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>13–24 years</td>
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<tr>
<td>25–34 years</td>
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<tr>
<td>35–44 years</td>
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<tr>
<td>45–54 years</td>
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<tr>
<td>55–64 years</td>
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<tr>
<td>≥65 years</td>
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<tr>
<td>EAPC: Estimated annual percent change</td>
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• Increases in HIV Transmission
  • MSM: 94% versus 62% of all others
  • Hispanic/Latino: 49% versus 28%
  • Age under 30 at diagnosis: 68% versus 41%
  • Under-30 MSM: 63% versus 31%
  • Under-30 Hispanic/Latino MSM: 32% versus 9%
  • Enhanced prevention efforts for use & Latino MSM
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- PrEP Usage Update from Gilead Sciences
- CDC: 400,000 US MSM could benefit from PrEP
- Gilead: 120,000 have started PrEP since 2012
- Underestimate? Only includes 80% of prescriptions
- No Central Data Collection
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• PrEP Usage Update from Gilead Sciences

• Still lagging in some groups

• 83,672 men; average age of 38

• 15,060 women, some trans women; average age of 35

• 73% white, 13% Latino, 10% black, 4% Asian

• New cases: 45% black, 25% white, 24 Latino, 2% Asian
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- Previous PrEP MSM Reduced Risk of HIV Results
  - French IPERGAY OLE: 92%
  - Great Britain: PROUD 86%
  - Demo Project: DC 88%, Miami 65%, SF 90%
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- Long-Term PrEP MSM Reduced HIV Risk Results
  - Great Britain: PROUD 86% in year 1
  - 60% of people still on PrEP 2-4 years later
  - High rates of STIs confirm PrEP is still needed
  - Reduced rates of HIV transmission sustained
  - High adherence = durable effectiveness
  - HIV infections are the result of non-adherence
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- French Ipergay “On Demand” Study
  - If taken correctly, PreP works “on demand”
  - Double dose of PrEP 24 hours before sex
  - Single dose for 2 days thereafter
  - Sex more than 2X weekly = almost daily use
  - “On demand” has had worst adherence record
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• French Ipergay “On Demand” Study
  • 2/3 “on demand” users at least one two month period
  • Much smaller numbers than the entire trial
  • No HIV transmission if PrEP users are adherent
  • 3000 PrEP users in France; half “on demand”
  • Public health significance even with this small study
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• ÉCLAIR Study: Safety and acceptability CTG (CROI 2017)

• Mostly gay and bi-sexual men at low risk for HIV

• 800mg intramuscular (IM) injection every 12 weeks
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• CTG was absorbed quickly and did not last as long as expected

• Injection site reactions (ISRs) more frequent and prolonged

• Nevertheless 3/4 of participants said the would continue IM CTG
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• IAS 2017: HTPN 077: CTG in 199 low risk participants

• Purpose: To measure safety & drug levels to determine optimal dose

• Informed by ÉCLAIR: CTG 600mg IM every 8 weeks
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- Long-Acting Cabotegravir (CTG) for HIV Prevention
  
  - Conducted in Brazil, Malawi, South Africa, United States
  
  - Average age 30; 2/3 women, but in US, mostly men
  
  - 6 trans men and 1 trans women; 40% black, 27% white, 24% Latino
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• Participants first received oral CTG to ensure safety

• Thereafter, CTG at a 3/1 ratio (3 CTG arms, 1 arm placebo)

• 41 week dosing period with 52 weeks of follow-up initially

• Longer follow-up needed based on study results
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- Long-Acting Cabotegravir (CTG) for HIV Prevention

- 52 weeks extended because of the “long CTG tail” in some

- Long CTG tail could cause HIV resistance after stopping PrEP

- 94% completed oral phase; 75% completed all injections
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• Both men and women had high completion rates

• 8% discontinued from side effects, risk behavior change, pregnancy

• Drug level drops steeper in men than women; some accumulation
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- Long-Acting Cabotegravir (CTG) for HIV Prevention
  - 52 weeks extended because of the “long CTG tail” in some
  - 600mg dose every 8 wks met PK targets for both men and women
  - 94% completed oral phase; 75% completed all injections
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• Most had mild to moderate ISRs; 34% v. 2% with placebo

• 90% ISRs after 1st injection; 60% after 5th injection; 1 discontinued

• Headaches 15% with CTG v. 2% with placebo
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• Long-Acting Cabotegravir (CTG) for HIV Prevention

• Every 8 wk injections = sufficient drug levels to protect against HIV

• Next steps: Larger studies to see whether this dose will prevent HIV

• HPTN 083: Injectable CTG v. Truvada is now underway
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• Long-Acting Rilpivirine for HIV Prevention
  • Phase 1 study; multiple rilpivirine doses to measure drug levels
  • Lower cervical tissue levels than rectal tissue, no cervical protection
  • Clinical development stopped
  • Side effects and cost were biggest concerns
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• Long-Acting Oral MK-8591 for HIV Prevention

• Novel NRTI (like AZT) prevention drug class known as Efda

• Good drug distribution levels in cervical and rectal tissue in monkeys

• 2 arms of 8 monkeys in each arm received MK-8591 or placebo

• Weekly doses with a maximum of 14 doses
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- Long-Acting Oral MK-8591 for HIV Prevention

- Rectal SHIV exposure on day 6, weekly thereafter, 12 max exposures

- No SHIV transmission after 12 initial wks and 12 wks follow-up

- All placebo arm monkeys became infected after 1-4 exposures

- MK-8591 will go on to further development
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• Low Burden Measurements for PrEP Adherence

• PrEP adherence is mandatory for PrEP effectiveness

• We need easy to implement measurements to check adherence

• 88 MSM patients from Washington University; average age = 27

• 58% white, 30% black, 6% Latino, 69% college graduates

• 71% reported condomless anal sex in the past 3 months
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• Low Burden Measurements for PrEP Adherence
  • Self-report (SR): What patients tell us about their adherence
  • Medication possession ratio (MPR): pharmacy pill or refill counts
  • Study compared SR and MPR v. dried blood spot tests
  • In the real world, SR and MPR correlated with dried blood spots
  • Per this small study, SR and MPR may be used to check adherence
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• MSM Reasons for Not Using PrEP
  • National online survey from Boston Fenway
  • From an MSM sex website in men over 18
  • 21% 18-24, 18% 25-29, 23% 30-39, 38% 40+
  • 48% white, 25% black, 11% Latino, 16% multi-racial
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• MSM Reasons for Not Using PrEP

  • 75% condomless sex twice or more in 3 mos

  • 8% once; 18% no condomless sex

  • About 17% PrEP ever used PrEP

  • 1/4 of non-PrEP users never heard of PrEP
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- MSM Reasons for Not Using PrEP
  - 40.2% cited cost as their reason for non-use
  - 31.4% cited concerns over potential side effects
  - 30.6% did not know how to access PrEP
  - 19.5% were concerned about insurance impact
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• MSM Reasons for Not Using PrEP
  • 19.3% not at risk of HIV transmission and provider’s reaction
  • 15.1% extremely likely to use PrEP in the future, 23.8% likely
  • 44.5% undecided, 9.8% unlikely, 6.3% extremely unlikely
  • 65.3% same condomless sex frequency, 30.2% more, 4.5% less
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• Summary of MSM Reasons for Not Using PrEP
  • Cost and side effects: Men with more than High School education
  • Cost and side effects: Men 30 or older
  • Cost concerns: Men who had condomless in the past 3 months
  • Access issues: Blacks, non-US born, condomless sex/past 3 months
  • Insurance concerns: Condomless sex in the past 3 months
  • Lack of perceived risk in monogamous men
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• No HIV Infections with Generic PreP Use in London

• UK PHS does not pay for either Truvada or generic PrEP

• As a result, some people buy generic PrEP on the internet

• London’s Chelsea & Westminster HIV Clinic began offering testing for HIV and STIs testing, and kidney and PrEP drug levels (2-2016)

• 641 generic PrEP users; median time on generic PrEP was 202 days
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- No HIV Infections with Generic PrEP Use in London

- 99.7% MSM, 81% white, 75% used daily PrEP; 14% “on demand”

- No fake PrEP discovered; drug levels similar to those on Truvada

- Before PrEP 16% had an STI; on PrEP, 26% got an STI

- Through 336 person years of follow-up, there were no HIV infections

- 10-15 to 6-17 new infections dropped from 69 to 15 per month
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- Undetectable VL & HIV Transmission in Gay Couples

- Opposites Attract: (TASP) Observational study in 3 countries

- 3 cities in Australia (157), Rio, Brazil (105), Bangkok, Thailand (96)

- 343 discordant couples, (one positive and one negative)

- Some men had other partners
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- Undetectable VL & HIV Transmission in Gay Couples
  - 12,000 condom free male anal sex acts in 3/4 of couples
  - Positive: 3/4 using ARVs throughout follow-up and started in study
  - 3/4 had undetectable viral loads throughout follow-up
  - Negative: About 1/3 using PrEP at some point during the study
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• Undetectable VL & HIV Transmission in Gay Couples

• No HIV- man became infected by his HIV+ partner (no PrEP use)

• Virus testing can determine how you were infected

• 0 to 1.56% estimated annual risk of HIV

• 0 to 2.70% estimated annual risk in the European PARTNER study
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• Undetectable VL & HIV Transmission in Gay Couples

• Confirms PARTNER study with even better results

• PARTNER + Opposites Attract = 34,911 condomless anal sex acts

• Condomless sex, with HIV+ partner who is undetectable = safe sex

• CAUTION: VL remains detectable in the first months after ARVs
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• Next Town Hall Meeting
  • Wednesday, November 15, 2017

• Time
  • 6:30 to 8:00 PM

• Place
  • Waxter Center
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• THANK YOU
  • Baltimore City Health Department
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• THANK YOU
  • Johns Hopkins Reach Initiative
  • Chase Brexton Health Care
  • Gilead Sciences
  • PrEP UP: Falina Chanel, Alvin Moody, Jeffrey Grabelle, Jay Mangum