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>Year</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>EAPC</th>
<th>P</th>
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<tbody>
<tr>
<td>All MSM</td>
<td>27,026</td>
<td>26,740</td>
<td>26,338</td>
<td>26,092</td>
<td>26,308</td>
<td>25,726</td>
<td>26,637</td>
<td>-0.4</td>
<td>&lt;0.1</td>
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<tr>
<td>Black</td>
<td>10,018</td>
<td>10,102</td>
<td>9,962</td>
<td>9,862</td>
<td>9,770</td>
<td>9,771</td>
<td>10,173</td>
<td>-0.1</td>
<td>0.7</td>
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<tr>
<td>Hispanic/ Latino</td>
<td>6,071</td>
<td>6,070</td>
<td>6,087</td>
<td>6,196</td>
<td>6,485</td>
<td>6,354</td>
<td>6,907</td>
<td>2.0</td>
<td>&lt;0.001</td>
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<tr>
<td>White</td>
<td>9,280</td>
<td>8,992</td>
<td>8,694</td>
<td>8,381</td>
<td>8,360</td>
<td>7,994</td>
<td>7,950</td>
<td>-2.6</td>
<td>&lt;0.001</td>
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<td>13–24 years</td>
<td>6,097</td>
<td>6,474</td>
<td>6,945</td>
<td>6,998</td>
<td>7,180</td>
<td>7,029</td>
<td>7,300</td>
<td>2.6</td>
<td>&lt;0.001</td>
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<tr>
<td>25–34 years</td>
<td>7,703</td>
<td>7,786</td>
<td>7,783</td>
<td>7,911</td>
<td>8,354</td>
<td>8,423</td>
<td>9,182</td>
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<tr>
<td>35–44 years</td>
<td>7,138</td>
<td>6,583</td>
<td>5,861</td>
<td>5,403</td>
<td>5,108</td>
<td>4,770</td>
<td>4,804</td>
<td>-6.9</td>
<td>&lt;0.001</td>
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<tr>
<td>45–54 years</td>
<td>4,433</td>
<td>4,285</td>
<td>4,175</td>
<td>4,119</td>
<td>4,046</td>
<td>3,749</td>
<td>3,690</td>
<td>3</td>
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<td>55–64 years</td>
<td>1,330</td>
<td>1,312</td>
<td>1,272</td>
<td>1,328</td>
<td>1,292</td>
<td>1,393</td>
<td>1,305</td>
<td>0.3</td>
<td>0.7</td>
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<td>65+ years</td>
<td>326</td>
<td>300</td>
<td>301</td>
<td>334</td>
<td>328</td>
<td>361</td>
<td>357</td>
<td>2.7</td>
<td>0.2</td>
</tr>
</tbody>
</table>

EAPC: Estimated annual percent change
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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 in Latino MSM and youth

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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 (CAB) 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 (CAB) for HIV Prevention
  • CAB 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 they would continue IM CAB

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• Long-Acting Cabotegravir (CAB) for HIV Prevention
  • IAS 2017: HTPN 077: CAB in 199 low risk participants
  • Purpose: To measure safety & drug levels to determine optimal dose
  • Informed by ÉCLAIR: CAB 600mg IM every 8 weeks
• Long-Acting Cabotegravir (CAB) 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

• Participants first received oral CAB to ensure safety

• Thereafter, CAB 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 (CAB) for HIV Prevention

• 52 weeks extended because of the “long CAB tail” in some

• Long CAB tail could cause HIV resistance after stopping PrEP

• 94% completed oral phase; 75% completed all injections

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• Long-Acting Cabotegravir (CAB) 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 (CAB) for HIV Prevention
  - 52 weeks extended because of the “long CAB 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 (CAB) 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 (CAB) 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 CAB 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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• 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

- 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

- 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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**PrEP UP Town Hall Meeting**

- Next Town Hall Meeting
  - Wednesday, March 28, 2017
- Time
  - 6:30 to 8:00 PM
- Place
  - Waxter Center
PrEP UP Town Hall Meeting

• 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