

AIDSACTIONBALTIMORE PREP UP

**Town Hall Meeting
IAS PrEP Update
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November 15, 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 1. HIV diagnoses by year of diagnosis, United States, 2008–2014.

	2008	2009	2010	2011	2012	2013	2014	EAPC	P
All MSM	27,026	26,740	26,338	26,092	26,308	25,726	26,637	-0.4	<0.1
Black	10,018	10,102	9,962	9,862	9,770	9,771	10,173	-0.1	0.7
Hispanic/ Latino	6,071	6,070	6,087	6,196	6,485	6,354	6,907	2.0	<.0001
White	9,280	8,992	8,694	8,381	8,360	7,994	7,950	-2.6	<.0001
13–24 years	6,097	6,474	6,945	6,998	7,180	7,029	7,300	2.6	<.0001
25–34 years	7,703	7,786	7,783	7,911	8,354	8,423	9,182	2.8	<.0001
35–44 years	7,138	6,583	5,861	5,403	5,108	4,770	4,804	-6.9	<.0001
45–54 years	4,433	4,285	4,175	4,119	4,046	3,749	3,690	-3	<.0001
55–64 years	1,330	1,312	1,272	1,328	1,292	1,393	1,305	0.3	0.7
≥65 years	326	300	301	334	328	361	357	2.7	0.2

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

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- **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**

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- **Long-Acting Cabotegravir (CAB) for HIV Prevention**
- **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 Efd**
- **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, March 28, 2017**
- **Time**
 - **6:30 to 8:00 PM**
- **Place**
 - **Waxter Center**

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• **THANK YOU**

- **Baltimore City Health Department**



Initiative to Maximize
Prevention, Access,
Care & Treatment
A Baltimore City Health
Department **campaign**

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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**