PREP UPDATE

NY STATE AIDS INSTITUTE, AUGUST 26^{TH}, 2015

KENNETH H. MAYER, M.D.

Disclosures: Unrestricted Research Grants from Gilead Sciences and ViiV
Why PrEP? Missed Prevention Opportunities

HIV-Infected: >25 Years of Age (n=896,800)

- Unaware of Infection: 12%
- Diagnosed: ~73%
- Retained in Care: ~40%
- Viral Suppression: ~28%

HIV-Infected: 13-29 Years of Age (n=78,949)

- Unaware of Infection: 60%
- Diagnosed: 25%
- Retained in Care: 11%
- Viral Suppression: 6%

Leaks in the cascade may reduce TasP effectiveness: SF example (and Australian paradox, De Wit, AIDS Impact, 2015)

Figure 1.2  New HIV diagnoses, deaths, and prevalence, 2006-2013, San Francisco

Clinical trial evidence for oral and topical tenofovir-based prevention (April 2015)

- **Partners PrEP - daily oral TDF/FTC** (Discordant couples - Kenya, Uganda)
  - Effect size (95% CI): 75% (55; 87)

- **iPrEx - daily oral TDF/FTC** (MSM - North and South America, Thailand, South Africa)
  - Effect size (95% CI): 44% (15; 63)

- **PROUD - daily TDF/FTC** (MSM - UK)
  - Effect size (95% CI): 86% (58; 96)

- **IPERGAY - intermittent TDF/FTC** (MSM – France, Canada)
  - Effect size (95% CI): 86% (40; 69)

- **Heterosexual men and women**
  - **TDF2 - daily TDF/FTC** (Heterosexual men and women - Botswana)
    - Effect size (95% CI): 62% (22; 84)

- **CAPRISA 004 - “BAT-24” dosing vaginal tenofovir gel** (Women - South Africa)
  - Effect size (95% CI): 39% (6; 60)

- **FACTS 001 - “BAT-21” dosing vaginal tenofovir gel** (Women - South Africa)
  - Effect size (95% CI): 0% (-1; 2)

- **MTN 003/Voice - daily vaginal dosing tenofovir gel** (Women - South Africa, Uganda, Zimbabwe)
  - Effect size (95% CI): 15% (-21; 40)

- **FEMPrEP - daily oral TDF/FTC** (Women - Kenya, South Africa, Tanzania)
  - Effect size (95% CI): 6% (-52; 41)

- **MTN 003/Voice - daily oral TDF/FTC** (Women - South Africa, Uganda, Zimbabwe)
  - Effect size (95% CI): -4% (-49; 27)

- **MTN 003/Voice - daily oral tenofovir** (Women - South Africa, Uganda, Zimbabwe)
  - Effect size (95% CI): -49% (-129; 3)

- **People who inject drugs**
  - **Bangkok tenofovir study – daily oral tenofovir** (IDUs - Thailand)
    - Effect size (95% CI): 49% (10; 72)

PrEP works, but adherence is key

Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention

Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Source: Salim S. Abdool Karim, CAPRISA
PrEP is well-tolerated, discontinuations rare  (WHO Guidelines, 2015)

<table>
<thead>
<tr>
<th>Study name</th>
<th>Subgroup within study</th>
<th>Comparison</th>
<th>Risk ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>ZValue</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BKK TDF Study</td>
<td>Men and Women</td>
<td>daily PrEP vs. placebo</td>
<td>0.979</td>
<td>0.797</td>
<td>1.203</td>
<td>-0.202</td>
<td>0.840</td>
</tr>
<tr>
<td>CDC Safety Study</td>
<td>MSM</td>
<td>daily PrEP vs. placebo</td>
<td>1.357</td>
<td>0.890</td>
<td>2.059</td>
<td>1.420</td>
<td>0.155</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>Women</td>
<td>daily PrEP vs. placebo</td>
<td>1.446</td>
<td>0.855</td>
<td>2.445</td>
<td>1.376</td>
<td>0.169</td>
</tr>
<tr>
<td>IAVI Kenya Study</td>
<td>MSM and FSW</td>
<td>multiple PrEP dosing</td>
<td>4.592</td>
<td>0.257</td>
<td>81.944</td>
<td>1.037</td>
<td>0.300</td>
</tr>
<tr>
<td>IAVI Uganda Study</td>
<td>Men and Women</td>
<td>multiple PrEP</td>
<td>1.170</td>
<td>0.007</td>
<td>4.025</td>
<td>-1.097</td>
<td>0.272</td>
</tr>
<tr>
<td>Ipergay</td>
<td>MSM</td>
<td>intermittent PrEP</td>
<td>1.226</td>
<td>0.622</td>
<td>2.420</td>
<td>0.589</td>
<td>0.566</td>
</tr>
<tr>
<td>iPrEx</td>
<td>MSM and TG</td>
<td>daily PrEP vs. placebo</td>
<td>1.226</td>
<td>0.622</td>
<td>2.420</td>
<td>0.589</td>
<td>0.566</td>
</tr>
<tr>
<td>Partners PrEP-Main</td>
<td>Men and Women</td>
<td>daily PrEP vs. placebo</td>
<td>1.077</td>
<td>0.954</td>
<td>1.215</td>
<td>1.194</td>
<td>0.233</td>
</tr>
<tr>
<td>Project PrEPare</td>
<td>MSM</td>
<td>daily PrEP vs. placebo</td>
<td>2.850</td>
<td>0.324</td>
<td>25.069</td>
<td>0.944</td>
<td>0.345</td>
</tr>
<tr>
<td>TDF2</td>
<td>Men and Women</td>
<td>daily PrEP vs. placebo</td>
<td>0.652</td>
<td>0.370</td>
<td>1.150</td>
<td>-1.477</td>
<td>0.140</td>
</tr>
<tr>
<td>VOICE</td>
<td>Women-All PrEP</td>
<td>daily PrEP vs. placebo</td>
<td>1.016</td>
<td>0.916</td>
<td>1.127</td>
<td>0.305</td>
<td>0.760</td>
</tr>
</tbody>
</table>

• No difference in proportion of participants reporting any adverse event (RR=1.01, 95% CI: 0.99-1.03, p=0.27) or any grade 3 or 4 adverse event comparing PrEP to placebo study arms.
• Several studies noted subclinical declines in renal functioning and bone mineral density among PrEP users.
Influences on PrEP Adherence and Protection

- Trial (lots of stated negatives) vs. real world
- Self-perception of risk
- Medical trust/mistrust
- Biology (“forgiveness” when missing doses)
- Support for adherence
- Integrating behavioral health with PrEP
- Modality (Next Gen PreP)

(Auerbach, Marrazzo, VanDamme, Van der Straten, Stadler, Tolley, Hendrix, Abdool Karim, Saethre, Corneli)
“Forgiveness”
Tenofovir Concentration: Rectal > Cervical > Vaginal

Days post single-dose

Patterson KB et al. Sci Transl Med. 2011.
<table>
<thead>
<tr>
<th><strong>PrEP: Risk, Compensation, Adherence, Coverage</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Best Case:</strong> “risky” person is highly adherent (good coverage)</td>
</tr>
<tr>
<td><strong>Worst case:</strong> “risky” person is not adherent (poor coverage)</td>
</tr>
<tr>
<td><strong>Risk compensation? Not often relevant</strong></td>
</tr>
<tr>
<td>• Possible, not often seen in studies to date</td>
</tr>
<tr>
<td>• But what if condoms are never used?</td>
</tr>
<tr>
<td><strong>Match counseling messages and prevention intervention to risk</strong></td>
</tr>
</tbody>
</table>
UK GU Med Clinics: PROUD Study

- Significantly fewer new HIV infections with immediate versus deferred PrEP (3 versus 19 cases)
  - 86% reduction ($P=0.0002$)
  - Number needed to treat to prevent 1 infection: 13
- PEP used by 31% in deferred arm
- Preliminary analysis found that risk behaviors were similar between the 2 arms

HIV Incidence

<table>
<thead>
<tr>
<th></th>
<th>HIV Incidence (per 100-person-years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deferred</td>
<td>8.9 (6.0-12.7)</td>
</tr>
<tr>
<td>Immediate</td>
<td>1.3 (0.4-3.0)</td>
</tr>
</tbody>
</table>

PEP: post-exposure prophylaxis.

Open Label PrEP in San Francisco:

81% still on PrEP at 12 months,¹
92% on PrEP use 4+ tablets per week.²

1. Grant Lancet ID 2014 14(9):820-9;
2. Estimated from dried blood spots in iPrEx OLE in San Francisco.
New technologies and PrEP adherence

- ↑ treatment adherence with text messaging (Lester, Lancet, 2010)

- Wisepill: modified Life-Steps HAART adherence intervention, including daily SMS with pts→84% had levels c/w daily used at 6 months (Mayer/Safren)

- Next step counseling in iPrEX Ole, augmented by electronic diary in SF and Chicago was associated with ↑ adherence (Amico/Hosek)

- Feedback on drug levels been studied as adjunct to counseling (Landovitz)

- SexPro App including diary features and adherence support, tested in NYC, SF, Lima and Rio (Buchbinder)
Preliminary DBS Adherence Data (06/15/15)

- 3M (n = 171)
- 6M (n = 136)
- 12M (n = 49)

<table>
<thead>
<tr>
<th></th>
<th>4+ pills/week (≥700 fmol)</th>
<th>Recent dose (past 48-72 hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>92.4%</td>
<td>93.6%</td>
</tr>
<tr>
<td>6M</td>
<td>92.6%</td>
<td>94.9%</td>
</tr>
<tr>
<td>12M</td>
<td>93.9%</td>
<td>96.0%</td>
</tr>
</tbody>
</table>

R01AA022067 (Golub, PI)
*BLQ – 30: No drug/up to a single dose in the past 48 hours.
60 – 80: Trough concentration at steady state with daily dosing for at least 48 hours.
200 – 300: Peak concentration at steady state with daily dosing for at least 48 hours.

Landovitz et al
Tailoring PrEP for Key Populations

HPTN 073 Black MSM
Client-centered care coordination (C4)
(Wheeler/Fields)

ATN 110/113
• YMSM 15-22 y.o.
• PreP + Individual vs. group EBI behavioral intervention (Hosek et al)

We’ve launched a new PrEP demonstration project for Black men who have sex with men.

Participate in the live Twitter chat on Wednesday, August 14 at 10 am PT / 1 pm ET
With our guests: @JonPaulLucas and @cchauncey
Be sure to follow @HIVptn

Join the HPTN 073 Webinar:
“Introducing HPTN 073: A BMSM PrEP Demonstration Study” at 11 am PT / 2 pm ET

Find out more about HPTN 073 at
Impact of age on adherence

• iPrEX sub-study *(Liu, JAIDS, 2014)*

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Never Detected, %</th>
<th>Sometimes Detected, %</th>
<th>Always Detected, %</th>
<th>OR (Some vs. Never) (95% CI)</th>
<th>P</th>
<th>OR (Always vs. Never) (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤20</td>
<td>58</td>
<td>29</td>
<td>13</td>
<td>Ref</td>
<td></td>
<td>Ref</td>
<td></td>
</tr>
<tr>
<td>21–25</td>
<td>28</td>
<td>45</td>
<td>27</td>
<td>4.04 (1.66 to 9.85)</td>
<td>0.002</td>
<td>6.32 (2.09 to 19.09)</td>
<td>0.001</td>
</tr>
<tr>
<td>26–30</td>
<td>32</td>
<td>44</td>
<td>24</td>
<td>3.42 (1.21 to 9.67)</td>
<td>0.02</td>
<td>4.74 (1.26 to 17.76)</td>
<td>0.021</td>
</tr>
<tr>
<td>&gt;30</td>
<td>16</td>
<td>29</td>
<td>55</td>
<td>5.13 (1.87 to 14.07)</td>
<td>0.001</td>
<td>33.24 (9.91 to 111.45)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

• Partners PrEP sub-study
  – AOR 1.7 (1.3–2.1, p=0.01) for <80% MEMS adherence *(Haberer, PLoS Med, 2013)*
ATN 110: PrEP Demonstration Project and Safety Study for Young MSMs in the US

- Phase 2, open-label study
  - 18 to 22 years old
  - Self reports evidence of high risk for acquiring HIV
  - HIV negative
- Primary objectives
  - Safety data on emtricitabine/tenofovir DF
  - Acceptability, patterns of use, rates of adherence, drug exposure
  - Patterns of sexual behavior

Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Enrolled (n=200)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>20.2</td>
</tr>
<tr>
<td>White/black/Hispanic/Asian (%)</td>
<td>21/53/17/2</td>
</tr>
<tr>
<td>Gay/bisexual (%)</td>
<td>78/14</td>
</tr>
<tr>
<td>Completed high school/some college (%)</td>
<td>34/45</td>
</tr>
<tr>
<td>Not currently working (%)</td>
<td>30.2</td>
</tr>
<tr>
<td>Partners in past month (number)</td>
<td>5</td>
</tr>
<tr>
<td>Condomless sex (%)</td>
<td>81</td>
</tr>
<tr>
<td>Condomless receptive anal intercourse with last partner (%)</td>
<td>58</td>
</tr>
<tr>
<td>Any positive STI test (%)</td>
<td>22</td>
</tr>
</tbody>
</table>

High risk for HIV: condomless anal intercourse with an HIV-infected male partner or a male partner of unknown HIV status; anal intercourse with ≥3 male sex partners; exchange of money, gifts, shelter, or drugs for anal sex with a male partner; sex with a male partner and has had a STI; sexual partner of an HIV-infected male with whom condoms were not consistently used; or at least one episode of anal intercourse where the condom broke or slipped off.

ATN 110: Main Outcomes of PrEP Demonstration Project and Safety Study for Young MSM

- Safety
  - Discontinued (n=25)
  - Treatment-related adverse events (n=3)
    - Nausea, weight loss, headache (all grade 3)
- HIV seroconversions (n=4)
  - HIV incidence: 3.29/100 person-years
  - No drug resistance
- Sexual behavior and adherence
  - STI diagnoses remained constant over time
  - Higher adherence and tenofovir diphosphate levels among those participating in condomless sex and condomless receptive anal intercourse
  - Adherence decreased for all participants over time

Intravaginal rings

Vaginal & Rectal Microbicides

Injectables: ARVs and mAbs

New Oral PrEP Drugs and Dosing Strategies

Novel Adherence Strategies
## CORRELATES OF PREP PROTECTION

(Grant et al, Lancet ID, 2014)

### Table 2: Effect of tenofovir diphosphate in dried blood spots on HIV infection

<table>
<thead>
<tr>
<th></th>
<th>BLQ</th>
<th>LLOQ to &lt;350 fmol per punch</th>
<th>350-699 fmol per punch</th>
<th>700-1249 fmol per punch</th>
<th>≥1250 fmol per punch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated dose (tablets per week)</td>
<td>None</td>
<td>&lt;2</td>
<td>2-3</td>
<td>4-6</td>
<td>7</td>
</tr>
<tr>
<td>Follow-up (% of visits)</td>
<td>25%</td>
<td>26%</td>
<td>12%</td>
<td>21%</td>
<td>12%</td>
</tr>
<tr>
<td>HIV infections (n)</td>
<td>18</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Person-years per infection</td>
<td>384</td>
<td>399</td>
<td>179</td>
<td>316</td>
<td>181</td>
</tr>
<tr>
<td>HIV incidence (95% CI)</td>
<td>4.70 (2.99-7.76)</td>
<td>2.25 (1.19-4.79)</td>
<td>0.56 (0.00-2.50)</td>
<td>0.00 (0.00-0.61)</td>
<td>0.00 (0.00-1.06)</td>
</tr>
<tr>
<td>HR vs previous placebo (95% CI)*</td>
<td>1.55 (0.88-2.56)</td>
<td>0.69 (0.32-1.32)</td>
<td>0.19 (0.01-0.88)</td>
<td>0.00 (0.00-0.25)</td>
<td>0.00 (0.00-0.50)</td>
</tr>
<tr>
<td>HR vs concurrent off-PrEP (95% CI)†</td>
<td>1.25 (0.60-2.64)</td>
<td>0.56 (0.23-1.31)</td>
<td>0.16 (0.01-0.79)</td>
<td>0.00 (0.00-0.21)</td>
<td>0.00 (0.00-0.43)</td>
</tr>
</tbody>
</table>

HR=hazard ratio. PrEP=pre-exposure prophylaxis. BLQ=below limit of quantification. LLOQ=lower limit of quantification. *Adjusted for study site. †Adjusted for study site, age, number of sexual partners, non-condom receptive anal intercourse, and syphilis. Drug concentration measurements were not available for 5% of visits.
ANRS Ipergay Trial: Event-Driven PrEP

- Significantly fewer new HIV infections with intermittent PrEP versus placebo (2 versus 14 cases)
  - 86% reduction after a mean follow-up of 13 months ($P=0.002$)
- Safety of on-demand PrEP was similar to placebo except for GI adverse events
- Adherence to PrEP was good, supporting the acceptability of on-demand PrEP

HIV Incidence

<table>
<thead>
<tr>
<th>HIV Incidence (per 100-person-years)</th>
<th>Placebo</th>
<th>Intermittent PrEP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.6</td>
<td>0.94</td>
</tr>
</tbody>
</table>

86% Reduction ($P=0.002$)

**Median number of pills/month (IQR):** 16 pills (10-23) in the placebo arm and 16 pills (12-24) in the TDF/FTC arm (p=0.84)

**48 participants (12%) received PEP**
25 (13%) in the TDF/FTC arm and 23 (11%) in the placebo arm (p=0.73)
HPTN 067/ADAPT Study: Proportion Achieving Detectable Tenofovir Concentrations at Week 30

With sex in the past 7 days.
Cape Town and Bangkok (tenofovir diphosphate >9.1 fmol/M PBMC).
Harlem (tenofovir >5 ng/mL plasma).

Partners Demonstration Project: TasP and PrEP

- Open-label prospective study
  - Heterosexual discordant couples not using ART or PrEP in Kenya & Uganda
  - At high risk for HIV transmission based on risk scoring tool
  - ART per national guidelines (treat all seropositive partners in a discordant relationship)
  - PrEP (open-label emtricitabine/tenofovir DF) until HIV-positive partner is on therapy for 6 months as a ‘bridge’ to ART
- 858 person-years of follow-up
- 95% uptake of PrEP and 80% on ART

HIV Incidence

Expected 37 Infections

Observed 2 Infections

96% Reduction ($P<0.0001$)

New PrEP Starts per Quarter

Total Unique Individuals = 8,512

IMS National Prescription Database accounts for approx. 39% of all TVD prescriptions

Bush, S. et al; IAPAC Prevention 2015; #74
## PrEP Eligibility and Use in SF

<table>
<thead>
<tr>
<th>Group</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV negative at substantial risk:</td>
<td></td>
</tr>
<tr>
<td>MSM with 2+ non-condom anal sex (ncAI) partners</td>
<td>12,589</td>
</tr>
<tr>
<td>MSM with 0 ncAI and an STI in the last year</td>
<td>2,325</td>
</tr>
<tr>
<td>Female partners of HIV+ MSM</td>
<td>653</td>
</tr>
<tr>
<td>Trans women</td>
<td>522</td>
</tr>
<tr>
<td><strong>TOTAL estimated PrEP eligibility</strong></td>
<td><strong>16,089</strong></td>
</tr>
<tr>
<td><strong>TOTAL reporting any PrEP in past year</strong></td>
<td><strong>5,059</strong></td>
</tr>
<tr>
<td><strong>Percent of eligible people using PrEP in the past year</strong></td>
<td><strong>31%</strong></td>
</tr>
</tbody>
</table>

1. SF City Clinic 2014 survey x HIV negative MSM population of 50,000;
2. SF NHBS self report of STI among MSM with 0 ncAI in 2014 x HIV negative MSM population of 50,000;
3. SF NHBS MSM reporting female partners in 2014 x HIV positive MSM population of 14638.
4. IDU and ncRAI in est. 923 HIV negative trans women in SF, adapted from Wilson *BMCID* 2014 14:430.
5. SF NHBS 2014, data on file.

Grant CROI Abstract 25 Seattle 2015.
Fenway Health: PrEP Experience

- 85.5% of initiators still on PrEP; Longest: 3.8 years
- 79.7% White; 8% Black; 12.3% Latino
- 95.1% identified as gay
- 158 zip codes
- “Gayborhood” <10%
- Private Ins: 80.7%; Medicare: 9%; Medicaid: 8.7%
- 25.9% who d/c’ed PrEP, initiated again
- More than 30 prescribers
Factors Associated with PrEP Use among US MSM
Multivariable Model, Manhunt Survey, 1/14
(under review)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Multivariable OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>College graduate or above (vs. less than college education)</td>
<td>5.33 (1.25 to 22.7)</td>
</tr>
<tr>
<td>Ever diagnosed with an STI</td>
<td>2.74 (1.36 to 5.52)</td>
</tr>
<tr>
<td>Used PEP</td>
<td>16.0 (8.24 to 31.2)</td>
</tr>
<tr>
<td>Comfortable talking with provider about MSM sex</td>
<td>4.19 (1.51 to 11.6)</td>
</tr>
</tbody>
</table>

MSM in states that were more LGBT supportive were more likely to use PrEP, be out to their providers, and less likely to engage in condomless sex (Oldenburg et al, AIDS, in press, 2015)
New England providers perceived numerous barriers to prescribing PrEP (Krakower, PLOS ONE, in press 2015)

- Lack of patient requests: 7% not a barrier, 22% minor barrier, 45% moderate barrier, 26% major barrier
- Concerns about insurance coverage: 10% not a barrier, 26% minor barrier, 31% moderate barrier, 32% major barrier
- Clinicians not trained to prescribe PrEP: 14% not a barrier, 22% minor barrier, 30% moderate barrier, 35% major barrier
- Clinicians not aware of CDC guidance: 19% not a barrier, 22% minor barrier, 33% moderate barrier, 25% major barrier
- Time constraints: 22% not a barrier, 38% minor barrier, 31% moderate barrier, 9% major barrier
- Clinicians not aware of PrEP: 23% not a barrier, 27% minor barrier, 31% moderate barrier, 20% major barrier
- Limited # at-risk patients: 27% not a barrier, 33% minor barrier, 25% moderate barrier, 15% major barrier

Numbers represent percentage for each response category: not a barrier, minor barrier, moderate barrier, major barrier. Bars total to 100%
Purview paradox: contradictory beliefs about who should prescribe PrEP
(Krakower D, AIDS and Behavior, 2014; Smith D, JAIDS, 2014)

HIV providers: PrEP best prescribed
By PCP

Primary care providers: PrEP meds are too complicated

<table>
<thead>
<tr>
<th>HIRI-MSM Risk Index*</th>
<th>1 How old are you today (yrs)?</th>
<th>2 How many men have you had sex with in the last 6 months?</th>
<th>3 In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?</th>
<th>4 How many of your male sex partners were HIV positive?</th>
<th>5 In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?</th>
<th>6 In the last 6 months, have you used methamphetamines such as crystal or speed?</th>
<th>7 In the last 6 months, have you used poppers (amyl nitrate)?</th>
<th>8 Add down entries in right column to calculate total score</th>
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<td></td>
<td>&lt;18 years</td>
<td>18–28 years</td>
<td>29–40 years</td>
<td>41–48 years</td>
<td>≥49 years</td>
<td>&gt;10 male partners</td>
<td>0–5 male partners</td>
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<td>Total score†</td>
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Conclusions

- Oral PrEP works, if used
- Adherence is the 1^0 issue to ensure success
- Behavioral interventions may ↑ adherence
- New technologies to measure adherence are being developed
- New technologies to enhance adherence are also being developed
- New delivery systems for PrEP may obviate some challenges for PrEP (e.g. quarterly injections)
- Providers need to be engaged
- PrEP is a work in progress
Antiretrovirals alone are not sufficient

Interventions to Increase Testing

- Test
  - HIV Negative
    - Risk Assessment
    - PrEP, Adherence Counseling
  - HIV Positive
    - Positive Prevention
    - Linkage To Care
- Enroll in Care
  - ART Initiation
  - Treat
    - Adherence to ART
- Maintain Viral Suppression
- Decrease in HIV Transmission

Address concomitant concerns: depression, substance use, relationship dynamics
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