HIV Treatment and Prevention for Sexual and Gender Minority Patients

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HIV tests determine the next prevention step, PrEP or HIV treatment.

86% of people with HIV know they have it.
TARGET: 95%

PREVENT
People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.

HAVE PREP PRESCRIPTION 18%  TARGET 50%

TREAT
People who know they have HIV should take medicine daily to control the virus.

HAVE HIV UNDER CONTROL 63%  TARGET 95%
Multifactorial Drivers of SGM HIV/STI Risk

Biology
• Anal intercourse ↑ susceptibility to HIV and STI
• Role versatility: receptive can be insertive, ↑ efficiency

Individual Behavior
• Number of partners over time

Social Networks (↑ risk of encountering HIV/STI)
• Sexual venues, e.g. bathhouses, social media
• Assortative mixing in sub-groups, e.g. racial minorities

Structural/Societal
• Lack of acceptance → early developmental stress → syndemics → depression, lack of self-efficacy, and risk
• Criminalization and discrimination in health care settings delay receipt of timely health services
HIV Therapy Recommended Regardless of CD4: START Trial

- HIV-infected adults with CD4 >500
- Randomized to immediate or deferred ART
- Greatest benefit: age >50, VL >50,000, CD4:CD8 <0.5, Framingham score >10%

Number of Serious Events

- Composite Endpoint: Deferred ART (n=2359) vs Immediate ART (n=2326)
  - 96 vs 42
  - 57% Reduction (P<0.001)
- AIDS-Related:
  - 50 vs 14
  - 72% Reduction (P<0.001)
- Non-AIDS Related:
  - 47 vs 29
  - 39% Reduction (P=0.04)

The Paradigm: Treat as soon as ready

- HPTN 052: Treatment as Prevention
- START and Temprano Studies: Early Treatment
- Begin treatment at any CD4+ T-cell count
- Public Health Benefit
- Individual Health Benefit
86 people with HIV referred to SFGH with recent infection (<6 mo) or CD4 <200

RAPID group (n=39): ART (usually DTG + TDF/FTC) on day of dx, usually 1st dose in clinic.
- Baseline CD4 474 (3-1391)

Standard of care universal ART (n=47): ART started median of 21 d.
- Baseline CD4 417 (11-1194)

Median time from referral to viral suppression, 1.8 mo in RAPID vs. 4.3 mo. in Standard p<0.001

C Pilcher et al, JAIDS, 2016
Current snapshot of HIV in the US

New HIV diagnoses for the most-affected populations, 2017

<table>
<thead>
<tr>
<th>Population</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black, Male-to-Male Sexual Contact</td>
<td>9,807</td>
<td>4,008</td>
</tr>
<tr>
<td>Hispanic/Latino, Male-to-Male Sexual Contact</td>
<td>7,436</td>
<td></td>
</tr>
<tr>
<td>White, Male-to-Male Sexual Contact</td>
<td>6,982</td>
<td></td>
</tr>
<tr>
<td>Black Women, Heterosexual Contact</td>
<td>1,717</td>
<td>1,058</td>
</tr>
<tr>
<td>Hispanic/Latina Women, Heterosexual Contact</td>
<td>1,058</td>
<td></td>
</tr>
<tr>
<td>White Women, Heterosexual Contact</td>
<td>999</td>
<td></td>
</tr>
</tbody>
</table>

New HIV diagnoses by age, 2017

- 13-24: 8,164
- 25-34: 13,433
- 35-44: 7,397
- 45-54: 5,735
- 55-64: 3,026
- 65+: 885

CDC. HIV in the United States and dependent areas. 2019.
Exposure risk per contact with HIV-infected source

<table>
<thead>
<tr>
<th>Activity</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous (blood)(^1)</td>
<td>0.3%</td>
</tr>
<tr>
<td>Mucocutaneous (blood)(^2)</td>
<td>0.09%</td>
</tr>
<tr>
<td>Receptive anal intercourse(^3)</td>
<td>1 - 2%</td>
</tr>
<tr>
<td>Insertive anal intercourse(^4)</td>
<td>0.06%</td>
</tr>
<tr>
<td>Receptive vaginal intercourse(^5)</td>
<td>0.1 – 0.2%</td>
</tr>
<tr>
<td>Insertive vaginal intercourse(^6)</td>
<td>0.03 – 0.14%</td>
</tr>
<tr>
<td>Receptive oral (male)(^7)</td>
<td>0.06%</td>
</tr>
<tr>
<td>Female-female orogenital(^8)</td>
<td>4 case reports</td>
</tr>
<tr>
<td>IDU needle sharing(^9)</td>
<td>0.67%</td>
</tr>
<tr>
<td>Vertical (no prophylaxis)(^10)</td>
<td>24%</td>
</tr>
</tbody>
</table>

Daily Oral TDF/FTC PrEP Trials: Effectiveness Improves With Adherence

- **VOICE[1]/FEM-PrEP[2]**
  - Efficacy 0%/6%
  - Adherence 29%/≤ 37%

- **iPrEx[3]**
  - Efficacy 44%
  - Adherence 51%

- **Partners PrEP[5]**
  - Efficacy 75%
  - Adherence 81%

- **TDF2[4]**
  - Efficacy 62%
  - Adherence 80%

- **PROUD[6]**
  - Efficacy 86%
  - Adherence ~ 100%

*Reduction in HIV incidence vs control. †Based on pill counts or the detection of study drug in plasma.

Is TDF/FTC PrEP Safe?

- Meta-analysis of randomized, placebo-controlled PrEP studies demonstrated that the risk of adverse events not increased for TDF-based PrEP vs placebo\(^1\)

- Reversible changes in creatinine, ↑ in older pts.

- Bone safety:
  - Small net decrease in spine and total hip BMD with TDF/FTC vs placebo, but no difference in fracture rate
  - BMD recovered following PrEP discontinuation

- Not 100% effective, but close to it
  - 7 infections in patients who were adherent.

Risk Compensation, Adherence, Coverage

**Best Case**
“Risky” person is highly adherent to PrEP
No HIV transmission

**Worst Case**
“Risky” person is not adherent to PrEP
HIV transmission; Select for resistance

Risk Compensation (not often relevant)
Possible, but uncommon in studies
What about real-life setting (no more placebos)?

Match Counseling Messages and Prevention Intervention to Risk
## CDC Guidance for PrEP Use

### MSM
- Any male sex partner in past 6 mos
- Not in monogamous relationship with a recently tested, HIV-negative man

*And ≥ 1 of These Criteria*
- Any anal sex without a condom in past 6 mos
- Bacterial STI (syphilis, gonorrhea, or chlamydia) in

### Heterosexual Women/Men
- Any sex with opposite sex partner in previous 6 mos
- Not in monogamous relationship with a recently tested, HIV-negative partner

*And ≥ 1 of These Criteria*
- Is a bisexual male
- Infrequent condom use with ≥ 1 partner(s) with unknown HIV status at substantial risk of HIV infection (PWID or bisexual male)
- Is in ongoing relationship with HIV-positive partner
- Bacterial STI (syphilis, gonorrhea in females/males) in last 6 mos

### Injection Drug Users
- Any injection of drugs not prescribed by a clinician in past 6 mos

*And ≥ 1 of These Criteria*
- Any sharing of injection/drug preparation equipment in past 6 mos
- Risk of sexual acquisition

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In any category, individual expected to be an adult or adolescent weighing > 35 kg with no acute or established HIV infection.
USPHS/CDC Guidelines on Prescribing PrEP

• Determine Eligibility (negative HIV test, at high-risk for HIV acquisition, renal function, screen/treat for STIs, screen/vaccinate for Hep B, HCV Ab; pregnancy test)

• Prescribe tenofovir-emtricitabine 1 tablet by mouth daily

• Provide condoms and risk-reduction counseling

• Monitor closely (q 2-3 mo: HIV test, risk assessment/counseling; q 6 mo: renal function, STI screen (q 3 months for some populations?)

Higher TFV-DP Levels in PBMCs With TAF vs TDF

- TDF (300 mg)
- TAF (25 mg)

Plasma TFV levels ~ 90% lower with TAF vs TDF

TAF delivers 4-7-fold higher TFV-DP


Slide credit: clinicaloptions.com
DISCOVER: FTC/TAF vs FTC/TDF for HIV Prevention

- International, randomized, double-blind, active-controlled phase III study

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HBV-negative cis-MSM and transgender women at high risk of HIV* with eGFR ≥ 60 mL/min; prior PrEP use permitted (N = 5387)

FTC/TAF 200/25 mg + FTC/TDF Placebo QD (n = 2694)
FTC/TDF 200/300 mg + FTC/TAF Placebo QD (n = 2693)

Option for open-label FTC/TAF up to Wk 144

Wk 96

*Defined as ≥ 2 episodes of condomless anal sex within past 12 wks or rectal gonorrhea, chlamydia, or syphilis within past 24 wks. Prevention services (eg, risk reduction, condoms/lubricant) and adherence counseling provided at entry and every 12 wks.

Primary endpoint: HIV incidence/100 PY
- Noninferiority upper bound of 95% CI for IRR of FTC/TAF vs FTC/TDF: < 1.62
- Expected incidence 1.44/100 PY based on prior studies

Secondary endpoints: safety, including renal biomarkers and BMD substudy
- Critiques: insufficient enrollment of POC
- No parallel study of cisgender women and transgender men

Hare. CROI 2019. Abstr 104LB. NCT02842086.
DISCOVER: FTC/TAF Noninferior to FTC/TDF for HIV Prevention in Primary Analysis

- Primary analysis conducted when 100% completed Wk 48, 50% completed Wk 96\(^1\)
- Noninferiority of FTC/TAF maintained:
  - In sensitivity analysis excluding 5 suspected baseline infections\(^1\)
    - IRR: 0.55 (95% CI: 0.20-1.48)
  - Through Wk 96 analysis\(^2\)
    - IRR: 0.54 (95% CI: 0.23-1.26)

Clinical Decisions Regarding PrEP Choice

<table>
<thead>
<tr>
<th>Clinical feature</th>
<th>Favors</th>
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<tbody>
<tr>
<td>Pre-existing renal or bone disease/risk factors</td>
<td>TAF/FTC</td>
</tr>
<tr>
<td>Patient is MSM or transgender women without a vagina</td>
<td>TDF/FTC or TAF/FTC</td>
</tr>
<tr>
<td>Patient has receptive vaginal sex*</td>
<td>TDF/FTC</td>
</tr>
<tr>
<td>Patient has hyperlipidemia and/or is obese</td>
<td>TDF/FTC</td>
</tr>
</tbody>
</table>

*efficacy trial in African cisgender women underway
Considerations for On-Demand PrEP

- Off-label in the US (approved by WHO)
- Only efficacy data are from studies in MSM
- Not recommended for cis-gender or trans-gender women
  - Cis-gender women: lower drug concentrations in vaginal vs rectal tissue[^1]
  - Transgender women: lower drug concentrations in transgender women using estrogens vs cis gender men[^2]

- On-demand PrEP for MSM requires careful consideration, patient discussion
  - Frequency of sex acts, ability to plan ahead for medication use

ANRS Ipergay Trial Open-Label Extension Study: Efficacy of On-Demand PrEP in High-Risk MSM

- French/Canadian MSM
- 2 pills within 24 hours of sex, and a pill a day X 2 days after
- Generally well tolerated
  - Drug-related GI AEs (10%)
  - 33% acquired a new STD
- Estimated efficacy
  - 97% relative reduction in HIV transmission versus placebo
  - Rare infections in non-adherent or pts acutely infected when they started PrEP
- On demand PrEP can work, but pts were sexually active and adherent (18 pills/month)

HIV Seroconversion Rates


- Electronic patient-level data from 82% of US retail pharmacies with FTC/TDF dispensed for PrEP
  - January 2013 to March 2016
- 67,403 individuals initiated FTC/TDF PrEP
- Quarter-by-quarter growth in utilization 770% overall
  - 72% among women
  - 1350% among men

- In 2015 and Q1 2016, likelihood of initiating PrEP 3.4 and 4.2 times higher for white vs black or Latino women, respectively
  - Likelihood 8.1 and 6.6 times higher for white vs black or Latino men, respectively

<table>
<thead>
<tr>
<th>FTC/TDF PrEP Start by Race/Ethnicity Within Sex Subgroups, %</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>65</td>
<td>76</td>
</tr>
<tr>
<td>Black</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>Latino</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Asian</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Active PrEP Prescriptions in the United States (Q4 2017)

- Number of active PrEP prescriptions for Q4 2017 (n=70,395)
- Only <10% of the 1.2 million people indicated for PrEP are potentially receiving protection
  - Individuals in the Southern United States
    - Account for 52% of new HIV infections
    - Had lower levels of PrEP use relative to new HIV infections

Active PrEP use: ≥1 day of PrEP use in a 3-month period.

Why Some MSM are not using PrEP

- National on-line sample of US MSM recruited on 2 sex networking sites (n=4698)
- 75% condomless anal sex ≥2x in past 3 mo
- Most (85%) had not used PrEP, 22% were unaware of PrEP
- Major barriers to PrEP uptake: structural factors (cost, access, insurance), anticipated side effects, and low perceived risk
  - Anticipated side effects: older MSM
  - Access concerns: black MSM, less educated MSM, MSM born outside of the US

Reasons for not Using PrEP Among Informed Non-Users (n=2926)

<table>
<thead>
<tr>
<th>Concerns about:</th>
<th>Respond. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs</td>
<td>40</td>
</tr>
<tr>
<td>Potential side effects</td>
<td>31</td>
</tr>
<tr>
<td>Effects on insurance</td>
<td>20</td>
</tr>
<tr>
<td>Medical provider’s reaction</td>
<td>18</td>
</tr>
<tr>
<td>Reaction of sexual partner</td>
<td>5</td>
</tr>
<tr>
<td>Do not know where to access PrEP</td>
<td>31</td>
</tr>
<tr>
<td>Do not feel at risk</td>
<td>19</td>
</tr>
<tr>
<td>Did not think it would be effective</td>
<td>5</td>
</tr>
</tbody>
</table>

Tailoring PrEP for Key Populations

HPTN 073 Black MSM
Culturally-Tailored
Client-centered care coordination (C4)

ATN 110/113

- YMSM 15-22 y.o.
- PreP + Individual vs. group 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 www.HPTN.org and at Facebook/HIVptn
HPTN 073: PrEP for Black MSM

- Evaluating PrEP acceptance, initiation, adherence, safety among black MSM in LA, DC, Chapel Hill, NC
  - PrEP coupled with client-centered care coordination (C4): individualized prevention counseling, support, and service coordination; participants followed for 12 mos
  - 226 HIV-uninfected black MSM; 40.2% younger than 25 yrs of age

- Of 178 who accepted PrEP in study, 5 acquired HIV (incidence: 2.9; 95% CI: 0.9-6.8) vs 3 of those who never accepted PrEP (incidence: 7.7; 95% CI: 6-22.5)
  - several discontinued PrEP prior to seroconversion

- 2.9% incidence is still too high, but HPTN 073 showed client-centered care coordination beneficial and PrEP acceptable, feasible with high uptake among black MSM

PrEP Barriers Among Adolescents

- ATN 110/113 showed adherence is a challenge among adolescents, decreasing PrEP efficacy vs adults
  - Because adherence was highest during first 3 mos when clinic visits were monthly, it may make sense to have more frequent contact with youth when they initiate PrEP
  - Nonetheless, PrEP is approved for all weighing >30 Kg.

- Laws regarding consent vary by state concerning consent, confidentiality, parental disclosure, and reporting
  - In some states, emancipated minor laws allow for direct provision of PrEP to the adolescent without parental engagement (e.g., Florida, Massachusetts)
  - Parental insurance coverage can result in unintended disclosure

- Specific considerations are needed made for LGBTQ adolescents to reduce stigma and health disparities

Transgender People and PrEP

- 11 HIV infections among transgender women (TGW) in iPrEx who got PrEP, 10 infections in placebo group
  - None of the TGW who became infected had detectable drug at visit where HIV was first detected
  - Lack of protection for 11 in PrEP group “seems to be primarily a result of low adherence”

- PrEP protective in subgroup of TGW with high adherence

- PrEP meds do not alter feminizing hormone levels, but high dose estrogens mildly decrease tenofovir levels, making adherence to daily regimen important.

- Much less known about transgender men (TGM), but a recent national survey found that some TGMSM had high levels of HIV risk and low levels of PrEP knowledge, suggesting a major unmet need exists

PrEP and “risk compensation”

- Fear for increase in risky behavior in persons using PrEP
- Increase in STI incidence

- Older fear around introduction of biomedical sexual health interventions:
  - penicillin in the 1950’s
  - oral contraceptives in the 1960’s
  - HPV vaccination in the 2000’s
## STI Incidence Before/After PrEP among MSM

- 1378 participants of the PrEPX study in Australia with pre-enrollment testing data
- Mean follow-up of 1.1 years

<table>
<thead>
<tr>
<th></th>
<th>STI Incidence 1 year before</th>
<th>STI Incidence Post Entry</th>
<th>Incidence Rate ratio (95% CI)</th>
<th>Adjusted IRR* (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All</strong></td>
<td>69.5</td>
<td>98.4</td>
<td>1.41 (1.29-1.56)</td>
<td>1.12 (1.02-1.23)</td>
</tr>
<tr>
<td><strong>PrEP-Exp</strong></td>
<td>92.4</td>
<td>104.1</td>
<td>1.13 (0.99-1.28)</td>
<td>1.05 (0.92-1.19)</td>
</tr>
<tr>
<td>(n=541)</td>
<td></td>
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</tr>
<tr>
<td><strong>PrEP-Naive</strong></td>
<td>55.1</td>
<td>94.2</td>
<td>1.71 (1.49-1.96)</td>
<td>1.21 (1.06-1.39)</td>
</tr>
<tr>
<td>(n=837)</td>
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</tbody>
</table>

*Adjusted for testing frequency

Traeger M. et al, JAMA 2019;321:1380
Incidence of Gonorrhea and Chlamydia among MSM using PrEP

Over the next decade, 40% of NG and CT infections would be averted (40% PrEP coverage)

Jenness et al CID 2017
CDC: PrEP Persistence in the United States (2012-2016)

- PrEP persistence assessed using commercial and Medicaid insurance databases (2012-2016)
  - Non-persistence: >30-day gap from end of 30-day PrEP supply to refill of PrEP prescription
  - Most PrEP users were male and >24 years of age
- Medicaid insured PrEP users persisted for less time than commercially insured PrEP users
- Commercially insured non-persistent PrEP users: more likely to be younger, female, rural.
- Medicaid insured non-persistent PrEP users
  - More likely to be of younger age, female, and black

*Inclusion criteria: 18 to 64 years of age (continuously enrolled in health plan 6 months before/after PrEP prescription date)

*P<0.01 and P<0.05.

PrEP Pricing

• Currently, both meds cost the same (20K/year)
• Generic TDF/FTC should be available from one manufacturer in Sept, 2020 → modest ↓ cost
• 6 months later, any generic manufacturer can produce TDF/FTC, which should lower costs substantially
• Questions include:
  - impact on drug assistance programs
  - 340B pricing
## Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms...

<table>
<thead>
<tr>
<th>Drug Access</th>
<th>PrEP Clinical Visits &amp; Lab Costs</th>
<th>Counseling and Linkage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Uninsured</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer Patient Assistance Program</td>
<td>PrEP DAPs (state funded)</td>
<td>PrEP DAPs (state funded)</td>
</tr>
<tr>
<td>PrEP Drug Assistance Programs or “PrEP DAPs” (state funded)</td>
<td>CDC prevention funds to pay for HIV/STD testing</td>
<td>CDC prevention grants and 340B savings</td>
</tr>
<tr>
<td>Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings</td>
<td>Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings</td>
<td>Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings</td>
</tr>
<tr>
<td><strong>Insured</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covered by payers; co-pay assistance through manufacturer assistance program</td>
<td>Largely covered, but with patient co-pays</td>
<td>Not well covered by public or private insurance</td>
</tr>
<tr>
<td></td>
<td>PrEP DAPs pay for lab/clinical visit co-pays (state funded)</td>
<td></td>
</tr>
</tbody>
</table>
Purview paradox: contradictory beliefs about which providers will prescribe PrEP
(Krakower, AIDS and Behavior, 2014)

HIV providers:
Primary care providers are in the best position to prescribe PrEP

Primary care providers:
It would not be feasible to prescribe PrEP
Expanding PrEP Service Providers

- Expanding service delivery locations and to other providers – primary care, NP, pharmacy
  - Addresses stigma, geographic barriers

Not enough health care providers know about PrEP.
Pre-exposure prophylaxis (PrEP) is a medicine taken daily that can be used to prevent HIV infection. PrEP is for people without HIV who are at very high risk for acquiring it from sex or injection drug use.

- 90% Daily PrEP can reduce the risk of sexually acquired HIV by more than 90%.
- 70% Daily PrEP can reduce the risk of HIV infection among people who inject drugs by more than 70%.
- 1 in 3 1 in 3 primary care doctors and nurses haven’t heard about PrEP.

CDC. Vital Signs. 2015.
Online PrEP Tools

- Various online tools providing range of service levels from full PrEP service provision to directories for assistance finding a PrEP provider
  - Eg, *Nurx*, *PlushCare*, *PleasePrEPMe*
- With some online tools, individuals still need a location to access lab services
- Insurance coverage still needed
- These approaches may addresses stigma-related barriers by allowing anonymity in PrEP and empowering PrEP users
- Could be particularly useful for younger, tech-saavy populations
Provider Hotline, Provider Education

- **PrEPline**: CDC and UCSF Clinical Consultation Center
  - [http://nccc.ucsf.edu](http://nccc.ucsf.edu)

**Clinically supported advice on PrEP for healthcare providers**

Up-to-date clinical consultation for PrEP decision-making, from determining when PrEP is an appropriate part of a prevention program to understanding laboratory protocols and follow-up tests.

**Call for a Phone Consultation**

(855) 448-7737 or (855) HIV-PrEP

Monday – Friday, 9 a.m. – 8 p.m. ET

**PrEP ECHO**: [www.lgbthealtheducation.org](http://www.lgbthealtheducation.org)
<table>
<thead>
<tr>
<th>Efficacy Trial</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaginal Ring</strong></td>
<td><strong>HOPE (MTN 025)</strong></td>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 2,500 women in Malawi, South Africa, Uganda, Zimbabwe</td>
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<tr>
<td><strong>Dapivirine Ring</strong></td>
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<tr>
<td><strong>DREAM (IPM 032)</strong></td>
<td>Open-label trial of the once-monthly slow-release dapivirine vaginal ring; ongoing in 1,400 women in South Africa and Uganda</td>
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<tr>
<td><strong>Antibody</strong></td>
<td><strong>AMP (HVTN 704/HPTN 085)</strong></td>
<td>Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 2,700 MSM and transgender men &amp; women in Brazil, Peru, Switzerland, and US</td>
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<tr>
<td><strong>VRC01</strong></td>
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<tr>
<td><strong>AMP (HVTN 703/HPTN 081)</strong></td>
<td>Randomized controlled trial of the VRC01 antibody infused every two months; ongoing in 1,500 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe</td>
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<tr>
<td><strong>Oral PrEP</strong></td>
<td><strong>DISCOVER</strong></td>
<td>Randomized controlled trial of once-daily F/TAF as PrEP; ongoing in 5,000 MSM and transgender women at approximately 90 sites in Europe and the Americas</td>
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<tr>
<td><strong>F/TAF</strong></td>
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<tr>
<td><strong>Long-Acting Injectable</strong></td>
<td><strong>HPTN 083</strong></td>
<td>Randomized controlled trial of injectable cabotegravir every two months; ongoing in 4,500 MSM and transgender women in Argentina, Brazil, India, Peru, South Africa, Thailand, US, Vietnam</td>
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<tr>
<td><strong>Cabotegravir</strong></td>
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<td><strong>HPTN 084</strong></td>
<td>Randomized controlled trial of injectable cabotegravir every two months, planned for 3,200 women in southern and East Africa</td>
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<tr>
<td><strong>Preventive HIV Vaccine</strong></td>
<td><strong>ALVAC/gp120 w/MF59</strong></td>
<td>Randomized controlled trial of ALVAC/gp120 prime-boost with MF59 adjuvant, five doses over 12 months; ongoing in 5,400 men and women in South Africa</td>
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<td><strong>HVTN 702</strong></td>
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<tr>
<td><strong>Ad26/gp140 boost</strong></td>
<td><strong>HPX2008/HVTN 705</strong></td>
<td>Randomized controlled trial of Ad26 prime with gp140 boost; planned for women in southern Africa</td>
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- **Open-label**
- **Randomized Controlled**
- **Ongoing**
- **Planned**
Decrease in HIV and STI transmission

Maintain viral suppression

Retain

Enroll in care

Linkage to care

ART initiation

Retain

Adherence to ART

Maintain viral suppression

Decrease in HIV and STI transmission

Address concomitant concerns:
depression, substance use, relationship
dynamics, structural/social issues, STI

Risk assessment
PrEP, adherence counseling

Test

HIV negative

HIV positive

Positive prevention

Need to Address more than PrEP and U=U
Contact/Resources

- Amy Killelea, NASTAD (akillelea@nastad.org)
- NASTAD PrEP Resources – [https://www.nastad.org/prepcost-resources/additional-resources](https://www.nastad.org/prepcost-resources/additional-resources)
- PrEPcost.org – NASTAD’s online plan assessment tool for PrEP
Thank you

Kevin Ard
Alex Keuroghlian

Amy Killilea

Aaron Siegler
Patrick Sullivan

NIAID, NIMH, NIDA, NICHD, CDC, HRSA, Mass DPH, Gilead