HPTN 2020
State of the Network

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on behalf of the HPTN
HPTN Mission

The HIV Prevention Trials Network (HPTN) advances HIV prevention through research:

• Integrated HIV prevention strategies
• Improve pre-exposure prophylaxis (PrEP)
• New strategies for key populations
2020 in Review

• 2 studies completed
• 13 studies ongoing
• 6 new studies in development
• 65 active sites
• 31 presentations
• 50+ publications
Agents of Pre-Exposure Prophylaxis (PrEP)
PrEP: Today

Approved July 2012

Approved October 2019
PrEP = Daily oral FTC/TDF

Decline
Accept
Provide PrEP, enhanced adherence support, SOC (~200 women)
SOC and offer PrEP (~≤200 women)
Randomize PrEP Acceptors 1:1

Provide PrEP, standard adherence support, SOC (~200 women)

Enroll
Accept
Decline

SOC and offer PrEP (~≤200 women)

Standard Adherence Support
- CBT counseling
- SMS texting
- Adherence clubs

Enhanced Adherence Support
- CBT counseling
- SMS texting
- Adherence clubs
- Drug level feedback counseling

In-depth interviews about women’s decisions to use PrEP, adhere to PrEP, and acceptability. (~75 total, including acceptors and decliners)

HPTN 082
HPTN 082: Results

- 95% PrEP uptake (95%) among young women.
- No effect of drug level feedback on proportions with detectable TFV-DP or high adherence by arm at 6 months.
- Women who perceived themselves to be at risk of HIV and were motivated to use PrEP (HPRM score) had higher adherence at 6 months.
- Adherence declined significantly after month 3.
- Low HIV incidence (1%) given the risk profile of this cohort.
- Counterfactual analysis suggests novel success in PrEP use in some young women.
Initiation, discontinuation, and restarting HIV pre-exposure prophylaxis: ongoing implementation strategies

Sarah E Rutstein, Dawn K Smith, Shona Dalal, Rachel C Baggaley, Myron S Cohen
PrEP: Tomorrow?

- Cabotegravir
- Capsid Inhibitors
- Rings
- Implants
- Transdermal Needles and Patches
HPTN 083 Study Design

CAB

TDF/FTC

Landovitz RJ et al. AIDS 2020, #OAXLB0101

(20% Intralipid solution)
Long-Acting Cabotegravir for PrEP

May 18, 2020
DSMB review
“Long-acting Injectable Cabotegravir is Highly Effective for the Prevention of HIV Infection in Cisgender Men and Transgender Women Who Have Sex with Men”

July 7, 2020
HPTN Press Release
“HPTN 083 Study Demonstrates Superiority of Cabotegravir for the Prevention of HIV”
Long-Acting Injectable Drug Prevents HIV Infections
by Jon Cohen
May 18, 2020

“It’s not an AIDS vaccine but it may be the closest thing to one so far.”
HPTN 084

Step 1
5 weeks
Placebo-controlled*

Group A
- CAB Active
- TDF/FTC Placebo

Group B
- CAB Placebo
- TDF/FTC Active

Step 2
Up to 185 weeks (3.5 years)
Placebo-controlled*

- Injection, every 8 weeks+
- Oral tablet, daily

Step 3
48 weeks
Open-label*

- TDF/FTC Active

*In Steps 1 and 2, the tablets and the injections will look alike, so staff and participants will not know if they are getting the active or placebo products. In step 3, everyone will be given active TDF/FTC.

+In step 2 the first two injections are four weeks apart and eight weeks apart thereafter.
HPTN 083-01
Prevention for Teens

Step 1
5 weeks
Daily Pill
CAB Pill

Step 2
29 weeks
Shot Every 8 Weeks
CAB Shot

Step 3
48 weeks
Daily Pill
TDF/FTC Pill

*In step 2, the first two shots are four weeks apart and 8 weeks apart after that.
The HIV-1 gp120/gp41 Trimer Accessible to Antibodies

### Passive Antibody Prevention

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRC01 10 mg/kg</td>
<td>1534</td>
</tr>
<tr>
<td>VRC01 30 mg/kg</td>
<td>1534</td>
</tr>
<tr>
<td>Control</td>
<td>1534</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4600</strong>*</td>
</tr>
</tbody>
</table>

10 infusions total; Infusions every 8 weeks. Study duration: 24 months

*Due to randomization scheme the number of active product and control recipients may vary slightly.
Theoretical combinations of bnAbs

Panel of 208 HIV-1 strains

Adapted from M Cohen and T Gamble
New PrEP Agents and Approaches

• New ARVs
  - Islatravir (MSK 8591; potent pill or implant)
  - Lenacapravir (G 6207, sub Q)

• New Devices
  - Dapivirine Rings (Favorable EMA Regulatory Review)
  - Implants
  - Transdermal needles and patches
  - Multipurpose technologies
Integrated Strategies

- Biomedical Interventions
- Behavioral Interventions
- Structural Interventions
One of four recently unblinded treatment as prevention trials

HPTN 071 (PopART)

Arm A
- Full PopART intervention
- including
- immediate ART irrespective of CD4 count

Arm B
- PopART intervention except
- ART initiation according to current national guidelines

Arm C
- Standard of care at current service provision levels
- ART initiation according to current national guidelines

7 communities per arm (N=21)
- 12 in Zambia
- 9 in South Africa

~ 2,500 random sample from each community: Population Cohort N = 52,500

Primary outcome: HIV incidence at 36 Months

Total Population ~1M

HIV
- Home-based HCT & referral for ART

TB
- Screening for TB, sputum collection & referral for treatment

STIs
- STI symptom screening & referral

Condom provision, referral for VMMC, ANC & family planning

CHEPs work in pairs...
- delivering the PopART intervention door-to-door.

Clients are referred to care at the local clinic
90:90:90 targets were reached, leading to 20% reduction in incidence.

Missing 25-40 men is a big gap, accounting for 40% of transmissions.

- Finding missing men is effective even if yield is much lower

40% of transmissions occurred in first year of infection. 60-70% of transmissions occur later, some much later.

- Annual testing is needed
- Sustained viral suppression is also needed

20% of transmissions linked different PopART sites.

- We may have under-estimated impact of the PopART intervention
- Continuity of care as people move is vital
The Way Forward
STAY Tuned
HPTN Community Programs

- External stakeholder consultations
- CWG capacity-building sessions
- Education, recruitment, retention materials
- Social media marketing
- Cross-network collaboration
HPTN Scholars

- 64 Scholars since 2010
- 52 Mentors have graciously provided expertise and time
- 19 study datasets: HPTN 037-HPTN 082
- 34 first-authored HPTN manuscripts
CoVPN Partners

HIV Prevention Trials Network

The HIV Prevention Trials Network (HPTN) develops and tests the safety and efficacy of non-vaccine interventions designed to prevent the transmission of HIV.

HIV Vaccine Trials Network

The HIV Vaccine Trials Network (HVTN) is the world’s largest publicly funded international collaboration focused on the development of vaccines to prevent HIV/AIDS.

AIDS Clinical Trials Group

The ACTG established and supports the largest Network of expert clinical and translational investigators and therapeutic clinical trials units in the world. These investigators and units serve as the major resource for HIV/AIDS research on treatment and care for persons living with HIV/AIDS.

Infectious Disease Clinical Research Consortium

NIAID established the Infectious Diseases Clinical Research Consortium in 2019. It encompasses the Institute’s long-standing Vaccine and Treatment Evaluation Units (VTEUs) and a new leadership group.
‘Provocative results’ boost hopes of antibody treatment for COVID-19

By Jon Cohen
Sep. 30, 2020, 5:15 PM

Companies are developing COVID-19 treatments using monoclonal antibodies, Y-shaped immune proteins that target the pandemic coronavirus.

KTSDESIGN/Science Source

Teamwork

• Study participants and communities
• Site investigators, staff, and community representatives
• BMGF, USAID, PEPFAR/OGAC, ViiV Healthcare, Gilead, VRC, PANGEA, and many other partners
• NIH (NIAID, NIMH, Office of the Director, NIDA), OAR
• HPTN Scientific Advisory Group, Executive Committee, LOC, SDMC, LC, Network Oversight, Scientific Committees, and Working Groups