HPTN
State of the Network
Achievements and Way Forward

June 2016

Wafaa El-Sadr, MD, MPH, MPA
Myron Cohen, MD
HPTN Mission

To advance HIV prevention through the use of integrated strategies, centered on reducing HIV incidence in populations at greatest risk for infection.
Focus of the Research

- To identify new PrEP agents/regimens
- To design/implement integrated strategy studies
The Year in Review

• Four studies completed
• Four new studies launched and one to be launched shortly
• Completed enrollment of four studies:
  – First two studies of injectable long-acting ARVs for PrEP among women
  – Study among HIV+ PWID and their partners in Eastern Europe and southeast Asia
  – Study assessing feasibility of recruitment and retention of MSM in SSA (very, very close to complete enrollment)
• Launch of two monoclonal antibody studies (VRC 01) for HIV prevention in collaboration with HVTN
The Year in Review

- Progress in HPTN 071 (PopART), *the largest HIV prevention study to date!*
- Design of the *first non-inferiority phase 3 HIV prevention study (HPTN 083)*
- Findings from six studies presented at major conferences
- Expanded network reach and engaged in new collaborations around the world
- Expanded HPTN domestic scholars program to include international scholars
Studies Completed

- HPTN 068 (Financial incentives, conditional on school attendance, in young women SA)
- HPTN 052 (ART for prevention in discordant couples)
- HPTN 069/ACTG A5305 (Safety and tolerability of maraviroc-containing regimens for PrEP)
- HPTN 073 (Uptake and adherence with TDF/ FTC PrEP among Black MSM)
HPTN 068: Effects of cash transfer for the prevention of HIV in young women in South Africa

Enrollment 2,537
- Enrolled in grades 8, 9, 10 or 11 in participating high schools
- Age 13-20 years

Follow Up: Completed March 2015

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,263</td>
<td>1,274</td>
</tr>
<tr>
<td>Cash transfer conditional on school</td>
<td>No cash</td>
</tr>
<tr>
<td>attendance</td>
<td></td>
</tr>
</tbody>
</table>
HPTN 068: Key Findings

- Overall HIV incidence: 1.8%,
  - 16 year olds: 1%
  - > 20 years: 5%
- High school attendance in both study arms
- School enrollment and attendance were protective for HIV acquisition irrespective of study arm.
  - Three fold higher risk of HIV infection in school drop outs to non-drop outs
    [HR 3.21 (95% CI 1.81, 5.71, p<.0001)]

Insights from the study:
- Interventions should focus on 18-24 year olds and out of school youth
- Cash transfer may be efficacious in settings with low school enrollment

No difference in HIV incidence
  HR 1.17 (95% CI 0.80-1.72, P=0.42)
No difference in HSV-2 incidence,
  RR 0.92 (0.71- 1.18) (P=0.492)
**HPTN 052**

1,763 sero-discordant couples
HIV-infected (CD4 350 to 550 cells/µL)
HIV discordant partner

**Randomization** Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, US, Zimbabwe

Immediate ART
350-550 cells/µl

Deferred ART
CD4 <250>200

**NEJM, August 2011**

96% decrease in HIV transmission

The benefit of early ART for HIV prevention among HIV-discordant couples is durable
Overall 93% risk reduction
HPTN 069/ACTG A5305—Safety and tolerability of Maraviroc for PrEP

**Study Design**
- Phase 2
- Double-blind
- Randomized

**Location**
- 13 sites – U.S. only

**Study arms**
- Arm 1: MVC
- Arm 2: MVC+FTC/TDF
- Arm 3: MVC+FTC
- Arm 4: TDF

**Study Status**
- Follow-up completed April 2015
- Final results at CROI 2016
- Follow-up completed November 2015
- Final results to be presented at AIDS 2016

Maraviroc-containing regimens were comparably safe and well-tolerated to TDF+FTC
HPTN Prevention Strategy
Prevention of HIV Transmission

ART for Prevention

General, KP, PP

POPULATION

HIV-POSITIVE

Initiate ART

Retain, Counsel, Monitor & Support

HIV TREATMENT

Undetectable Viral Load

Prevention Toolbox:
VMMC, PrEP, Condoms, Risk Reduction

Link & Retain in Prevention Services

Support Adherence, Repeat HIV Testing

Remains HIV-Negative

HIV-NEGATIVE
Prevention of HIV Acquisition
Pre-exposure Prophylaxis

General, KP, PP

POPULATION

HIV-POSITIVE

Initiate ART

HIV TREATMENT

Retain, Counsel, Monitor & Support

UNDETECTABLE VIRAL LOAD

Adherence Support

HIV-NEGATIVE

LINK & RETAIN IN PREVENTION SERVICES

Prevention Toolbox: VMMC, PrEP, Condoms, Risk Reduction

REMAINS HIV-NEGATIVE

Support Adherence, Repeat HIV Testing
Prevention of HIV Transmission
ART for Prevention

General, KP, PP

POPULATION

HIV-POSITIVE

Initiate ART

HIV TREATMENT

Retain, Counsel, Monitor & Support

Adherence Support

UNDETECTABLE VIRAL LOAD
UNAIDS Global Targets By 2020

90% of all people living with HIV will know their HIV status

90% of all people diagnosed with HIV will receive sustained antiretroviral therapy

90% of all people receiving antiretroviral therapy will have durable suppression
Optimizing Use of ART for Prevention

Community-Level
**Study objective:** To determine the impact of a community-level, combination HIV prevention package on community-level HIV incidence.

**Population Cohort**

<table>
<thead>
<tr>
<th>Enrolled or Participated</th>
<th>PC0</th>
<th>PC12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>&gt;38,000</td>
<td></td>
</tr>
<tr>
<td>New participants</td>
<td>&gt;4600</td>
<td></td>
</tr>
<tr>
<td>Follow-up participants</td>
<td>&gt;24,700</td>
<td></td>
</tr>
<tr>
<td>Specimens collected</td>
<td>&gt;74,500</td>
<td></td>
</tr>
</tbody>
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**Interventions by CHiPs**

<table>
<thead>
<tr>
<th></th>
<th>Round 1</th>
<th>Round 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Households Visited</td>
<td>161,000</td>
<td>117,486</td>
</tr>
<tr>
<td>Adults consented</td>
<td>317,000+</td>
<td>220,634</td>
</tr>
<tr>
<td>Agreed to HIV test</td>
<td>239,000+</td>
<td>174,884</td>
</tr>
<tr>
<td>Or Reported HIV+</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 90-90: Estimated uptake, total HIV+ adult population
**Arm A - Zambia (R1)**

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th></th>
<th>Women</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estimated total HIV-positive</strong></td>
<td>6,340</td>
<td>100%</td>
<td>11,001</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Knows HIV status</strong></td>
<td>5,042</td>
<td>100%</td>
<td>9,546</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Known HIV-positive</strong></td>
<td></td>
<td>79%</td>
<td></td>
<td>87%</td>
</tr>
<tr>
<td><strong>On ART</strong></td>
<td>52%</td>
<td>73%</td>
<td>56%</td>
<td>73%</td>
</tr>
<tr>
<td><strong>On ART</strong></td>
<td>53%</td>
<td>56%</td>
<td>52%</td>
<td>52%</td>
</tr>
</tbody>
</table>
Optimizing Use of ART for Prevention

MSM in the US
New HIV infections in the US, 2014

Two thirds of new HIV infections in the US occurred among MSM

CDC 2015
HPTN 078: Enhancing Recruitment, Linkage to Care and Treatment for HIV-Infected MSM in US

<table>
<thead>
<tr>
<th>Screened population</th>
<th>Enrolled participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>2700</td>
<td>356</td>
</tr>
<tr>
<td>MSM &gt; 16 yo</td>
<td>MSM/ HIV+</td>
</tr>
</tbody>
</table>

Study Duration: 12 M Enrollment 24 M Follow-up

Primary objectives: Recruitment feasibility and viral suppression

All sites activated, enrollment started

- Atlanta
- Baltimore
- Birmingham
- Boston
Optimizing Use of ART for Prevention

PWID in Eastern Europe and Southeast Asia
**HPTN 074: A study comparing an integrated intervention including supported ART to standard of care for PWID**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Standard of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>125 HIV +</td>
<td>375 HIV +</td>
</tr>
<tr>
<td>188 HIV – Partners</td>
<td>563 HIV – Partners</td>
</tr>
</tbody>
</table>

**15 Months Recruitment**  
**12 Months Follow-Up**

- Ukraine
- Vietnam
- Indonesia
Primary Objective: Assess HIV incidence, recruitment, retention, and feasibility and barriers of the intervention

Enrollment completed ahead of schedule! 484/500 Index Participants and 725/750 Partners
Prevention of HIV Acquisition
Pre-exposure Prophylaxis (PrEP)
Clinical Trial Evidence for PrEP

**Prevention of sexual transmission**

- PROUD – daily oral TDF/FTC (MSM – United Kingdom)
- IPERGAY – event-driven TDF/FTC (MSM – Canada, France)
- Partners PrEP – daily oral TDF/FTC (Serodiscordant couples – Kenya, Uganda)
- Partners PrEP – daily oral TDF (Serodiscordant couples – Kenya, Uganda)
- TDF2 – daily TDF/FTC (Heterosexual men and women – Botswana)
- iPrEx – daily oral TDF/FTC (MSM – North and South America, South Africa, Thailand)
- CAPRISA 004 – BAT-24 dosing vaginal tenofovir gel (Women – South Africa)
- RV 144 – six injectable ALVAC/AIDSVAX (Heterosexual men and women – Thailand)
- The Ring Study – monthly vaginal ring containing dapivirine (Women – South Africa, Uganda)
- ASPIRE – monthly vaginal ring containing dapivirine (Women – Malawi, South Africa, Uganda, Zimbabwe)
- MTN 003/VOICE – daily dosing vaginal tenofovir gel (Women – South Africa, Uganda, Zimbabwe)
- FACTS 001 – event-driven vaginal tenofovir gel (Women – South Africa)
- MTN 003/VOICE – daily oral TDF/FTC (Women – South Africa, Uganda, Zimbabwe)
- MTN 003/VOICE – daily oral TDF (Women – South Africa, Uganda, Zimbabwe)
- Bangkok Tenofovir Study – daily oral TDF (PWID – Thailand)

**Effect size (CI)**

- MSM Couples
  - Prevention in people who inject drugs
    - Bangkok Tenofovir Study – daily oral TDF (PWID – Thailand)
  - Prevention in couples
    - PROUD – daily oral TDF/FTC (MSM – United Kingdom)
    - IPERGAY – event-driven TDF/FTC (MSM – Canada, France)
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- Effectiveness (%)
  - MSM Couples
    - Prevention in people who inject drugs
      - Bangkok Tenofovir Study – daily oral TDF (PWID – Thailand)
    - Prevention in couples
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- Women
  - Prevention in people who inject drugs
    - Bangkok Tenofovir Study – daily oral TDF (PWID – Thailand)
  - Prevention in couples
    - PROUD – daily oral TDF/FTC (MSM – United Kingdom)
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    - MTN 003/VOICE – daily oral TDF (Women – South Africa, Uganda, Zimbabwe)

- PWID
  - Prevention in people who inject drugs
    - Bangkok Tenofovir Study – daily oral TDF (PWID – Thailand)
  - Prevention in couples
    - PROUD – daily oral TDF/FTC (MSM – United Kingdom)
    - IPERGAY – event-driven TDF/FTC (MSM – Canada, France)
    - Partners PrEP – daily oral TDF/FTC (Serodiscordant couples – Kenya, Uganda)
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    - MTN 003/VOICE – daily oral TDF (Women – South Africa, Uganda, Zimbabwe)
Association between Adherence and Effectiveness

![Graph showing the association between adherence and relative risk (RR) for placebo vs active treatment, with separate lines for women and men.](image)
One-third of new HIV infections globally occur in young African women (15-24 yrs)
HPTN 082: Uptake and adherence to daily oral TDF/FTC PrEP in young (16-25 yrs) Southern African women

Study Population

Uninfected women
Ages 16-25 yrs
South Africa
Zimbabwe

Target Enrollment

• 400 women who accept PrEP at enrollment
• ≤ 200 women who decline PrEP at enrollment
Study Design

**PrEP = Daily oral FTC/TDF**

Enroll

- **Accept**
  - Randomize PrEP Acceptors 1:1
  - SOC and offer PrEP (≤200 women)

- **Decline**
  - Provide PrEP, enhanced adherence support, SOC (~200 women)
  - Provide PrEP, standard adherence support, SOC (~200 women)

**In-depth interviews exploring factors that influence women’s decisions to use PrEP, to adhere to PrEP, and acceptability of PrEP in the first 3 months after PrEP acceptance. (~75 total, including acceptors and decliners)**

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

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

**Primary objectives:**
Assess the proportion and characteristics of women who accept versus decline PrEP

**Training for study initiation in July 2016**
New HIV infections in the US, 2014

Two thirds of new infections in the US occurred among MSM

More than half of new infections among MSM in the US occurred among Black MSM
HPTN 073: Uptake of and adherence to TDF/FTC PrEP among Black MSM in the US

- **Enrollment**: 226
- **Population**: BMSM/HIV-
- **Study Duration**: 12 M

**Study Status**
- Follow-up completed September 2015
- Self-reported uptake and adherence presented at CROI 2016
- Additional results to be presented at AIDS 2016

**Offer PrEP**
- Daily Oral TDF/FTC

**Client Centered Care Coordination (C4)**
- Ongoing management of health & psychosocial needs
Client Centered Care Coordination (C4):

A Culturally Specific Intervention Package to Support PrEP Use in HIV Risk Reduction Menu of Options

PrEP Uptake: 79%
12-Month Retention: 92%
Transition to Community Follow-Up
HPTN 075: Feasibility of recruitment and retention of African MSM

Observational study:

400 MSM in 4 Sites
- Men 18-44 years living in sub-Saharan Africa who report anal sex with a man in the past 3 months

12 Months of Follow-Up
- 5 study visits with structured HIV behavioral assessments, medical examinations, and collection of biological samples

Primary Objective
To assess retention of a cohort of MSM to inform feasibility of an intervention study

Almost Completed enrollment!
389 of 400 men enrolled
Long-acting Agents for HIV Prevention
Two studies of safety of long-acting injectable PrEP initiated and enrollment completed

HPTN 076: Safety and acceptability of injectable rilpivirine (TMC278 LA) for PrEP
136

HPTN 077: Safety, tolerability and pharmacokinetics of injectable cabotegravir (CAB) in men and women
194

Primary objective: Evaluate the safety and tolerability of the product

Fully enrolled
HPTN 083: Phase 2B/3 Study of Efficacy of injectable cabotegravir for PrEP in MSM and transgender women

N = 4500 (10% TGW overall; 50% of US BMSM; 50% overall < 30 year old)

<table>
<thead>
<tr>
<th>Step</th>
<th>CAB</th>
<th>TDF/FTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Daily oral CAB and oral TDF/FTC placebo</td>
<td>Daily oral TDF/FTC and oral CAB placebo</td>
</tr>
<tr>
<td>Step 2</td>
<td>Injectable CAB and daily oral TDF/FTC placebo</td>
<td>Daily oral TDF/FTC and injectable placebo</td>
</tr>
<tr>
<td>Step 3</td>
<td>Open-label daily oral TDF/FTC for up to 48 weeks</td>
<td>Open-label daily oral TDF/FTC for up to 48 weeks</td>
</tr>
</tbody>
</table>

Primary objective: HIV Incidence

40+ sites chosen in the Americas (Argentina, Brazil, Peru, US) and Asia (Thailand, Vietnam; India pending)

HPTN 084: Phase 2B/3 Study of efficacy of injectable cabotegravir for PrEP in women (under development)
Monoclonal Antibodies for HIV Prevention

VRC01 MAb

VRC01 attaches to the CD4 binding site on gp120 envelope protein of HIV

VRC01 neutralize ~ 90% of diverse viral isolates
MSM+TG AMP: HVTN 704/HPTN 085

Enrolled participants

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2700 MSM &amp; TG in US</td>
<td></td>
</tr>
<tr>
<td>Study duration</td>
<td>92 weeks</td>
</tr>
</tbody>
</table>

Regimen

<table>
<thead>
<tr>
<th></th>
<th>N*</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRC01 10 mg/kg</td>
<td>900</td>
</tr>
<tr>
<td>VRC01 30 mg/kg</td>
<td>900</td>
</tr>
<tr>
<td>Control</td>
<td>900</td>
</tr>
<tr>
<td>Total</td>
<td>2700</td>
</tr>
</tbody>
</table>

Infusions every 8 weeks through Week 92

Study opened 31 March, 2016
As of end of May, 110 participants enrolled!
SSA Women AMP: HVTN 703/HPTN 081

<table>
<thead>
<tr>
<th>Enrolled participants</th>
<th>1500 South African Women (First enrollments expected by mid-May)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study duration</td>
<td>92 weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regimen</th>
<th>N*</th>
<th>Infusions every 8 weeks through Week 92</th>
</tr>
</thead>
<tbody>
<tr>
<td>VRC01 10 mg/kg</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>VRC01 30 mg/kg</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1500</td>
<td></td>
</tr>
</tbody>
</table>

Study started enrollment
34 Sites in the U.S.

1 Site in Puerto Rico
4 Sites in Brazil
2 Sites in Argentina
5 Sites in Peru

16 Sites in Africa
1 Site in India
1 Site in Indonesia
3 Sites in Thailand
2 Sites in Vietnam
1 Site in Ukraine
1 Site in Puerto Rico

2 Sites in Argentina

1 Site in Puerto Rico

9 Sites in South Africa

9 Sites in South Africa

2 Sites in Malawi

1 Site in Zambia

1 Site in Botswana

2 Sites in Zimbabwe

1 Site in Kenya
Community Engagement

- Eight capacity building community workshops for HVTN 703/HPTN 081, HVTN 704/HPTN 085 and HPTN 083

- In 1st quarter 2016, 31 CRSs provided education/outreach at 508 events

- Cross-network (HPTN & HVTN & MTN) biomedical research summit (NAESM Conference)

- Five-day science (HPTN & MTN) writing workshop
  - writing teams developed, several abstracts presented
HPTN Scholars Program

**Goal:** To develop the next generation of HIV prevention scientists

- Scholars utilize HPTN data to develop analytic skills, conduct reviews, give presentations, write publications

**To date:**
- 21 scholars completed program
- 31 mentors engaged
- K awards, R03, R21, faculty positions
- 12 presentations, 17 publications
  (+ 1 in press, 2 under review)

*Sten Vermund*
*Darrell Wheeler*
*Ken Mayer*
*Quarraisha Abdool Karim*
*David Serwadda*
HPTN Publications 2015-2016

• 46 Publications
• Presentations
  – IAS 2015 - 15
  – CROI 2015 – 7
  – CROI 2016 - 26
  – AIDS 2016 – 28
SPECIAL ISSUE:
HIV Prevention for Transgender Populations

Transgender People and HIV Prevention: What We Know and What We Need to Know
Kenneth Mayer, Beatriz Grinsztejn, and Wafaa M. El-Sadr

Global epidemiology of HIV infection and related syndemics affecting transgender people
Tonia Poteat, Ayden Scheim, Jessica Xavier, Sari L. Reisner, and Stefan Baral

Behavioral Interventions to Prevent HIV Transmission and Acquisition for Transgender Women: A Quick Review
Robert Garofalo, Lisa E. Kuhns, Sari L. Reisner, and Matthew J. Mimiaga

Transgender Women in Clinical Trials of Pre-Exposure Prophylaxis
Robert M. Grant, Joe Sevelius, Valdilea G. Veloso, and Madeline Deutsch

Pharmacologic considerations for Pre-Exposure Prophylaxis in Transgender Women
Peter Anderson

Integrated and Gender-Affirming Clinical Care and Research Programs for Transgender People to Address Disparities in HIV Infection
Sari L. Reisner, Asa Radix, and Madeline Deutsch

Engaging Transgender People in NIH-funded HIV/AIDS Clinical Trials Research

Design Issues in Transgender Studies
Jim P. Hughes, Lynda Emel, Brett Hanscom, and Sahar Zangeneh

Ethical Issues to Consider in the Design of HIV Prevention Trials Involving Transgender People
Jerome Amir Singh
Conclusions

- Success in recruitment of important at risk populations, e.g., US Black MSM, PWID and their partners, MSM in SSA
- HPTN study results are informing future research by the network and other groups
- Suite of vanguard studies developed to identify how best
d  - to recruit, engage specific populations and
d  - to determine the uptake, adherence with and outcomes of key interventions
- New collaborations established, robust community engagement accomplished and continued commitment to a new generation of prevention researchers
Acknowledgements

- NIH Institutes (NIAID, NIMH, NIDA)
- PEPFAR; Bill and Melinda Gates Foundation; CDC; and pharmaceutical partners
- Elsie Talavera and her team
- Study participants and participating communities
- Investigators, staff and community representatives

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Thank you!