HPTN: 2006 to 2012
A dynamic HIV prevention landscape!

STEN H. VERMUND
JUNE 27, 2012 JOINT HPTN-IMPAACT PLENARY
Overview

• HIV prevention in 2006
  – Many negative trials, considerable concern about feasibility of success in prevention

• HPTN has built a strong foundation to respond to the HIV pandemic through a focus on key epidemics & populations
  – Strengthening the domestic agenda
  – Addressing key challenges in Africa, Asia, & So. America

• New hope in HIV prevention – we can stop the pandemic!
  – Treatment for Prevention WORKS!!
  – Enhancing oral PrEP efforts
  – Integrated prevention (combining what works)
HPTN 061: Can we access and follow Black MSM in the US, preparing for interventions?

Black MSM represent 25% of incident HIV infections.

1553 men in Atlanta, Boston, Los Angeles, New York City, San Francisco, Washington DC
HPTN 064: Can we identify and engage the most HIV-vulnerable women in the US?

The Women’s HIV SeroIncidence Study (ISIS)

2099 women from 10 communities in 6 regions:

- Bronx/Harlem, NYC
- Newark, NJ (North/South)
- Baltimore, MD
- Washington, DC
- Durham/Wake County, NC
- DeKalb/Fulton County, Atlanta, GA
HPTN 065: Can we substantially increase large scale testing and successful linkage to care?

TLC-Plus: Expansions in testing, linkage to care, retention, adherence, positive prevention, healthcare worker cART education

Bronx and Washington DC

Collaboration with health departments, health care agencies, and the CDC
LINKAGE TO CARE: HPTN 065

- Observational
- Social Mobilization
- 16 hospitals
- Expanded HIV Testing

- Site Randomized
- 38 Testing sites
- Linkage to Care

- Site Randomized
- 39 Care sites
- Viral Suppression

- Individual Randomized
- N=660 in each of 2 communities
- Prevention for Positives

- Cross sectional (pre and post)
- Care providers
- Provider & Patient Surveys

DC  Bronx

Social Mobilization
HPTN 062: Risk reduction in acute infection

Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection

Study conducted at one site in Malawi as a collaboration with CHAVI, 28 acutely infected persons enrolled
HPTN 063: Positive prevention on 3 continents

Preparing for international prevention trials involving HIV-infected individuals in care settings

Brazil, Thailand, Zambia
N=751
HPTN 068: Can cash incentives keep girls in school and HIV-free?

Girls have increased HIV vulnerability simply due to trade-offs that they make to go to school.

Agincourt region (Bushbuckridge) in eastern Mpumalanga, South Africa

N=2500
HPTN 043: Does testing expansion reduce HIV transmission

Phase III RCT of Community Mobilization, Mobile Testing, Same-Day Results, and Post-Test Support for HIV in Sub-Saharan Africa and Thailand

Primary endpoint being evaluated by Network Lab (> 50,000 samples)
# Increasing HIV Testing: HPTN 043

**NIMH Project ACCEPT**

<table>
<thead>
<tr>
<th></th>
<th>Tanzania (10 sites)</th>
<th>Zimbabwe (8 sites)</th>
<th>Thailand (14 sites)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S-VCT clients</strong></td>
<td>N=6733</td>
<td>N=12150</td>
<td>N=10033</td>
</tr>
<tr>
<td><strong>CB-VCT clients</strong></td>
<td>N=6250</td>
<td>N=10700</td>
<td>N=11290</td>
</tr>
<tr>
<td><strong>1st time HIV test</strong></td>
<td><strong>9%</strong></td>
<td><strong>5%</strong></td>
<td><strong>23%</strong></td>
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<td><strong>37%</strong></td>
<td><strong>51%</strong></td>
<td><strong>69%</strong></td>
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**CB-VCT** = community-based VCT  
**S-VCT** = standard clinic-based VCT

**REF:** Sweat M, et al. NIMH Project ACCEPT. *Lancet Infect Dis* 2011
HPTN 058: Novel approach to IDU risk reduction in Asia

A Phase III RCT to evaluate the efficacy of drug treatment (oral buprenorphine/naloxone) in prevention of HIV infection and death among opiate dependent injectors

Final patient visits July 2012, n=1252. Now focused on its secondary endpoints as HIV incidence was too low to assess
May 2011: ART prevents HIV transmission from infected partners in discordant couples (HPTN 052)

Prevention of HIV-1 Infection with Early Antiretroviral Therapy

Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H.,
Theresa Gamble, Ph.D., Mina C. Hosseinipour, M.D.,
Nagalingeswaran Kumarasamy, M.B., B.S., James G. Hakim, M.D.,
Johnstone Kumwenda, F.R.C.P., Beatriz Grinsztejn, M.D., Jose H.S. Pilotto, M.D.,

1763 discordant couples in Africa, Asia, & Americas

Effect on ART (HIV +ve) on HIV: 96% (CI: 73% - 99%)
“HPTN 052 is a game changer,”
Michel Sidibe, Exec. Director of UNAIDS

The New York Times
Early H.I.V. Therapy Sharply Curbs Transmission

The Wall Street Journal
Scientists See Breakthrough in the Global AIDS

msnbc.com
Starting HIV meds quickly helps protect partner

Associated Press
Earlier HIV therapy protects against virus spread
2012 → NEW PROMISE FOR PREVENTION NOW!

ADVANCING THE ARV FOR PREVENTION AGENDA
– ORAL PREP: HPTN 066, 067, AND 069

BRIDGING THE EFFICACY-EFFECTIVENESS GAP VIA COMBINATION PREVENTION – HPTN 071
Dose-Proportionality and Intra-Individual Variability of Intracellular FTC/TDF in 38 Healthy Volunteers

Baltimore and Chapel Hill
HPTN 067: How will intermittent PrEP be used in real world conditions?

Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral FTC/TDF PrEP

MSM in Bangkok, Women in Cape Town New York City
HPTN 069: Is maraviroc a promising option for PrEP?

Safety and Tolerability for PrEP
- Maraviroc (MCV)
- Maraviroc + Emtricitabine
- Maraviroc + Tenofovir
- TDF + FTC

A dozen sites in the HPTN and the ACTG in the USA
HPTN 071: Can combination prevention anchored on universal therapy reduce community HIV transmission?

Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART):
A cluster-randomized trial of the impact of a combination prevention package on population-level HIV incidence in Zambia and South Africa
PopART HPTN071

HIV-neg. COHORT
N=52,500 (2,500x21)

HIV incidence

Behavioral data

CHiPs (Arm A+B)

PROCESS MEASURES

PMCT uptake
MMC uptake
Test uptake
Link
Retention

CLINIC BASED SURVEILLANCE

TB incidence

Clinic attendance
Reasons for clinic visit

Viral load
CD4, CBC, Biochem
WHO stage/clinical

Genotype if treatment failure
Hospitalization
HPTN 073: Black MSM

Evaluating Integrated Interventions to Optimize HIV PrEP Adherence Among Black MSM

Protocol in development (Sites to be selected)
A salute to the site leaders and their talented staff. A thank you to the volunteers and our community partners.

Scientific productivity: 2006-2012

- 18 US/48 International Sites active in HPTN science
- 14 390 individually randomized participants enrolled
- > 400 000 community randomized participants: 192,823 in 043 and >250 000 in 065
- 225 peer reviewed publications (138 high impact)
Where is the HPTN in 2012?

- Robust science agenda focused on key priorities
- Knowledge of how to locate populations at highest risk
- Oral PrEP agenda addresses adherence, dosing, new drugs
- Bridging proof of concept and effectiveness by optimizing combination prevention
- Contributions to laboratory and statistical advances
- Design and conduct complex trials with HIV endpoints
- Community partnership and highest ethical standards!
- Mentoring new HIV science partners: HPTN Scholars
Evolving Leadership for HPTN 2012-13 and beyond

and

many, many more

from sites, labs,
SWGs, EC,
community, ethics,
stat/data, NIH,
partners from
other networks...!
ACKNOWLEDGEMENTS

• Sponsored by NIAID, NIDA, NIMH under Cooperative Agreement # UM1 AI068619 and all the cooperative agreements for SDMC, NL, and CTUs

• Additional support: OGAC, BMGF

• Kathy Hinson and Nirupama Sista

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• David Burns, Katherine Davenny; Carl Dieffenbach, Michael Gilbreath, Diane Rausch, Sheryl Zwerski
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Quarraisha and Sten are grateful for the privilege of working with you all in striving to defeat HIV/AIDS in our own nations and throughout the globe.