HPTN Scientific Agenda
Key Updates for 2021 and Beyond

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Director, ICAP at Columbia University
Director, Columbia World Projects
Mathilde Krim-amfAR Chair of Global Health
Columbia University
Overview of Presentation

- State of the HIV Epidemic
- HPTN vision and conceptual framework
- Ongoing HPTN studies
- Recent and planned HPTN studies
- Looking ahead
- Conclusions
Adults and children living with HIV | 2019

Total: 38.0 million [31.6 million–44.5 million]
Reaching Global HIV Treatment Targets

Number of people living with HIV on antiretroviral therapy

26 million people on HIV treatment worldwide in June 2020


UNAIDS 2020
HIV Testing and Treatment Cascade

![Graph showing HIV testing and treatment cascade with percentage data for years 2015 to 2019.](image-url)
Number of new HIV infections | 2019

Total: 1.7 million [1.2 million–2.2 million] people
Number of New HIV Infections

- 1.8 Million
- <0.5 million

UNAIDS 2020
HPTN
Strategic Vision
Foundation of HIV Prevention

Primary Prevention
- Pre-exposure Prophylaxis

Secondary Prevention
- Antiretroviral Therapy

Primary Prevention
- Pre-exposure Prophylaxis

Secondary Prevention
- Antiretroviral Therapy
Scientific Aims

1. Identify **novel antiretroviral (ARV)-based methods and delivery systems** for HIV prevention.

2. Develop **multi-purpose technologies** for HIV prevention as well as for contraception, prevention of other sexually transmitted infections or opioid dependence.

3. Evaluate **broadly neutralizing antibodies** alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network.

4. Design and conduct population-specific **integrated strategy studies** that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness.
HPTN Scientific Agenda: Conceptual Framework

Abbreviations
- ARV antiretroviral
- PrEP pre-exposure prophylaxis
- MPT multipurpose technology
- bnAbs broadly neutralizing antibodies
- PK pharmacokinetic
- PWID people who inject drugs
- TGW transgender women
- MSM men who have sex with men
I. Discovery

New Prevention Tools and Methods

- Novel ARV Methods and Delivery Systems
- Multi-Purpose Prevention Technologies (MPTs)
- Broadly Neutralizing Antibodies (bNabs)
II. Achieving Population Impact
Integrated Strategies

- Biomedical Interventions
- Behavioral Interventions
- Structural Interventions
Integrated Strategies

Reduce HIV incidence

PUBLIC HEALTH IMPACT
Who is getting newly infected?

- Remaining population: 38%
- People who inject drugs: 10%
- Sex workers: 8%
- Gay men and other men who have sex with men: 23%
- Clients of sex workers and sex partners of all key populations: 19%
- Transgender people*: 2%

UNAIDS 2020
HPTN Study Updates
HPTN 083
A Phase IIb/III Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), for Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men
HPTN 084

A Phase III Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV Uninfected Women
HPTN 083 Open Label Extension (OLE)
HPTN 084 Open Label Extension (OLE)
HPTN 083-01

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males
**HPTN 083-01**
Study Participant Plan

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
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<tbody>
<tr>
<td>5 weeks</td>
<td>29 weeks</td>
<td>48 weeks</td>
</tr>
<tr>
<td>Daily Pill</td>
<td>Shot Every 8 Weeks</td>
<td>Daily Pill</td>
</tr>
<tr>
<td>CAB Pill</td>
<td>CAB Shot</td>
<td>TDF/FTC Pill</td>
</tr>
</tbody>
</table>

*In step 2, the first two shots are four weeks apart and 8 weeks apart after that.*
HPTN 084-01

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females
HPTN 084-01
Study Participant Plan

**Step 1**
5 weeks
Daily Pill
CAB Pill

**Step 2**
29 weeks
Shot Every 8 Weeks
CAB Shot

**Step 3**
48 weeks
Daily Pill or Shot Every 8 Weeks
Option of TDF/FTC Pill or CAB Shot

*In step 2, the first two shots are four weeks apart and 8 weeks apart after that*
New and Planned Studies
HPTN 091: Integrated Strategy Study Among Transgender Women

To assess the feasibility, acceptability, and preliminary impact of a multi-component strategy to improve pre-exposure prophylaxis (PrEP) uptake and adherence:

- **PrEP**: biomedical HIV prevention
- **Co-located gender-affirming transgender care** (hormonal therapy and medical monitoring)
- **Peer Health Navigation (PHN) using Strengths-Based Case Management (SBCM)** professional supervision
HPTN 091: Study Design

- **PrEP Provision**: STI Screening & Treatment
  - Immediate Intervention Arm
  - Deferred Intervention Arm

- **Co-Located Services**
  - Gender Affirming Hormone Therapy
  - Peer Health Navigation Using Strengths-Based Case Management

- **Linkage to Services**
  - Gender affirming hormone therapy and case management services

- **Randomization 1:1 Assignment**: 310 TGW Enrolled

- **Time Periods**
  - (0-6 months)
  - (6-18 months)
HPTN 094: Integrated Strategy Study Among Persons Who Inject Drugs

INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for:

- Addiction
- HIV
- Hepatitis C
- Primary Care
**Study Design**

**Mobile Unit**
Consent, Screening, Enrollment

**Randomization**

**Intervention Arm**
Primary and Some Secondary Outcomes Evaluation

**Active Control Arm**
Secondary Outcomes Evaluation

**Assessments:**
- Baseline
- 26 weeks
- 52 weeks

**INTERVENTION**
“One stop Model” services in van, with peer navigation: MOUD, ART or PrEP, HCV, STI, primary care, and harm reduction

**ACTIVE CONTROL**
Navigation to health services available at community-based agencies
HPTN 096: An Integrated Strategy for Men who have Sex with Men in US South

To evaluate an integrated, HIV status-neutral, population-based approach to reduce HIV incidence among Black men who have sex with men (MSM) in the US South by increasing:

• HIV testing
• uptake and use of pre-exposure prophylaxis (PrEP) among Black MSM living without HIV
• viral suppression rates among Black MSM living with HIV
HPTN 096: Study Design

- **I<sub>c</sub>**: Health equity
  - **Increase multi-level social support**
  - Social media influencers
  - Intersectonal stigma reduction
- **I<sub>o</sub>**: Peer support
  - Reduced structural barriers to healthcare services
- **I<sub>ip</sub>**: Increase in Black MSM who are virally suppressed
  - Increased PrEP use in cross-sectional assessments and prescription data
- **Increased HIV and STI Testing**
  - Increased PrEP uptake, increased PrEP adherence
  - Increased ART uptake, increased ART adherence
- **Reduction in HIV incidence**
  - Measured by cross-sectional HIV incidence estimation in a subset of communities' cross-sectional assessments
- **Reduction in Black MSM vulnerable to infection (PrEP)**
  - Measured using HIV surveillance data and data from cross-sectional assessments
HPTN 096: Study Population

- 16 communities identified from the southern counties and states included in the Ending the HIV Epidemic plan
  - 8 intervention communities
  - 8 standard of care communities
Looking Ahead
Key updates

• HPTN Leadership

• Working Groups and Science Committees

• Induction of HPTN 2021-2022 Scholars
Network Structure - Leaders

Executive Committee (EC)
- Myron S. Cohen
- Wafaa El-Sadr
- Quarraisha Abdool Karim
- Chris Beyrer
- Sinead Delany-Morelwe
- Deborah Donnell
- Susan Eshleman
- Sybil Hosek
- Raphael Landovitz
- Nyaradzo Mgodi
- David Serwadda
- Sten Vermund
- Nirupama Sista
- Melissa Turner
- Darrell Wheeler
- 2 NIH Representatives

Leadership and Operations Center (LOC) FHI 360
- Nirupama Sista

Statistical and Data Management Center (SDMC) SCHARP
- Deborah Donnell

Laboratory Center (LC) Johns Hopkins University
- Susan Eshleman
## Committee/Working Group Leadership

<table>
<thead>
<tr>
<th>Science Committees</th>
<th>Chair</th>
<th>Co-Chair</th>
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<tbody>
<tr>
<td>Adolescents at Risk</td>
<td>Audrey Pettifor</td>
<td>Linda-Gail Bekker</td>
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<tr>
<td>Sexual and Gender Minority</td>
<td>Kenneth Mayer</td>
<td>Nittaya Phanuphak</td>
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<td>Substance Users</td>
<td>Steffanie Strathdee</td>
<td>Nabila El-Bassel</td>
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<tr>
<td>Women at Risk</td>
<td>Ada Adimora</td>
<td>Philippa Musoke</td>
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<th>Working Groups</th>
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<tbody>
<tr>
<td>Biomedical Sciences</td>
<td>Jeanne Marrazzo</td>
<td>Joseph Eron</td>
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<tr>
<td>Community</td>
<td>Melissa Turner</td>
<td>Ntando Yola</td>
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<tr>
<td>Ethics</td>
<td>Jeremy Sugarman</td>
<td>Jerome Singh</td>
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<tr>
<td>Socio-Behavioral Sciences</td>
<td>Ariane van der Straten</td>
<td>Julie Pulerwitz</td>
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### Technical Liaisons

Susan Buchbinder, Connie Celum, Sharon Hillier
HPTN 2021-2022 Domestic Scholars

Noelle M. St. Vil, PhD, MSW  
University of Buffalo  
Mentor(s): Danielle Haley, Gina Wingood  
Project: An Exploration of the Social Determinants of Violence Against Women At-Risk of HIV

Ndidiamaka Amutah-Onukagha, PhD, MPH  
Tufts University  
Mentor(s): Audrey Pettifor  
Project: Examining the role of social support in PrEP uptake and utilization for young African women: implications for HIV prevention

Donaldson F. Conserve, PhD, MS  
George Washington University  
Mentor(s): Chris Beyrer  
Project: Assessment of Case Manager Intervention Dosage Impact on Viral Suppression among MSM: A Mixed Method Study

Adedotun Ogunbajo, PhD, MPH  
Harvard University  
Mentor(s): Kenneth Mayer  
Project: Intimate Partner Violence, Social Support, and Substance Use among Black men who have sex with men (BMSM) in the United States
Manuela Bullo, MD, MPH

**Mentor(s):**
Audrey Pettifor

**Project:**
Alcohol Use and HIV-HSV2 Incidence in Female Adolescents in Rural South Africa

Nomtha Bell-Mandla, PhD candidate, DTTC

**Mentor(s):**
Peter Bond, Lungiswa Nkonki, Ayana Moore

**Project:**
Determinants strategies and cost implications for participant recruitment, and retention in an HIV cohort, perspectives from HPTN 071 (PopART)

Bwalya Chiti, MPH

**Mentor(s):**
Virginia Bond, Musonda Simwinga

**Project:**
Thinking on their feet: Lessons learnt from the role, identity and experiences of community-based HIV service providers in delivering Universal Test and Treat within the (PopART) trial in Zambia and South Africa
HPTN Concept Solicitation

- **January 2021**: Broad Solicitation
- **March 1, 2021**: Letters of Intent Submitted (76)
- **April 12, 2021**: Concepts Submitted (27)
- **April 12–May 10, 2021**: Review by HPTN Scientific Committees and Working Groups
- **May 11–27, 2021**: Ad hoc Committee Review
Focus Areas of Submitted Concepts

**Novel ARV Based Methods and Delivery Systems**
- Cabotegravir implants for PrEP
- Cabotegravir microneedle patches for PrEP
- Oral islatravir vs. intramuscular cabotegravir for PrEP among MSM and TGW
- On demand rectal vs. oral TFV-based PrEP
- Lencapavir vs TDF/FTC among US women
- Long-active injectable lencapavir vs. oral TD/FFTC for PREP

**Multi-purpose Technologies (MPTs)**
- Injectable PrEP + contraception
- Tailored STI care + HIV PrEP intervention
- HIV prevention + stimulant and opioid injection treatment
- Fast dissolving non-ARV MPT insert
- MPT for HIV + pregnancy
- MPT for HIV + STI

**Integrated Strategies**
- Drug use prevention and treatment + HIV prevention
- Social marketing of HIV services to improve update & retention in high burden settings
- Digital HIV health intervention among diverse adolescents & young adults
- Daily vs. long-acting PrEP among young adults in SSA
- HIV, STI, and unintended pregnancy prevention in Southern Africa
- Client-centered, status neutral, community-based ARVs for PrEP and ART in high prevalence settings in Southern Africa
- Leveraging HIV self-testing and sexual networking to engage men in HIV services
- PrEP choice and adherence package vs. wait-list in cisgender men, transgender and gender nonbinary persons who have sex with men and TGW
- Tele-PrEP and peer-delivered behavioral risk reduction among TGW and MSM in US
- Integration HIV prevention strategies in US county jails
- Rapid HIV testing to reduce transmission
Conclusions

• Substantial progress has been achieved in confronting the HIV epidemic, but major gaps remain in prevention of new HIV infections

• HPTN aims to identify new HIV prevention tools and to optimize the use of new and existing tools to achieve desired HIV prevention impact in diverse populations

• New ambitious global targets have been set for 2025 in order to achieve the end of AIDS as a public health threat by 2030

• HPTN is poised to contribute the research results that will advance progress towards reaching the 2025 targets
Acknowledgments

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- Office of the Director (OD), National Institutes of Health (NIH)
- National Institute on Drug Abuse (NIDA)
- National Institute of Mental Health (NIMH)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).

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