Priority Areas as per RFA

- Identify **novel ARV-based methods and delivery systems** for HIV prevention
- Develop **multi-purpose technologies (MPTs)** for HIV prevention as well as for contraception, prevention of other STIs
- Evaluate **broadly neutralizing antibodies (bnAbs)** alone or in combination that prevent HIV acquisition, in collaboration with the HVTN
- Design and conduct population-specific **integrated strategy studies** that combine biomedical, socio-behavioral and structural interventions for HIV prevention to maximize their effectiveness
HPTN Mission

• Develop new biomedical interventions:
  – Novel ARV methods and delivery systems
  – Multi-Purpose Technologies (MPTs)
  – Broadly neutralizing antibodies (bnAbs)

• Optimize integration of proven interventions to achieve high effectiveness and impact:
  – Biomedical
  – Socio-behavioral
  – Structural
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

Integrated Strategies
- MSM
- PWID
- TGW
- Women
- Adolescents
- Others

Population Level HIV Prevention

Social/Behavioral Interventions

Structural Interventions
Aim 1: Design and conduct studies of long-acting antiretroviral (ARV) agents and delivery systems for pre-exposure prophylaxis (PrEP)

- Identify promising ARV for PrEP
- Test products through phase 1-3 drug development studies
- Evaluation various delivery systems e.g. injections/infusions, implants, patches and topical products with promising systemic effects
- Collaborate with partners to access new agents and delivery systems

Image source: Hannah Balfour (European Pharmaceutical Review)
Aim 2: To design and conduct studies that evaluate multipurpose prevention technologies (MPTs) that concurrently prevent HIV and pregnancy, other sexually transmitted infections or opioid dependence

- **MPTs of interest (examples):**
  - **HIV prevention + contraception**
    - Vaginal rings and inserts
    - Implants and devices
  - **HIV prevention + STI prevention**
  - **HIV prevention + opioid dependence management**
    - Long-acting substance use medications (oral, injection, and implant)
Delivery Options for MPTs

**Co-formulated:**
Multiple API formulated into a single dose

**Co-administered:**
Two independent products used together

**Co-packaged:**
Two different doses packaged together in a single product for simultaneous co-use

Source: HPTN presentation “Multipurpose Technologies for Prevention,” Hillier & Sweet.
Aim 3: To design and conduct studies, in collaboration with HVTN, to evaluate broadly neutralizing antibodies (bnAbs) alone or in combination for PrEP.

- **Products of interest (examples):**
  - bnAbs alone
  - combination of bnAbs
  - Tri-specific bnAbs
Aim 4: To design and conduct integrated strategies for HIV prevention

- Behavioral Interventions
- Structural Interventions
- Biomedical Interventions

Population Level HIV Prevention

- MSM
- PWID
- Women
- Adolescents
- Others
Aim 4: To design and conduct integrated strategies for HIV prevention

• Approach
  – Focus on priority populations most impacted by HIV
  – Tailor to individual and social contexts
  – Embrace a status-neutral approach to avoid stigma of HIV
  – Design different types of studies: e.g. vanguard and definitive studies
  – Incorporate rapidly new tools and delivery methods
### Integrated Strategies for Populations at Risk (U.S.)

<table>
<thead>
<tr>
<th>U.S. Populations</th>
<th>Proposed Integrated Strategy (and Design)</th>
</tr>
</thead>
</table>
| **MSM in U.S. (HPTN 096)** | • County randomization in U.S. South  
• Study arms: Integrated community plus individual interventions vs. SOC  
• Interventions:  
  • Community interventions: provider sensitization, community workshops  
  • Individual interventions: status-neutral, client-centered coordination and intensive case management for adherence support |
| **Young MSM (YMSM)**    | • Vanguard study with individual randomization  
• Study arms:  
  • MHealth using apps and internet platforms for risk assessment, referral for HIV testing, care and prevention interventions, peer support  
  • SOC: Facility-based SOC interventions |
| **Women at risk**       | • Vanguard study with individual randomization  
• Study arms:  
  • Community delivery of PrEP HIV prevention interventions, SMART design for intensified adherence support  
  • SOC: Facility based SOC interventions |
| **PWID (HPTN 094)**     | • Individual randomization  
• Study arms:  
  • Mobile units at venues frequented by PWID (consisting of HIV, HCV, & STI testing, prevention/management, MAT, harm reduction, overdose education, naloxone)  
  • SOC: Referral to facilities and programs in community |
## Integrated Strategies for Populations at Risk (Globally)

<table>
<thead>
<tr>
<th>Population</th>
<th>Proposed Integrated Strategy (and Design)</th>
</tr>
</thead>
</table>
| **Women in SSA** | • Cluster (family planning clinics) randomized step-wedge design  
• Interventions:  
  • Integrated strategies with HIV, STI and FP interventions, SMS texting, POC urine ARV with immediate feedback  
  • SOC | |
| **Heterosexual men in SSA** | • Individual randomization  
• Interventions:  
  • Integrated strategies through mobile units at work and leisure venues frequented by men: HIV self-testing, status-neutral, HIV PrEP and ART with other health interventions, WhatsApp support by champions and peers  
  • SOC | |
| **MSM and TGW in SSA, South America and Asia** | • Two-level factorial design  
• Interventions:  
  • Community plus individual interventions  
    • Community interventions: provider sensitization, community workshops, risk mitigation  
    • Individual interventions: Status-neutral approach, PrEP or ART, per HIV status, peer support  
  • SOC | |
| **TGW in Americas HPTN 091** | • Individual randomization  
• Interventions:  
  • Co-located provision of PrEP plus gender-affirming hormones plus strength-based case management  
  • SOC | |
| **Non-injection substance users among MSM in Americas** | • Individual randomization  
• Interventions:  
  • Mitrazapine, two-way text messaging reminders  
  • SOC | |
Objectives

1. To assess acceptability and feasibility of delivering integrated HIV prevention services co-located with gender-affirming hormone therapy (GAHT) and peer-delivered health navigation supported by strengths-based case management (SBCM) for TGW.

2. To assess PrEP uptake and adherence (including PrEP persistence) in both the Immediate Intervention Arm and the Deferred Intervention Arm.
Integrated Strategies: HPTN 091

- **PrEP Provision**
  - STI Screening & Treatment

- **Co-Located Services**
  - Gender Affirming Hormone Therapy

- **Peer Health Navigation Using Strengths-Based Case Management**

**Immediate Intervention Arm**
- Randomization 1:1 Assignment
- 310 TGW Enrolled

**Deferred Intervention Arm**
- (0-18 months)
- (0-6 months)
- (6-18 months)
• Evaluate “one stop” integrated services delivered in a mobile health delivery unit on uptake and adhere
  – medication for opioid use disorder (MOUD)
  – HIV treatment and prevention medications – to PWID improve uptake and adherence compared to a control arm that provides referrals to existing services at static facilities
• Two-arm, individually randomized, controlled, open label study
HPTN 094

**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 shop” 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
To assess an integrated, HIV status-neutral, population-based approach designed to reduce HIV incidence among Black men who have sex with men (Black MSM) in the Southern US by increasing HIV testing, pre-exposure prophylaxis (PrEP) uptake and adherence, and viral suppression rates
HPTN 096: Mechanisms of Action

Integrated Strategy
- Health Equity
  - Community Level
- Social Media Influencers
  - Community Level
- Intersectional Stigma Reduction
  - Organizational Level
- Peer Support
  - Interpersonal Level
- HIV/STI Testing
  - Individual Level

Mechanisms of Action
- Multi-level Social Support
- Multi-level Intersectional Stigma
- Structural Barriers to Healthcare Services
- Individual-level Agency

Outcomes
- Viral Suppression
  - Positive Test
- Negative Test
- HIV Testing
- HIV Incidence
- PrEP Use
Moving the Science Forward

- **Science Committees:**
  - Population-specific
  - Responsible for informing HPTN science, generation and review of concepts
  - Liaisons focused on specific agenda elements, e.g. Susan Buchbinder & Connie Celum for integrated strategies, Sharon Hillier for MPTs

- **Working Groups:**
  - Cross-cutting expertise
  - Inform HPTN protocol and concept teams
  - Advance cross protocol harmonization and synergy

- **Chairs:**

<table>
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<tr>
<th>Science Committees</th>
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<th>Co-Chair</th>
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<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>Beatriz Grinsztejn</td>
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<tr>
<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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<tr>
<th>Working Groups</th>
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<th>Co-Chair</th>
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<tr>
<td>Biomedical Sciences</td>
<td>Jeanne Marazzo</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>
</tr>
<tr>
<td>Socio-Behavioral and Structural Sciences</td>
<td>Ariane van der Straten</td>
<td>Julie Pulerwitz</td>
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Thank you