HPTN: Priority Focus Areas

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## Scientific Aims

<table>
<thead>
<tr>
<th>Stage</th>
<th>Aim</th>
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<tbody>
<tr>
<td>Identifying</td>
<td>Novel antiretroviral (ARV)-based methods and delivery systems for HIV prevention</td>
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<td>Developing</td>
<td>Multi-purpose technologies for HIV prevention as well as for contraception, prevention of other sexually transmitted infections or opioid dependence</td>
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<td>Evaluating</td>
<td>Broadly neutralizing antibodies alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network</td>
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<tr>
<td>Designing and conducting</td>
<td>Population-specific integrated strategy studies that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness</td>
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Focus Areas

1. **STI and HIV**
   - **Gap:** Study of STI prevention interventions that will reduce risk of HIV transmission/acquisition: inflammatory STI, including gonorrhea, HSV-2, vaginal dysbiosis.

2. **Broadly neutralizing monoclonal antibodies (bnAbs) for HIV Prevention**
   - **Gap:** Optimizing design of combined bnAbs - selection of bNAbs, dose and combination.

3. **Choice**
   - **Gap:** Interventions and tools to choose the best method with the goal of improving PrEP persistence (e.g. for adolescents and young participants and in pregnant women).
Focus Areas

4. **Treatment as Prevention: (Status Neutral Approach)**
   
   **Gap:** Status-neutral approach in populations with the highest prevalence. For e.g. PWID (follow-up of HPTN 074), general population (follow-up of HPTN 071) MSM (follow-up of HPTN 075) etc.

5. **Implementation:** Scale-up of PrEP in real world
   
   **Gap:** How to get PrEP out of clinics for healthy, uncomplicated cases – delivery out of clinic could improve persistence

6. **People who use Drugs (PWUD):** Outside the US
   
   **Gap:** Studies determining the best combinations of MOUD and PrEP formulations (including long acting MOUD, oral PrEP, CAB-LA and lenacapavir) to reduce HIV incidence among PWUD. Studies in other substance users.
Focus Areas

7. Studies in Pregnant Women

8. Follow-up of HPTN 075 and 091: Status-neutral approach in MSM and transgender persons in Africa
Strategy for prioritization

• **Identified based on:**
  - Recurring themes across committees/groups
  - Alignment with scope of HPTN

• **Rejected ideas based on:**
  - Concepts addressing significant societal issues
  - Unfocused ideas
  - Same idea in different populations (unclear of prevalence or why outcome will be different)
  - Topical agents beyond 106 (until results are available)
  - Early FIH trials that are being done in MATRIX
Status of Biomedical Agents

- Current HPTN studies evaluating biomedical agents
- Timelines for drug availability for integrated strategies
- Planning for what comes next
Biomedical Interventions

Injectable CAB LA
- HPTN 083-OLE
- HPTN 084-OLE

Multi-purpose Prevention Technology (MPT)
- HPTN 104

Injectable
Lenacapavir
- HPTN 102
- HPTN 103

Rectal Microbicide
- HPTN 106
• **Approvals:** US, Australia, Zimbabwe, South Africa, Malawi, Botswana, Brazil

• **Submissions:** Kenya, Uganda, Vietnam, Malaysia, Myanmar, Philippines, Peru, China, European Medicines Agency (EMA), Thailand, Ukraine, Zambia

• Direct discussions with many donors and procurers and with the Global PrEP Coalition with respect to affordability and availability.

• Timelines for programmatic roll out are part of those discussions.

• For generic manufacturing, the Medicines Patent Pool announced licensing agreements with 3 generic manufacturers, timelines to be determined.

• **Speculation:** Programmatic rollout: Q2 2024? Generic version: Q 4 2025?
Injectable lenacapavir, q 6months (LEN) Efficacy and Safety Studies:

- **Purpose 1:** cis-gender Women
- **Purpose 2:** MSM and transgender women having sex with men

Data available in 2025

**Speculation: Approvals in late 2026?**
Dapivirine Vaginal Ring

• Reduced HIV risk in trials: 27% (ASPIRE) – 35% (The Ring Study)
• Open-label extension studies: increased adherence

Current regulatory and procurement status

• US FDA application voluntarily withdrawn
• Approved by multiple regulatory bodies in Africa
• 2021 WHO recommendation for cis-gender women ≥ 18 yrs unable to take oral PrEP
• 2022 PEPFAR guidance supports procurement for research only.
• The Global Fund will support procurement of PrEP ring for program delivery.
• Speculation: available for Integrated Strategy in 2024?
DPP (co-formulated TDF/FTC + ethynyl estradiol/levonorgestrel oral contraceptive pill (OCP))

Manufacturer: Viatris

- Approval of DPP is through 503B pathway (bioequivalence data is sufficient)
- BE 4 pilot completed Aug 2023. Bioequivalence demonstrated!
- Pivotal BE: Results expected Q3 2024

Speculation: submissions (Q4 2024). Approval; Q4 2025?

F/TAF-MPT DPP

Manufacturer: Medicines 360 in partnership with Pop Council (prototype)

- Needs to find a GMP manufacturer

Possibly available for phase 1 in 2024?

Injectable CAB-LA-levonorgestrol

Manufacturer: Conrad

- FIH phase 1: 2025

Speculation: Phase 2 Q4 2026 – Q1 2027 with HPTN?
What next?

Are there research gaps for any agent for PrEP/TasP?

• Use in special populations (e.g. pregnant women, Latino MSM, adolescents)
• Are there other new agents?

What is needed for integrated strategies?

• Regulatory approval in the region? Availability of agents? Need for generics?
• Engaging diverse populations
• Providing options for the needs/realities of different communities
## What next?

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Thank you
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