

## Imelda Mahaka, AVAC

“No intervention is just biomedical. If you only think about product and not the person...policy you will never succeed.”

“Steps to improve access for long-acting products once or if they become available: from a community perspective.”

## Improving access to LA HIV products for anticipated public health impact.

Approach.

- Find and reach individuals at high risk for HIV and PWH not in care – Critical first step.
- Universal test and connect to appropriate care, HIV prevention or treatment.
- Maximize ART and HIV prevention effectiveness using a combination of behavioral, structural, and biomedical strategies.

Community perspective: guiding principles need to be adopted.

- Always lead with equity while putting the community and user at the center.
- Accelerate scale and speed while delivering impact.
- Do not wait for new evidence – work with what we know and have while adding to the evidence base.

## Key areas that need to be addressed to improve access to LA HIV prevention and treatment products.

Accelerate the regulatory pathway from proof of efficacy to programmatic scale.

- **Expansive, simultaneous dossier submissions and parallel regulatory approvals – not FDA first, then others.**
  - TDF/FTC (efficacy demonstrated in 2000): took 7 years for approvals and 10 years to programmatic scale (2y to first approval, 5y to first African approval, 6y to LMIC availability).
  - CAB (efficacy demonstrated in 2020): shorter pathway, but still took 2 to 3 years for approvals and LMIC availability; Some LMICs are still waiting for CAB; and Only one sub-Saharan African country has begun programmatic roll-out.

Timely voluntary licensing agreements and manufacturing equity.

- **Need distributive manufacturing, plans for voluntary licenses (i.e., MPP collaboration), engagement with generic suppliers, and plans for technology transfer shortly after proof of efficacy – not years after first approval.**

Cost-effective, affordable, and transparent pricing to accelerate early launch and roll-out.

- **Not-for-profit pricing for all LA HIV products and a single public sector price for all LMICs (i.e., individual governments, public sector donors, and UN agencies) based on public health imperatives – not World Bank classifications or geographic location.**
  - Thailand, Vietnam, and Brazil are unable to access CAB because they are classified as middle-income countries, and pricing is prohibitive.

Well-coordinated product introduction approach to continuously address evidence gaps, improve adoption and scale up, and accelerate programming.

- **An implementation science agenda where ongoing research, implementation science, and scale programs are designed, funded, and implemented in parallel – not sequentially.**
  - PEPFAR has made progress in this area; LA CAB was introduced in parallel with implementation science in Zambia, Malawi, and Zimbabwe, enabling increased access while gathering more data.
- **Understand the market size for HIV PrEP and how many options the market can afford.**
  - Choice matters, but who decides? Users, policy makers, or funders?
  - Some donors and policy makers remain resistant to the Dapivirine ring, yet community groups see it as a viable option.
- **Innovative demand creation strategies for new formulations (e.g., injectable PrEP) and “choice” among options with a process to test, iterate, and share across projects.**
  - This area is always under-funded due to concerns that the demand will outstrip supply, yet without demand creation, there will never be a market.

Early health and community systems preparedness to ensure accelerated and sustained access to new products once available.

- **Country-level preparedness.** Update national guidelines, policies, and essential medicines lists and begin to transition health systems to accommodate new formulations **soon after proof of efficacy – not after approvals.**
- **Healthcare worker training.** Develop or adapt clinician materials and tools, including patient reminder systems. This should be **prioritized and well-timed with transition plans** to ensure adoption and buy-in.
- **Community engagement.** Strengthen engagement of civil society, communities, and patient groups via advocacy, information gathering, and sharing to improve prevention and treatment literacy, promote demand, and **ensure that demand generation and delivery approaches are person centered and community led.**
  - Matrix work under USAID intentionally incorporates robust secondary engagement – convenes different groups (product developers, regulators, stakeholders, and end-users) and created a rapid response network to tap into immediate feedback.

### **Advancing the community agenda for improved access to LA HIV products.**

- Civil society caucus of the Coalition to Accelerate Access to LA PrEP.
  - Hosted a symposium last week with ViiV, Gilead, Pop Council, and PEPFAR focused on the key issues just highlighted.
- Can we include pediatrics in LA formulations?