

PLENARY 4



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“The adoption and business case for LA ARVs: HIV as a case study”

“How governments and partners think about adoption of new products ... everything they weigh”

LA products face a high barrier to entry and widespread adoption in LMICs

LAIs will require an overhaul of all systems in place for HIV.

- The HIV response has been designed around daily oral ART for 20y.
 - ◊ From supply chain to service delivery, prevention, and treatment.
- Current products are affordable and highly effective.

Framework for evaluating and creating new products.

- Strong Clinical Profile; Simple Logistics; Affordable Cost; Meets User Preferences; Plugs Remaining Gaps.

Strong clinical profile

Current SOC regimens are effective, well-tolerated, and can be used across the population.

- DTG-based regimens for HIV treatment.
 - ◊ 96-97% viral suppression among adults/high 80% among children in PEPFAR countries.
 - ◊ 95% of adults (~24M) are taking a DTG-based regimen in LMICs.
- Oral PrEP for HIV prevention.
 - ◊ 99% effective when taken as directed.

Simple logistics

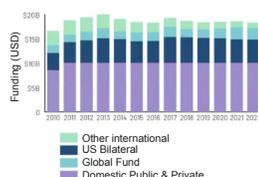
Ministries will weigh the benefits of new LA products vs new logistical requirements and challenges.

- Potential challenges with LA products.
 - ◊ Additional burdens on HCPS.
 - ◊ Additional requirements for consumables (e.g., Needles, sharps boxes, etc.).
 - ◊ Potential changes in monitoring requirements.
 - ◊ **Increased number of visits and facility touch points.**
 - ◊ New complexities in distribution/storage (e.g., Cold chain; LA formulations may not be as forgiving as oral ARVs).
- Current DSD models have moved care for HIV treatment outside the facility and reduced contact points with HCWs (Especially since COVID).
 - ◊ Most countries have endorsed a community DSD model (Only two countries have solely facility-based care models).
 - * Instead of monthly facility-based ART visits (pre-COVID), one person picks up ARVs for multiple people or a community health worker distributes medicine in a community setting.
 - ◊ Less frequent clinical consultation within DSD.
 - * Q6M is most common; A few countries have moved to Q1Y; Only three countries have Q3M.
- LAIs will likely require facility-based administration.
 - ◊ Q8W injection would require a huge change for increasingly overburdened and underfunded healthcare systems.
 - ◊ **How do we address this gap?**

Affordable cost

Current HIV landscape in LMICs.

- Stagnant funding for decades.
- Growing need. The number of people started on treatment or prevention increases by millions each year.
- TLD currently costs 10 cents/day.
 - ◊ TLD (Oral treatment) \$37 PPPY.
 - ◊ TDF/FTC (Oral PrEP) \$40 PPPY.



The cost of LA products must compete with current oral regimens to achieve broad uptake.

- COGs analysis of LEN (Andrew Hill) and CAB-LA (CHAI) show low-cost generic production is feasible, but the cost will still limit uptake.
 - ◊ CAB-LA (API synthesis, formulation, and sterilization).
 - \$30-40 PPPY at launch vs \$14-18 PPPY at medium-scale volumes (~800,000 annual users).
 - ◊ LEN (API cost, formulation, and excipients).
 - \$145 PPPY current vs \$61 PPPY at launch vs \$29 PPPY at year 3.
 - ◊ **Combination of CAB and LEN would be 2-fold higher than TLD.**
 - \$50 to \$70 PPPY.
- Low cost is an important determinant of uptake for any product.
 - ◊ Historic uptake of TLD after first approval and volume guarantee in 2017.
 - TLD was introduced at a lower price than TLE/TEE and achieved 50% of the market share in 3y.
 - ◊ Contraceptive implant scale-up after access agreement and volume guarantee (2012).
 - Steady increase in market share from 2011 to 2020; Implants account for most of the increase in couple-years of protection from 2011 to 2020.

Meets user preferences

We don't really know what people want for their own care.

- Patients are not a homogeneous group.
- Literature review on user preferences for HIV prevention (CHAI).
 - ◊ Product effectiveness is consistently most important, but the extent that it dominates decision-making varies widely across populations and geographies.
 - * 11% (YW in SA and Zimbabwe) vs 20% (YW in SA and Kenya) vs >50% (W in SA) vs 61% (Adults, AGYW, FSW in SA).
 - ◊ Product formulation is consistently the second most important attribute.
 - * LAIs are frequently the most preferred form; Daily oral pills are frequently the least preferred form.
 - ◊ Dosing frequency is more challenging to interpret (Often combined with the product form).
 - * Mixed preferences. Longer acting is generally better, but some populations did not prefer the longest dosing interval (e.g., AGYW in SA prefer Q3M vs Q6M).
 - * **People have a variety of needs.**
 - ◊ Pregnancy prevention is important.
 - * A majority across studies prefer a dual-indication product over a single-indication product.
- Significant data gaps.
 - ◊ Preference data on prevention are extremely limited outside of E and S Africa and among men and key populations (i.e., Hardest to reach).
 - ◊ Patient preferences on HIV treatment formulations is hugely understudied, especially in LMICs and key populations (i.e., Women, children, MSM, and sex workers).

Plugs remaining gaps

Ministries want products that fill gaps in their HIV response.

- HIV treatment: Significant progress toward global targets, but high-level reporting masks unequal progress among various groups and geographies.
 - ◊ Treatment access: 89% who know their HIV status are on ART.
 - * Men and key populations (context-dependent) are less likely to be on ART.
 - * Geographic inequalities.
 - * Subnational differences in ART coverage.
 - * Inconvenient care leading to significant cycling in and out of care (20-50% of ART initiates in SSA are "re-initiations"); Current delivery models are not meeting people's unique needs.
 - * Poor data systems.
 - ◊ Viral suppression: 93% on ART have suppressed viral load.
 - * Regional inequalities.
 - * Gender gaps.
 - * Poor failure management (People remain on failed regimens).
 - * Adherence issues (Poor mental health; Persistent stigma; Burden of QD dosing; Suboptimal ART).
- HIV prevention: Global progress toward new infection targets is off-track and huge inequalities remain.
 - ◊ 2020 UNAIDS target was missed by 1M infections.
 - * New HIV infections declined by 4.5% per year from 2015 to 2021; Will need a 35% per year decline to reach the 2025 target (Innovations are needed to close the gap).
 - * 6 of 7 new infections in SSA are among young girls (15-19y).
 - * Globally, key populations and their partners contributed 70% of all new HIV infections in 2021.

“Ministries seek products that fill their specific gaps and are affordable, meet the needs of their population, and are at least as good as what we have.”