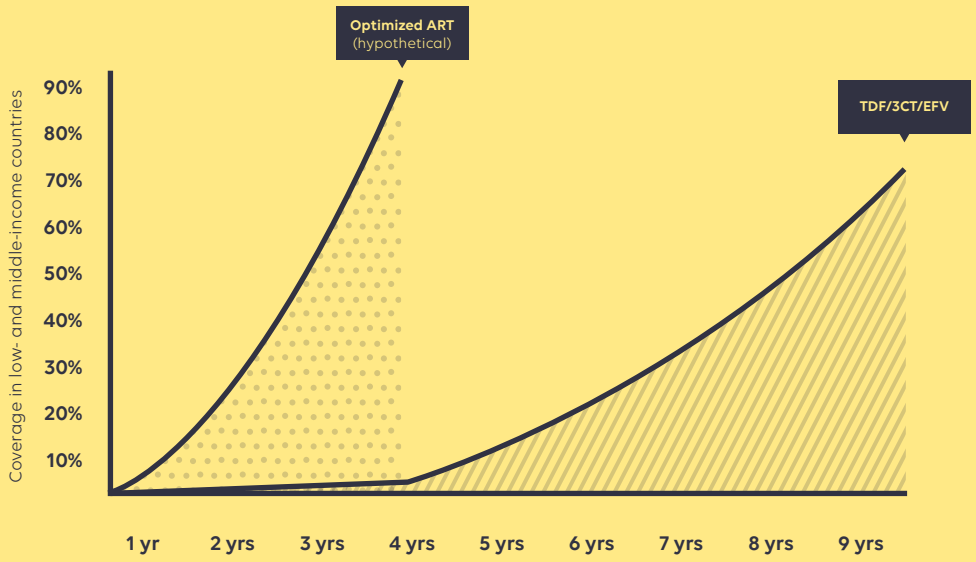
Accelerating Access to Optimized Antiretroviral Treatment

OPTIMIZE – a global partnership to accelerate access to simpler, safer, and more affordable HIV treatment – works with low- and middle-income countries (LMICs) to accelerate the adoption and uptake of optimized antiretroviral (ARV) treatment in accordance with national priorities.

Current reality

The Joint United Nations Programme on HIV/AIDS 90-90-90 targets and the World Health Organization "Treat All" guidelines require a **rapid expansion of access to optimized antiretroviral therapy (ART).** Historically, introduction and scale-up efforts following new drug approvals have been slow, delaying patient access to lifesaving ARVs.



EFV efavirenz | **TDF** tenofovir disoproxil fumarate | **3TC** lamivudine | **3TC** emtricitabine

TDF/*3TC (FTC)/EFV

2006: Change text to: The U.S. Food and Drug Administration approves the first once-daily single tablet regimen containing tenofovir disoproxil fumerate (TDF), emtricitabine (FTC) and efavirenz (EFV).

2009: Approval of generic regimens (TDF + FTC + EFV and TDF + 3TC + EFV) enables LMICs to access the novel once-daily single tablet.

2015: Seventy percent of adults in LMICs are on a once-daily single tablet regimen containing TDF, 3TC or FTC and EFV.

***3TC and FTC are considered interchangeable**

Optimized ART (hypothetical)

By applying business-minded approaches to address market access issues and improving introduction planning in LMICs, the time from availability of optimized ARVs to patient uptake at-scale can be reduced.

This accelerated access can result in reducing the per-patient, per-year cost of HIV treatment, allowing countries to extend better and safer forms of lifesaving ART to millions more within the same budgets.

How much can efforts to accelerate access to optimized ARVs reduce the time from approval to patient uptake at-scale?

Traditional process*

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8

Optimized process*

1 — 2 — 3 — 4 — 5 — 6 — 7 — 8

*Illustrative key steps but timing and order may vary

2- 3 years

9 years

1. Stringent regulatory approval
2. Inclusion in global clinical guidelines
3. Available by generic supplier(s)
4. Development of country transition plan
5. National regulatory approval and inclusion in national guidelines
6. Trained healthcare workers
7. Launch with appropriate post-market surveillance
8. Patient uptake at-scale

How can OPTIMIZE accelerate access to optimized ART in LMICs?

Global market-shaping efforts facilitate product introduction at the country level, resulting in more rapid uptake of optimized ART and healthier patients and communities.

Product introduction at the country level requires a comprehensive approach that addresses the following key, summarized elements.

Supporting service delivery, monitoring and visibility

Engage patients and communities on the changes in services, the rationale and benefits.

• Map the current market landscape, identify priority target users and plan for a phased introduction approach.

• Train and prepare healthcare workers to appropriately prescribe optimized ARVs and manage transitions to new treatment regimens.

• Conduct intensified patient monitoring and analysis, focusing on regimen optimization, adverse events, viral load suppression and ARV drug resistance.

Coordinating Sufficient Supply and Well-Planned Distribution

• Support accurate country-level forecasting for optimized ARVs to align procurement with anticipated demand.

• Communicate with manufacturers to ensure production of sufficient supply of optimized ARVs to meet countries' demand to avoid stockouts.

• Ensure appropriate distribution of optimized ARVs at country level and provide feedback on rates of uptake of optimized ARVs to strengthen supply chain management.

Fostering an Enabling Environment for Optimized ARV Transitions

• Define and promote the public health value and economic benefits of optimized ARVs.

• Support updates to national treatment guidelines for the inclusion of optimized ARVs.

• Work across regulatory bodies and manufacturers to improve communication and coordination to accelerate regulatory approval processes.

• Share country experiences, lessons learned and best practices with global and national stakeholders; expedite the dissemination of critical evidence on optimal ARVs.

Coordinating management and planning processes.

• Develop phased transition plans that address demand generation, communication and monitoring and evaluation (M&E).

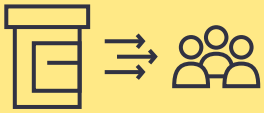
> Generate demand for optimized products among patients and providers.

> Communicate transition plan, roles and responsibilities to stakeholders.

> Set national, sub-national and facility targets & strengthen capacity for transition M&E.

• Revise tools and standard operating procedures (SOPs) for training and mentoring clinicians.

Conclusion



OPTIMIZE works to rapidly decrease the time from the introduction into the marketplace of optimized ARVs to patient uptake at-scale in low-income settings with a high burden of HIV infection.

Powered by OPTIMIZE, a global partnership unifying distinct voices to achieve a common goal: accelerating access to simpler, safer and more affordable HIV treatment.

For further information or to request technical assistance from OPTIMIZE, please contact info@optimize.icap.columbia.edu

OPTIMIZE (AID-OAA-A-15-00069), is funded by the United States Agency for International Development (USAID) under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). This assistance is from the American people. The views expressed do not necessarily reflect the views of the United States Government. ICAP led the research and development of this brief.

Published November 2017. USAID and Project OPTIMIZE. 2017. "Accelerating Access to Optimized Antiretroviral Treatment." Washington, DC: USAID.