Efficacy of TLD regimen in viral suppression among HIV patients in Venezuela: the "Plan Maestro" initiative.

M. Comegna, E. El Hage, Once Trece Foundation.
Category: B6 Antiretroviral therapies and clinical issues in adults
Country of research: Venezuela, Bolivarian Republic of

Introduction

Universal free distribution of antiretrovirals (ARVs) has long been a public policy in Venezuela, with most ARVs acquired through the PAHO/WHO Strategic Fund. However, the economic crisis since 2017 led to significant challenges in ARV procurement, culminating in a near-total shortage of ARVs by 2018. This shortage severely impacted the health outcomes of people living with HIV, increasing the risk of HIV transmission and AIDS-related complications.

To address this crisis, the "*Plan Maestro para el fortalecimiento de la respuesta al VIH, la tuberculosis y la malaria desde una perspectiva de salud pública*" (Master Plan for Strengthening the Response to HIV, Tuberculosis, and Malaria from a Public Health Perspective), known as "Plan Maestro," was developed in June 2018. This plan secured resources from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), entirely allocated for ARV procurement and social monitoring. The Tenofovir/Lamivudine/Dolutegravir (TLD) formulation was acquired to meet at least 85% of the active population's needs registered with the National AIDS Program (PNSIDA/ITS) in 2019. This initiative marked a significant step toward stabilizing HIV treatment and ensuring continuous access to comprehensive healthcare for affected individuals.

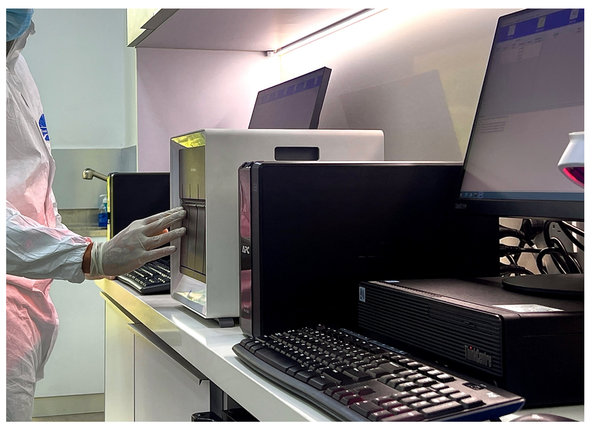
Objectives

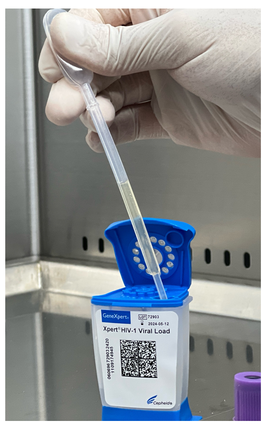
General Objective

Determine the viral suppression of HIV with the TLD treatment regimen in patients attending the Once Trece Foundation Medical Service in Caracas from April 2022 to December 2023.

Specific Objectives

a) Establish the demographic characteristics of the study population.
b) Determine the prevalence of virological failure in patients living with HIV.





Background

With a critical shortage of antiretrovirals in Venezuela, reaching 99% in 2017, the "Plan Maestro" was initiated in June 2018. This collaborative strategy, led by UNAIDS, WHO, scientific societies, and civil society, aimed to ensure continuous access to comprehensive healthcare for people living with HIV, tuberculosis, and malaria. The initiative, funded by the Global Fund, introduced the TLD (Tenofovir/Lamivudine/Dolutegravir) regimen. Proyecto Once Trece, recognizing the need for improved viral load testing, acquired GeneXpert equipment to assess the response to the TLD regimen provided through the Global Fund.

Methods

This prospective, cross-sectional, descriptive study was conducted from April 2022 to December 2023 at the Once Trece Foundation Medical Service laboratory. The study involved 2,306 individuals living with HIV who had been on the TLD regimen for over three months. Participants included 413 women, 1,878 men, and 15 transgender women. HIV-1 viral load tests were performed using GeneXpert technology, a sophisticated molecular test that detects HIV-1 RNA with high sensitivity and specificity. The tests were conducted free of charge, with informed consent, maintaining confidentiality on a voluntary basis. This comprehensive approach ensured accurate monitoring of viral loads and facilitated immediate intervention for those with virological failure. The demographic characteristics of the participants were documented to better understand the population under study.

Table 1: Classification by Sex (Viral Suppression)

Category	N. Individuals	W (413)	M (1878)	TW (15)
Total Participants	**2306** (100%)	**413** (17.90%)	**1878** (81.43%)	**15** (0.65%)
Viral Suppression <1000 copies/ml	**2127** (92.67%)	**374** (17.58%)	**1738** (81.71%)	**15** (0.70%)
Viral Load >1000 copies/ml	**179** (7.76%)	**39** (21.78%)	**140** (78.21%)	**0** (0.0%)

Table 2: Classification by Sex (New Diagnoses and Reinitiated/Changed to TLD)

Category	N. Individuals	W (413)	M (1878)	TW (15)
Reinitiated/Changed to TLD	**1332** (57.8%)	**199** (14.9%)	**1128** (84.7%)	**5** (0.4%)
New Diagnoses	**974** (42.2%)	**214** (22.0%)	**750** (77.0%)	**10** (1.0%)

Table 3: Viral Suppression Classification by New Diagnoses and Reinitiated/Changed to TLD

Category	N. Individuals	VL <1000 copies/ml	VL >1000 copies/ml
Reinitiated/Changed to TLD	**1332** (57.8%)	**1275** (95.7%)	**57** (4.3%)
New Diagnoses	**974** (42.2%)	**852** (87.47%)	**122** (12.52%)

Results

Out of the 2,306 individuals tested, viral suppression was observed in 2,097 individuals who maintained viral loads below 1,000 copies/ml, meeting WHO criteria for effective viral suppression. Only 179 individuals (7.76%) had viral loads exceeding 1,000 copies/ml, indicating virological failure. Demographically, 79.49% of the participants were men who have sex with men (MSM), representing 97.60% of the male population. Transgender women accounted for 0.65% of the cohort, and 19.95% did not belong to any key population. The average age of participants was 40 years.

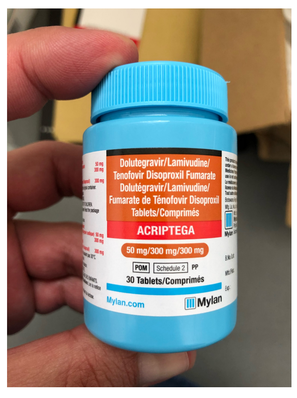
Furthermore, the TLD regimen proved effective both in individuals with recent diagnoses and in those who reinitiated or changed their treatment to TLD. These participants previously used other treatment regimens based on protease inhibitors and non-nucleoside reverse transcriptase analogs. The switch to TLD resulted in significant improvements in viral suppression, underscoring the regimen's broad applicability and effectiveness across different participants populations and prior treatment histories. This highlights the TLD regimen's potential as a robust and versatile option in HIV treatment protocols.

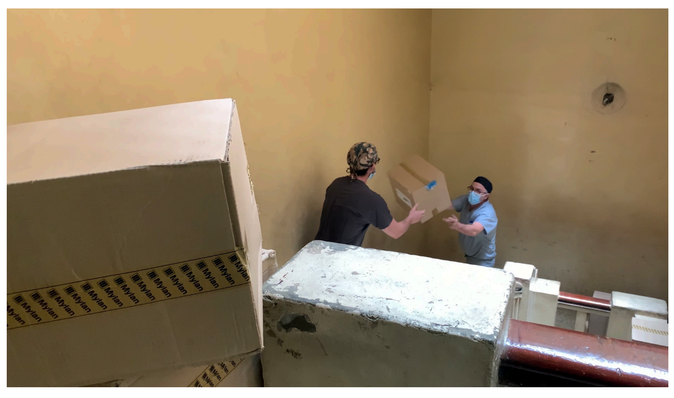
These results demonstrate the high efficacy of the TLD regimen in achieving viral suppression, suggesting its suitability as a treatment option for people living with HIV in similar contexts.

Conclusions

The "Plan Maestro" initiative, alongside the TLD regimen, significantly improved viral suppression rates among people living with HIV in Venezuela. The strategy's effectiveness underscores its potential as a model for addressing HIV treatment challenges in similar settings. The incorporation of GeneXpert technology by Proyecto Once Trece was crucial in verifying viral suppression, enabling timely interventions for those with virological failure. The active involvement of organized civil society is vital for ensuring the continuity of antiretroviral regimen supplies in complex environments like Venezuela. Sustained efforts and international support are essential to maintain and enhance these health outcomes.

Download this abstract





Contact:

Email: info@oncetrece.org
Organization: Once Trece Foundation 501 (c)
Phone: +1 (954) 982-1113
Web: oncetrece.org

Follow us and support our work on social media. Stay updated with our latest research and initiatives by connecting with us online