# Viral Response with Transition to Dolutegravir-Based Treatment, 2018–2020, Homa Bay, Kenya

FOA # and Cooperative Agreement # NU2GGH001948-01-00

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

NASCOP

REPUBLIC OF KENYA
MINISTRY OF HEALTH

HOMA BAY COUNTY

Elizabeth Glaser
Pediatric AIDS Foundation
Fighting for an AIDS-free generation

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Ministry of Health, Homa Bay County, Kenya
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**USG Disclaimer**

The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the funding agencies.

**Conflict of Interest:** The team of investigators declare no conflict of interest.

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# Contents

## Acronyms

| | |
|---|---|
| **ART** | Antiretroviral Therapy |
| **ABC** | Abacavir |
| **BB** | Backbone |
| **CASCO** | County AIDS and STIs coordinators |
| **CDC** | Centers for Disease Control and Prevention |
| **CD4** | Cluster of differentiation 4 |
| **CHMT** | County health management teams |
| **CRH** | County referral hospital |
| **DTG** | Dolutegravir |
| **EFV** | Efavirenz |
| **EGPAF** | Elizabeth Glaser Pediatric AIDS Foundation |
| **ERC** | Ethics review committee |
| **HC** | Health center(s) |
| **IQR** | Interquartile range |
| **IRB** | Institutional review board |
| **KNH-UoN** | Kenyatta National Hospital University of Nairobi |
| **LTFU** | Lost to follow-up |
| **MOH** | Ministry of Health |
| **NAMSAL** | New antiretroviral and monitoring strategies in HIV-infected adults in low-income countries |
| **NASCOP** | National AIDS and STI Control Programme |
| **NNRTI** | Non-nucleoside reverse-transcriptase inhibitor |
| **NRTI** | Nucleoside reverse transcriptase |
| **PI** | Protease inhibitor |
| **PPOP** | Patient and program outcome protocol |
| **SCH** | Sub-county hospital |
| **SD** | Standard deviation |
| **TDF** | Tenofovir |
| **VL** | Viral load |
| **WHO** | World Health Organization |
| **3TC** | Lamivudine |

## Executive Summary

### Background

Dolutegravir (DTG) is an integrase inhibitor that has been shown to have safety and efficacy benefits compared to the current efavirenz (EFV)-based first-line antiretroviral therapy (ART) and to have a high barrier to resistance. The World Health Organization (WHO) recommends that if countries adopt transition from current ART regimens to DTG-based ART by substituting DTG as the core ART drug in the absence of viral load testing, close monitoring of outcomes and assessing viral load levels and drug resistance needs to be done. Standardized prospective studies and cross-sectional national HIV drug resistance surveys are encouraged to generate critical data on the safety and efficacy of this approach. In Kenya, the transition to DTG for first- and second-line treatment, in accordance with international guidelines, began in late 2017 and has been rolled out to most health facilities in the country, including 163 facilities supported by Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in Homa Bay County.

### Methods

Through observational retrospective cohort methods, this study aimed to evaluate the clinical and virological outcomes of HIV-positive clients starting on or transitioning to DTG-based ART and how these outcomes may differ by factors such as baseline viral load, previous ART regimen, sex, and age. This study used routinely collected clinical and laboratory data, as well as to assess pregnancy outcomes in pregnant women on DTG-based ART. Data was collected for clients on ART in EGPAF-supported sites between September 2018 and June 2020 in 19 health facilities.

### Findings

Out of 1273 participants enrolled into the study, 385 (30.2%) were ART-naïve and 888 (69.8%) were ART-experienced. Prior to DTG transition, viral suppression for ART-experienced clients was 94.6% (542/573). This increased to 96.6% (364/377) six months after transition and 96.8% (399/412) at 12 months following transition. Among ART-naïve clients, at 6 months, viral load suppression was 94% (233/248), and this increased to 97.3% (71/73) at 12 months. Among ART-experienced clients who had a nucleoside reverse transcriptase inhibitor (NRTI) backbone switch at the time of DTG transition, viral load outcomes before transition, six months after transition,

and 12 months after transition were slightly higher compared to those whose NRTI backbone was not switched at the time of DTG transition.

Among the 64 pregnant participants enrolled in the study, slightly more than half (57.8%) were ART-naïve: 76.6% of the pregnant women had live births and 15.6% were still pregnant at the time of data collection. In total, 60.9% (n=39) of the pregnant women were initiated on ART during pregnancy and 64.1% (n=24) of these were on a DTG based ART regimen during pregnancy. Cumulatively, 95.3% (n=41) of pregnant women who had a viral load taken within three months of delivery were virally suppressed. For those with live births, the median birth weight was 3.1 kilograms.

## Conclusion

The results show a steady transition towards DTG use and progressive improvement in viral suppression outcomes among clients on DTG.

# Introduction

Dolutegravir (DTG) is an integrase inhibitor that has been shown to have safety and efficacy benefits compared to the current efavirenz (EFV)-based first-line antiretroviral therapy (ART).[1] DTG has a high barrier to resistance, and in the face of growing transmitted and acquired drug resistance (especially to non-nucleoside reverse-transcriptase inhibitors [NNRTIs] like EFV), DTG offers a strong first-line therapy alternative.[2] DTG has also been shown to be effective and safe when used for second-line therapy in combination with an optimized nucleoside reverse transcriptase (NRTI) backbone in individuals with virologic failure on NNRTI or protease inhibitor (PI)-based first-line regimens. All studies to date investigating the use of DTG in second-line treatment typically choose the best available NRTI backbone based on history or genotyping results. The World Health Organization (WHO) now recommends DTG as a preferred first-line drug for treatment, as well as a preferred second-line drug in combination with optimized NRTI backbone in individuals failing NNRTI or PI-based therapy.[3]

Additionally, because of the improved tolerability, efficacy and lower cost, large-scale substitution of DTG-based regimens in clinically stable individuals who are currently receiving EFV-based first-line ART has programmatic advantages and is being considered by many countries. Switching clinically stable persons with known viral suppression from EFV to DTG has been shown to maintain viral suppression. Although conducting a viral load assessment before substituting DTG for EFV is considered good practice, many low- and middle-income countries have limited access to routine viral load monitoring. Thus, they may not be able to readily identify individuals for whom ART is failing before switching to a DTG-based ART regimen. The WHO recommends that if countries adapt DTG substitution in the absence of viral load testing, close monitoring of outcomes and assessing viral load levels and drug resistance needs to be done. Standardized prospective studies and cross-sectional national HIV drug resistance surveys are encouraged to generate critical data on the safety and efficacy of this approach.[3] Additionally, the recent NAMSAL trial, which compared DTG to EFV 400 mg as first-line therapy in Africa, suggested that ART with either regimen had lower rates of efficacy (~60%) in individuals starting ART with a viral load greater than 100,000 copies/mL.[4]

In Kenya, transition to DTG for first- and second-line treatment, as aligned with international guidelines, began in late 2017.[5] DTG has been available in the country since October 2017 as a pilot in 24 health facilities across Kenya. DTG has now been rolled out to most facilities in the country, including 163 facilities supported by the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) in Homa Bay County. Pediatric DTG (for all children >3 kilograms) has also been rolled out in 12 counties nationwide, which accounts for 50% of HIV-positive children. A greater understanding is needed of the programmatic implications following implementation of the new guidelines.

This study aimed to evaluate the clinical and virological outcomes of HIV-positive clients starting on DTG-based-ART and these outcomes may differ by factors such as baseline viral load, previous ART regimen, gender, and age, using routinely collected clinical and laboratory data, as well as an assessment of pregnancy outcomes in pregnant women on DTG-based ART.

## Study Objectives

**Primary study objectives**

1. To determine the proportion of clients who are ART-naïve and initiated on DTG as first-line ART.
2. To determine the proportion of ART-naïve clients who started on a DTG-based regimen and have a suppressed viral load (<1000 copies/mL) at six and 12 months after starting ART.
3. To determine the proportion of clients who are ART-experienced and who have been switched to a DTG-based regimen.
4. To determine the proportion of ART-experienced clients who have been switched to DTG-base ART who are virally suppressed (<1000 copies/ml) at six and 12 months after the switch to a DTG-based ART.
5. To describe adverse pregnancy outcomes (e.g., stillbirth, birth weight, gestational age) in pregnant women on DTG-based ART by
    a. Timing of ART initiation (i.e., before vs. during pregnancy)
    b. ART regimen
    c. Viral load near time delivery (e.g., within 3 months)

## Methods

### Study Design

The evaluation used was an observational retrospective cohort method through a secondary analysis of routinely-collected aggregate and individual-level clinical, laboratory, facility, community, and program data from September 2018 to June 2020 in 19 selected health facilities supported by EGPAF in Homa Bay County.

### Study Population

The study population included children (eligible for DTG switch, currently defined as those weighing ≥ 20 kilograms), adolescents, and adults of all ages who were currently on ART at the selected EGPAF-supported facilities and who were covered by the approved Patient and Program Outcome Protocol (PPOP). Children weighing less than 20 kilograms were excluded from the study population, since at the time of data collection, the lower dose pediatric DTG dispersible formulation had not been rolled out in the country. Other adolescents and adults not on DTG (either due to ineligibility or some other reason), were included as part of the denominators for objectives one and three.

### Location of Study

The study was conducted in selected facilities from the 163 EGPAF-supported facilities in Homa Bay County. A random sample of 19 facilities were selected as study sites and were stratified by facility type (i.e., County Teaching and Referral Hospital, Sub-County Hospital, Health centre, and Dispensary) to ensure representation (Table 1).

**Table 1. Selected EGPAF-supported study sites in Homa Bay County, September 2018–June 2020**

| | Facility | Facility Type |
|---|---|---|
| 1 | Homa Bay County Teaching and Referral Hospital | County Referral Hospital |
| 2 | Rangwe Sub-District Hospital | Sub-County Hospital |
| 3 | Kabondo Sub-County Hospital | Sub-County Hospital |
| 4 | Nyangiela Sub District Hospital | Sub-County Hospital |
| 5 | Rachuonyo District Hospital | Sub-County Hospital |
| 6 | Othoro Sub District Hospital (Rachuonyo) | Sub-County Hospital |
| 7 | Ndhiwa Sub-County Hospital | Sub-County Hospital |

| | | |
|---|---|---|
| 8 | Nyalkinyi Health Centre | Health Center |
| 9 | Homa Lime Health Centre | Health Center |
| 10 | Kitare Health Centre | Health Center |
| 11 | Wakula Health Centre | Health Center |
| 12 | Makongeni Health Centre | Health Center |
| 13 | Magina Health Centre | Health Center |
| 14 | Raruowa Health Centre | Health Center |
| 15 | Adiedo Dispensary | Dispensary |
| 16 | Randung Dispensary | Dispensary |
| 17 | Lwanda Gwassi Dispensary | Dispensary |
| 18 | Maram Dispensary | Dispensary |
| 19 | Simbi Kogembo Dispensary | Dispensary |

### Inclusion Criteria

The inclusion criteria were clients that were in care during the period September 2018 to June 2020 in the selected EGPAF-supported sites.

The following definition of terms were used for the evaluation:

- **Retention:** A patient was considered retained if they attended the health facility for any reason at least 30 days before the date of data abstraction, and had not subsequently been documented to have died, lost to follow-up (LTFU), or had stopped ART.
- **Treatment adherence**: Adherence assessment by clinician as documented in the patient records.
- **Viral suppression**: Viral suppression was defined as any viral load test with HIV RNA**<**1000 copies/ml.
- **Lost to follow-up:** A patient was considered LTFU if they missed an ART refill for a period of at least 30 days after the last scheduled follow up date and there was no documentation of death or transfer out.
- **ART-experienced:** ART experienced patients were described as those who had been on ART for at least three months.
- **ART-naïve**: These are people living with HIV who were not on ART previously or had been on ART for less than three months.

## Sampling and Sample Size

The sample size for this evaluation was calculated separately for the population of ART-naïve clients initiated on DTG-based ART and ART-experienced clients from another ART regimen to DTG-based ART. For ART experienced clients, a switching rate to DTG-based ART of 50% was assumed, as there was no preliminary data available for the switching rates. Based on program data, a 60% initiation on DTG-based regimens was assumed for the ART-naïve clients.

**Table 2: Sample size estimates for different precision levels**

| Precision | Treatment naïve patients 60% DTG initiation rate | Treatment experienced patients 50% DTG switch rate |
|---|---|---|
| ±1% | 9220 | 9604 |
| ±2% | 2305 | 2401 |
| ±3% | 1025 | 1068 |
| ±4% | 577 | 601 |
| ±5% | 369 | 385 |

Table 2 shows the sample size estimates needed to estimate the proportion initiating on DTG-ART and the proportion switching to DTG-ART for different precision estimates. Enrolling a minimum of 369 ART-naïve patients would allow us to estimate the proportion initiated on DTG with a precision better than ±5%, assuming 60% of ART-naïve patients are initiated on DTG-based regimens. With 601 ART-experienced patients, we can estimate the proportion of patients switched to DTG-based regimens with a precision of ±4% or better, assuming 50% of ART-experienced patients are transitioned to DTG-based regimens.

## Data Collection

Research assistants who were specifically trained in the objectives and procedures of the evaluation abstracted data from paper-based registers, client files, and electronic databases for clients on ART between September 2018 and June 2020. The data were anonymized by assigning unique identifiers to participants during the abstraction process. The data were recorded into a data collection tool in a password-protected database created specifically for the evaluation. The study database and electronic forms were developed with built-in data quality checks.

## Ethical Considerations

This evaluation was implemented as part of the Patient and Program Outcome Protocol (PPOP), approved by Kenyatta National Hospital-University of Nairobi-Ethical Review Committee (KNH-UoN ERC) and Advarra Institutional Review Board (IRB) in the United States. It was also reviewed in accordance with the U.S. Centers for Disease Control and Prevention (CDC) human research protection procedures. The evaluation was determined to be research, but the CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

## Data Analysis

Demographic, clinical, and laboratory data were summarized using appropriate descriptive statistics, including frequencies and percentages for categorical variables and mean (SD) or median (IQR) for continuous variables depending on their distributions. Client records were stratified by ART experience (ART naïve and ART experienced), and by DTG transition status in order to describe different outcomes.

We calculated the duration in months to define ART duration for an individual as three months or less for ART-naïve and more than three months for ART-experienced. Using this, the proportion of ART-naïve clients initiated on DTG-based regimen as a first-line regimen and ART-experienced clients transitioned to DTG-ART was calculated and compared across different characteristics.

In this study, we also calculated the proportion of virally suppressed clients at six and-12 --months post-initiation or transition to a DTG-based ART regimen, and compared this by ART-naïve and ART experienced persons across different client characteristics. The proportions of those virally suppressed at six and 12 months post-DTG transition among ART experienced clients were also compared by NRTI regimen backbone switch across different characteristics. We further described the demographic and clinical factors associated with viral suppression and client treatment status post-DTG transition or initiation. Data were analyzed using SAS (9.0) software.

## Results

A total of 1273 participants were enrolled into the study. Among study participants, 385 (30.2%) were ART naïve and 888 (69.8%) were ART-experienced. Among the ART-naïve, 377 (97.9% [95% CI (Confidence Interval): 96.5%–99.3%]) were initiated on DTG, and among the ART experienced, 691 (77.8% [95% CI: 75.1%–80.5%]) were transitioned to DTG-based ART (Figure 1).

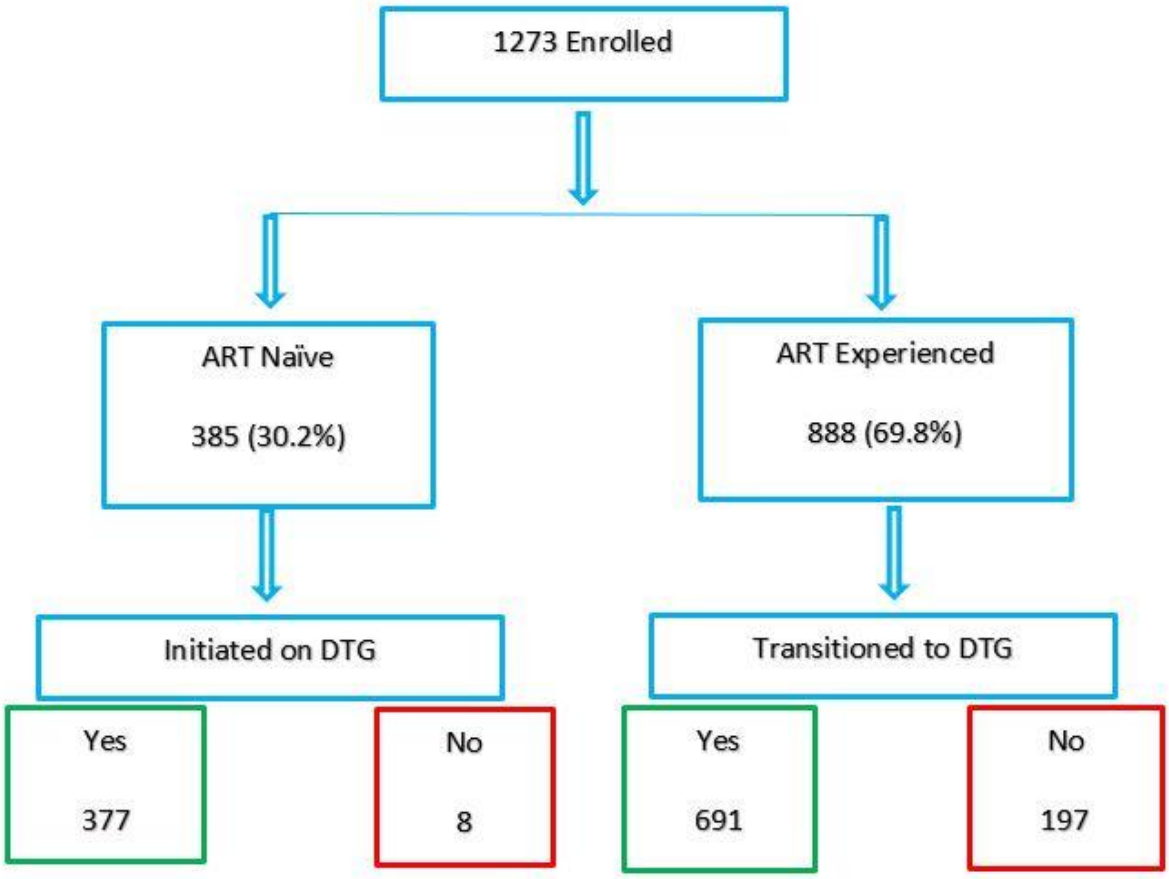


**Figure 1: Study flow for participants on ART enrolled in the study from the study sites, Homa Bay County, September 2018–June 2020. The flowchart presents the number of participants enrolled in the study, disaggregated by ART-naïve or ART-experienced, and further by whether newly initiated or transitioned to DTG-based ART.**

Of the 1273 participants, 58.8% (n=748) were female, 8.6% (n=64) of whom were pregnant. Over 65% (n=845) of the participants were married or living with a partner, and 6% (n=76) were minors under age 18 years.

Over 60% (n=807) of the clients were receiving their care at level four or five facilities (county or sub county level referral hospitals). Slightly under 25% (n=57) were categorized as WHO Clinical Stage III or IV, while 22.5% (n=286) had a CD4≤ 200cells/mm$^3$. Overall, about 25% had advanced HIV disease (AHD; defined as WHO Clinical Stage III/IV or CD4 ≤ 200 cells/mm$^3$ (Table 3). Homa Bay County Teaching and Referral Hospital and sub-county hospitals accounted for almost two-thirds of the study participants (63.4% [n=807]), compared to 36.6% (n=466) among health centers and dispensaries.

**Table 3. Participant demographic and clinical characteristics in selected study facilities in Homa Bay County, Sept 2018–June 2020**

| Factor | Level | ART Naïve, n=385, n(%) | ART Experienced, n=888, n(%) | Total, N=1273, n(%) |
|---|---|---|---|---|
| **Age in years** | 0–14 | 9(2.3) | 67(7.5) | 76 (6.0) |
| **Mean(SD)** | 15+ | 376(97.7) | 821(92.5) | 1197 (94.0) |
| **Sex** | Male | 155(40.3) | 370(41.7) | 525 (41.2) |
| | Female | 230(59.7) | 518(58.3) | 748 (58.8) |
| **Pregnant** | Yes | 37(16.1) | 27(5.2) | 64(8.6) |
| **Marital status** | Married/living with partner | 243(63.1) | 602(67.8) | 845 (66.4) |
| | Not married | 106(27.5) | 189(21.3) | 295 (23.2) |
| | Minor | 9(2.3) | 67(7.5) | 76 (6.0) |
| | Missing | 27(7.1) | 30(3.4) | 57(4.4) |
| **Facility type** | *CRH/SCH | 206(53.5) | 601(67.7) | 807 (63.4) |
| | HC/Dispensaries | 179(46.5) | 287(32.3)) | 466(36.6) |
| **WHO Clinical Stage at ART initiation** | I/II | 351(91.1) | 607(68.3) | 958(75.2) |
| | III/IV | 32(8.3) | 276(31.1) | 308(24.2) |
| | Missing | 2(0.6) | 5(0.6) | 7(0.6) |
| **CD4 at ART initiation (cells/mm$^3$** | ≤200 | 48(12.5) | 238(26.8) | 286 (22.5) |
| | >200 | 151(39.2) | 465(52.4) | 616 (48.4) |
| | Missing | 186(48.3) | 185(20.8) | 371(29.1) |

*CRH- County Referral hospital, SCH-sub county referral hospital, SD-standard deviation

Prior to transition to DTG-based ART, 94.6%, (542/573) of ART-experienced clients had viral suppression, and this increased to 96.6% (364/377) six months after transition and 96.8% (399/412) at 12 months after transition. Among ART-naïve clients, viral load suppression was 233/248 (94%) at six months after starting DTG-based ART, increasing to 97% (71/73) at 12 months (Figure 2).

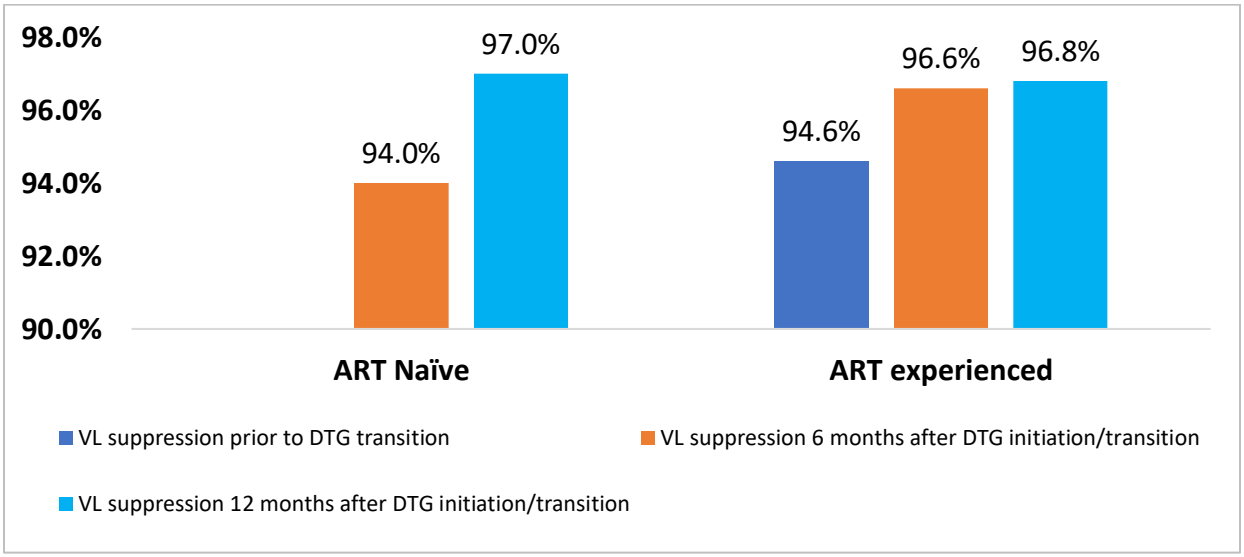


**Figure 2: Viral load outcomes at baseline, six months, and 12 months following DTG initiation/transition, Homa Bay County, Sept 2018–June 2020**

Among ART-experienced clients who were transitioned to DTG, 82.9% (n=573/691) had a baseline viral load prior to transition. Seventeen percent (17.1%) were transitioned without a baseline viral load.

For the ART-experienced clients, a comparison of viral load outcomes before transition, 6months after transition and 12 months after transition was made between those with the NRTI backbone (BB) changed versus those without the NRTI BB changed at the time of transition to DTG-. Improvement in viral suppression rates from baseline to 6 and 12 months was slightly higher in those with their NRTI BB changed (improved by +2.4% at 6 and another +2.3% at 12 months) compared to those whose NRTI BB was not changed (improved by +1.5% at 6 and then decreased by -0.6% at 12 months) (Figure 3). The absolute rate of suppression at 12 months was >95% in both those who switched or did not switch their NRTI BB (97.5% and 95.3%, respectively).

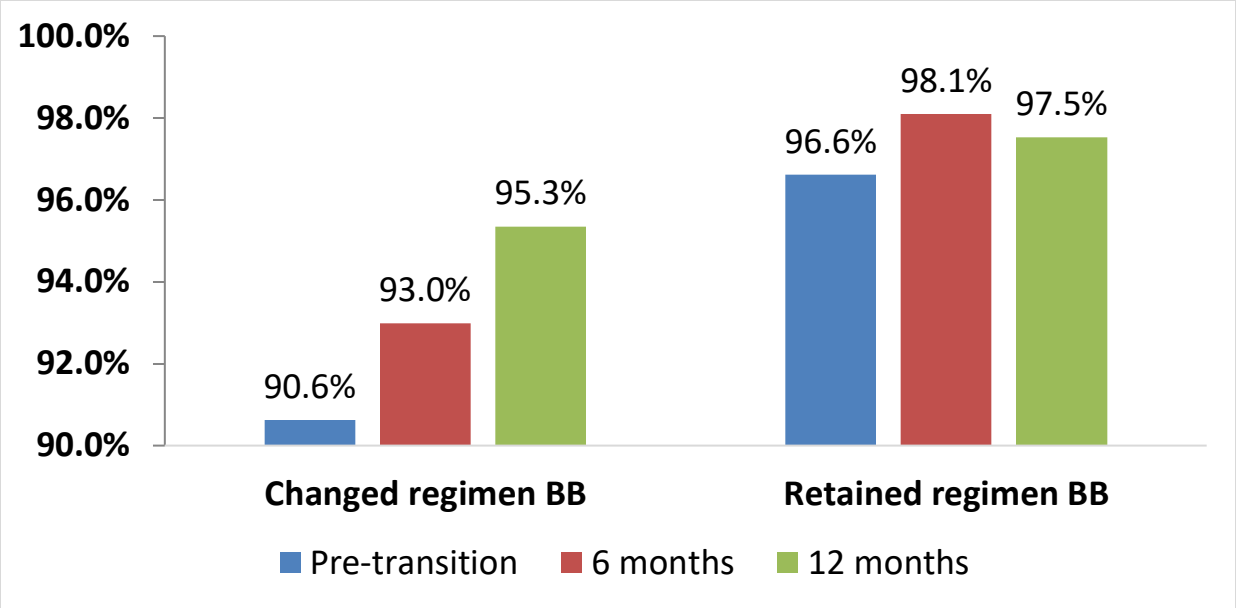


**Figure 3: Viral load outcomes for participants with backbone (BB) changed compared to those with same backbone, Homa Bay County, Sept 2018–June 2020**

Among the 64 pregnant participants enrolled in the study, slightly more than half (57.8%) were ART naïve. The mean age was 29 years (SD=6.2); 76.6% (n=49) of the 64 pregnant women had live births; 15.6% (n=10) were still pregnant at the time of data collection; one had a miscarriage; and four had unknown pregnancy status. Sixty-one percent (60.9%, n=39/64) of the pregnant women were initiated on ART during pregnancy. Over 64.1% (n=41/64) of the pregnant women were on a DTG regimen during pregnancy (Table 2). Cumulatively, 95.3% (n=41/43) of pregnant women who had a live birth (n=49/64), and had a viral load taken within three months of delivery, were virally suppressed. A total of 12.2% (n=6/49) of the pregnant women did not have a viral load (VL) available for the same period. For pregnant women who had live births (n=49/64), the median birth weight was 3.1 kilograms [IQR: 2.9, 3.5].

All ART naïve pregnant women (n=37/37) were initiated on a DTG-based regimen, while 66.7% (n=18/27) of ART experienced pregnant women were transitioned to a DTG-based regimen. Overall, 85.9% (n=55/64) of pregnant women were initiated/transitioned to a DTG-based regimen, of whom 54.5% (n=30/55) were initiated/transitioned to a DTG-based regimen during pregnancy (Table 4).

**Table 4: Characteristics of pregnant women initiated or transitioned to DTG in selected study facilities in Homa Bay County, September 2018–June 2020**

| Characteristic | ART-naïve | ART-experienced | Total |
|---|---|---|---|
| **Pregnant women** | 37 | 27 | **64** |
| **Initiated/transitioned to DTG** | 37(100%) | 18(66.7%) | **55(85.9%)** |
| **Initiated/transitioned to DTG prior to pregnancy** | 13(35.1%) | 12(66.7%) | **25(45.5%)** |
| **Initiated/transitioned to DTG during pregnancy** | 24(64.9%) | 6(33.3%) | **30(54.5%)** |

## Discussion

This study showed that clients who transitioned or who were initiated on DTG-based ART had a viral suppression rate > 90% at six months following transition or initiation. In addition, viral suppression improved further by 12 months following transition/initiation. These results mirror results from SWORD-1 and SWORD-2 trials that showed that switching to DTG-ART was associated with improved viral suppression at 48 weeks.[6] Another study that compared the safety and efficacy of DTG-based regimens among HIV-1-infected pediatric and young adult patients reported viral suppressions ranging from 72.5%–87.9%, lower than what is reported from our study; only 6% of our population were age <15 years.[7] Of the pregnant women who were on DTG during pregnancy and delivered during the study period, 49/50 (98%) had positive pregnancy outcomes, while 1/50 (2%) had a spontaneous abortion. Slightly poorer outcomes were reported from an analysis of the data from the Euro guidelines in Central and Eastern Europe (ECEE) Network Group that investigated DTG-ART receipt among 415 women with exposure to DTG during pregnancy in 7 centers in Czech Republic, Finland, Greece, Poland, Slovakia, and Turkey. 90.9% positive pregnancy outcomes and 4.5% spontaneous abortions.[8] In ART-experienced clients transitioned to DTG-based ART, while improvement in viral suppression at 6 and 12 months was slightly higher among those who switched their NRTI backbone at the time of DTG switch than those who did not switch backbone, overall suppression rates at 12 months were >95% in both groups. Similarly, high rates of viral load

suppression to HIV RNA <50 copies/mL (97.9%) were observed at 12 months after DTG transition in 1762 clients who transitioned to DTG-based ART from EFV-based ART without having viral load testing and without switching NRTI backbone in Malawi, including in 88.3% of 94 clients who had viremia prior to DTG transition.[9]

Because of the retrospective design of this study, we cannot exclude potential indication bias concerning the patients on DTG-ART, particularly in ART-experienced patients transitioning to DTG. Moreover, this non-randomized retrospective approach prevents direct comparison with results obtained in large randomized trials. Since these data had already been collected when the evaluation was initiated (retrospective analysis), the study team was not able to fully address gaps in data quality and completeness.. Our analysis is limited to descriptive. However, because DTG-ART has been rolled out to all populations, these data on its use in 'real-life' clinical practice could be very helpful for clinicians, especially in resource-limited settings similar to ours.

## Conclusion

Overall, the majority of clients were initiated or transitioned to DTG-based ART during the evaluation period. Viral suppression for those transitioned to DTG-ART was >90% at six months and improved further to 96% at 12 months for both ART-naïve and experienced clients. Among pregnant women, the majority were either on DTG when they became pregnant or were started on DTG during pregnancy, with three-quarters of live births having birth weight  three kilograms and above. Viral suppression was 95.3% (90.0% and 100% among ART naïve and ART experienced, respectively) among pregnant women receiving DTG-ART who had a live birth and had a viral load within three months of delivery.

## Key Takeaways

1. Consider accelerating transition to DTG-ART, including provision of pediatric DTG formulations based on the revised national HIV prevention and treatment guidelines.

2. High viral suppression rates of clients on DTG-ART were observed at six and 12 months (> 90%). among ART-experienced patients who did not switch their NRTI backbone at the time of DTG transition, viral suppression was similar to those who switched NRTI backbone. Longer-term follow-up is needed to determine sustainability of suppression over time.

## Stakeholder Engagement

EGPAF worked closely with various stakeholders throughout the course of the evaluation. The County Director of Health and County and sub-county health management teams (S/CHMT) were involved with the formulation at the formation of the study. S/CHMTs and health care workers (HCWs) were supported data collection.

## Dissemination

The findings have been disseminated in the County to the CHMT, HCWs, and other implementing partners in the county. Representatives from the CDC were also present during the dissemination meeting. The final report will be shared with CHMT and partners.

| | **Target Audience** | **Action Point** | **Channel of Communication** | **Time and Place** |
|---|---|---|---|---|
| 1 | CHMT, Facility In-charges, health care workers | Share evaluation findings and key recommendations to strengthen program implementation | PowerPoint presentation | Homa Bay County, meeting on 27th July 2022 |
| 2 | NASCOP, County Director of Health, CASCO | Submit signed copies of the report | Report | October 2022 |

## Acknowledgement

We would like to acknowledge and give our gratitude to the clients who contributed their data from the data abstraction exercise, and Faridah Oluoch, Jack Omondi, and Angella Onguko for diligently collecting the data.

### Budget

The cost of data collection was USD 7826, but the other costs of the study, including but not limited to LOE for data analysis, study oversight, and result dissemination, were covered under the Timiza90 project budget.

### List of Appendices

1. DTG transition evaluation plan
2. Data collection tool
3. CVs
4. Research Ethics certification

## References


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## Appendices


**Elizabeth Glaser Pediatric AIDS Foundation**
**Research Confidentiality Agreement**

As an employee with the Elizabeth Glaser Pediatric AIDS Foundation, a subcontracted employee, partner or governmental personnel, consultant, intern, or visiting professional, I understand that I will be exposed to privileged participant/patient information in the conduct of my duties as a member of a research team. Examples include but are not limited to medical conditions, HIV status, medical treatments, finances, living arrangements, and sexual orientation. The study participant/patient's right to privacy is not only a policy of the Elizabeth Glaser Pediatric AIDS Foundation, but is specifically guaranteed by research ethical and governmental regulations. I understand that intentional or involuntary violation of the confidentiality policies is subject to appropriate disciplinary action(s) that could include being discharged from my position and/or being subject to other penalties. By signing this document, I further agree that:

1. I will never discuss patient information with any person outside of the facility or study that is not directly affiliated with the study participant's care or the conduct of the study.
2. I will handle confidential data as discretely as possible and I will never leave confidential information in view of others unrelated to the specific activity. I will keep all confidential information in a locked cabinet when not in use. I will encrypt all computer files with personal identifiers when not in use.
3. I will shred any document that has been authorized to be disposed if that contains personal identifiers. Electronic files will be permanently deleted when required.
4. I will maintain my computer protected by power on and screen saver passwords. I will not disclose my computer passwords to unauthorized persons.
5. I understand that I am responsible for preventing unauthorized access to or use of my keys, passwords, and other security codes.
6. I understand that I am bound by these policies, even upon resignation, termination, or completion of my activities.
7. I agree to abide by the Elizabeth Glaser Pediatric AIDS Foundation Research Confidentiality Policy.

I have received, read, understand, and agree to comply with these guidelines.

_____ _____
Signature Date (dd/mm/yyyy)

_____
Printed Name

_____ _____
Supervisor's Name and Signature Date (dd/mm/yyyy)