# EVALUATION OF DIFFERENTIATED SERVICE DELIVERY MODEL

ENDELEZA (NAIROBI) AND TIMIZA (KISII AND MIGORI) PROGRAMS

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NASCOP

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CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

# Evaluation of Differentiated Service Delivery Model

## Endeleza (Nairobi) and Timiza (Kisii and Migori) Programs


### Project title
Evaluation of differentiated service delivery model has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of NU2GGH001962/ NU2GGH001949.

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### 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 agency.


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# ABBREVIATIONS

| | |
|---|---|
| **AIDS** | Acquired immune deficiency syndrome |
| **ART** | Antiretroviral therapy |
| **ARV** | Antiretroviral |
| **BMI** | Body mass index |
| **CAG** | Community ART Groups |
| **CDC** | Centers for Disease Control and Prevention |
| **CHMT** | County health management teams |
| **Ciheb** | Center for International Health, Education and Biosecurity |
| **CIs** | Confidence intervals |
| **CQI** | Continuous quality improvement |
| **DCM** | Differentiated care model |
| **DHIS-2** | District Health Information Software |
| **DQA** | Data quality assurance |
| **DSD** | Differentiated service delivery |
| **DTG** | Dolutegravir |
| **EFV** | Efavirenz |
| **EMR** | Electronic medical records |
| **FSW** | Female sex workers |
| **HEI** | HIV-exposed infants |
| **HTS** | HIV testing services |
| **IQR** | Interquartile range |
| **IRB** | Institutional Review Board |
| **KP** | Key populations |
| **LTFU** | Loss to follow up |
| **MOH** | Ministry of Health |
| **MSM** | Men who have sex with men |
| **NASCOP** | National AIDS and STI Control Program |
| **NVP** | Nevirapine |
| **PACT** | Partnership for Advanced Care and Treatment |
| **PEPFAR** | President's Emergency Plan for AIDS Relief |
| **PLHIV** | People living with HIV |
| **PWID** | People who inject drugs |
| **RR** | Relative risk |
| **STI** | Sexually transmitted infections |
| **TB** | Tuberculosis |
| **UMB** | University of Maryland, Baltimore |
| **WHO** | World Health Organization |

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Key investigators CV can be found in Appendix 1. Procedures have been established during evaluation development, the review process, and data collection activities monitoring, to ensure that the results are credible, and biases are mitigated. In addition, the PI and other investigators have no conflict of interest.

# 1. INTRODUCTION

## 1.1 Project Background

The University of Maryland, Baltimore (UMB) received two five-year grants from the President's Emergency Plan for AIDS Relief (PEPFAR) through cooperative agreements with the United States (U.S.) Centers for Disease Control and Prevention (CDC) Kenya to support the provision of Human Immunodeficiency Virus (HIV) prevention, care, and treatment services. These projects were implemented in Nairobi county, Kenya, through the Partnership for Advanced Care and Treatment (PACT) Endeleza (Grant Number NU2GGH001962) program and in Kisii and Migori Counties through the PACT Timiza program (Grant number NU2GGH001949), for the period September 30, 2016 to September 29, 2021. UMB collaborated with county health management teams to expand access to HIV services in 49 facilities in Nairobi, 109 in Kisii, and 73 in Migori.

**Project goal and objectives**

The overall goal of the PACT Timiza and PACT Endeleza programs was to achieve the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95-95-95 goals and to reduce HIV incidence and acquired immune deficiency syndrome (AIDS)-related mortality by providing timely HIV services, including testing and antiretroviral therapy (ART). UMB's support for HIV services under these agreements was focused on the following objectives:

1. Optimizing the identification and enrollment of people living with HIV (PLHIV) through HIV testing services (HTS) and linkage strategies for all populations to achieve HIV epidemic control goals.
2. Delivering comprehensive HIV care and treatment services, including ART for all patients in line with current guidelines and to achieve and sustain HIV epidemic control in Kenya.
3. Strengthening the delivery of quality services for HIV-infected pregnant and breastfeeding women and HIV-exposed infants (HEI) to eliminate mother-to-child HIV transmission in pursuit of an AIDS-free generation.
4. Enhancing the delivery of quality integrated tuberculosis (TB)/HIV services to end the TB epidemic, which remains a major driver of morbidity and mortality in PLHIV.
5. Strengthening quality-assured laboratory and commodity management systems for HIV diagnosis and monitoring tests and for antiretroviral (ARV) drugs management.
6. Institutionalizing continuous quality improvement (CQI) practices when delivering HIV

and other health care-related services.
7. Streamlining and implementing efficient data management systems to improve data use for program improvement.
8. Strengthening the provision of HIV/sexually transmitted infection (STI) prevention, care and treatment services for key and priority populations, including female sex workers (FSWs) and men who have sex with men (MSM), and HIV prevention services, including opioid substitution therapy with methadone in two facilities for people who inject drugs (PWID), in order to curb new HIV infections.
9. Strengthening the capacity of county health management teams (CHMT) in Nairobi, Migori, and Kisii counties to offer oversight and effectively plan for sustainable delivery and management of high-quality HIV care and treatment services with minimal external technical support.

## 1.2 Background on Differentiated Service Delivery

Innovative models of delivery of care adapted to the individual patient's needs are required to improve coverage and retention. The differentiated care model (DCM) has been widely proposed as the primary framework to expand access and quality of HIV care and treatment while meeting the unique needs of the varying client populations (1,2). The shift from a "one-size-fits-all" approach of service provision to a DCM is predicated on the recognition that patient needs require different degrees of engagement with clinical teams. Differentiated care includes different strategies, including fewer clinic visits, task-shifting from physicians to other types of health providers, multi-month prescriptions, community or facility adherence groups, and community ART distribution groups (3–5). At the end of June 2020, 87,042 PLHIV were receiving HIV treatment in PACT Timiza (Kisii and Migori counties), and 28,481 in PACT Endeleza (Nairobi County).

In 2016, the Kenya Ministry of Health (MOH) adopted differentiated care service delivery and published guidance in "Improving the Quality and Efficiency of Health Services in Kenya: A Practical Handbook for HIV Managers and Service Providers on Differentiated Care" (6). In August 2016, the MOH revised the clinical encounter form, which now captures information at each visit on the patient's status, stable vs unstable (Table 1), and type of differentiated service delivery received, either standard of care or the facility-based fast-track system or Community ART Groups (CAGs) for ART refills (6). The Differentiated Care Operational Guide is designed to provide healthcare workers with strategies for implementing differentiated care as described in the 2016 and updated 2018 Kenya Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (7,8). As part of these efforts, the Center for International Health, Education, and Biosecurity (Ciheb) of UMB conducted an evaluation of DCM in UMB-supported health facilities to examine the uptake and clinical outcomes across the different types of service delivery models in Kenya.

**Table 1 MOH Criteria for Stable Patients**

| Stable Patients |
| --- |
| Stable Patients (have achieved all of the following):<br>• On their current ART regimen for ≥ 12 months<br>• No actives OIs (including TB) in the previous 6 months<br>• Adherent to scheduled clinic visits for the previous 6 months<br>• Most recent VL < 1,000 copies/ml<br>• Has completed 6 months of IPT<br>• Non-pregnant/not breastfeeding<br>• BMI ≥ 18.5<br>• Age ≥ 20 years<br>• Healthcare team does not have concerns about providing longer follow-up intervals for the patient*<br><br>Note: some patients may not meet all eligibility criteria but could benefit from specific aspects of the stable patient package of care, such as community-based ART delivery (e.g. patients with disabilities), or less frequent follow-up (e.g. children at boarding school) |

# 2. EVALUATION DESIGN AND METHODS

## 2.1 Evaluation Objectives

Section A

1. To assess the uptake of facility-based fast-track ART refills.

Section B

1. To assess the factors associated with:
   a) enrolling in fast-track ART refills
   b) transitioning from fast-track ART to the standard of care among stable clients.
2. To compare lost to follow-up (LTFU), mortality, and viral rebound between models of care (traditional standard of care and fast-track ART refill).

## 2.2 Evaluation Design and Setting

Section A: For uptake of the differentiated service delivery (DSD) model across time, we used a cross-sectional study design aggregated in quarters from January 2018 to December 2019 in Nairobi, Migori, and Kisii.

Section B: We conducted a retrospective cohort study from July 1, 2017 to December 31, 2019. We established July 2017 as a starting period because we excluded the early implementation period of DSD (January 2017-June 2017). We conducted this evaluation across 32 UMB-supported health facilities located in Nairobi (n=17), Kisii (n=7), and Migori (n=8) counties (see the section on evaluation sampling for further information). Kisii and Migori are in the southwestern part of Kenya, while Nairobi is in the central part of Kenya. According to the latest HIV population-based survey, HIV prevalence is 3.8% in Nairobi, 6.1% in Kisii, and 13% in Migori (9).

## 2.3 Summary of Stakeholder Engagement

UMB worked closely with the National AIDS and STI Control Program (NASCOP) and the county and sub-county health management teams to support the DCM's implementation per national guidelines. This evaluation aligned with the scope of work of the PACT Timiza in Kisii and Migori counties and PACT Endeleza in Nairobi City County. UMB has engaged the US CDC Kenya, NASCOP, and CHMTs while preparing and conducting this evaluation, from protocol conceptualization and development to collecting data and reviewing results. UMB has promoted a data-driven feedback loop to communicate results across all levels of the health system, including at the facility level. The UMB team met quarterly, or as needed, with the MOH, participating facilities, the CDC, and other stakeholders to discuss and share data on program performance and ongoing evaluations.

## 2.4 Ethical Consideration

This protocol was reviewed in accordance with CDC human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to personal identifiable data or specimens for research purposes (project ID: 0900f3eb81af410a). The protocol was also approved by the Kenyatta National Hospital and University of Nairobi Ethics Review Committee approved the protocol on February 2, 2021 (IRB reference number: KNH-ERC/A/44) and the University of Maryland, Baltimore IRB (HP-00085196).

## 2.5 Evaluation Population

Section A: For the uptake of the DSD model (facility and community fast-track ART refill), our unit of analysis was the program.

Section B: Clients receiving HIV services were eligible to enter into the facility-based fast-track model of care if they met the following MOH criteria: 1) if they were 20 years and older; 2) if they were initiated on ART for at least one year before; 3) if they were virally suppressed (<1000 copies/ml); and 4) if clinicians identified that the client was stable at the visit on the MOH patient-level registration HIV form. We included clinical and ART refill visits conducted between July 2017 and December 2019, and we excluded health facilities with fewer than 500 clients on ART.

## 2.6 Evaluation Sampling

Section A: All ART sites were included irrespective of the number of clients on treatment.

Section B: A two-stage sampling approach was used to select the cohort for analysis. In the first stage, health facilities were stratified by location (Nairobi, Kisii, and Migori) and facility size based on the number of clients on ART (1. 500-999; 2. 1,000-1,999; and 3. 2,000 and above). In total, 32 health facilities were randomly selected from a total of 268 supported health facilities. In the second step, files from clients were randomly selected using probability proportional to size from each of the 44 facilities using a sampling table recommended by the Kenya MOH to achieve 95% representativeness of its population (10). We excluded supported health facilities with less than 500 clients on ART; a total of 32 facilities were included as part of this analysis.

## 2.7 Interventions

All clients received a standard package of care as recommended by the 2018 Kenya Guidelines on Use of Antiretroviral Drugs for Treating HIV Infection (7). The standard of care included a clinical evaluation at every clinical visit, adherence counseling and support, cotrimoxazole prophylaxis, baseline CD4, yearly viral load testing, ART initiation, assessment for drug toxicity, TB screening and treatment, isoniazid presumptive treatment (IPT) initiation among eligible patients, STI screening and treatment, and family planning services.

Patients eligible for fast-track ART refills were offered three multi-month prescriptions. ART prescriptions were able to be refilled directly at the pharmacy without consulting clinicians. Clients had a clinical appointment every six months or as needed (Table 2).

Once patients completed 12 months of treatment, they were classified as stable or unstable. Thereafter, the patients are assessed at each clinical visit to evaluate whether they were stable or unstable following MOH guidelines (Table 1). Likewise, during ART refill visits, a checklist was referenced to re-evaluate status. If stable, the patient could opt to join multi-month prescriptions and pharmacy fast-track refills. Patients enrolled in multi-month prescriptions and fast-track refills went directly to the facility pharmacy to receive 3-month ART refills—they were not required to have a clinician consultation at each ART pick-up; rather, they were scheduled for a clinical appointment every six months or as needed (Table 2).

**Table 2 Components of facility-based fast-track and standard of care service delivery models**

| Service Delivery Model | Components | Frequency/timing | Location | Provider |
|---|---|---|---|---|
| **Facility-based fast-track System for ART refills (express)** | ART refills | At least every three months | Pharmacy | Pharmacists |
| | Clinical consultations | Every six months or more frequently as needed | Clinic | Clinicians, Nurses |
| | Psychological support | As needed | Clinic | Clinicians, Nurses |
| **Individual Standard of care** | ART refills | Every one or two months according to the National Guidelines or as needed | Clinic | Clinicians, Nurses |
| | Clinical consultations | Every one or two months according to the National Guidelines or as needed | Clinic | Clinicians, Nurses |
| | Psychological support | As needed | Clinic | Peers/ Community health volunteers or Clinicians, Nurses. |

## 2.8 Outcomes

Outcomes of interest included:

Section A

1. Uptake of DSD: proportion of clients on fast-track ART refills among eligible stable clients in a supported health facility by quarter. For the purposes of this report, the terms DSD and fast-track ART-refills will be used interchangeably.

Section B

1. Fast-track ART enrollment was defined as individuals receiving 89 ART pills or more at a given visit.
2. Model of care transition was defined as the transition from fast-track ART refills to the

standard of care and vice versa.

3. Lost to follow-up after 90 days was defined as having no contact with the clinic for ≥ 90 days after the expected return date. The expected return date was calculated using the previous visit date plus the number of ART pills provided (in days) during this previous visit plus 90 days. This expected return date was compared to the actual visit date. If a patient did not return by the calculated return date, the client was classified as lost to follow-up.
4. Lost to follow-up after 180 days was defined as having no contact with the clinic for ≥ 180 days after the expected return date. The expected return date was calculated using the previous visit date plus the number of ART pills provided (in days) during this previous visit plus 180 days. This expected return date was compared to actual visit date. If a patient did not return by the calculated return date, the client was classified as LTFU.
5. Viral rebound was defined as when the next viral load measurement available was above ≥1,000 copies per milliliter after a previous suppression.
6. Mortality was defined as having a date of death available in the chart by the end of follow-up. The characteristics from the client's last visit will be used for analysis.

## 2.9 Data Collection

Section A: We used routinely collected programmatic data, including ART refill forms, differentiated care register, the pharmacy antiretroviral dispensing tool (ADT) database (Web ADT), and electronic medical records (EMR).

Section B: The evaluation team extracted routine clinical data from the HIV client form and pharmacy records paper files into the District Health Information Software (DHIS-2) tracker platform (11). Information collected included baseline information (sex, age, marital status, type of population [general or key populations (KPs) defined FSW or MSM], HIV diagnosis date, ART initiation date, baseline CD4 count, viral load at entry into the cohort, World Health Organization (WHO) HIV stage, ART refills, and clinical consultations.

Data quality assurance (DQA) measures included built-in validation rules and checks, and the designated supervisor conducted DQA on 10% of the selected samples daily. Data concordance of less than 95% between supervisor and data officers led further investigation to confirm values and additional training and supervision. All data collections tools can be found in the Appendices 4-7.

## 2.10 Statistical Analysis

Section A: We conducted a non-parametric trend analysis to assess a significant change in slope during the evaluation period.

Section B: We examined the data using univariate analysis to describe the frequency and

distribution of outcomes of interest and covariates. Client characteristics were summarized using means and standard deviations (SD), or medians and interquartile ranges (IQR) for continuous variables and proportions with 95% confidence interval (CI) for categorical variables. We used Pearson chi-square and Wilcoxon rank-sum tests to compare outcomes between clients joining ART fast-track or standard of care. Due to the small number of clients in the CAG intervention (0.03% of the visits), we excluded them from the analysis.

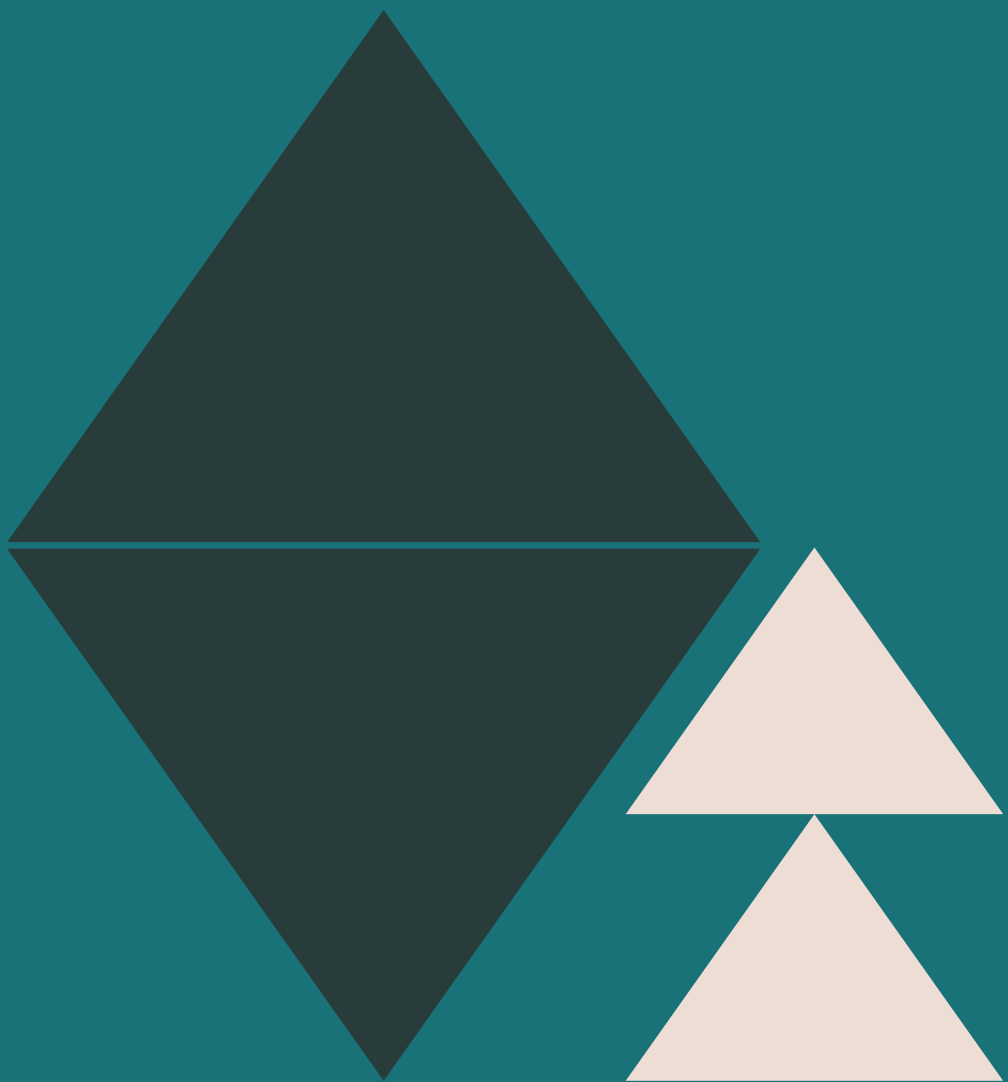
As the type of care was defined during every visit, all eligible visits were included in this analysis. Individuals who died during the follow-up period were excluded when analyzing LTFU and viral rebound. Similarly, multilevel Poisson regression models with robust 'sandwich' standard errors were used to evaluate patient and facility characteristics associated with clinical outcomes. For developing the multivariate model for LTFU 90 days, variables with a p-value <0.25 in the bivariate analysis and those found to be important confounders based on the scientific literature review were included in the multivariate model. However, only statistically significant variables (p-value <0.05) and known confounders were kept in the final model.

For the LTFU 180 and viral rebound models, only variables with p-value <0.05 or known confounders (age, sex) were included in the multivariate model due to the small number of events. Multicollinearity was accessed by estimating the variation inflation factor (VIF). If a VIF was greater than 10, multicollinearity was observed (12). Data was analyzed using SAS 9.4 (Cary, NC) and STATA 17.0 (STATA Corporation, College Station, TX). All statistical tests were done at 5% level of significance.

Individuals who died during the follow-up period were excluded when analyzing LTFU and viral rebound. Similarly, multilevel Poisson regression models with robust 'sandwich' standard errors were used to evaluate patient and facility characteristics associated with clinical outcomes. For LTFU 90 days, the same model strategy described for the previous models was used. However, for LTFU 180 and viral rebound, only variables with p-value <0.05 or known confounders (age, sex) were included in the multivariate model due to the small number of events. Data was analyzed using SAS 9.4 (Cary, NC) and STATA 17.0 (STATA Corporation, College Station, TX). All statistical tests were done at 5% level of significance.

# 3. RESULTS - SECTION A

Uptake of DSD during the Evaluation Period



## 3.1 Uptake of DSD

Overall, the uptake of DSD across both programs increased from 53% to 85% between July 2018 and December 2019. In PACT Endeleza, the average facility DSD uptake increased from 42% to 86%, leading to a borderline-significant positive trend on DSD uptake observed for July 2018 to December 2019 (p-value=0.05). In PACT Timiza, the average facility DSD uptake increased from 54% to 84%, leading to a significant positive trend on DSD uptake was observed for January 2018 to December 2019 (p-value=0.03) (Figure 1).

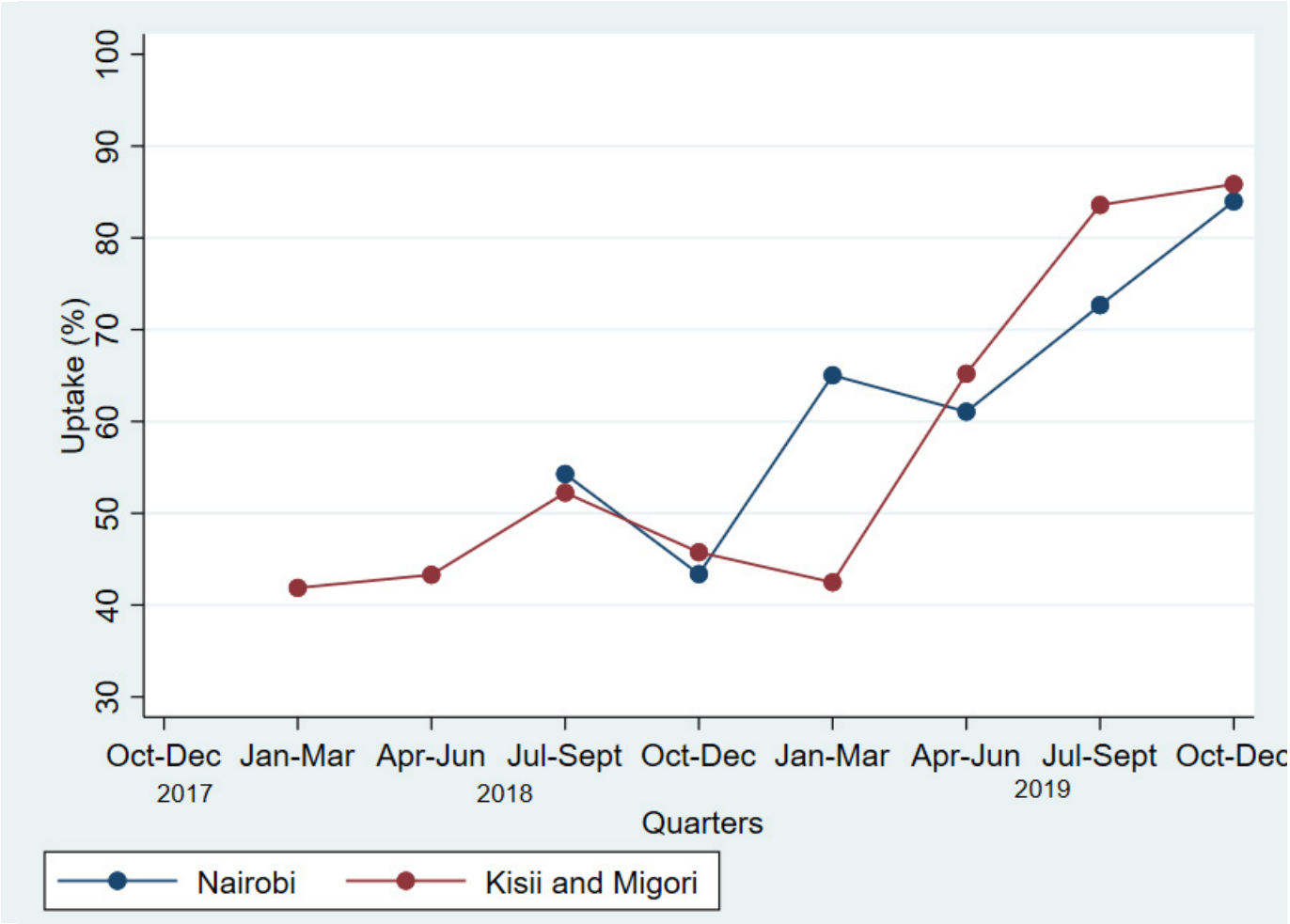



**Figure 1** DSD uptake from January 2018 to December 2019 by program (county).

# 4. RESULTS - SECTION B

Effect of Fast-Track ART Refills Program on Clinical Outcomes

## 4.1 Summary of the Effects of Fast-Track ART Refills Program on Clinical Outcomes

- LTFU at 90 and 180 days in this cohort was less than 3%.
- Viral rebound was less than 1%.
- A total of 9 (0.25%) individuals died during the evaluation period.
- In the adjusted analysis, individuals on fast-track ART refills had a higher likelihood of being LTFU at 90 days compared to standard of care. However, no difference was observed between the models of care for LTFU at 180 days, which suggests that patients may be late to their drug pick-up/clinical appointment, but ultimately, they returned to care. The latter is also confirmed by the low number of viral rebounds observed.
- In the adjusted analysis, individuals on the fast-track had a lower likelihood of experiencing viral rebound compared to those on the standard of care.
- More than three-quarters of individuals on DTG were DSD.

## 4.2 Patient's Characteristics of the Study Sample

The final sample included 3,501 patients on ART from 32 UMB-supported health facilities from PACT Endeleza in Nairobi County (n=17) and PACT Timiza in Kisii and Migori counties (n=15). Overall, the majority were females (69.0%), married or cohabitating (66.2%), 1 to 4 years on ART (56.1%), EFV-based regimen (59.7%), first-line ART regimen (95.8%), and 58.8% accessed HIV services in health facilities providing services to 500-999 PLHIV (Table 3). Overall, the median age was 40 years old (IQR, 33 – 48). The general population represented 95.4%, while the remaining was KP (4.6%). Both program populations were significantly different by the distribution of all of these characteristics except sex (Suppl. Table 5). Baseline (at the time of enrollment into HIV care) characteristics of the included population are included in Supplemental Table 1.

Overall 64.8% (2,267/3,501) of patients were on fast-track ART refills, while the remaining were on the standard of care. In PACT Endeleza, a total of 1,808 patients were included in this evaluation, with 1,166 (64.5%) in facility-based fast-track ART refills. The distribution of sex, age, type of population and current ART regimen differed significantly by outcome (Table 9). The distribution for marital status, time on ART (years), line of ART regimen at the time of entry to cohort, switching ART regimen, and facility volume did not differ by type of care in Nairobi (Table 9).

For PACT Timiza, a total of 1,693 patients were included with 1,101 (65.0%) in facility-based fast-track ART refills. The distribution of sex, age, marital status, and current ART regimen differed significantly by outcome. The type of population, line of current ART regimen, switching ART regimen, and health facility volume did not differ by type of care (Table 4).

In PACT Endeleza, most visits in 2017 and 2019 included fast-track ART refill visits (63% and 57.1%); however, in 2018, most visits were in the standard of care cohort (p-value<0.01) (Suppl. Table 6). In PACT Timiza, most visits across the years were fast-track ART refills programs (p-value=0.37).

## 4.3 Clinical Outcomes

**Lost to Follow-Up.** In PACT Endeleza, among the 12,554 visits, 376 visits (3.0%) were identified as LTFU at 90 days including 1.12% for standard of care, and 1.87% for fast-track ART refills (p-value<0.01) (Table 5). For LTFU at 180 days, 70 visits were identified (0.56%) including 0.25% for standard of care and 0.30% for fast-track ART refills (p-value=0.50) (Table 5).

In PACT Timiza, among the 13,138 visits, 272 visits (2.07%) were identified as LTFU at 90 days including 0.67% for standard of care, and 1.40% for fast-track ART refills (p-value<0.01) (Table 6). For LTFU at 180 days, 30 visits were identified (0.23%) including 0.13% for standard of care and 0.10% for fast-track ART refills (p-value=0.38) (Table 6).

**Viral rebound.** In PACT Endeleza, among the 12,222 visits with available viral load data, 26 visits (0.21%) included clients who were not virally suppressed, including 0.20% for the standard of care and 0.02% for fast-track ART refills (p-value<0.01) (Table 5). In PACT Timiza, among 12,803 visits, 32 visits (0.25%) included clients who were not virally suppressed, including 0.23% for the standard of care, and 0.02% for fast-track ART refills (p<0.01) (Table 6).

## 4.4 Factors Associated with Clinical Outcomes

We ran a multilevel Poisson model adjusting for clustering by facility and repeated individual measures to identify factors associated with each clinical outcome. No multicollinearity was observed in any of the final models (VIF<2).

For LTFU 90 days, in the unadjusted and adjusted analysis, the type of care was significantly associated with the outcome (Table 7). In adjusted analysis, individuals on fast-track ART refills had a higher likelihood of getting lost to follow-up at 90 days than those on standard of care (aRR 1.68, 95% CI 1.13-2.51). Males had a higher likelihood of getting lost to follow-up at 90 days (aRR 1.27, 95% CI 1.04-1.56). Individuals on DTG had a lower likelihood of experiencing LTFU 90 days compared to those on EFV-based regimens (aRR 0.53, 95% CI 0.37-0.76). After adjusting for confounders, there was no significant difference in the likelihood of experiencing LTFU 90 days between both programs.

In the unadjusted and adjusted analyses, there was no difference in LTFU at 180 days between the two types of care (aRR 1.06, 95% CI 0.70-1.63). After adjustment, individuals on DTG had a lower likelihood of experiencing lost to follow-up at 180 days (aRR 0.41, 95% CI 0.24-0.69) than those on EFV-based regimens. Individuals in Kisii and Migori had a lower likelihood of experiencing lost follow-up at 180 days than those in Nairobi (aRR 0.41, 95% CI 0.20-0.82) (Table 8). In both the unadjusted and adjusted analysis, fast-track ART refills was protective for viral rebound (aRR 0.05 95% CI 0.01-0.22). Likewise, switching from standard of care to fast-track ART refills was also a protective factor (Table 9).

**Table 3: Characteristics of adults accessing HIV care and treatment services at UMB-supported sites in Kenya at the time of entry into the cohort starting on July 1, 2017 by program**

| | Overall population n (%) (N=3,501) | PACT Endeleza n (%) n=1,808 | PACT Timiza n (%) n=1,693 | P-value |
|---|---|---|---|---|
| Sex | | | | |
| Male | 1,086 (31.0) | 549 (30.4) | 537 (31.7) | |
| Female | 2,415 (69.0) | 1,259 (69.6) | 1,156 (68.3) | |
| Age at time of entry into cohort (years) | | | | <0.01 |
| 20-24 | 161 (4.6) | 83 (4.6) | 78 (4.6) | |
| 25-29 | 346 (9.9) | 214 (11.8) | 132 (7.8) | |
| 30-34 | 636 (18.2) | 375 (20.7) | 261 (15.4) | |
| 35-39 | 589 (16.8) | 326 (18.0) | 263 (15.5) | |
| 40-44 | 620 (17.7) | 317 (17.5) | 303 (17.9) | |
| 45-49 | 447 (12.8) | 228 (12.6) | 219 (12.9) | |
| 50 or more | 702 (20.1) | 265 (14.7) | 437 (25.8) | |
| Marital status | | | | |
| Single | 528 (15.1) | 433 (24.1) | 95 (5.6) | <0.01 |
| Married/ Cohabitating | 2,308 (66.2) | 1,041 (58.0) | 1,267 (74.8) | |
| Separated/Divorce/ Widow | 651 (18.7) | 320 (17.8) | 331 (19.6) | |
| Type of population | | | | <0.01 |
| General population | 3,329 (95.4) | 1,639 (91.2) | 1,690 (99.8) | |
| KPs* | 162 (4.6) | 159 (8.8) | 3 (0.2) | |
| Time on ART (years) | | | | |
| 1-4 | 1,965 (56.1) | 1,158 (64.0) | 807 (47.7) | <0.01 |
| 5-9 | 1,312 (37.5) | 562 (30.1) | 750 (44.3) | |
| 10 or more | 224 (6.4) | 88 (4.9) | 136 (8.0) | |
| Current ART regimen at time of entry to cohort | | | | |
| DTG-based | 350 (10.0) | 188 (10.4) | 162 (9.6) | <0.01 |
| EFV-based | 2,089 (59.7) | 1,254 (69.4) | 835 (49.3) | |
| NVP-based | 838 (23.9) | 260 (14.4) | 578 (34.1) | |
| Other | 224 (6.4) | 106 (5.9) | 118 (7.0) | |

| | | | | |
|---|---|---|---|---|
| Line of current ART regimen at time of entry to cohort | | | | |
| First-line | 3,353 (95.8) | 1,757 (97.2) | 1,596 (94.3) | <0.01 |
| Second-line | 148 (4.2) | 51 (2.8) | 97 (5.7) | |
| Facility volume | | | | |
| 500-999 | 2,058 (58.8) | 1,010 (55.9) | 1,048 (61.9) | <0.01 |
| ≥1000 | 1,443 (41.2) | 798 (44.1) | 645 (38.1) | |
| Location type | | | | |
| Urban | 1,808 (51.6) | 1,808 (100) | - | - |
| Rural | 1,693 (48.4) | - | 1,693 (100) | |
| Year of entry into cohort | | | | |
| 2017 | 1,266 (36.2) | 626 (34.6) | 640 (37.8) | 0.11 |
| 2018 | 1,693 (48.4) | 903 (49.9) | 790 (46.7) | |
| 2019 | 542 (15.5) | 279 (15.4) | 263 (15.5) | |

*Key population is composed FSW, MSM, and PWID.
Due to rounding, column sum percent may not be equal to 100%.

**Table 4: Characteristics of clinically stable adults accessing HIV care and treatment services at UMB-supported sites in Kenya at the time of entry into the cohort starting on July 1, 2017 by program**

| Variables | Type of care as entrance into the cohort, PACT Endeleza (N=1,808) | | P-value | DCM type as entrance into the cohort, PACT Timiza (N=1,693) | | P-value |
|---|---|---|---|---|---|---|
| | Standard of care n(%) n=642 | Fast-track ART refills n(%) n=1,166 | | Standard of care n(%) n=592 | Fast-track ART refills n(%) n=1,101 | |
| Sex | | | <0.01 | | | <0.01 |
| Male | 162 (29.5) | 387 (70.5) | | 144 (26.9) | 393 (73.1) | |
| Female | 480 (38.1) | 779 (61.9) | | 448 (38.8) | 708 (61.2) | |
| Age at time of entry into cohort (years) | | | <0.01 | | | <0.01 |
| 20-24 | 39 (47.0) | 44 (53.0) | | 36 (46.2) | 42 (53.8) | |
| 25-29 | 90 (42.1) | 123 (57.9) | | 60 (45.5) | 72 (54.5) | |
| 30-34 | 147 (39.2) | 228 (60.8) | | 97 (37.2) | 164 (62.8) | |
| 35-39 | 113 (34.7) | 213 (65.3) | | 98 (37.3) | 165 (67.7) | |
| 40-44 | 92 (29.0) | 225 (71.0) | | 103 (34.0) | 200 (66.0) | |
| 45-49 | 78 (34.2) | 150 (65.8) | | 70 (32.0) | 149 (68.0) | |
| 50 or more | 83 (31.3) | 182 (65.7) | | 128 (29.3) | 309 (70.7) | |
| Marital status | | | 0.59 | | | 0.03 |
| Single | 146 (33.7) | 287 (66.3) | | 36 (37.9) | 59 (62.1) | |
| Married/ Cohabitating | 374 (35.9) | 667 (64.1) | | 421 (33.2) | 846 (66.8) | |
| Separated/ Divorce/ Widow | 119 (37.2) | 201 (62.8) | | 135 (40.8) | 196 (59.2) | |
| Type of population | | | <0.01 | | | 0.95 |
| General population | 560 (34.2) | 1,079 (65.8) | | 591 (35.0) | 1,099 (65.0) | |
| KPs* | 82 (48.5) | 87 (51.5) | | 1 (33.3) | 2 (66.7) | |
| Time on ART (years) | | | 0.34 | | | <0.01 |
| 1-4 | 425 (36.7) | 733 (63.0) | | 318 (39.4) | 489 (60.6) | |
| 5-9 | 186 (33.1) | 376 (66.9) | | 228 (30.4) | 522 (69.6) | |
| 10 or more | 31 (35.2) | 57 (64.8) | | 46 (33.8) | 90 (66.2) | |

*KPs are composed FSW, MSM, and PWID.

**Table 5: Outcomes by model of care (PACT Endeleza program)**

| Outcomes | Type of care at the last appointment before the outcome | | | |
|---|---|---|---|---|
| | Standard of care n (%) | Fast-track ART refills n (%) | Total n (%) | $X^2$ P-value |
| LTFU up to 90 days, N= 12,554 visits | 141 (1.12) | 235 (1.87) | 376 (3.00) | <0.01 |
| LTFU up to 90 days, N= 1,805 clients | 127 (7.04) | 207 (11.47) | 334 (18.50) | - |
| LTFU up to 180 days N=12,554 visits | 32 (0.25) | 38 (0.30) | 70 (0.56) | 0.50 |
| LTFU up to 180 days N= 1,805 clients | 32(1.77) | 36 (1.99) | 68 (3.76) | - |
| Viral rebound N=12,222 | 24 (0.20) | 2 (0.02) | 26 (0.21) | <0.01 |
| Viral rebound N=1,805 clients | 23 (1.27) | 2 (0.11) | 25 (1.38) | |

**Table 6: Outcomes by model of care type (PACT Timiza program)**

| | Type of care at the last appointment before the outcome | | | |
|---|---|---|---|---|
| | Standard of care n (%) | Fast-track ART refills n (%) | Total n (%) | $X^2$ P-value |
| LTFU up to 90 days, N= 13,138 visits | 88 (0.67) | 184 (1.40) | 272 (2.07) | <0.01 |
| LTFU up to 90 days, N= 1,687 clients | 85 (5.04) | 156 (9.25) | 241 (14.29) | - |
| LTFU up to 180 days N=13,138 visits | 13 (0.10) | 17 (0.13) | 30 (0.23) | 0.38 |
| LTFU up to 180 days N= 1,687 clients | 13 (0.77) | 17 (1.00) | 30 (1.78) | - |
| Viral rebound N=12,803 visits | 30 (0.23) | 2 (0.02) | 32 (0.25) | <0.01 |
| Viral rebound N= 1,687 clients | 30 (1.77) | 2 (0.12) | 32 (1.90) | - |

**Table 7: Factors associated with LTFU (+90 days) among clients receiving HIV care and treatment at UMB supported sites in both programs**

| Covariates | Unadjusted RR (95% CI) | P-value | Adjusted RR (95% CI) * |
|---|---|---|---|
| Model of care type before outcome | | <0.01 | |
| Fast-track ART refills | 1.83 (1.22-2.74) | | 1.68 (1.13-2.51) |
| Standard of care | Ref. | | Ref. |
| Model of care type at time of entry | | <0.01 | |
| Fast-track ART refills | 1.32 (1.21-1.96) | | 1.31 (1.07-1.60) |
| Standard of care | Ref. | | Ref. |
| Model of care transition** | | | |
| Fast-track ART to Standard | 1.84 (1.31-2.61) | <0.01 | |
| Standard to Fast-track ART | 1.28 (0.99-1.67) | | |
| No switch | Ref. | | |
| Clinical status at time of outcomes | | <0.16 | |
| Stable | Ref. | | |
| Unstable | 0.84 (0.66-1.07) | | |
| Sex | | | |
| Male | 1.13 (0.94-1.35) | 0.19 | 1.27 (1.04-1.56) |
| Female | Ref. | | Ref. |
| Marital status | | | |
| Single | Ref. | 0.63 | |
| Married /Cohabitating | 0.94 (0.77-1.18) | | |
| Separated/Divorce/Widow | 1.08 (0.84-1.38) | | |
| Age at visit | | | |
| 20-24 | 0.95 (0.59-1.53) | 0.61 | 0.89 (0.56-1.42) |
| 25-29 | 0.82 (0.59-1.15) | | 0.86 (0.63-1.16) |
| 30-34 | 0.87 (0.65-1.16) | | 0.85 (0.64-1.14) |
| 35-39 | 0.95 (0.69-1.30) | | 0.91 (0.67-1.24) |
| 40-44 | 1.06 (0.85-1.33) | | 1.02 (0.81-1.28) |
| 45-49 | 1.07 (0.85-1.37) | | 1.08 (0.86-1.35) |
| 50 or more | Ref. | | Ref. |
| Type of population | | | |
| General population | Ref. | 0.54 | |
| KPs | 1.27 (0.59-2.77) | | |
| Time on ART at entry into cohort | | | |
| 1-4 | | | |
| 5-9 | 0.90 (0.71-1.13) | 0.58 | |
| 10+ | 0.90 (0.72-1.11) | | |
| | Ref. | | |

| | | | |
|---|---|---|---|
| ART regimen on before outcome | | | |
| DTG-based | | | |
| EFV-based | 0.61 (0.45-0.84) | <0.01 | 0.53 (0.37-0.76) |
| NVP-based | Ref. | | Ref. |
| Other | 1.18 (0.88-1.57) | | 1.11 (0.85-1.46) |
| | 0.64 (0.44-0.95) | | 0.68 (0.46-1.00) |
| Line of ART regimen before outcome | | | |
| First-line | Ref. | 0.04 | |
| Second-line | 0.69 (0.48-0.98) | | |
| Facility volume | | | |
| 500-999 | Ref. | 0.21 | |
| ≥1000 | 1.36 (0.84-2.21) | | |
| Location type | | | |
| Urban | Ref. | 0.14 | |
| Rural | 0.70 (0.44-1.13) | | |
| Year of entry of the cohort | | | |
| 2017 | Ref. | 0.05 | |
| 2018 | 0.91 (0.73-1.12) | | |
| 2019 | 0.47 (0.26-0.87) | | |

*Variables with a p<0.25 in the bivariate model or known confounders were included in the multivariate model; however, only variables with a p-value <0.05 in the multivariable model and known confounders (age and sex) remained in the final model and were included in the adjusted RR column.
**To evaluate the transition across models of care, the switch on model of care type on the previous visit before the outcome occurring was estimated.

**Table 8: Factors associated with LTFU (+180 days) among clients receiving HIV care and treatment at UMB supported sites in both programs**

| Covariates | Unadjusted RR (95% CI) | P-value | Adjusted RR (95% CI) * |
|---|---|---|---|
| Model of care type before outcome | | | |
| Fast-track ART refills | 1.24 (0.78-1.98) | 0.36 | 1.06 (0.70-1.63) |
| Standard of care | Ref. | | Ref. |
| Model of care type at time of entry | | | |
| Fast-track ART refills | 1.22 (0.86-1.76) | 0.26 | |
| Standard of care | Ref. | | |
| Model of care transition** | | | |
| Fast-track ART to Standard | 1.51 (0.97-2.34) | 0.17 | |
| Standard to Fast-track ART | 1.24 (0.73-2.11) | | |
| No switch | Ref. | | |
| Clinical status at time of outcomes | | | |
| Stable | Ref. | 0.94 | |
| Unstable | 1.03 (0.51-2.08) | | |
| Sex | | | |
| Male | 0.99 (0.62-1.58) | 0.97 | 1.32 (0.78-2.25) |
| Female | Ref. | | Ref. |
| Marital status | | | |
| Single | Ref. | 0.08 | |
| Married /Cohabitating | 0.84 (0.51-1.38) | | |
| Separated/Divorce/Widow | 1.44 (0.89-2.31) | | |
| Age at visit | | | |
| 20-24 | 1.09 (0.47-2.57) | 0.89 | 0.28 (0.05-1.68) |
| 25-29 | 0.77 (0.39-1.51) | | 0.71 (0.38-1.34) |
| 30-34 | 0.76 (0.46-1.28) | | 0.75 (0.38-1.48) |
| 35-39 | 0.80 (0.36-1.76) | | 0.72 (0.26-2.01) |
| 40-44 | 0.81 (0.42-1.57) | | 0.73 (0.33-1.59) |
| 45-49 | 0.90 (0.50-1.63) | | 0.91 (0.48-1.73) |
| 50 or more | Ref. | | Ref. |
| Type of population | | | |
| General population | Ref. | 0.73 | |
| KPs | 0.80 (0.22-2.89) | | |

| | | | |
|---|---|---|---|
| Time on ART at entry into cohort | | | |
| 1-4 | 0.89 (0.52-1.52) | 0.90 | |
| 5-9 | 0.88 (0.50-1.56) | | |
| 10+ | Ref. | | |
| ART regimen on before outcome | | | |
| DTG-based | 0.50 (0.29-0.87) | <0.01 | 0.41 (0.24-0.69) |
| EFV-based | Ref. | | Ref. |
| NVP-based | 1.85 (1.19-2.89) | | 1.86 (1.21-2.85) |
| Other | 0.14 (0.02-1.01) | | 0.15 (0.02-1.02) |
| Line of ART regimen before outcome | | | |
| First-line | Ref. | 0.17 | |
| Second-line | 0.24 (0.03-1.82) | | |
| Facility volume | | | |
| 500-999 | Ref. | 0.38 | |
| ≥1000 | 1.44 (0.64-3.28) | | |
| Location type | | | |
| Urban | Ref. | | Ref. |
| Rural | 0.47 (0.25-0.90) | 0.02 | 0.41 (0.20-0.82) |
| Year of visit[ϖ] | | | |
| 2017 | Ref. | 0.03 | - |
| 2018 | 0.46 (0.19-1.13) | | |
| 2019 | 0.70 (0.28-1.77) | | |

**To evaluate the transition across models of care, the switch on model of care type on the previous visit before the outcome occurring was estimated.
[ϖ] Year of entry at the cohort did not converge; therefore, it was substituted with year of visit analyzed. Year of visit did not converge in the multivariable model.
*Due to the small number of events, only variables with a p-value<0.05 in the bivariate model or know confounders (age and sex) were included in the multivariate model. Variables with a p-value less than 0.05 in the multivariate model were kept in the final model and reported in the adjusted RR column, in addition to the our main exposure (Model of care type).

**Table 9. Factors associated with viral rebound among clients receiving HIV care and treatment at UMB-supported sites in both programs**

| Covariates | Unadjusted RR (95% CI) | P-value | Adjusted RR (95% CI)* |
|---|---|---|---|
| Model of care type before outcome | | | |
| Fast-track ART refills | 0.07 (0.02-0.24) | <0.01 | 0.05 (0.01-0.22) |
| Standard of care | Ref. | | Ref. |
| Model of care type at time of entry | | | |
| Fast-track ART refills | 0.84 (0.49-1.44) | 0.53 | |
| Standard of care | Ref. | | |
| Model of care transition** | | | |
| Fast-track ART to Standard | 0.09 (0.01-0.73) | 0.02 | 0.84 (0.07-10.34) |
| Standard of care to Fast-track ART | 0.46 (0.20-1.07) | | 0.22 (0.10-0.47) |
| No switch | Ref. | | Ref. |
| Clinical status at time of outcomes | | | |
| Stable | Ref. | 0.75 | |
| Unstable | 1.14 (0.52-2.50) | | |
| Sex | | | |
| Male | 0.96 (0.58-1.58) | 0.87 | 0.98 (0.58-1.67) |
| Female | Ref. | | Ref. |
| Marital status | | | |
| Single | Ref. | 0.44 | |
| Married /Cohabitating | 0.83 (0.35-1.99) | | |
| Separated/Divorce/Widow | 1.14 (0.44-2.98) | | |
| Age at visit | | | |
| 20-24 | 1.19 (0.26-5.45) | 0.60 | 0.83 (0.18-3.75) |
| 25-29 | 0.63 (0.18-2.24) | | 0.44 (0.12-1.62) |
| 30-34 | 1.57 (0.78-3.16) | | 1.30 (0.61-2.78) |
| 35-39 | 1.21 (0.52-2.81) | | 1.10 (0.46-2.68) |
| 40-44 | 1.10 (0.49-2.47) | | 1.14 (0.48-2.75) |
| 45-49 | 1.22 (0.58-2.59) | | 1.25 (0.57-2.71) |
| 50 or more | Ref. | | Ref. |
| Type of population | | | |
| General population | Ref. | 0.36 | |
| KPs | 0.31 (0.03-3.81) | | |
| Time on ART at entry into cohort | | | |
| 1-4 | 0.56 (0.23-1.38) | 0.45 | |
| 5-9 | 0.60 (0.24-1.52) | | |
| 10+ | Ref. | | |

| | | |
|---|---|---|
| ART regimen on before outcome | | |
| DTG-based | 1.50 (0.80-2.80) | |
| EFV-based | Ref. | 0.04 |
| NVP-based | 0.78 (0.34-1.76) | |
| Other | 2.64 (1.13-6.15) | |
| Line of ART regimen before outcome | | |
| First-line | Ref. | 0.03 |
| Second-line | 2.80 (1.08-7.29) | |
| Facility volume | | |
| 500-999 | Ref. | 0.51 |
| ≥1000 | 0.82 (0.46-1.47) | |
| Location type | | |
| Urban | Ref. | 0.58 |
| Rural | 1.18 (0.66-2.11) | |
| Year of visit[ϖ] | | |
| 2017 | | |
| 2018 | - | |
| 2019 | | |

***To evaluate the transition across models of care, the switch on model of care type on the previous visit before the outcome occurring was estimated.*

*[π] Year of entry at the cohort did not converge; therefore, it was substituted with year of visit analyzed.*

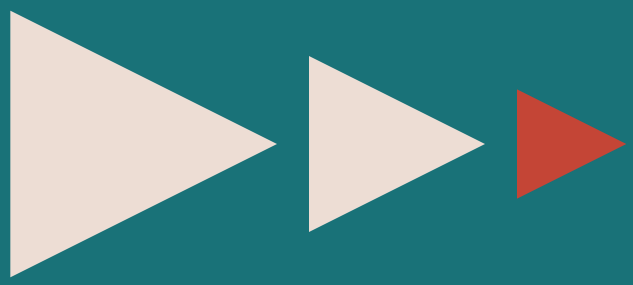
**Due to the small number of events, only variables with a p-value<0.05 in the bivariate model or know confounders (age and sex) were included in the multivariable model. However, only variables with p-value <0.05 in the multivariable model and known confounders and kept in the final mode and reported in the adjusted RR column.*

*[π] Year of entry or year of visit did not converge in the bivariate model.*

# 5. LIMITATIONS

Limitations include potential misclassification of the client's stability status, which would have impacted their eligibility to enroll into fast-track ART refill and transition between types of model of care services. Missing data on some DSD eligibility criteria [i.e., opportunistic infections (e.g., tuberculosis), pregnancy, the WHO's HIV stages (beyond enrollment), and body mass index (BMI) status] limited our ability to confirm client eligibility. However, these variables are part of the criteria used by the healthcare providers to classify clients as stable, which is captured under the field variable "client type" in the green form that we used in this analysis (Appendix 7). Data sources for individuals on fast-track ART refills differed at 90 days compared to individuals who received the traditional standard of care. In addition, differences in data quality between pharmacy and clinic records may have biased our results. Another limitation of our evaluation was the small number of LTFU and viral rebound; further analysis could be performed to examine retention and viral suppression.

# 6. KEY CONSIDERATIONS



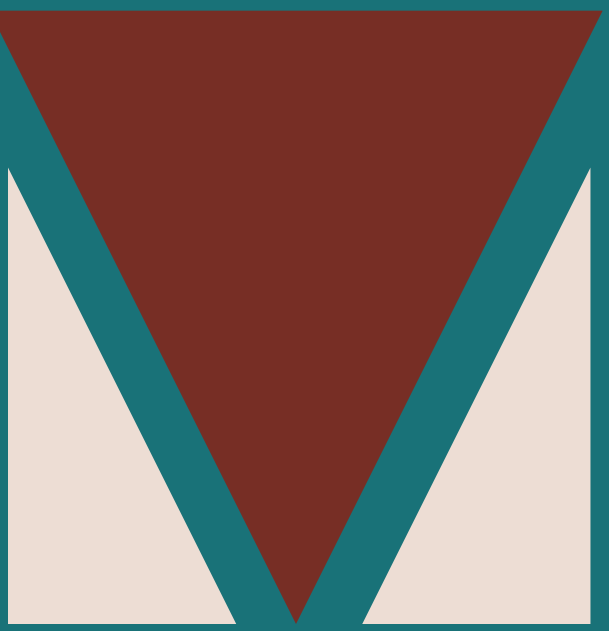
Based on the findings from this evaluation, we propose the following considerations for continuous improvement of the implementation and operationalization of DSD:

1. Our findings suggest that individuals return to the clinic by 6 months (180 days) irrespective of the type of care. Further investigations may be conducted to determine differences in terms of clinical practices (e.g., a reminder for a clinical appointment) and data quality for clinical and ART refill visits at 3 months.

2. Continue to support the rollout of DTG among eligible patients. DTG was identified as protective factor for LTFU at 90 and 180 days.

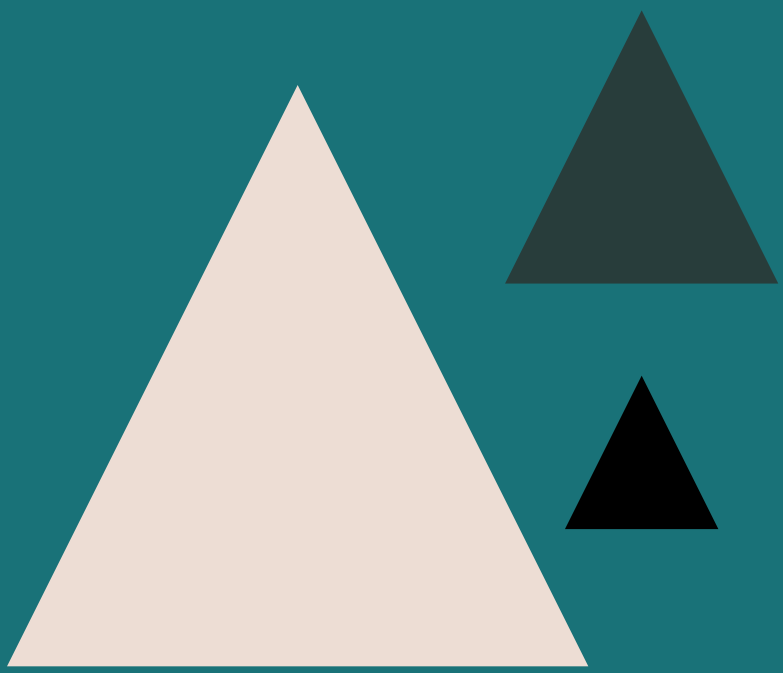
3. Consider offering training and refresher training to health providers on eligibility criteria for facility-based fast-track ART refills. Train clinicians and data officers on data entry into EMR, data quality assurance and variables related to DSD (type of DSD, and clinical status of clients) including pharmacists to capture ART refills accordingly.

# 7. CONCLUSION



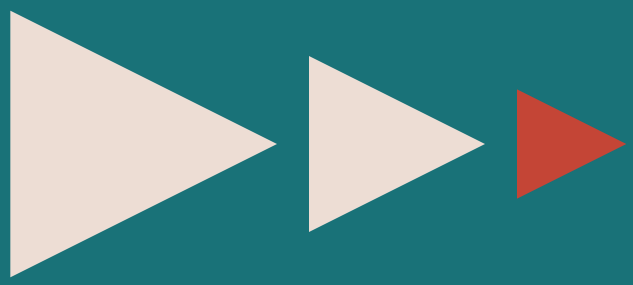
In line with the national HIV treatment guidelines recommendations, DSD has been rolled out across health facilities during the evaluation period in UMB's PACT Endeleza and PACT Timiza programs. An uptake was observed among eligible populations, with the majority receiving a multi-month prescription. Based on our findings, DSD is an effective model for retaining clients and maintaining viral suppression. Further evaluation examining preferences, barriers, and enablers from clients and health workers on DSD may be helpful to complement this evaluation to support and improve the implementation of DSD.

# 8. DISSEMINATION STRATEGY



This evaluation report will be posted on a publicly accessible website within 90 days of clearance. We will organize a meeting with the CHMTs from the three counties to discuss the results and develop strategies to close the gaps identified. We will further discuss the results with NASCOP in collaboration with US CDC Kenya through the ART task force (IPs, PLHIV groups, community-based organizations, civil society organizations) to present the findings of the evaluation and seek additional input. Evaluation findings will further be disseminated as abstracts/presentations in national and international conferences and as manuscripts; they will also be made available on Ciheb-Kenya and PEPFAR resource sites.

# 9. References



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# 10. SUPPLEMENTAL TABLES

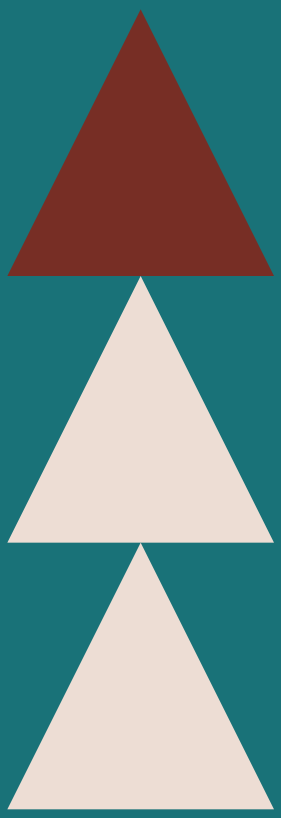
**Supplemental Table 1: Baseline characteristics (at time of enrollment into HIV care) of adults accessing HIV care and treatment services at UMB-supported sites in Kenya by program**

| Variables | PACT Endeleza n (%) N=1,808 | PACT Timiza n (%) N=1,693 | Total n (%) N=3,501 |
|---|---|---|---|
| **Age at enrollment in care (years)** | | | |
| Less than 10 | 1 (0.1) | 2 (0.1) | 3 (0.1) |
| 10-14 | 9 (0.5) | 12 (0.7) | 21 (0.6) |
| 15-19 | 52 (2.9) | 51 (3.0) | 103 (2.9) |
| 20-24 | 238 (13.2) | 173 (10.2) | 411 (11.7) |
| 25-29 | 368 (20.3) | 298 (17.6) | 666 (19.0) |
| 30-34 | 394 (21.8) | 312 (18.5) | 706 (20.2) |
| 35-39 | 312 (17.3) | 258 (15.3) | 570 (16.3) |
| 40-44 | 217 (12.0) | 212 (12.5) | 429 (12.3) |
| 45-49 | 106 (5.8) | 168 (9.9) | 274 (7.8) |
| 50+ | 111 (6.1) | 207 (12.2) | 318 (9.1) |
| **Place of first diagnosis/Entry Point** | | | |
| HBTC | 6 (0.3) | 37 (2.2) | 43 (1.2) |
| VCT site | 1,162 (64.2) | 609 (36.0) | 1,771 (50.6) |
| OPD | 204 (11.3) | 846 (50.0) | 1,050 (30.0) |
| MCH | 236 (13.1) | 130 (7.7) | 366 (10.5) |
| TB Clinic | 59 (3.3) | 9 (0.5) | 68 (1.9) |
| IPD-Child | 3 (0.2) | 4 (0.2) | 7 (0.2) |
| IPD-Adult | 7 (0.4) | 19(1.1) | 26 (0.7) |
| CCC | 8 (0.4) | 12 (0.7) | 20 (0.6) |
| Self-test | 1 (0.1) | - | 1 (0.0) |
| Other | 122 (6.7) | 27 (1.6) | 149 (4.3) |
| **BMI at time of enrollment in care** | | | |
| Underweight | 162 (9.1) | 259 (15.4) | 421 (12.2) |
| Normal range | 997 (56.0) | 1,119 (66.8) | 2,116 (61.2) |
| Overweight | 392 (22.2) | 226 (13.4) | 618 (17.9) |
| Obese | 227 (12.7) | 74 (4.4) | 301 (8.7) |
| **CD4 Level at time of enrollment in care (cells/mm3)** | | | |
| ≤ 200 | 454 (29.5) | 442 (32.2) | 896 (30.8) |
| > 200 | 1,083 (70.5) | 932 (67.8) | 2,015 (69.2) |
| **WHO Stage at time of enrollment in care** | | | |
| I | 1,188 (65.8) | 666 (39.4) | 1,854 (53.0) |
| II | 320 (17.7) | 660 (39.0) | 980 (28.0) |
| III | 272 (15.1) | 337 (19.9) | 609 (17.4) |
| IV | 25 (1.4) | 28 (1.7) | 53 (1.6) |

**Supplemental Table 2: Distribution of visits included in cohort.**

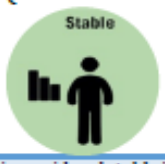
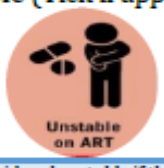
| | Type of care at visit, PACT Endeleza (N=10,878) | | P-value | Type of care at visit, PACT Timiza (N=14,753) | | P-value |
|---|---|---|---|---|---|---|
| **Year of visit** | **Standard n(%) n=6,993** | **Fast-track ART refills n=7,760** | <0.01 | **Standard n(%) n=6,993** | **Fasttrack ART refills n=7,760** | 0.37 |
| 2017 | 383 (37.0) | 652 (63.0) | | 599 (48.2) | 645 (51.8) | |
| 2018 | 3,055 (52.4) | 2,772 (47.6) | | 2,675 (48.0) | 2,898 (52.0) | |
| 2019 | 3,161 (42.9) | 4,209(57.1) | | 3,719 (48.9) | 4,217(53.1) | |

# 11. APPENDICES



| **Documents** | |
|---|---|
| Appendix 1: Key Investigator Cvs | Documents available upon request. Please contact Dr. Caroline Ng'eno at CNgeno@mgic.umaryland.edu. |
| Appendix 2: Approved Protocol | |
| Appendix 3. Cdc Ads Approval | |
| Appendix 4: Differentiated Care Patient Categorization Checklist | |

## APPENDIX 4: DIFFERENTIATED CARE PATIENT CATEGORIZATION CHECKLIST

| Date of Visit | **Stable (Use Codes Below)**   | **Unstable (Tick if appropriate)**   | Comments |
|---|---|---|---|
| | *A patient is considered stable if they meet all of the following criteria:*<br>• On their current ART regimen for ≥ 12 months<br>• No active OIs (including TB) in the previous 6 months<br>• Adherent to scheduled clinic visits for the previous 6 months<br>• Most recent VL < 1,000 copies/ml<br>• Has completed 6 months of IPT<br>• BMI ≥ 18.5<br>• Age ≥ 20 years<br>• Healthcare team does not have concerns about providing longer follow-up intervals for the patient | *A patient is considered unstable if they have any of the following:*<br>• On their current ART regimen for < 12 months<br>• Any active OIs (including TB) in the previous 6 months<br>• Poor or questionable adherence to scheduled clinic visits in the previous 6 months<br>• Most recent VL ≥ 1,000 copies/ml<br>• Has not completed 6 months of IPT<br>• Pregnant or breastfeeding<br>• BMI < 18.5<br>• Age < 20 years<br>• Healthcare team has concerns about providing longer follow-up intervals for the patient | |
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| **ART Refill Model Codes for Stable Clients** | |
|---|---|
| STD = Standard care<br>FT = Fast Track<br>CADH = Community ART Distribution – HCW Led | CADP = Community ART Distribution – Peer Led<br>FADG = Facility ART Distribution Group |

## APPENDIX 5: DIFFERENTIATED CARE ART DISTRIBUTION FORM

**A. ART Distribution Form for Stable Patients** — Complete at time of dispensing

Client Name: _____ Client Unique No: _____

Date of ARV Distribution: DD _____MM_____YYYY_____

ART Refill Model: _____

Patient Phone No: Treatment Supporter Phone No:

ARVs regimen being distributed: Quantity (mths):

**Other drugs/supplies being distributed and quantity**

☐ CPT / Dapsone, quantity (mths): ☐ Oral Contraception, quantity (mths): ☐ Condoms (yes/no):

| | |
|---|---|
| ☐ Other: , quantity (days): | ☐ Other: , quantity (days): |
| Name of pharmacist/person dispensing:<br><br>Signature: | Name of ART distributor:<br><br>Signature: |

**B. Patient review checklist** ***(if yes to any of the questions below, confirm they have enough ART until they can reach the clinic and refer back to clinic for further evaluation; book appointment and notify clinic)*** — Complete at time of distribution

Any missed doses of ARVs since last clinic visit: ☐Yes ☐No

If yes, how many missed doses: _____

Any current/worsening symptoms:

| | | | |
|---|---|---|---|
| Fatigue: ☐Yes ☐No | Fever: ☐Yes ☐No | Nausea/vomiting: ☐Yes ☐No | Diarrhea: ☐Yes ☐No |
| Cough: ☐Yes ☐No | Rash: ☐Yes ☐No | Genital sore/discharge: ☐Yes ☐No | Other: |

Any new medications prescribed from outside of the HIV clinic: ☐Yes ☐No

If yes, specify:

| | |
|---|---|
| Family planning: ☐Yes ☐No<br><br>Method used: | Pregnancy status: ☐Pregnant ☐Not Pregnant ☐Not Sure |

Referred to clinic: ☐Yes ☐No

If yes, appointment date: DD____ MM____ YYYY _____

Signature of patient upon receipt of the ART:

## APPENDIX 6: DIFFERENTIATED CARE FACILITY FORM

National AIDS & STI Control Program - NASCOP

Differentiated Care Facility Summary Form (Interim Tool)

Jan 2017

County: _____ Sub County: _____ Facility: _____ Month: _____ Year: _____

| 1. HIV Testing Services | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **1.1 HIV Positivity - Facility** | | | **1.2 HIV Positivity - Community** | | | **1.3 Linkage to Care from Facility Testing** | | | **1.4 Linkage to Care from Community Testing** | | |
| HIV Testing Facility | DC 01-01 | | HIV Testing Community | DC 01-04 | | Linked Facility | DC 01-07 | | Linked Community | DC 01-11 | |
| HIV Positive Results Facility | DC 01-02 | | HIV Positive Results Community | DC 01-05 | | HIV Positive 3 mo Ago Facility | DC 01-08 | | HIV Positive 3 mo Ago Community | DC 01-12 | |
| HIV Positivity Facility (Yield) | DC 01-03 | | HIV Positivity Community (Yield) | DC 01-06 | | % Linked Facility | DC 01-09 | | % Linked Community | DC 01-13 | |
| **2. HIV Care and Treatment** | | | | | | | | | | | |
| **2.1 Newly Enrolled - Well PLHIV** | | | **2.3 ART Initiation** | | | **2.4 Timely ART Initiation** | | | **2.5 12 Month Retention on ART** | | |
| Enrolled Well PLHIV | DC 02-01 | | Start ART Well PLHIV | DC 02-05 | | Start ART ≤ 2 weeks Well PLHIV | DC 02-09 | | On ART 12 months Well PLHIV | DC 02-13 | |
| Enrolled Total | HV03-011 | | Enrolled Total | HV03-011 | | Start ART ≤ 2 weeks Total | HV03-026 | | Net Cohort 12 months | HV 03-041 | |
| % Enrolled Well PLHIV | DC 02-02 | | % Start ART Well PLHIV | DC 02-06 | | % Start ART ≤ 2 weeks Well PLHIV | DC 02-10 | | % Retention Well PLHIV | DC 02-14 | |
| Enrolled Advanced Disease | DC 02-03 | | Start ART Advanced Disease | DC 02-07 | | Start ART ≤ 2 weeks Advanced Disease | DC 02-11 | | On ART 12 months Advanced Disease | DC 02-15 | |
| % Enrolled Advanced Disease | DC 02-04 | | % Start ART Advanced Disease | DC 02-08 | | % Start ART ≤ 2 weeks Advanced Disease | DC 02-12 | | % Retention Advanced Disease | DC 02-16 | |
| | | | | | | | | | | | |
| **2.6 ART Refill Program Uptake** | | | **2.7 ART Refill Program Coverage** | | | **2.8 12 Month Retention for Stable & Unstable PLHIV** | | | | | |
| Stable PLHIV ART ≥ 3mo Facility | DC 02-17 | | Stable PLHIV ART ≥ 3mo Facility | DC 02-17 | | On ART 12 months Stable STD | DC 02-28 | | % Retention Stable CADH | DC 02-34 | |
| Stable PLHIV Total | DC 02-18 | | On ART Total | HV 03-038 | | Net Cohort 12 months Stable | DC 02-29 | | On ART 12 months Stable CADP | DC 02-35 | |
| Uptake ART Refill Program Facility | DC 02-19 | | Coverage ART Refill Program Facility | DC 02-24 | | % Retention Stable STD | DC 02-30 | | % Retention Stable CADP | DC 02-36 | |
| Stable PLHIV ART ≥ 3mo Community | DC 02-20 | | Stable PLHIV ART ≥ 3mo Community | DC 02-25 | | On ART 12 months Stable FT | DC 02-31 | | On ART 12 months Unstable | DC 02-37 | |
| Uptake ART Refill Program Community | DC 02-21 | | Coverage ART Refill Program Community | DC 02-26 | | % Retention Stable FT | DC 02-32 | | Net Cohort 12 months Unstable | DC 02-38 | |
| Stable PLHIV & on time drug pick up | DC 02-22 | | | | | | | | | | |
| % Stable PLHIV & on time drug pick up | DC 02-23 | | Coverage ART Refill Program Total | DC 02-27 | | On ART 12 months Stable CADH | DC 02-33 | | % Retention Unstable | DC 02-39 | |
| **2.9 Viral suppressed 12 months after categorization into stable or unstable** | | | | | | | | | | | |
| Viral Suppression Stable STD | DC 02-40 | | Viral Suppression Stable FT | DC 02-43 | | % Suppressed Stable CADH | DC 02-46 | | Viral Suppression Unstable | DC 02-49 | |
| Net Cohort 12 months Stable | DC 02-41 | | % Suppressed Stable FT | DC 02-44 | | Viral Suppression Stable CADP | DC 02-47 | | Net Cohort 12 months Unstable | DC 02-50 | |
| % Suppressed Stable STD | DC 02-42 | | Viral Suppression Stable CADH | DC 02-45 | | % Suppressed Stable CADP | DC 02-48 | | % Suppressed Unstable | DC 02-51 | |

**APPENDIX 7: CLINICAL ENCOUNTER FORM**

File No: MOH 257 Ver. Aug. 2016

MINISTRY OF HEALTH

**Clinical Encounter Green Card**

Name of Facility: _____ Tier_____

MFL code: ☐☐☐☐☐ Sub County_____ County_____

**Client Profile**

Unique Number (CCC No.): ☐☐☐☐☐☐ — ☐☐☐☐☐☐

Name (FIRST, MIDDLE, LAST): Sex: M☐ F☐

Social status: **Date of Birth** DD / MM / YYYY Age _____ (If under 18yr) Orphan? **Y**☐ **N**☐ In school. Y☐ N☐

**Child**: Parent/Guardian name (FIRST/LAST):_____ _____

**Adult:** ID Number_____ ☐ Single ☐ Cohabiting

☐ Married Monogamous ☐ Married Polygamous ☐ Separated/Divorced

**Pop. Type:** ☐ **Gen Pop** ☐ **Key Pop (Tick one) MSM_____ FSW_____PWID_____**

**Entry Point & Transfer status**

Referred from (Place of first diagnosis):

HBTC ☐ VCT site ☐ OPD ☐ MCH ☐

TB clinic ☐ IPD-Child ☐ IPD-Adult ☐ CCC ☐

Self-test ☐ Other (*eg STI*) _____

Transfer in: (Date TI) DD / MM / YYYY N/A:

ART start date: DD/ MM/ YYYY Regimen_____

Facility transferred from: _____

MFL Code_____ County from _____

**Diagnosis & ARV history**

Date of HIV diagnosis: ☐☐ ☐☐ ☐☐☐☐

Date of enrollment: ☐☐ ☐☐ ☐☐☐☐

WHO stage at enrollment: 1: ☐ 2: ☐ 3: ☐ 4: ☐

Date of ART initiation: ☐☐ ☐☐ ☐☐☐☐

History of ART use: ☐Prep ☐PEP ☐PMTCT ☐None

| Purpose | Regimen | Date last used |
|---|---|---|
| a) | | |
| b) | | |
| c) | | |

**Baseline assessment & Treatment Initiation (Tick as appropriate)**

HBV infected Y☐ N☐ Pregnant? Y☐ N☐

TB Infected Y☐ N☐ Breastfeeding? Y☐ N☐

WHO stage _____ CD4 Count _____ MUAC_____

Weight (Kgs) _____ Height (cm) _____ BMI _____

**Date started on 1st line:** DD / MM / YYYY

ART Cohort_____ Regimen_____

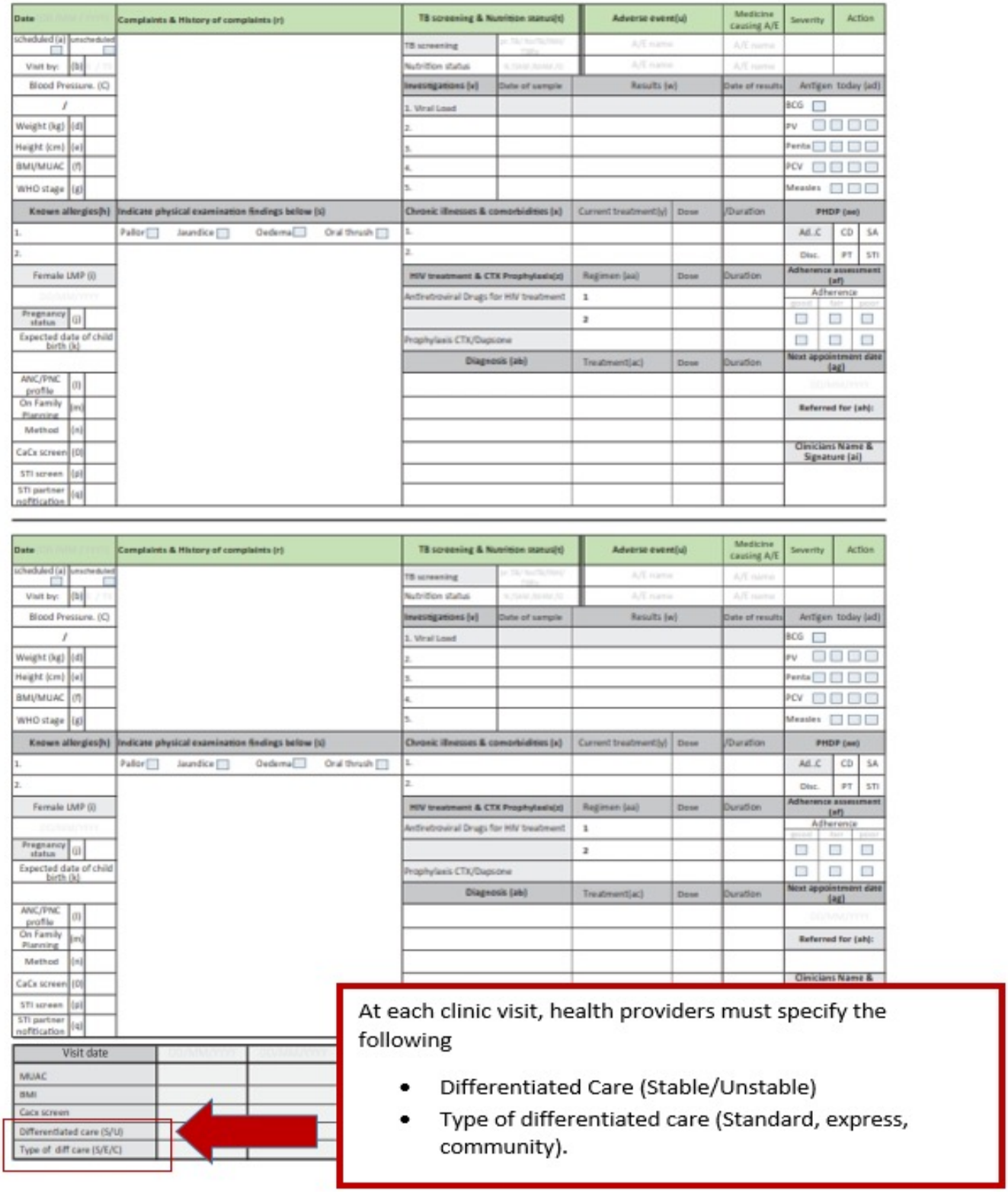
Baseline Viral load: _____ Date: DD / MM / YYYY

**Exit:** Transfer out (Date): DD/MM/YYYY Death: DD/MM/YYYY

**Viral Load and treatment changes tracker**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Viral load tracker | Sample date | | | | | | | | |
| | VL reason | | | | | | | | |
| | Results | | | | | | | | |
| Treatment Interruptions | Date | | | | | | | | |
| | Regimen | | | | | | | | |
| | Reason | | | | | | | | |
| Substitutions | Date | | | | | | | | |
| | New drug | | | | | | | | |
| | Reason | | | | | | | | |
| Switch | Date | | | | | | | | |
| | New regimen | | | | | | | | |
| | Reason | | | | | | | | |

APPENDIX 8…?


Date
Complaints & History of complaints (r)
TB screening & Nutrition status(t)
Adverse event(u)
Medicine causing A/E
Severity
Action
scheduled (a)
unscheduled
Visit by: (b)
TB screening
Nutrition status
Blood Pressure. (C)
Investigations (v)
Date of sample
Results (w)
Date of results
AntiTgen today (ad)
/
1. Viral Load
BCG
Weight (kg) (d)
2.
PV
Height (cm) (e)
3.
Penta
BMI/MUAC (f)
4.
PCV
WHO stage (g)
5.
Measles
Known allergies(h)
Indicate physical examination findings below (s)
Chronic illnesses & comorbidities (x)
Current treatment(y)
Dose
/Duration
PHDP (ae)
1.
Pallor
Jaundice
Oedema
Oral thrush
2.
Ad..C
CD
SA
Disc.
PT
STI
Female LMP (i)
HIV treatment & CTX Prophylaxis(z)
Regimen (aa)
Dose
Duration
Adherence assessment (af)
Antiretroviral Drugs for HIV treatment
1
Adherence
Pregnancy status (j)
2
Prophylaxis CTX/Dapsone
Expected date of child birth (k)
Diagnosis (ab)
Treatment(ac)
Dose
Duration
Next appointment date (ag)
ANC/PNC profile (l)
On Family Planning (m)
Referred for (ah):
Method (n)
CaCx screen (o)
Clinicians Name & Signature (ai)
STI screen (p)
STI partner notification (q)
Visit date
MUAC
BMI
Caca screen
Differentiated care (S/U)
Type of diff care (S/E/C)
At each clinic visit, health providers must specify the following
Differentiated Care (Stable/Unstable)
Type of differentiated care (Standard, express, community).