

Evaluation Performance Measurement Plan (EPMP) Report: Effectiveness of Differentiated Service Delivery on HIV Retention and Outcomes in Kisumu County, Kenya UCSF-KEMRI FACES

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Executive Summary

This evaluation was led by the University of California San Francisco (UCSF) and Kenya Medical Research Institute (KEMRI) Family AIDS Care and Education Services (FACES) program (https://faces.ucsf.edu). FACES is a long-standing, family focused, comprehensive HIV prevention, care and treatment program working collaboratively with the Kenya Ministry of Health (MOH) to build sustainable HIV care systems in Kisumu County, Kenya. FACES supports 63 health facilities providing HIV care and treatment services with 53,727 adults and children currently on antiretroviral therapy (ART) by March 2021. FACES conducted a process and outcome evaluation of the Differentiated Service Delivery (DSD) approach to HIV care in Kisumu County, Kenya. The primary objectives of the evaluation were to 1) examine retention and viral load suppression among clients enrolled in DSD models and 2) to determine if outcomes differ by sex, age and model of DSD. The secondary objectives were to 1) explore preferences for HIV service delivery models among clients on ART, and 2) examine health care worker and client experiences with the different DSD models of care. Following the dissemination of DSD services in the National ART Guidelines in 2016 and National AIDS and STI Control Program (NASCOP) Operational Guide in January 2017, FACES prepared to roll out differentiated services across supported facilities. Technical teams used NASCOP tools and guidelines to train, sensitize, and equip health facilities for differentiated care services and to implement the approach. DSD was implemented on a rolling basis throughout 2017; all DSD models include clinic visits every 6 months with ART refills every 3 months. The DSD models in this evaluation include FastTrack ART delivery, a facility-based system to streamline the 3-monthly ART refills for clients; Facility Based ART Groups (FB-AG), a support-group structured model with ART refills provided to clients through a defined support group every 3 months; and Community ART Groups (CAGS) led by either a health care worker (HCW) or peer living with HIV, who coordinates ART refills in the community every 3 months at an agreedupon delivery point.

We used two approaches to evaluate outcomes among clients receiving DSD: 1. A client-level pre-poststudy conducted in 14 health facilities from January 2014 - September 2020, which examined retention and viral load suppression (<1000 copies/mL) in a cohort of stable clients aged 20 years and above immediately preceding DSD start (pre-DSD), 12 months post-DSD implementation (midline), and 24 months post-DSD (endline); and, 2. A facility-based aggregate-level analysis of proxy retention in 59 health facilities at 12 and 24 months after DSD implementation using linear multivariable regression and interrupted time series analysis. Formative approaches were used to address the secondary objectives, including a Discrete Choice Experiment (DCE) survey to assess client preferences among a sample of adult clients (N=242) at six health facilities in February-March 2019, and through Focus Group Discussions (FGDs) (9 FGDS, N=90) to assess DSD experiences among a sample of health care workers and adult clients in August 2020.

Findings from the client-level pre-post analysis of clients assigned to DSD in 14 health facilities showed a significant increase in retention at 12 months (99.2%) and 24 months (98.9%) as compared to the pre-DSD period (86.4%; p<0.001). Although stable clients receiving the standard of care (SOC) also had increased

retention at 12 months (98.3%) and 24 months (98.5%) as compared to the pre-DSD period (86.4%) stable clients enrolled in DSD had equivalent or slightly higher retention comparatively (p<0.001). These trends were also observed when retention was stratified by gender, age, Kenya Essential Package of Health level, and urban vs. rural residence. **Results from analysis of aggregated data** on proxy retention across 59 health facilities were consistent with findings from the client-level analysis—demonstrating significant improvement in retention at 12 and 24 months after DSD was implemented. The **DCE findings** revealed that respondents had a very strong preference for a health facility as the location of ART refill, welcoming attitude of the health care workers, and adherence support provision. The predominant themes among clients and healthcare workers who participated in FGDs were high satisfaction with DSD due to the efficiency of services, improved staff attitudes, and reduced clinic workload. Participants also expressed a strong preference for facility-based models owing to perceived stigma and privacy concerns associated with community models. As our studies were observational in nature, it is possible that findings may not be a result of DSD services alone; programmatic initiatives such as multi-faceted retention efforts from 2018 and transitioning of clients to Dolutegravir (DTG) in 2019 likely contributed to secular trends in client retention and viral suppression.

This evaluation demonstrates that DSD models are an effective and acceptable means to provide clientcentered HIV care. It also provides important insights on how to improve and expand DSD services for optimal client-centered care and sustained outcomes. We plan to sustain the FastTrack model and expand facility-based ART groups to all facilities. We also plan to expand CAGS after reviewing community distribution policies and strategizing for improved privacy and confidentiality measures within delivery points for discrete community delivery. We will provide refresher updates on all the available DSD models including potential benefits of each model to both client and health care worker populations. In response to FGD recommendations to consider increasing refill duration, we will discuss evaluating the feasibility and effectiveness of 3- vs 6- monthly dispensing of ART to stable HIV clients and explore combining it with enhanced adherence support. This report serves as an important resource for discussion with key stakeholders to guide decision-making for DSD improvement and sustained client outcomes.

Project Background

This evaluation was led by the University of California San Francisco (UCSF) and Kenya Medical Research Institute (KEMRI) Family AIDS Care and Education Services (FACES) program (https://faces.ucsf.edu). FACES is a long-standing, family-focused, comprehensive HIV program working collaboratively with the Kenya Ministry of Health (MOH) to build sustainable HIV care systems in Kisumu County, Kenya. FACES is funded by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through a cooperative agreement with the US Centers for Disease Control and Prevention (CDC) Kenya. The FACES program was launched in 2004, supporting health facilities in Nairobi, Migori, Homa Bay, and Kisumu counties. In 2016, FACES support transitioned to county-wide support in Kisumu County. FACES supports 63 health facilities to provide HIV prevention, care and treatment services, with 53,727 adults and children in Kisumu County receiving antiretroviral therapy (ART) at FACES supported facilities as of March 2021.

In 2019, there were an estimated 1.5 million people living with HIV (PLHIV) in Kenya (1). Over the past decade, the Government of Kenya, with support from PEPFAR implementing partners, has scaled up HIV services in response to Kenya's HIV epidemic, including the adoption a universal treat-all policy in 2016. HIV prevalence has decreased substantially among adults from a peak of 7.2% in 2007 to 4.9% in 2018 (2, 3).

Despite nationwide progress made towards HIV epidemic control, significant gaps in reaching the Joint United Nations Programme on HIV/Acquired immunodeficiency syndrome (AIDS) (UNAIDS) 95-95-95 goals by 2030 (4) remain, especially in the highest HIV prevalence counties and Kisumu county in particular, where HIV prevalence is 17.5% (3). Additionally, the treat-all policy adopted in 2016, saw a rapid increase in adults enrolled in HIV care and treatment further increasing burden in the already constrained health facilities. To relieve the additional burden, the MOH embraced the introduction and roll out of Differentiated Service Delivery (DSD) models aiming to optimize client-centered care for stable clients, while reducing strain on health care workers and facilities. DSD was included in the Kenya National ART Guidelines in 2016, and the National AIDS and STI Control Program (NASCOP) Differentiated Operational Guide in 2017, which recommended a variety of DSD strategies including: clinic visit spacing, rapid facility drug pick-up (FastTrack), Community-based ART Groups (CAGs), Facility-based ART Groups [FB-AGs], decentralization to dispensaries, task shifting to nurse visits, and community ART distribution points, among others (5).

Following the dissemination of DSD services in the National ART Guidelines in 2016 (6) and Operational Guide in January 2017 (7), FACES prepared for the roll-out of differentiated services. Prior to implementation, FACES technical teams used NASCOP tools and guidelines to train, sensitize, and equip supported health facilities to effectively provide differentiated care services. DSD was implemented on a rolling basis throughout 2017. Table 1 summarizes DSD models implemented by FACES beginning in 2017.

After initiating DSD in supported health facilities, the FACES program sought to evaluate key processes and outcomes associated with DSD models and client and health care worker experiences and perceptions of DSD. **The primary objectives** of this mixed methods evaluation were to 1) examine the DSD models of care and its reach and effectiveness at improving or maintaining client retention and optimal health outcomes and 2) to determine if the individual DSD model options improve outcomes and if this effect differs by sex and age subgroups. **The secondary objectives** were to 1) explore client preferences for HIV service delivery models among clients on ART and 2) examine health care worker and client experiences with the different DSD models of care.

This evaluation was carried out between October 2016 through March 2021 in Kisumu County, Kenya for a total cost of \$542,367 over five years (Appendix 9), with an average per year of \$108,473; years 1 and 5 were the highest due to evaluation design, protocol development, and preparation in year 1 and data cleaning, analysis, and report writing in year 5. The evaluation includes DSD pre-post outcome evaluation and two smaller formative components: a Discrete Choice Experiment (DCE) with clients and Focus Group Discussions (FGDs) with clients and health care workers. The DCE was carried out in February-March 2019 at a cost of \$600 excluding staff time and FGDs were conducted in August 2020 at a cost of \$1,338 excluding staff time. Evaluation findings have important implications for HIV-related services and epidemic control efforts in Kenya and other resource-limited settings.

Table 1: Summary of Differentiated Service Delivery Model Implementation at FACES-supported health facilities in Kisumu

DSD Training and Roll-Out

FACES established 4 DSD training centers, one per Sub-county. Sub-county level DSD training involved the participation of all health facility staff (e.g. clinicians, nurses, pharmacist, lay health care workers, receptionists) engaged in HIV service delivery in a 3-day staff training using the NASCOP curriculum for the new ART Guidelines, including orientation on the differentiated care delivery. Training was held virtually between October-December 2016 via the Extension for Community Healthcare Outcomes (ECHO) platform with didactic sessions followed by face-to-face group-led case-based discussions.

Starting in January 2017, 1-day facility level sensitization and induction sessions were conducted by Sub-county multi-disciplinary technical teams. During these sessions, a review of differentiated care models, tools, eligibility criteria and clinic flow was conducted using the NASCOP Differentiated Care curriculum and materials. All health facility staff involved in HIV services participated, including clinicians, nurses, pharmacists, laboratory technologists, receptionists, data clerks, and lay health care workers. After the 1-day session, the NASCOP Facility Readiness Self-Assessment (7) was carried out by Sub-county technical teams to determine if the facility achieved readiness to begin differentiated services. If readiness was demonstrated, differentiated FastTrack services were launched that day. Supported health facilities that had not achieved readiness. High volume facilities, such as Sub-county and County hospitals, were recruited for differentiated care roll out first, followed by medium and smaller facilities on rolling basis from January to December 2017, approximately 2 to 3 per month. Following roll-out, technical teams conducted routine follow up visits monthly to monitor and mentor staff on differentiated services.

In addition, a 1-day sensitization on differentiated care and plans was conducted by MOH in Kisumu County in September 2017. This training had been delayed, but complemented the training carried out by FACES. This training was organized by the national program tasked with sensitizing county teams on the approach, sharing roll out and monitoring plans, since Kisumu County had been selected as one of the initial 8 counties to start differentiated care.

DSD Eligibility Screening and Enrollment

Clients were considered eligible for DSD following the national guidelines: stable in HIV care, meaning if on their current ART regimen for ≥ 12 months, had no active OIs (including Tuberculosis [TB]) in the previous 6 months, adherent to scheduled clinic visits for the previous 6 months, Most recent VL < 1,000 copies/ml, had completed 6 months of IPT, was not pregnant or breastfeeding, Body Mass Index (BMI) \geq 18.5, age was \geq 20 years, and the healthcare team did not have concerns about providing longer follow-up intervals for the client (8,9).

DSD Models

FastTrack ART delivery: This is a facility-based system for ART (and other medication) refills whereby the pharmacist prepares the medications the day prior for client drug pick-up and the client proceeds directly to the pharmacy dispensing window, bypassing all other health care services and reducing the overall time needed to acquire the refill. ART refills are quarterly with clinical review visits with health care workers every 6 months. All medication distributions are properly logged in by pharmacists and staff.

Facility Based ART Groups (FB-AG): This model uses a support-group structure to provide ART refills to clients. Each client in the FB-AG is required to come to the facility every 6 months for a clinical review appointment, with ART refills distributed through the FB-AG every 3 months between these facility appointments. Membership to a FB-AG is voluntary and offered within facilities for eligible stable clients. The members are expected to be comfortable disclosing their status to each other since they will likely be coming from a common community/village. Clients meet every 3 months, at an agreed upon date in the facility, where they will receive their ART refills and discuss any concerns with the FB-AG facilitator, bypassing clinical staff and adherence support unless referred for further consultation by the FB-AG facilitator.

Community-based ART Groups (CAGs): This model uses a support-group structure to provide ART refills to clients in the community. CAGs may be led by either a health care worker (HCW-led CAG), such as nurse or clinical officer, or a peer living with HIV, (peer-led CAG). In the peer-led CAG, a peer educator or willing PLHIV, preferably a member of the community, is trained on how to assist in dispensing ART at a community dispensing point. The dispensing point caters to approximately 20 to 30 clients per HCW or peer leader to allow for efficient tracking and follow-up. Each client in the CAG is required to come to the facility every 6 months for a clinical review appointment, with ART refills distributed through the CAG every 3 months between these facility appointments. Pre-packed medicine and ART Distribution Forms/Register are

dispatched to the HCW, lay worker/peer educator or PLHIV responsible for distributing ART at the dispensing point. The distributor completes the ART Refill Register and dispenses the prepackaged medication to clients participating in the CAG. When dispensing, the CAG lead assesses client health status and concerns and refers clients in need of further clinical evaluation or adherence counseling to the clinic. CAG membership is voluntary and mapped out according to the client's geographical location to improve convenience and reduce transport costs. Members are expected to be comfortable disclosing their status to each other since they will likely be coming from a common community/village. Clients meet every 3 months at an agreed upon community venue and time.

Evaluation Design, Methods, and Limitations

We used quantitative approaches to evaluate outcomes among clients receiving DSD, including: 1. A **client-level pre-post- study** conducted in 14 health facilities from January 2014 - September 2020, which examined retention and viral load suppression (<1000 copies/mL) in a cohort of stable clients aged 20 years and above in the 12-month period preceding DSD start (baseline), and at 12-months (mid-line), and 24-months (end-line) after DSD initiation; and, 2. **Analysis of Proxy Retention Using Aggregate Facility Level Data** from 59 health facilities at 12- and 24-months after DSD implementation using linear multivariable regression and interrupted time series analysis.

Two process studies were used to address the secondary objectives, including a cross-sectional **Discrete Choice Experiment (DCE) survey** carried out among a sample of adult clients (N=242) at six health facilities in February-March 2019, and through qualitative **Focus Group Discussions (FGDs)** (9 FGDS, N=90) to assess experiences with DSD and perceptions among a sample of health care workers and adult clients in August 2020.

Evaluation Questions	Study Design
Primary Objectives: evaluate key processes and outcomes	Design
associated with DSD models	
What is the reach and effectiveness of differentiated models	Aggregate-level data:
of care, including Community Based ART, in improving or	Interrupted time series design;
maintaining client retention and optimal health outcomes (VL	59 supported health facilities
suppression)?	
	Client-level data:
	Pre-post cohort study design;
	14 supported health facilities
Do outcomes differ by sex, age and model of DSD received?	
	Client-level:
	Pre-post cohort study design;
	14 supported health facilities

Table 2: Summary of Evaluation Questions and Study Design

How long did it take DSD to roll out across all facilities?	Site-level:
	61 supported sites
	Heat map by quarter in roll-out
	year
Secondary Objectives: explore client and health care workers	Design
experiences and perceptions of DSD	
What are client preferences for HIV service delivery models	Cross sectional Discrete Choice
among ART clients?	Experiment at six supported
	health facilities
What are health care worker and client experiences	
(facilitators, barriers, satisfaction) with the different DSD	9 Focus Group Discussions at
models of care?	three supported health facilities

Analysis of Proxy Retention Using Aggregate Facility Level Data

We conducted an analysis of routinely collected aggregate data from 59 supported health facilities, using two modelling approaches: 1) a weighted, linear multivariable regression and 2) a single-group interrupted times series (ITS) analysis (8). For the first model, data on retention were pulled from routinely collected indicators submitted to the Kenya Health Information System (KHIS) and PEPFAR's Data for Accountability Transparency and Impact Monitoring (DATIM), for the period of January 2014 through December 2018. We abstracted two indicators: new on ART care (TX_NEW) and current in care (TX_CURR) for cleints aged 15 and older. These values were used to construct facility-level cohorts, defined as *the number of clients current on ART less the number new on ART* for the 12 months pre-DSD and 24 months post-DSD, for a total of 36 time points. We then calculated the rolling monthly percentage retained at 12 months as a proxy for individual retention. To further investigate the pattern of change in retention over time, we applied these predicted values to an interrupted time series analysis 12 months pre- and post-DSD.

Aggregate Sampling

Sampling Strategy: All 59 health facilities supported by FACES in Kisumu County during the study period were included in the analysis.

Inclusion criteria: We analyzed routine data on retention and viral load suppression collected in January 2014 to September 2020 from all clients aged 15 years and above at one of the 59 FACES-supported health facilities in Kisumu.

Client-level Assessment of Retention and Viral Load Suppression using at Pre-Post Intervention Cohort Analysis

To further assess the relationship between DSD and retention and viral suppression at the client level, we conducted a pre-post intervention cohort study in 14 FACES-supported health facilities. Health facilities with electronic medical records (EMR) systems and readily available client-level outcome data for the period January 2014 to September 2020 were selected for inclusion. For all stable clients, we defined

exposure as receiving either DSD or SOC at the time DSD was implemented at each facility, as recorded in the medical record. Clients who were noted as being in SOC but who had a clinic visit history reflective of differentiated care (N=3,646) were imputed to be in differentiated care (FastTrack). We calculated the proportion of clients retained in care in the 12 months prior to DSD implementation, and at 12 +/- 1 months and 24 +/- 1 months after DSD was implemented. We also calculated the proportion of clients with viral load suppression at 12 and 24 months after implementation. Patient demographic and clinical data were collected on standardized MOH clinical forms entered into OpenMRS and KenyaEMR, the two EMR systems used at FACES supported facilities.

Client level Sampling

Sampling strategy: 14 health facilities with electronic medical records systems and readily available clientlevel outcome data for the period January 2014 to September 2020 were purposively selected for inclusion.

Inclusion criteria: All stable clients aged 20+ years enrolled in one of the 14 selected facilities in the period January 2014 – September 2020 were assessed for the analysis. At baseline we created a open cohort of stable clients. Stable at baseline was defined as having been on the current ART regimen for the past 12 months, virally suppressed in their most recent viral load in the prior 12 months, not pregnant or breastfeeding, and an absence of opportunistic infections and tuberculosis in the prior 6 months. Individuals who transferred their care to a different health facility were excluded. Clients left the cohort due to dropping out of care, transfer, death, and becoming unstable. Clients who had not yet matured in care at the mid-line and end-line timepoints were removed their respective analytic sample. Clients also entered the cohort as a result of transferring in, maturing in care, and meeting the stability definition.

Exclusion criteria: Clients were considered ineligible for DSD following the national guidelines: unstable in HIV care, meaning if not on their current ART regimen for \geq 12 months, having active OIs (including TB) in the previous 6 months, non-adherent to scheduled clinic visits for the previous 6 months, most recent VL > 1,000 copies/ml, had not completed 6 months of IPT, pregnant or breastfeeding, BMI \leq 18.5, age was \leq 20 years, and the healthcare team having concerns about providing longer follow-up intervals for the client.

Data Collection Methods: Data was collected from routine EMR service delivery databases. Routine (weekly) Data Quality Assessments (DQA) were conducted to review the data and address anomalies that were raised by the data management and analysis team. These included misclassifications and data gaps, among others.

In the differentiated care model groups, clients were classified based on the inclusion criteria and documentation of their DSD model in the EMR system. In cases where the model was not documented, additional queries were run in the EMR to identify those who met the inclusion criteria and had DSD refill and clinic visit schedules indicative of receiving differentiated care.

Data Management: Data was managed in STATA 16.1 for all data quality and analysis purposes. A data request was developed with all the required variables which was then forwarded to the programming team to write queries for extraction from both KenyaEMR and OpenMRS databases. These extracts from 14 supported sites in MS Excel format were then appended together in STATA and evaluated.

The DQA involved the following aspects: proportion/number of clients missing viral load data and dates, number of observations having a valid viral load result but missing a valid viral load date, number of clients without differentiated care field marked completely, number of clinic visits without differentiated care category marked (date and model), number missing ART regimen, number of unstable clinic visits where this information is provided and number of unstable clients not on SOC.

Data Analysis: We described baseline demographic and clinical characteristics of patients by model of care delivery. We conducted bivariate analysis to compare client retention by sociodemographic characteristics at pre-DSD, midline (12 months) and endline (24 months). We also used bivariate analysis to compare retention among clients at baseline compared to midline and to endline by model of care and demographic and clinical characteristics. In addition, we conducted a sensitivity analysis of the people imputed to be in differentiated care to support the decision to collapse that group with those noted explicitly as being in DSD.

Multivariable Analysis: We performed logistic regression reporting odds ratios and 95% confidence intervals (CI) to appraise retention at baseline, midline, and endline, adjusted for demographic and clinical characteristics.

Limitations: An observational study design used in this evaluation limits the assignment of patients to those services for which they are eligible according to MOH guidance and to the differentiated care model available at the clinics at which they are seeking care. This may result in differences in the characteristics and timing of clients receiving various differentiated care model strategies. In order to address this issue of comparability in the analysis, we adjusted for clinical and demographic factors routinely captured in the EMR to control for any confounding by factors generally known (previously published) to be associated with outcomes of interest.

For non-EMR sites, analysis is limited to aggregate data analysis. With many program activities starting concurrently, it can be challenging to attribute changes in the outcome over time specifically to differentiated care activities. In the client-level analysis, some clients may have been maintained on SOC by clinicians based on reasons which were not documented in the client record, for instance readiness concerns or if a client had a recent viral load taken and the clinician preferred to review the results at the next visit prior to deciding to enroll the client in DSD.

For both EMR and non-EMR sites, our observed results may be biased if unmeasured confounders account for some or all the observed associations.

Cross sectional Discrete Choice Experiment at Six Health Facilities to Assess Client Preferences Across Service Delivery Models

We conducted a Discrete Choice Experiment (DCE) survey to assess preferences across service delivery models among a sample of adult clients (N=242) at six health facilities in February-March 2019.

DCE Sampling

Sampling Strategy: Four FACES supported facilities were purposively selected based on their population of HIV positive clients and their geographical distribution across urban and rural areas. Respondents were systematically selected at the point of exit of the facility, that is, at the pharmacy immediately after dispensing their medication. The interviewer selected every fifth individual who exited the pharmacy and introduced themselves and the study.

Data Collection Methods and Rationale: We surveyed adults (≥18 years of age) enrolled in HIV care for at least six months between February and March 2019 at six supported sites in Kisumu County, Kenya. Participants were not necessarily enrolled in DSD themselves, as some were in care less than 12 months and/or not stable. The discrete choice experiment was conducted on hand-held devices by trained evaluation assistants. The discrete choice experiment offered clients a series of comparisons between two treatment models each of which varied in seven attributes: ART refill location, quantity of ART dispensed at each refill, medication pick-up hours, type of adherence support (e.g., individual, group), clinical visit frequency, staff attitude, and professional cadre of person providing ART refills.

Data Management: We used both tab delimited spreadsheets (.csv) and STATA version 16.0 to manage and process the data from Sawtooth software, to perform a one-to-many merges with the sociodemographic variables after exporting from the Sawtooth Software module, and to transform into a format used to produce choice models.

We created dummy variables from the choices that were exported from the Sawtooth software. For instance, a variable *Location of ART Refill* had three options, encoded as 1) Home, 2) Health facility, 3) Community Refill Point. These were recoded to produce three new variables as follows: Location of ART Refill – Home coded as (1) while everything else coded as (0), Location of Art Refill – Health Center coded as (1) while everything else coded as (0), Location of Art Refill Point coded as (1) and everything else coded as (0). This process was repeated for the seven attributes.

We assumed that the predictors in the model were independent of the outcome. Age was measured as a continuous variable in complete years, income assumed an ordinal categorical variable and gender, education and residence were measured as categorical variables. Sociodemographic characteristics were computed using counts and proportions in STATA. Sub-analyses were done for the sociodemographic characteristics by gender and urbanity.

Data Analysis: The utility/ preference coefficient (β) was calculated using the hierarchical Bayesian models where the higher the positivity in beta, the stronger the preference. Latent Class Analysis (LCA) was used to determine the preferred packages of services.

Limitations: DCEs use hypothetical scenarios which may or may not reflect services on the ground. With limited resources, we were selective of the number of sites we could include, choosing diverse facilities in location and level of services. In addition, our sample size was limited to the software allowance of 240 respondents and not more. Therefore, it is possible that findings may not be representative of the population, however we employed random sampling of clients to mitigate any bias introduced by this limitation of the software program.

Focus Group Discussions around Health Care Worker and Client Experiences with DSD

We conducted health care worker and client FGDs to learn about their experiences with differentiated care models, and to answer the question "What are health care worker and client experiences (facilitators, barriers, satisfaction) with the different DSD models of care?". This approach allowed us to gain a deeper understanding of client and health care worker perspectives during their time in DSD.

FGD Sampling

Sampling Strategy: From among 14 EMR supported sites participating in the patient-level evaluation, we randomly selected one urban facility, one-semi-urban facility, and one rural facility for the FGDs and held three FGDs at each: 1. A health care worker FGD, 2. A client FGD among adult males, and 3. A client FGD among adult females. There were 9 FGDs altogether. We purposively sampled to ensure that each group included up to 10 participants representing a variety of client interactions for facility-based health care workers (clinical officers, pharmacy and laboratory technicians, receptionists, data clerks, lay health care workers) FGD sessions and representing multiple differentiated care options for the client FGD sessions.

Data Collection and Rationale: FGDs were carried out in August 2020. Health care workers FGDs were conducted in English and client FGDs were conducted in the language preferred by the group (English, Kiswahili, or Dholuo). The discussion focused on their experiences with differentiated care, challenges/barriers encountered, facilitators/benefits to differentiated care, satisfaction, and recommendations for improvement. A trained facilitator led the sessions using a guide and a note-taker was present to document the discussions. The sessions were audio-recorded, transcribed, and then coded and analyzed in Dedoose software by a qualitative research team.

Data Management: The sessions were audio-recorded, transcribed, and translated to English if a local language was used. Random transcription checks were conducted to compare recordings and transcriptions to assess for accuracy.

Data Analysis: The transcripts were uploaded to Dedoose software and coded by a qualitative researcher using a theory-informed coding framework based on the guide domains. Coded transcripts were analyzed in Dedoose by a two-person qualitative team. Codes were queried, and resulting excerpt segments were read and summarized by each team member. Teams met multiple times to review and identify patterns and key themes across the transcripts.

Limitations: Although we sought diversity in participants and health facility type, it is possible that opinions expressed in the FGDs may not represent all DSD participants or health care workers.

Stakeholder Engagement

Stakeholder engagement played a key role in DSD roll out and implementation; garnering stakeholder input, ideas, and concerns shaped implementation decisions and DSD success. Building on our long history of collaboration with the Kisumu County MOH, we began engaging with the County Health Management Team (CHMT), Sub County Health Management Teams (SCHMTs), and facility Health Management Teams (HMTs) in 2016 on DSD to plan and operationalize the NASCOP's Differentiated Operational Plan and ART Guidelines in Kisumu County, including plans for scheduling, refill points and client flow, staff considerations, and training. Concurrently, we also worked closely with US CDC Kenya to develop and implement the DSD evaluation plan and protocol as part of this Evaluation Performance Measurement Plan (EPMP). As recipients of DSD, client engagement was prioritized, we ensured that DSD was covered during client health talks in waiting bays and that health care workers sensitized clients during visits so that they could make informed decisions if eligible. Although FastTrack rolled out first, as the other models started, clients were sensitized about the different model options so they could choose the model that best suits their care and situational needs.

Ethical considerations and assurances

This evaluation obtained Institutional Regulatory Board (IRB) approval from the Kenya Medical Research Institute (KEMRI) Scientific Ethics Regulatory Unit (SERU), #1/2009; UCSF IRB, #11-05348, and the study was also reviewed in accordance with the U.S. Centers for Disease Control and Prevention (CDC) human research protection procedures and 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. The human subjects involved in this evaluation were PLHIV at FACES-supported health facilities in Kisumu County. A waiver of informed consent was obtained for the medical record abstracted data used in the pre- and post-design component of this evaluation. Verbal consent was obtained from the DCE and FGD participants prior to participation in the survey and discussion, respectively. The consent process involved discussing the voluntary nature of evaluation, evaluation goals, procedures, potential risks and benefits of participation, participation not affecting their clinical services or care in any way, and protection of confidentiality and privacy.

Safe-guarding client details, identifiable information, and confidentiality was prioritized and covered thoroughly during staff training and routine staff meetings. During clinical care, privacy was prioritized, trust with clients established, and sensitive discussions were conducted discreetly. Data was only accessible to evaluation authorized staff responsible for client care and for data entry. Our staff has well over a decade of experience discretely tracing PLHIV, which prioritizes not disclosing HIV status or information. Data abstracted from medical records was de-identified; personal identifiers were removed and replaced with a unique database-specific identifier to further protect patient privacy. All client paper files are stored securely in a locked room with limited access to authorized staff. Electronic medical record data is stored on password protected computers. For those who participated in the DCE survey and FGDs,

the evaluation involved no more than minimal risk and no client names or identifiers were used during data collection to protect client privacy.

Deviations and adjustments (if any) from the approved scope of work and/or protocol

This evaluation is in line with the protocol and expected scope of work.

Findings and Lessons Learned

a. Primary Objective Findings

Analysis of Proxy Retention Using Aggregate Facility Level Data

We analyzed aggregate data on proxy retention from 35,554 adults 15 years and older who received care at 59 supported health facilities between July 2016 and July 2019. Nine health facilities (15.3%) were located in urban centers (Kisumu East, West and Central sub-counties), and the remaining 50 (84.7%) were in rural areas: 20 (33.9%) in Muhoroni, 18 (30.5%) in Nyakach, and 12 (20.3%) in Nyando sub-counties. Overall, 40.7% of health facilities provided Kenya Essential Package of Health (KEPH) as Level 2 (health dispensary) facilities, 32.2% were Level 3 (health centre) facilities, and 27.1% were Level 4 (sub county/county hospitals) facilities, which serve over 50% of the clients at FACES supported sites.

Results from the linear regression model (Appendix 2, Table 1) show that, during the pre-DSD period, each one-unit increase in calendar month was associated with a 0.50% decline in retention (95% CI -1.00, 0.01), however this trend did not achieve statistical significance (p=0.06). Retention in Level 4 facilities was 5.7% significantly higher (95% CI 0.84, 10.49) than in Level 2 facilities. Sub County was not significantly associated with pre-DSD retention. In the pre-DSD period, retention in the rural sub counties increased compared to urban sub counties (Kisumu East, West, and Central); however, these changes were not significant; with Muhoroni, Nyakach and Nyando having a 4.8% (95% CI -0.18, 9.81), 0.20% (95% CI -4.90, 5.30), and 3.9% (95% CI -0.70, 8.58) increase in retention, respectively, during the period.

At 12 months post-DSD rollout, each one-unit increase in calendar month was associated with a 0.5% (95% CI 0.35-0.74significant increase in retention. As compared to Level 1 facilities, retention in KEPH Level 3 health facilities was 6.9% significantly higher (95% CI 4.50-9.24. As compared to the urban Kisumu (East, West and Central) sub-counties, Muhoroni, Nyakach and Nyando sub counties experienced a 2.6% (95% CI 0.70-4.54), 2.6% (95% CI 0.59-4.52) and 4.6% (95% CI 2.83-6.38) significant increase in retention, respectively, in the 12 months after DSD was implemented.

At 24 months post-DSD, each one-unit increase in calendar month was associated with a 0.9% (95% CI 0.72-1.07) significant increase in retention. In reference to KEPH level 2, level 4 health facilities experienced a 6.7% (95% CI 3.18-10.13), significant increase in retention. Nyando sub county had a significant increase in retention of 4.2% (95% CI 0.61-7.73), as compared to the urban Kisumu (East, West and Central) sub-counties.

Results from the ITS analysis (Figure 1) support these findings. Pre-DSD retention significantly decreased by an average of -0.58% (95% CI = -0.82, -0.34 per month (Appendix 2, Table 2). In the first month following DSD implementation, there was a significant step increase in retention of 3.9% (95% CI 1.10, 6.71) followed by a significant increase in trend of 0.66% (95% CI -0.47, 0.85per month, resulting in a significant increase in retention of 1.2% per month (95% CI = 0.98, 1.48 as compared to the pre-DSD trend.

Figure 1: Trends in proxy Retention in 59 health Facilities, Kisumu County 2016-2018



Client-level Assessment of Retention and Viral Load Suppression using at Pre-Post DSD Cohort Analysis

Of the 43,304 clients assessed at baseline (Figure 2), 24,296 stable clients were included in the analysis of retention in the pre-DSD period; 86.3% (20,967) were retained at the beginning of DSD rollout (Table 3). At the start of DSD implementation, 15,747 clients were stable and eligible for differentiated care services; 11,402 (72.4%) of these clients elected to receive care through a DSD model, and the remaining 4,345 elected to receive SOC. The majority (65%) of clients at baseline were female. As compared to clients receiving DSD, a larger proportion of clients on SOC were in the youngest age category (46.1% vs. 29.4% 20-34 years of age) and had a lower WHO stage at diagnosis (66.3% vs. 39.3% WHO Stage 1).

Figure 2: PRE-DSD FLOW CHART OF ASSESSMENT OF CLIENTS ELIGIBLE FOR DSD



*Transfer outs are excluded from the denominator and numerator

* Reflects all clients in care, based on Green Card and clinic visit history

Figure 3: DSD FLOW CHART OF ASSESSMENT OF CLIENTS ELIGIBLE FOR DSD AT MONTH 12 AND 24



*Transfer outs are excluded from the denominator and numerator

Table 3: Demographic and clinical characteristics stratified by model of care delivery at start of DSD period

	Тс	otal	Standard	l of Care	DSD		
Variables	N	%	N	%	N	%	
Total	15,747		4,345		11,402		
Sex							
Male	5,511	35.0	1390	32.0	4121	36.1	
Female	10,236	65.0	2955	68.0	7281	63.9	
Age							
20-34 years	5,352	34.0	2,001	46.1	3,351	29.4	
35-49 years	7,289	46.3	1,693	39.0	5,596	49.1	
50+ years	3,106	19.7	651	15.0	2,455	21.5	
Kenya Essential Package of Health Level							
Level 2	2,165	13.7	690	15.9	1,475	12.9	
Level 3	2,272	14.4	912	21.0	1,360	11.9	
Level 4	11,310	71.8	2,743	63.1	8,567	75.1	
Sub County							
Urban							
Kisumu East West Central	12,543	79.7	3,408	78.4	9,135	80.1	
Rural							
Muhoroni	273	1.7	11	0.3	262	2.3	
Nyakach	699	4.4	65	1.5	634	5.6	
Nyando	2,232	14.2	861	19.8	1,371	12.0	
Components of the package of ART distribution options							
Community ART Groups [CAGs - 8 sites]	230	1.5	-	-	230	2.0	
FastTrack ART/Express- 14 sites	11,108	70.5	-	-	11,108	97.4	
Facility-based ART Groups [FB-AG]- 8 sites	64	0.4	-	-	64	0.6	
Standard Care	4,345	27.6	4,345	100.0	-	-	
WHO Staging Start of Intervention							
WHO Stage 1	7,364	46.8	2,880	66.3	4,484	39.3	
WHO Stage 2	4,593	29.2	841	19.4	3,752	32.9	
WHO Stage 3	3,129	19.9	531	12.2	2,598	22.8	
WHO Stage 4	640	4.1	77	1.8	563	4.9	
Missing	21	0.1	16	0.4	5	0.04	

There was an overall significant increase in retention from the pre-DSD period (86.4%; Table 4) to the midline (99.2%; p<0.001) and endline (98.1%; p<0.001) time points. Of the 11,402 clients enrolled to a differentiated care model, 99.2% were retained after one year, and 98.9% were retained after two years

among those who had matured in care (n=4,630). These trends persisted when stratified by gender, age, KEPH level, and urbanity (Appendix 2, Table 5). In the group that remained on SOC (n=4,345), 98.3% were retained at one year (Table 5), and 98.5% were retained after two years among those who had matured in care (n=2,083). Overall, clients being treated using a differentiated care model had equivalent or higher retention compared to stable clients receiving SOC at 12 and 24 months (p<0.001), with no significant differences when stratified by important demographics and clinical characteristics.

	(Pre-DSD) 12+/-1 months from Baseline		DSD (Midline)		p -value	DSD (Endline)		p -value
Variables	N	%	N	%		N	%	
Overall Retention	20,967	86.4	11,313	99.2	P<0.001	4,581	98.9	P<0.001
Gender								
Male	7,513	85.6	4,093	99.5	P<0.001	1,714	98.9	P<0.001
Female	13,454	86.9	7,220	99.7	P<0.001	2,867	99.0	P<0.001
Baseline Age								
20-34 years	9,920	81.4	3,309	99.5	P<0.001	1,388	98.5	P<0.001
35-49 years	8,150	91.2	5,561	99.6	P<0.001	2248	99.4	P<0.001
50+ years	2,897	92.5	2,443	99.6	P<0.001	945	98.9	P<0.001
Baseline Components of the package of ART distribution options								
Community ART Groups [CAGs]	-	-	228	100	-	27	100	-
FastTrack ART/Express-	-	-	11,026	99.6	-	4,532	99.0	0.102
Facility-based ART Groups [FB-AG]	-	-	59	95.2	-	22	95.7	0.785

Table 4: Bivariate associations between demographic and clinical characteristic and retention at pre-DSD, midline (12 +/-1 months), and endline (24 +/- months) from 14 EMR supported sites

Gender: We observed a significant increase in retention among males from the pre-DSD to the midline period, 85.6% vs. 99.5% (p<0.001); a similar significant increase was also observed at endline (98.9%; p<0.001). Among females we also observed a significant increase in retention from the pre-DSD to midline period, 86.9% vs. 99.7% (p<0.001); a similar significant increase was also observed at endline 86.9% vs. 99.0% (p<0.001).

Age: Among 20-34-year-old, we observed a significant increase in retention from the pre-DSD period to midline, 81.4% vs. 99.5% (p<0.001); also, significant increase was observed at endline 81.4% vs. 98.5% (p<0.001). Among 35-49 years we observed a significant increase in retention from the pre-DSD period to midline, 91.2% vs. 99.6% (p<0.001); a significant increase was observed at endline 91.2% vs. 99.4% (p<0.001). Among 50+ years we observed a significant increase in retention from the pre-DSD period to midline, 92.5% vs. 99.6% (p<0.001); a significant increase was observed at endline 92.5% vs. 98.9% (p<0.001).

Baseline components of the package of ART distribution option: We observed no statistically significant difference in retention between baseline components of ART distribution at midline and endline.

	Baseline	Midline			Endline			
		SOC	DSD	_	SOC	DSD		
	N (%)	N (%)	N (%)	P-value*	N (%)	N (%)	P-value*	
Overall Retention	20,967 (86.4)	4,273 (98.3)	11,313 (99.2)	<0.001	2,051 (98.5)	4,581 (98.9)	<0.001	
Gender								
Male	7,513 (85.6)	1,368 (98.4)	4,093 (99.5)	<0.001	622 (98.1)	1,714 (98.9)	0.131	
Female	13,454 (86.9)	2,905 (98.3)	7,220 (99.7)	<0.001	1,429 (98.6)	2,867 (99.0)	0.492	
Age								
20-34 years	9,920 (81.4)	1,966 (98.3)	3,309 (99.5)	<0.001	993 (98.9)	1,388 (98.5)	0.403	
35-49 years	8,150 (91.2)	1,666 (98.4)	5,561 (99.6)	<0.001	766 (98.2)	2,248 (99.4)	0.003	
50+ years	22,897 (92.5)	641 (98.5)	2,443 (99.6)	0.001	292 (97.6)	945 (98.9)	0.304	
Components of the package of ART distribution options								
Community ART Groups [CAGs]			228 (100)			27 (100)		
FastTrack ART/Express			11,026 (99.6)			4,532 (99.0)		
Facility-based ART Groups [FB-AG]			59 (95.2)			22 (95.7)		

Table 5: Retention at Pre-DSD, Midline, and Endline by model of care and demographic and clinical characteristics among stable clients receiving SOC and DSD

* P-value is for comparison of SOC vs. DSD

In Table 5, we compare retention proportions in the pre-DSD, midline, and endline periods, by model of care. The reported p-values are for the comparison of retention between the SOC and DSD. At midline we observed that overall retention was slightly, but significantly, higher (p<0.001) in the DSD group (99.6%) compared to the SOC group (98.3%). The difference in overall retention is significantly higher (p<0.001) at endline with 98.9% of the DSD group retained compared to 98.5% of the SOC Group.

Gender: Among males, the proportion of clients retained at midline was significantly higher (p<0.001) for those in DSD (99.5%) compared to SOC (98.4%). There were no significant differences observed at endline (98.9% vs. 98.1%; p<0.131). Among females, the proportion retained at midline was significantly higher (p<0.001) for those in DSD (99.7%) compared to those in SOC (98.3%). There was no significant difference observed at endline (99.0% vs. 98.6%; p=0.492).

Age: In clients aged 20-34 years, retention was significantly higher (p<0.001) at midline for those in DSD (99.5%) compared to those in SOC (98.3%). No significant differences were observed at endline (98.5% vs. 98.9%) which was significantly higher (p=0.403). This pattern persisted for those aged 50+. Significant differences were observed for age group 35-49-years at endline (98.5% vs. 97.6%) which was significantly higher (p=0.003).

DSD Model: The majority of clients on a DSD model at baseline were enrolled in the FastTrack ART/Express model (97.1%; 11,077/11,402), 99.6% of whom were retained in care at midline. Clients in Community ART Groups and Facility-based ART Groups also achieved high rates of retention (100% and 95.2%, respectively). All three DSD models produced similar retention rates at endline.

In multivariable analysis (Appendix 2, Table 6), female sex, older age, and WHO stage were associated with increased retention at endline, although not all of these associations achieved significance. The odds of retention among males were 40% less compared to females (OR=0.60, 95% CI: 0.29-1.27). Age at baseline: The odds of retention among clients 35-49 years were about four-fold higher than among 20–34-year-olds (OR=3.99, 95% CI: 1.63-9.83). The odds of retention among 50+ year-olds were 2.29-fold higher than among 20–34-year-olds (OR=2.29, 95% CI: 0.80-6.57). Baseline WHO Staging: Compared to clients in WHO Stage 1, the odds of retention among clients in Stage 2 were nearly two-fold (OR=1.83, 95% CI: 0.77-4.34) and significant among those in Stage 3 (OR=3.75, 95% CI: 1.07-13.17), with a nearly four-fold increase. The odds of retention among clients in Stage 4 were 13% less than among clients with WHO Stage 1 (OR=0.87, 95% CI: 0.19-3.90).

Baseline DSD Categorization: The odds of retention among those in FastTrack/Express were higher at midline compared to Community ART Distribution (OR=7.48; 95% CI 1.63-34.2). At midline, clients enrolled in Facility ART Distribution had lower odds of retention compared to those in the Community ART group (OR=0.12; 95% CI 0.02-0.73). At endline, the odds of retention among those in FastTrack/Express were higher at midline compared to Community ART Distribution (OR=11.17; 95% CI 1.32-94.68)

Table 6 shows the program-level viral load suppression among clients on DSD at midline and endline compared to the pre-DSD period. There was an overall significant increase in viral suppression from the pre-DSD period compared to midline (90.9% vs. 93.9%; p<0.001) and endline (90.9% vs. 95.7%; (p<0.001).

Gender: Among males, there was a significant increase in viral suppression from the pre-DSD period to midline (90.9% vs. 93.1%; p<0.001) and endline (90.9% vs. 95.0%; p<0.001). Among females, there was a significant increase in viral suppression from the pre-DSD period to midline (91.2% vs. 94.4%; p<0.001) and endline (91.2% vs. 96.2%; p<0.001).

Age: Among 20–34-year-olds, there was a significant increase in viral suppression from the pre-DSD period to midline (89.3% vs. 93.2%; p<0.001) and endline (89.3% vs. 95.1%; p<0.001). Among 35–49-year-olds, there was a significant increase in viral suppression from the pre-DSD period to midline (92.0% vs. 94.3%; p<0.001) and endline (92.0% vs. 96.1%; p<0.001). Among 50+ year-olds, there was a significant increase in viral suppression from the pre-DSD period to midline (92.7% vs. 94.6%; p<0.001) and endline (92.7% vs. 96.2%; p<0.001).

Sub-County: In Nyando, Kisumu East, Kisumu West and Kisumu Central, there was a significant increase in viral suppression from the pre-DSD period to midline (93.6% vs. 95.2%; p<0.001) and endline (93.6% vs. 97.0%; p<0.001). In Muhoroni, there was a significant increase in viral suppression from the pre-DSD period to midline (87.7% vs. 91.7%; p<0.001) and endline (87.7% vs. 92.8%; p<0.001). In Nyakach, there was a significant increase in viral suppression from the pre-DSD period to midline (86.2% vs. 92.2%; p<0.001) and endline (86.2% vs. 92.5%; p<0.001).

Kenya Essential Package of Health Level: We observed significant increases in viral suppression by level of care over time. KEPH Level 2: there was a significant increase in viral suppression from the pre-DSD period to midline (88.2% vs. 93.2%; p<0.001) and endline (88.2% vs. 95.2; p<0.001). KEPH Level 3: there was a significant increase in viral suppression from the pre-DSD period to midline (89.0% vs. 92.4%; p<0.001) and endline (89.0% vs. 95.0%; p<0.001). KEPH Level 4: there was a significant increase in viral suppression from the pre-DSD period to midline (92.3% vs. 94.5%; p<0.001) and endline (92.3% vs. 96.2%; p-value<0.001).

Characteristics	Pre-DSD	Midline	p-value	Endline	p-value	
	Viral load <1,000 c/ml	Viral load <1,000 c/ml		Viral load <1,000 c/ml		
	N (%)	N (%)		N (%)		
Overall	31,124 (90.9%)	36,492 (93.9%)	<0.001	44,430 (95.7%)	<0.001	
Gender						
Female	21,108 (91.2%)	24,960 (94.4%)	<0.001	29,935 (96.2%)	<0.001	
Male	9,896 (90.9%)	11,504 (93.1%)	<0.001	14,494 (95.0%)	<0.001	
Age (years)						
20-34 years	11,821 (89.3%)	13,628 (93.2%)	< 0.001	15,381 (95.1%)	< 0.001	
35-49 years	13,113 (92.0%)	15,508 (94.3%)	<0.001	18,965 (96.1%)	<0.001	
50+ years	6,190 (92.7%)	7,312 (94.6%)	<0.001	10,084 (96.2%)	<0.001	
Sub county						
Nyando-Kisumu East West and Central	20,071 (93.6%)	22,982 (95.2%)	<0.001	25,422 (97.0%)	<0.001	
Muhoroni	5,405 (87.7%)	6,608 (91.7%)	<0.001	8,951 (92.8%)	<0.001	
Nyakach	5,648 (86.2%)	6,902 (92.2%)	<0.001	10,057 (95.5%)	<0.001	
Level						
Level 2	5,225 (88.2%)	6,422 (93.2%)	<0.001	8,715 (95.2%)	<0.001	
Level 3	4,624 (89.0%)	5,707 (92.4%)	<0.001	7,390 (95.0%)	<0.001	
Level 4	21,275 (92.3%)	24,363 (94.5%)	<0.001	28,325 (96.2%)	<0.001	

Table 6: Program-level viral load suppression among clients before and after implementation of differentiated care among clients aged >=20 years

We also observed significant differences in viral suppression at midline and endline by model of care (Table 7). At midline, a higher proportion of clients enrolled in DSD were virally suppressed (92.9%) compared to those in SOC (91.0%; p<0.001). However, at endline this pattern had shifted slightly, with 92.0% of clients virally suppressed in the SOC group compared to 91.3% (p<0.001) in the DSD group.

	Mic	dline		End		
	SOC DSD			SOC	DSD	
	N=4,341*	N=11,379		N=2,081*	N=4,630	
						p-
	N (%)	N (%)	p-value	N (%)	N (%)	value
Overall Viral	3,948	10,585				
Suppression	(91.0%)	(92.9%)	<0.001	1,915(92.0%)	4,228(91.3%)	<0.001

* Clients with missing VL values excluded from analysis

Adoption and reach: As previously described, DSD first started with FastTrack. FastTrack was launched on a rolling basis, 2 to 3 supported sites per month, from January to December 2017, reaching all 61 supported sites by the end of the year. Sites began offering other models of care including facility-based groups in January 2018, and peer led or HCW led CAGs in January 2018 and March 2018, respectively. Ultimately, of all supported sites, DSD implementation by model reached 61 (100%) FastTrack sites; 7 (11%) sites with Facility-based groups with 8 groups; 27 (44%) sites with HCW-led CAGS, including 30 groups; and 12 (20%) sites with peer-led CAGs with 18 groups.

Facilities Implementing DSD by Quarter, N=61

Facilities implementing		Q1 2017	Q2 2017	Q3 2017	Q4 2017
DSD, by quarter	Ν	1	6	55	60
quarter	%	1.7%	10.0%	91.7%	100.0%

* Note: one facility was excluded due to missing data

Among 14 FACES-supported sites using EMR in these analyses, by December 2018 all 14 (100%) sites had implemented FastTrack (Appendix 2, Table 3), 7 (50%) sites had Facility-based ART groups, 5 (36%) sites had HCW-led CAGs, and 6 (43%) sites had Peer-led CAGs. Of 21,334 stable, active clients 20 years and older, 16,288 (76%) were in differentiated care, including 98% in FastTrack and fewer than 1% in the other models of care.

b. Secondary Objective Findings

Cross sectional Discrete Choice Experiment to Assess Client Preferences Across Service Delivery Models

Of 242 patients enrolled into *Discrete Choice Experiment*, 128 (52.9%) were females and 150 (62.0%) lived in rural areas. The median age was 38 years (IQR= 13). Patients placed the greatest importance on ART

refill location [19.5% (95% CI: 18.4, 20.6)]; See Appendix 2, Table 8] and adherence support [19.5% (95% CI: 18.7, 20.3)], followed by staff attitude [16.1% (95% CI: 15.1, 17.2)].

Clients preferred to refill ART at the health facility (preference weight: β =0.54), receive 3- or 6- monthly clinic visits and ART refills (preference weight: β =0.39 & β =0.34 respectively), and to engage with nice staff (preference weight: β =0.46). Clients preferred individual or group support (preference weight: β =0.41), and for pharmacists (instead of lay health workers) to provide ART refill (preference weight: β =0.42). No differences were observed by gender or urbanity. Latent Class Attributes (LCA) revealed three distinct groups: 27.5% of clients sought a home-based care model and preferred group support; 39.6% desired ART refill at health facility (preference weight: β =1.20); clinic visits every 3 months (preference weight: β =0.85); and 32.8% desired ART refills at health facility (preference weight: β =0.66).(See **Appendix 2, Table 7**)

Respondents had a very strong preference for refill at the health facility, nice attitude of the and adherence support provision at group and individual level. They had a mild preference for refill every three months, and every six months, clinical visits every three months, and refill by a pharmacist.

There was a low preference for refill by the nurse, refill during weekdays in facility hours and early morning and evenings and the least preference for ART refill at the community meeting point.

In summary, survey participants preferred 3 to 6-month intervals for refill or clinic visit spacing, which DSD provides for stable client populations. However, while DSD has also encouraged community ART group options, the results suggest strong client preferences for ART refills from health centers or by pharmacists over lay health workers or community members. Notably, these preferences held across gender and urban/rural subpopulations. Furthermore, LCA points to groupings of preferences which should be carefully considered when optimizing a mix of DSD options.

Focus Group Discussions around Health Care Worker and Client Experiences with DSD

The DSD qualitative FGD findings from 9 FGDs, 6 with clients (3 male and 3 female FGDs) and 3 with health care workers including facility-based nurses, clinical officers, pharmacy and laboratory technologists, data clerks, and lay health care workers are summarized below, followed by a few illustrative quotes. A more detailed report is in Appendix 3, which is organized around four areas: 1. Experiences: satisfaction and benefits of DSD; 2. model preferences; 3. challenges, and 4. recommendations among clients and health care workers along with additional quotes.

Among clients and health care workers, the predominant emerging theme surrounding the benefits of DSD was the **high satisfaction with the efficiency of services** in the clinic. Clients appreciate spending less time at the clinic and have more time to focus on other personal responsibilities. Health care workers appreciate the reduced workload, less congested facilities, and ability to have more focused time for patients with clinical care needs. Both patients, health care workers noted **improved staff attitudes** and more meaningful patient encounters with the reduced workload. **Perceived stigma with community models was a common thread** among both clients and health care workers due to privacy and confidentiality concerns; therefore **facility-based models were overwhelmingly preferred** by clients.

Clients and health care workers agreed that **DSD services add to clients' motivation to adhere and stay virally suppressed** as they do not want to lose the privilege of DSD. Clients enjoy having more autonomy over their clinical care and **feel less stigmatized** and more normalized, since they are no longer spending a lot of time at the clinic. Recommendations centered on further spacing of refill and clinical visits, improved privacy measures and delivery points for discrete community delivery, more health care workers and client education on DSD services to stay abreast of updates and to promote adherence and suppression, and staggered clinic hours with staff incentives to accommodate clients who need to come early or late.

Illustrative quotes

Efficiency

Client: "there has been a great change, often a single mother like me could come to the clinic, stay up too late in the evening then because I rely on a day-to-day work and pay, I end up sleeping without food because the entire day had been spent at the clinic. So, this fact that when we come things are easier and faster taking very little time then going back to our work makes me happy."

Client: I am a fisherman; I sometimes move to far places in search of fish and the three months refill gives me an opportunity to concentrate on my work for a longer period and when time comes for refill it is easy to come and pick and get back to my work immediately without any delay.

Health care worker: Okay, I think differentiated care has really helped in the essence that the commission at the facility has reduced and it minimizes the time [clients take] for coming to the facility. And also give us health care workers time so that we [can] attend to the individual patient who has come with a problem without being on a rush..."

Staff attitude

Client: "The change I have noticed is that when you come for the six-monthly clinical visits the clinician takes much time with the patient compared to when I was coming on a monthly visit."

Health care worker: "We are having a happier workforce because the psychological challenge as a result of being fatigued all the time is a thing of the past."

Model preference / Stigma in community

Client: "I prefer the facility FastTrack model because the community- based ART groups are prone to stigmatization."

Health care worker: FastTrack. In FastTrack, the client's privacy is guaranteed for them in the facility.

Health care worker: "You know, once you get there and I see you with that envelope, and that blue plate motorbike, automatically I will know that you are taking ART because there are people, I will pretend that I am also a member but I want to know what is going on."

Less stigma

Client: "I don't come to the clinic frequently. People were used to seeing me leave my home for the clinic on a monthly basis but now they have even forgotten that I visit the clinic and can't notice to

stigmatize me when I visit. They now see me as equal to them because I am healthy, alive and going about my business just like all of them without any interruptions"

Health care worker: "Yeah, like taking it positively like they are just like any other person. ...they are not coming to the hospital ... every other time. So, it is normal, they are taking it like a normal lifestyle now."

Care motivation

Client: "…the motivation of having to come after three months for refill and six months for clinical visits have made me put more effort into adhering to medication so that I can continue with differentiated care services."

Health care worker: "Uh the impact is positive, in the sense that the clients who are in the FastTrack or given any form of the differentiated model of care, ... it makes them work harder on the adherence issues so that they maintain the same model of care."

Health care worker: "Okay, for the people who are taken for sample for viral load, when they come back for a refill, they are very much concerned about their viral load and if you tell them that they are virally suppressed, they are very happy and would wish to maintain their DSD model so that they continue in that model for long."

c. Overall Findings Summary

Client-level findings in 14 EMR-supported sites showed an overall significant increase in retention at the 12 months and 24 months post-intervention periods among clients qualifying for DSD at baseline (99.2% at 12 months and 98.9% at 24 months compared to 86.4% at pre-DSD). Additionally, stable clients who remained in SOC also reported significant increases in retention at 12 months and 24 months at 98.3% and 98.5% respectively, though clients in DSD had equivalent or significantly higher retention, comparatively. These trends were also observed when stratified by gender, age, KEPH level, and urbanity. Aggregated findings across 59 supported sites support these results, with significant improvement in retention at 12 month and 24 months post-differentiated care period. The DCE findings revealed that respondents had a very strong preference for a health facility as the location of ART refill, welcoming attitude of the health care workers, and adherence support provision at the individual and group level. FGDs findings among both clients and health care workers revealed high satisfaction with DSD due to the efficiency of services; improved staff attitudes; perceived stigma with community models due to privacy and confidentiality concerns, therefore there was a strong preference for facility-based models. DSD services were also perceived to add to patients' motivation to adhere and stay virally suppressed and clients expressed feeling less stigmatized with fewer visits and less time spent at the clinic.

Discussion

This evaluation found that DSD models had a significant impact on patient retention and viral suppression. Based on the client-level findings at 14 EMR-supported sites, retention increased to 99% at both the 12and 24-month follow-up periods compared to both the pre-DSD period and stable clients who remained in SOC. This improvement was observed across age-groups, gender, KEPH level, and urbanity. This is supported by aggregate findings, which also found significant increases in retention at the 12-month follow-up point across 59 supported sites. Interestingly, a systematic review of DSD models in sub-Saharan Africa found retention findings similar to those in SOC while viral suppression findings showed a little improvement in DSD compared to SOC; however, it is noted that few clients eligible for DSD had enrolled in DSD at the time of the study (9).

In this evaluation, stable clients continued to maintain high retention and suppression in DSD, even with less frequent clinic visits. As illustrated in the qualitative findings, clients and health care workers alike favored less frequent clinic visits for the reduced burden to clients, staff and health facilities. They appreciated the efficiencies of DSD - recognizing that less frequent visits translate into fewer costly and time-consuming trips to the clinic; reduced congestion and waiting time; improved staff attitudes, an important attribute based on the DCE findings in this evaluation; and having more time for other daily responsibilities. DSD tackles multiple obstacles to care that clients face, thereby facilitating healthy HIV care behaviors by making it easier and less demanding of them. Other research has shown that when adherence promoters are improved and barriers addressed, good adherence is sustained (10-14). DCE findings also pointed to a strong patient preference for adherence support, which is shown to improve health care worker and client communication, adherence, and viral suppression (15, 16). Clients expressed interest in expanding DSD by increasing the duration of ART refill from 3 months to 6 months with annual clinical review, a concept that has been tried at a smaller scale in similar settings with clients reporting greater sense of personal freedom and normalcy (17). However, emerging literature reports significant low rates of return for clinical reviews at 12 months, completion for viral load monitoring as well as lower viral load suppression for clients receiving 6 monthly ART dispensing and annual clinical review (18). Increased ART refill duration combined with strategies to increase adherence support through DSD models may be worth exploring.

This intervention yielded improvements in retention and viral suppression over time among clients already highly engaged in care with good outcomes, potentially due to the way DSD may augment intrinsic motivation. As explained by the self-determination theory, intrinsic motivation drives individuals to embrace behaviors for their own internal satisfaction (19). While PLHIV with optimal health outcomes may already have high levels of motivation to adhere to treatment for their health, their level of internal satisfaction may be further heightened by the benefits gained through DSD. During FGDs, both clients and health care workers indicated that clients recognize that their opportunity to participate in DSD is because they are doing well in care and they want to sustain the convenience of DSD. DSD may therefore help increase healthy behaviors to sustain its benefits. This is supported by other research connecting optimal HIV care and treatment behaviors with internal benefits gained (10, 16, 20, 21). Client empowerment may also play a role in heightened retention and outcomes. DSD gives clients more opportunity to self-manage and take responsibility for their care. Clients expressed feeling more trusted to adhere to their medication. This is also supported by the self-determination theory; when people have more autonomy and ability to

self-manage their life, they feel more motivated and show enhanced performance (19). Among those in the FastTrack model, they noted feeling more normalized about living with HIV and less stigmatized, which is associated with better outcomes (22, 23). DSD services also alleviated struggles some clients had with getting to the clinic, especially among those who needed to cover long distances to get to the clinic as well as for those whom a clinic visit means loss in income. With DSD, increased retention and suppression may go hand-in-hand with fewer access to care challenges. On the health care worker side, more time to focus on managing complex cases and bolstering quality of care may increase retention and suppression outcomes.

It is important to note that stable clients who remained in SOC also had increased retention outcomes. This may be explained, in part, by the clinic-wide added benefits of DSD: reduced clinic workload, less crowded facility, improved staff attitudes, therefore possibly enhancing their clinical experience when accessing clinic reviews every 3 months. Also, not all stable clients eligible for DSD were offered DSD, based on health care worker discretion. Program-wide intensified retention strategies likely played a role as well; both for increased retention among those in SOC and for patients on DSD models. The retention among those in DSD in this evaluation was ~99%, which is higher than most reported literature while viral suppression was 95.7% (9, 24). During the DSD evaluation period, beginning in 2018, the program employed a multifaceted approach to improve retention outcomes. Efforts included updating tracing algorithms to re-engage defaulting clients early with enhanced staff accountability. Ushauri, an mHealth retention management health information system platform, was rolled out across sites to streamline defaulter management, including 2 automated patient reminders before a visit and if a visit was missed, along with tracing procedures for re-engagement. Human resource strategies included lay health care worker and peer educator competency assessment and a performance improvement plan, with the best retained and new staff with higher qualifications recruited where needed, creation of team leads for supervision, increased remuneration of Sub-county lay health care worker leads, and refresher training on the enhanced systems national treatment guideline updates to strengthen staff capabilities. The social science department, responsible for defaulter management, merged with the care and treatment department, resulting in increased synergy for patient retention. Retention was further bolstered by data demand and use: facility-level dashboards leveraging Ushauri data were developed along with weekly leadership review of retention data as part of Leading Epidemic control through Accelerated Programming (LEAP) for review and swift action to maintain and increase retention performance. Data triangulation across electronic platforms (Ushauri, EMR and Web Antiretroviral Dispensing Tool (WebADT)) were implemented to enhance data quality and ensure no patients in need of re-engagement were missed. The high retention and viral load suppression could also be explained by clients being assigned models based on the DCE outcomes as well as the introduction of integrase Dolutegravir (DTG) as the preferred firstline regimen for all adults and adolescents with HIV in 2019. Kenya was among the first countries to adopt the WHO recommendations and rapidly transitioned and/or initiated all eligible PLHIV to a DTG based regimens in 2019.

As for different DSD models, most clients preferred the FastTrack model of care. The DCE findings support this, with results showing the health facility as the preferred ART refill location. This is supported by other studies (25-27). In addition to its efficiencies, the protection of privacy and confidentiality is a major concern and more secure in the health facility than in the community. This is substantiated by recent study

carried out in Ghana (27). Inadvertent disclosure of one's HIV status is too high a risk, especially if community members recognize ART packaging and motorcycles with certain license plates and if they become curious about unfamiliar visitors or community meeting points for ART pick up. These are important concerns to address and mitigate so as to sustain and increase patient participation in community models. Another benefit expressed by clients about the facility-based model is being able to access clinical care or advice when they come to the clinic for refills. Some clients did express the desire to have harmonized refill visits at the clinic which would encourage more clients to attend for the added adherence support it would provide from other PLHIV. This is supported by the DCE findings which showed adherence support at either the individual or group level as a preferred and important attribute of care for clients. Facility-based groups could potentially be enhanced and expanded to accommodate this suggestion (27, 28).

Lessons Learned

This evaluation provides important insights on how to improve and expand DSD services for optimal clientcentered care and sustained outcomes. Given client preference for facility models, we plan to scale-up facility-based ART groups to all supported health facilities. We will provide refresher updates on all the available DSD models including potential benefits of each model to both client and health care worker populations. This will provide clients with efficient quality care and the beneficial adherence support desired. We also plan to expand community models, but first we will address the reported perceived stigma and privacy concerns, we will review community distribution policies, provide ongoing training and mentorship on privacy and discretion in the community, and strategize for improved privacy and confidentiality measures within delivery points for discrete community delivery. We will discuss evaluating the feasibility and effectiveness of 3- vs 6- monthly dispensing of ART to stable HIV clients and scalability of this suggested initiative and explore the possibility of combining it with enhanced adherence support. This report serves as an important resource for discussion with key stakeholders to guide decision-making for differentiated service delivery improvement and sustained client health outcomes.

Conclusion

Differentiated service delivery models ensured sustained client retention and viral load suppression. Majority of the clients had preference for FastTrack facility-based models compared to community-based models citing challenges with privacy and confidentiality concerns during community delivery of ART. There is need to review implementation of community models and develop strategies to mitigate the perceived stigma among PLHIV.

Dissemination

FACES will share evaluation findings with the CDC, PEPFAR, Implementing Partners, national, regional and other stakeholders and community members engaged or interested in HIV epidemic control. Dissemination will take place in the form of oral presentations and discussion in HIV forums, written reports, scientific publication, and public dissemination. The purpose of dissemination will be to share scientific results on the effectiveness of this national approach, to see if there is agreement based on other's findings, to engage in discussions on lessons learned and priority areas for attention, to obtain additional information on remaining questions or concerns, and most importantly, to facilitate decision-making to guide differentiated service delivery and approach improvement plans.

Stakeholder Discussions: FACES will meet with MOH, CDC, policy makers, community leaders, community members, clients and County and facility health staff in annual and periodic stakeholder forums, such as Nyanza Western (NYAWEST) and NASCOP technical working groups, to facilitate a discussion on the implications of findings and recommendations to collectively strategize and make evidence-based

decisions on how to best advance DSD services to promote better access and health outcomes for individuals living with HIV.

Specifically, findings will be presented quarterly at HIV related task force meetings including the NYAWEST technical working group meeting in June/July 2021; MOH facility in-charge meetings, KEMRI lecture series in Kisumu, and NASCOP meetings with the aim of facilitating discussion and decision-making for improved HIV services delivery.

Written reports, abstracts, and manuscripts: We plan to disseminate scientific abstracts and manuscripts based on these evaluation findings. CDC and MOH will be invited to share their expertise as co-authors. All abstracts and manuscripts supported by the CDC will be submitted to the CDC Science office for approval following their standard procedures. We plan to disseminate at the annual University of Nairobi conference and other scientific venues such as International AIDS Society and to a scientific journal.

The EPMP report, dataset, and data documentation will be available on Dryad for data accessibility and transparency.

Public dissemination: Evaluation results will be shared on the FACES website (hosted by UCSF) (<u>https://faces.ucsf.edu/</u>) and in routine editions of FACES TALK (newsletter) to educate and promote interest in and support of HIV services. Results will also be shared on the KEMRI websites and FACES Facebook pages to raise awareness and engagement in FACES' HIV response.

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Appendices

- 1. Acronyms
- 2. Quantitative Data Tables
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- 8. Ethics Certification
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- 11. Protocol

List of Acronyms

AIDS	Acquired Immunodeficiency Syndrome	IRB	Institutional Regulatory Board
ART	Antiretroviral Therapy	ITS	Interrupted Time Series
BMI	Body Mass Index	KEPH	Kenya Essential Package of Health
CAGs	Community ART Groups	KHIS	Kenya Health Information System
CDC	Center for Disease Control and Prevention	KEMRI	Kenya Medical Research Institute
CGH	Center for Global Health	LCA	Latent Class Attributes
CHMT	County Health Management Team	LEAP	Leading Epidemic control through Accelerated Programming
CI	Confidence Interval	МОН	Ministry of Health
DATIM	Data for Accountability Transparency and Impact Monitoring	PLHIV	People Living with HIV
DCE	Discrete Choice Experiment	NyaWest	Nyanza and Western
DSD	Differentiated Service Delivery	NASCOP	National AIDS and STI Control Program
DTG	Dolutegravir	PEPFAR	U.S President's Emergency Plan for AIDS Relief
DQA	Data Quality Assessment	SCHMT	Sub County Health Management Teams
ECHO	Extension for Community Healthcare Outcomes	SERU	Scientific Ethics Regulatory Unit
EMR	Electronic Medical Record	ТВ	Tuberculosis
EPMP	Evaluation Performance and Measurement Plan	TX-CURR	Current on ART
FACES	Family AIDS Care and Education Services	TX-NEW	New on ART
FB-AG	Facility Based ART Groups	UCSF	University of California San Francisco
FGDs	Focus Group Discussions	UNAIDS	United Nations on HIV/AIDS
HCW	Health Care Worker	VL	Viral Load
HIV	Human Immunodeficiency Virus	WebADT	Web Antiretroviral Dispensing Tool
HMT	Health Management Team	WHO	World Health Organization

Appendix 2; Quantitative Data

Aggregate Tables 1-2

Appendix 2, Table 1: Retention in Care - Weighted Multivariable Linear Regression Model of Moving average over 5 values comparing Retention in the Pre-DSD period and the Midline and Endline Post-DSD Periods.

		Pre-DS	D Model		Midline	e Model post-D	(12-mont SD)	hs En	dline Model (24-months post- DSD)		
Percentage Retention		959	% CI		95%	95% CI		95%	95% CI		
	Coef.	Lower Limit	Upper Limit	Coef.	Lower Limit	Upper Limit	Coef.	Lower Limit	Upper Limit		
Differentiate d Care Month	-0.5	-1	0.01	0.54	0.35	0.74	0.9	0.72	1.07		
Kenya Essential Package of Health Level	(Dof)			(Dof)			(Pof)				
Level 2	(Ref)			(Ref)	4 5	0.24	(Ref)	2.02	4.76		
Level 3	1.33	-4.9	/.5/	6.87	4.5	9.24	0.42	-3.93	4.76		
Level 4	5.67	0.84	10.49	1.44	-0.43	3.31	6.66	3.18	10.13		
Sub County Urban											
Kisumu East West Central Rural	(Ref)			(Ref)			(Ref)				
Muhoroni	4.82	-0.18	9.81	2.62	0.7	4.54	-1.52	-5.22	2.18		
Nyakach Nyando	0.2 3.94	-4.9 -0.7	5.3 8.58	2.56 4.61	0.59 2.83	4.52 6.38	-0.16 4.17	-3.88 0.61	3.56 7.73		

Appendix 2, Table 2: Weighted Percentage of Interrupted Time Series Analysis of Retention Since DSD Start

	Coef.	959	% CI
Time since DSD start.	-0.578	-0.821	-0.336
Intervention period (from August 2017)	3.901	1.096	6.707
Interaction between Time Since DSD start* intervention period	1.234	0.984	1.483
Constant	88.766	87.573	89.959

Post intervention Linear Trend: 691 (Treated:_b[_t]+_b[_x_t691]

	Coef.		
Linear Trend		959	% CI
Intervention period	0.6555	0.465	0.846

Appendix 2, Table 3: Reach and Adoption of DSD Models including Standard Care, among Stable Clients at 14 EMR Sites

REACH and ADOPTION	As of December 2017		As of D	ecember 2018
EMR sites	# of EMR sites	N (%) active in care	# of EMR sites	N (%) active in care
Differentiated Care (overall)	14	14,064 (77%)	14	16,288 (76%)
Express care/Fast Track*	14	13,816 (98%)	14	15,975 (98%)
Facility-based ART Groups	7	66 (<1%)	7	88 (<1%)
HCW CAG	5	87 (<1%)	5	120 (<1%)
Peer-led CAG	6	95 (<1%)	6	105 (<1%)
Standard of Care	14	4,098 (23%)	14	5,046 (24%)
Total Active in Care (stable, 20 and older)		18,162		21,334

* We have applied a correction factor based on our baseline data quality exercise using visit history; 45.6% of clients (N=3,435 in Dec 2017 and 4,229 in Dec 2018) who were initially noted as Standard of Care in the EMR have been imputed as being enrolled in DSD/Fast Track.

Client-level Tables 4-6

Appendix 2, Table 4: Demographic characteristics with imputed client groups as their own colum
justifying the decision to collapse to DSD.

	SOC		DSD Based on Visit		DSD Based on Green		
		~ 	History		Card		
Variables	Ν	%	N	%	N	%	
Total	4345		3646		7749		
Sex							
Male	1390	32.0	1,396	38.3	2723	35.1	
Female	2955	68.0	2,250	61.7	5026	64.9	
Age							
20-34yrs	2001	46.1	1113	30.5	2236	28.9	
35-49years	1693	39.0	1792	49.1	3800	49.0	
50+ years	651	15.0	741	20.3	1713	22.1	
Kenya Essential Package of							
Health Level							
Level 2	690	15.9	299	8.2	1175	15.2	
Level 3	912	21.0	429	11.8	931	12.0	
Level 4	2743	63.1	2918	80.0	5643	72.8	
Sub County							
Urban							
Kisumu East West Central	3408	78.4	3215	88.2	5915	76.3	
Rural							
Muhoroni	11	0.3			260	3.4	
Nyakach	65	1.5	15	0.4	610	8.0	
Nyando	861	19.8	416	11.4	955	12.3	
Components of the package of ART distribution options							
Community ART Groups [CAGs]			5	0.1	225	2.9	
Fast Track/Express			3639	99.8	7462	96.3	
Facility-based ART Groups [FB-			2	0.1	62	0.8	
Standard of Care*							
WHO Staging Start of Intervention							
WHO Stage 1	2,880	66.3	2326	63.8	3056	39.4	
WHO Stage 2	841	19.4	709	19.5	2603	33.6	
WHO Stage 3	531	12.2	533	14.6	1660	21.4	
WHO Stage 4	77	1.8	75	2.1	429	5.5	
Missing	16	0.4	3	0.1	1	0.01	

Appendix 2, Table 4: This table compares the demographic characteristics of clients in SOC vs. those in DSD based on visit history vs. those whose DSD classification was based on the green card classification. Gender: Among males there was not much difference in the proportion of males whose DSD was based on visit history against those whose DSD was based on Green card. (38.3% vs. 35.1%). Among females the proportions were not much different in the DSD based on Visits vs DSD based on Green Card (61.7% vs.64.9%). A near similar observation was made by age groups in the two categories; i.e., among 20–34-year-old (30.5% vs. 28.9%), 35-49 years (49.1 % vs. 49.0%), 50 plus years (20.3% vs. 22.1%).

	Pre-D	SD	Midline (12 Months Post-DSD)			Endline (24 Post-E		
Variables	N	%	N	%	p -value	N	%	p -value
Overall Retention	20,967	86.4	11,313	99.2	<0.001	4,581	98.9	<0.001
Sex								
Male	7,513	85.6	4,093	99.5	<0.001	1,714	98.9	<0.001
Female	13,454	86.9	7,220	99.7	<0.001	2,867	99.0	<0.001
Age								
20-34 years	9,920	81.4	3,309	99.5	<0.001	1,388	98.5	<0.001
35-49 years	8,150	91.2	5,561	99.6	<0.001	2248	99.4	<0.001
50+ years	2,897	92.5	2,443	99.6	<0.001	945	98.5	<0.001
Essen. package of health level								
Level 2	5,541	85.5	1,465	99.7	<0.001	112	100	<0.001
Level 3	1,902	85.4	1,354	99.6	<0.001	643	99.8	<0.001
Level 4	13,524	87.0	8,494	99.6	<0.001	3826	98.8	<0.001
Sub County								
Urban								
Kisumu East West Central	17,209	86.6	9061	99.6	<0.001	3864	98.77	<0.001
Rural								
Muhoroni	508	86.4	260	100	<0.001	40	100	<0.001
Nyakach	1,562	84.3	628	99.4	<0.001	104	100	<0.001
Nyando	1,688	86.6	1364	99.6	<0.001	573	99.8	<0.001
Components of the package of ART distribution options								
Community ART Groups [CAGs]			228	100		27	100	
Fast Track/Express			11026	99.6		4532	99.0	0.102
Facility-based ART Groups [FB-AG]			59	95.2		22	95.7	0.785
WHO Staging Start of Intervention								
WHO Stage 1	8,797	84.8	4443	99.5	<0.001	1792	98.8	<0.001
WHO Stage 2	6,663	90.6	3736	99.7	<0.001	1429	99.0	<0.001
WHO Stage 3	4,329	91.9	2577	99.7	<0.001	1189	99.3	<0.001
WHO Stage 4	864	92.8	557	99.1	<0.001	171	98.8	<0.001
Viral Load								
<=1000	N/A*	N/A	10,520	99.4		4184	99.0	<0.001
>1000copies/ml	N/A	N/A	788	99.2		391	98.9	0.002

Appendix 2, Table 5: Bivariate associations between demographic and clinical characteristics and retention at the pre-DSD timepoint, midline (12 months post-DSD), and endline (24 months post-DSD)

* Eligibility for inclusion in the baseline cohort required viral suppression

	Pre-D	DSD		Midline		Endline			
				(12 Months DSD)	Post-		(24 Months Post-D		-DSD)
	N=23,	,405		N= 11,3	95		N	= 4,630	
	Odds	95%		Odds	95%		Odds	050	
	Ratio	CI		Ratio	CI		Ratio	33/	
Sex									
Female	1			1			1		
Male	0.605	0.545	0.672	1.012	0.601	1.705	0.602	0.285	1.27
Age at baseline									
20-34 years	1			1			1		
35-49 years	3.812	3.392	4.284	2.456	1.411	4.276	3.999	1.628	9.825
50+ years	7.804	6.427	9.476	2.921	1.398	6.105	2.29	0.798	6.572
Baseline WHO									
Staging									
WHO STAGE 1	1			1			1		
WHO STAGE 2	2.629	2.332	2.965	2.606	1.384	4.908	1.832	0.773	4.339
WHO STAGE 3	2.194	1.9	2.534	1.093	0.573	2.085	3.746	1.066	13.166
WHO STAGE 4	1.709	1.265	2.31	0.286	0.112	0.729	0.865	0.192	3.903
Baseline DSD Categori	zation								
Community ART Dist				1			1		
FastTrack/Express				7.483	1.635	34.236	11.171	1.318	94.677
Facility ART							1		
Distribution				0.122	0.02	0.732	T		

Appendix 2, Table 6: Multivariable pre-post analysis of retention, among clients on DSD, accounting for facility-level clustering

We compared the odds of retention in the pre-DSD period, midline (12 months post-DSD) and endline (24 months post-DSD).

Pre-DSD: Gender: The odds of retention among males were 40% less compared to females. Age at Baseline: The odds of retention among 35-49 years were nearly 4-fold in reference to 20–34-year-olds. The odds of retention among 50 plus year old was nearly eight-fold in reference to 20–34-year-olds. Baseline WHO Staging: The odds of retention among clients in who stage 2 was more than 2.5-fold in reference to WHO Stage 1. The odds of retention among clients in stage 3 was more than 2-fold in reference to WHO Stage 1. The odds of retention among clients in stage 4 was 1.7-fold in reference to WHO Stage 1.

Midline - 12 months post-DSD implementation: Gender: The odds of retention among males was nearly the same as among females. However, this was not statistically significant. Age at Baseline: The odds of retention among 35-49 years were more than 2.4-fold in reference to 20–34-year-olds. The odds of retention among 50 plus year old was nearly 3-fold in reference to 20–34-year-olds. Baseline WHO Staging: The odds of retention among clients in stage 2 was about 2.6-fold in reference to WHO Stage 1. The odds of retention among clients in stage 3 was just 1.09-fold in reference to WHO Stage 1. The odds of retention among clients in stage 4 was about 70% less in reference to WHO Stage 1. Baseline DSD Categorization: The odds of retention among those in Fast Track/Express was nearly 7.5 -fold in reference to other DSD categorizations (community/facility).

Endline - 24 months post-DSD implementation: The odds of retention among males were 40% less compared to females. Age at Baseline: The odds of retention among 35-49 years were about 4-fold in reference to 20–34-year-olds. The odds of retention among 50 plus year old was about 2.3-fold in reference to 20–34-year-olds. Baseline WHO Staging: The odds of retention among clients in stage 2 was nearly 4 -fold in reference to WHO Stage 1. The odds of retention among clients in stage 3 was nearly 4-fold in reference to WHO Stage 1. The odds of retention among clients in stage 4 was about 13% less in reference to WHO Stage 1. Baseline DSD Categorization: The odds of retention among those in Fast Track/Express was more than 11-fold in reference to other DSD categorizations (community/facility).

Discrete Choice Experiment (DCE) Tables 7-9

Appendix 2, Table 7: DCE: Sociodemographic Characteristics of Respondents

	Urban	Rural	p-value
Age (years; median and interquartile	29/21 45)	36(30-	
range)	56(51-45)	43.5)	
Income			
Below 5000	61(47.3%)	68(52.7%)	<0.001
5000 and above	20(18.3%)	89(81.7%)	
Education			
Primary education and below	74(54%)	63(46%)	<0.001
Secondary education and above	76(75.2%)	25(24.8%)	
Gender			
Male	71(54.6%)	39(45.4%)	0.652
Female	79(61.7%)	49(38.3%)	
Care frequency			
About every 6 months	24(85.7%)	4(14.3%)	
About every 3 months	80(56.3%)	62(43.7%)	0.007
More often than every 3 months	46(67.6%)	22(32.4%)	
Travel Time			
30 and below	79(61.7%)	49(38.3%)	0.012
30-60 mins	60(72.3%)	23(27.7%)	0.012
above 60 mins	11(40.7%)	16(59.3%)	

Sociodemographic Characteristics by Urbanicity of the DCE Eligible Participants

Overall average Importance of Attributes								
Attribute	Importance (%)	SD	Lower 95% Cl	Upper 95% Cl				
Location of ART refills	19.52	8.67	18.42	20.63				
Adherence support provided	19.52	6.35	18.71	20.33				
Attitude of facility staff	16.14	7.99	15.12	17.16				
Frequency of clinical visits	14.76	4.95	14.13	15.39				
Frequency of receiving ART								
refills	12.61	5.33	11.93	13.29				
Person providing ART refills	11.21	3.68	10.75	11.68				
Refill pick-up/delivery times	6.23	3.6	5.78	6.69				

Appendix 2, Table 9: DCE: Mixed Logit Model—(a) Preferences and (b) Heterogeneity of Preferences for Differentiated Service Delivery Attributes

Attributes	β		[95% Conf. Interval]
(a) Preferences			
Location of ART Refill-Health Centre*	1.577776	1.269317	1.886235
Frequency of ART Refill-3months*	.9528386	.7296924	1.175985
Frequency of ART Refill-6months	.8155911	.5705752	1.060607
Adherence Support-Individual*	1.545326	1.287442	1.80321
Adherence Support-Group	1.410811	1.136038	1.685584
Attitude of provider-Nice*	1.612035	1.360024	1.864047
Frequency of Clinical Visists-3 months*	.6729288	.4526586	.8931989
Frequency of Clinical Visists-6months	.4852511	.2522637	.7182385
Person Providing Refills-Nurse	.409277	.1682442	.6503098
Person Providing Refills-Pharmacist*	.6423873	.4291403	.8556343
Refill Delivery times -Weekday during facility hours	.0432411	1743359	.2608181
Refill Delivery times -Weekday early Morning and evenings*	.1446003	0604727	.3496733
Location of ART Refill-Community Meeting Point	101084	3435435	.1413755
Attributes	β		[95% Conf. Interval]
(b) Heterogeneity across preferences			
Location of ART Refill-Health center	1.427234	1.120632	1.733836
Frequency of ART Refill-3months	.0584586	1603454	.2772626
Frequency of ART Refill-6months	.5903686	.2970387	.8836985

* Referenced attribute level

Appendix 3 – FGD Detailed Findings

Qualitative Findings on DSD Experiences

Among clients and health care workers, the predominant emerging theme surrounding the benefits of DSD was the **high satisfaction with the efficiency of services** in the clinic. Clients appreciate spending less time at the clinic and have more time to focus on other personal responsibilities. Health care workers appreciate the reduced workload, less congested facilities, and ability to have more focused time for clients with clinical care needs. Both clients and health care workers noted improved staff attitudes and more meaningful client encounters with the reduced workload. Perceived stigma with community models was a common thread among both clients and health care workers due to privacy and confidentiality concerns; therefore facility-based models were overwhelmingly preferred by clients. Clients and health care workers agreed that DSD services add to clients' motivation to adhere and stay virally suppressed, they do want to lose the privilege of DSD; they enjoy having more autonomy over their clinical care and also feel less stigmatized and more normalized since they are no longer spending a lot of time at the clinic. Recommendations centered on further spacing of refill and clinical visits, improved privacy measures and delivery points for discrete community delivery, more provider and client education on DSD services to stay abreast of updates and to promote adherence and suppression, and staggered clinic hours with staff incentives to accommodate clients who need to come early or late.

The qualitative findings are organized around four areas: 1. Experiences: satisfaction and benefits of DSD; 2. model preferences; 3. challenges, and 4. recommendations. Results below are first presented from the client FGDs, then from Health Care Workers (HCWs) FGDs, along with illustrative quotes.

1. Experiences: Satisfaction and Benefits of DSD Clients

Among clients on DSD, the predominant emerging theme surrounding the benefits of DSD was the **high satisfaction with the efficiency of services** in the clinic. They deeply valued having more time to focus on other personal responsibilities. They indicated that DSD reduced clinic visit frequency and time taken during a clinic visit. This is a substantial change from the past, when clients needed to allocate an entire day for their clinic visit on a monthly basis, often missing out on meals, income, and interrupting work, home, and school life. For those employed in the formal sector, farmers, and those running households, it can be difficult to make arrangements to be gone for an entire day. For those in the informal sector, being able to concentrate on finding a daily wage is important. Employers are also much more understanding if employees needed only a brief time away occasionally. Differentiated care services also altered how clients perceived their experiences when at the clinic, noting the improvement in efficiency compared to previously.

Feeling less perceived stigma within their households and communities was a common thread reported by clients in DSD. Clients felt that people in their community recognized the frequency of their monthly visits to the clinic, especially with frequent request for transport assistance and help with the household (eg. childcare) while they were away and equated this to them being HIV infected. Now with DSD, clients are able to keep a regular home and work life schedule and be like everyone else (more normalized). The majority of clients had preference for Fast Track model over community models. This was primarily due to the perceived stigma with the community model, the clinic provides more privacy and confidentiality. They also like the **autonomy to make decisions** as to when they pick their

medications, opportunity to time to reach out to the clinicians should they have any health problems during refill visits, such advantages were lacking in the community models. Another emerging theme was the **positive impact DSD had on their adherence and health**. Recognizing that good adherence and viral suppression qualified them for this model motivated them to sustain the behavior and good health outcomes.

When asked about interactions at the clinic, a **positive change in clinic work ethic** since the implementation of differentiated care theme emerged. Clients noted that health care workers are more supportive and engaged, actively listening, taking their work seriously, being respectful, and overtly less stressed. This applies to other departments as well, for example noting friendly services in reception. Prior to differentiated care, the clinics were overcrowded, staff were overwhelmed. It was common to witness staff dis-engagement, rudeness, and disregard for the never-ending long queues. Interactions during refills were largely positive, noting that the process is quick in terms of picking up medications devoid of being asked many questions.

Efficiency

LU-F: "there has been a great change, often a single mother like me could come to the clinic, stay up to very late in the evening then because I rely on a day to day work and pay, I end up sleeping without food because the entire day had been spent at the clinic. So this fact that when we come things are easier and faster taking very little time then go back to our work makes me happy."

SA-M: I am a fisherman, I sometimes move to far places in search of fish and the three months refill gives me an opportunity to concentrate on my work for a longer period and when time comes for refill it is easy to come and pick and get back to my work immediately without any delayed.

Less stigma

LU-F: "I don't come to the clinic frequently. People were used to seeing me leave my home for clinic on a monthly basis but now they have even forgotten that I visit the clinic and can't notice to stigmatize me when I visit. They now see me as equal to them because I am healthy, alive and going about my business just like all of them without any interruptions"

SA-F: It was easy to suspect or know that I am going to facility for HIV medication when I was coming for monthly clinical appointments. Differentiated care makes stay for long before visiting the facility making it difficult for anyone to know whether I am on HIV care or not"

Autonomy/trust

SA-F: Before differentiated care, we were coming to the clinic every month, clients in need of services were many and queues were longer. Health care workers were overwhelmed most of the days, and sometimes could be rude to us because of much pressure. We have very many changes today; the health care workers are happy all the time, supportive and the services are of quality because people are few and manageable.

LU-F: They have set us free, when we come to the clinic [clinic visit] they welcome us warmly and ask questions related to one's adherence to medication

Adherence motivation

RA-F: "...the motivation of having to come after three months for refill and six months for clinical visits have made me put more effort into adhering to medication so that I can continue with differentiated care services."

Positive change in staff work ethic

LU-M: The change I have noticed is that when you come for the six-monthly clinical visits the clinician takes much time with the patient compared to when I was coming on a monthly visit."

RA-F: [in peer led CAG] "Interactions with providers during clinical visits are good because they are friendly and supportive. What the clinician discusses during the visit include checking if you are using any family planning methods, adherence assessment and encouragement to sustain adherence. Even though we are in a peer-led ART group, at the six monthly visits, everyone comes to the clinic for review and usually it depends on the time one comes to the facility..."

<u>HCWs</u>

Similar to what clients described, HCWs described high satisfaction with the DSD approach with the predominate **benefit being the efficiencies DSD** has brought: With less congested facilities there are no queues, decreased waiting time for clients and a faster processing time, clients have less travel time to the clinic which reduces their transport costs and allows for more time for other activities, work, and school. It is particularly beneficial to clients who live quite far, for instance in Nairobi, reducing the burden of clinic attendance. In terms of how it has affected HCWs, with the **reduced workload**, they have indicated that they have **more time to focus on individual client needs** without feeling rushed as well as attend to other clinical responsibilities, and **feel much happier** without the fatigue of being overwhelmed with the client load.

Additionally, HCWs noted that clients feel **less stigmatized** in DSD. With fewer clinic visits clients feel more like a normal person living a normal life.

HCWs also indicated that the DSD approach serves as a **motivation to clients to adhere and remain suppressed** so they can stay in the DSD model of care. They have observed clients having increased interest in their viral load and feeling assured with their sustained viral load results. HCWs also mentioned how DSD has helped some clients feel **more empowered and trusted**, a sense of autonomy over their health which helps them adhere. It was noted that a few HCWs felt some clients may adhere less to the clinical appointments perhaps because they want to be in and out as they are during refill visits, but overall DSD has been more of a motivating factor for clients.

Efficiency

RA_HCP: The differentiated care is really working for us, it eases the waiting time for our clients, and it gives the clients themselves also comfort so that rather than visiting the facility on a monthly basis, they are able to come like in a year maybe twice or thrice.

LUM_HCP: Okay, I think differentiated care has really helped in the essence that the commission at the facility has reduced and it minimizes the time [clients take] for coming to the facility. And also give us health care workers time so that we [can] attend to the individual patient who has come with a problem without being on a rush..."

Staff attitude

SA_HCP: "We are having a happier workforce because the psychological challenge as a result of being fatigued all the time is a thing of the past."

Less stigma

RA_HCP "Yeah, like taking it positively like they are just like any other person. ...they are not coming to the hospital ... every other time. So it is normal, they are taking it like a normal lifestyle now."

SA_HCP006: "The other thing is that the differentiated care model has helped demystify HIV of being a killer disease, currently the model has shown that HIV is not even a disease that impair somebody's

ability to function. So with that, it makes other patients strive hard for them to be put on this model in order for them to avoid frequent hospital visits. So, I think that is a positive thing on the side of differentiated care."

Motivation to adhere

LUM_HCP: "Uh the impact is positive, in the sense that the clients who are in the Fast Track or given any form of the differentiated model of care, ... it makes them work harder on the adherence issues so that they maintain the same model of care."

RA_HCP: "Okay, for the people who are taken for sample for viral load, when they come back for a refill, they are very much concerned about their viral load and if you tell them that they are virally suppressed, they are very happy and would wish to maintain their DFC model so that they continue in that model for long"

Autonomy/trust

SA_HCP: "I can only share about one patient, this patient used to have high viral load and all over sudden it was a low level viremia....this client who stays in Nairobi currently ...He really appreciates having been introduced into differentiated care compared to when he had high viral load and he was kind of subjected to one month at most or rather two weekly appointments. He says that he now has the opportunity to plan how to keep his drugs safely and divide when he wants to travel because he has enough."

SA_HCP: "...when a client is subjected to coming to the hospital frequently, they feel patronized and they feel like they are under somebody's watch."

DSD model preference

Clients

There was a predominate preference for facility-based models in comparison to community-based models, primarily due to perceived HIV related stigma coupled with lack of privacy and confidentiality. There was perception of fear that joining a community ART group could lead to people learning about one's HIV status. This fear extended to health care workers delivering ART in community, because their presence would increase suspicion. Also given the high volume of clients living with HIV, maximizing a health provider's reach to provide care for clients at the facility was emphasized. Perceived stigma carries a lot of weight and going to a health facility for HIV care is a way of control and reduce the risk of others knowing one's HIV status.

RA_M: "I prefer the facility Fast Track model because the community- based ART groups are prone to stigmatization."

RA_M: "HIV related stigma is the main issue at the community which is why I chose the option of joining an ART group but one which is based at the facility because all of the group members for from different communities, with this I escape the stigma that I may experience from my community."

SA M: "The problem is with the community members, when they will see medication being delivered to use, they will start gossiping about our HIV status and the medication we are taking. In my opinion, the suggestion by the clinician will not be possible at the community because of stigma, I think people should meet at the facility."

RA_M: "In my whole life, I don't like rumors and as a result to avoid stigmatization and gossip related to my HIV status, I made a choice be coming for my medication refills at the facility where I can meet the clinician when I want, and, in case I have a disagreement with a clinician I am confident that it will be resolved at the facility level without attracting community gossip. I don't like community ART groups for another reason, the providers leading the distribution of medicine at the community are not discreet in handling the medication refill distribution. I witnessed a provider walking in the village carrying the medicine and visibly one could see that she was carrying ARVs and to make it worse, she shared with people who bothered to ask where she was taking the medicine disregarding the confidentiality that is required. After that incident, I can only suggest that a better way should be used to distribute those medication at the community putting into consideration the privacy of the clients benefiting from the service."

<u>HCWs</u>

HCWs indicated that clients like the efficiency of Fast Track, no more queuing; it's convenient to go to the clinic if you know you will be in and out and return to your normal activities. For those in the formal work sector or living in distant locations (eg. Nairobi), Fast Track has helped reduce the burden of work interruptions due to fewer clinic visits. Fast Track also provides more privacy assurance; there are no issues of possible disclosure in the community or other unknowns. HCWs also expressed their preference for Fast Track due to perceived stigmatization in the community. One HCW did mention that although facility refills are preferred, the community option is sometimes preferred by those unable to get the facility.

RA_HCP: Fast Track. In Fast Track, the client's privacy is guaranteed for them in the facility.

LUM_HCP: Yes, most of them prefer facility refill because of fear of the unknown maybe they fear somebody will get to know their status outside there in the community.

LUM_HCP: I think the other reason why they prefer the facility where they are fast tracked is also the convenience because we have clients who have busy schedules so they are always glad that they have to come to the facility. They don't have to go through the hectic process of queuing, they just come and go to the pharmacy get their drugs and get back to what they have to do.

Challenges with DSD Clients

The predominant theme was being very pleased with differentiated care services and not experiencing challenges, as stated by *RA-M: Since I started differentiated care, I have not experienced any challenges.* The most pronounced challenged mentioned was lack of Septrin, although this issue is not related to DSD.

In terms of DSD challenges that were expressed, a theme of disinterest in community groups emerged due to perceived stigma occasioned by lack of privacy and confidentiality on the part of the distributor, leading to a strong preference for Fast Track model of DSD, see illustrative quotes above in "Model Preference". This was mentioned in all FGDs. In regards to the community model, one community member peer lead revealed the challenges of no shows when delivering ART to the agreed upon place and time - therefore, using his/her own time and transport money to look for the members and deliver their medication. Some may forget, others may be elderly or ill and unable to come.

There were some site specific challenges: Long queues at Sango Rota for clinic visits and refills possibly due to HIV/OPD integration, however some said it is because clients may come in late for their appointments (see notes below). Unwelcoming support staff was mentioned at Sang Rota. Little interaction with pharmacists emerged as a challenge at Lumumba "exchange of hands only", without the pharmacist asking how they are doing and feeling rushed at the refill point, therefore not feeling inclined to bring up any health issues they may experience.

<u>HCW</u>

When asked about challenges around DSD, the most pronounced theme indicated by HCWs was perceived stigma surrounding community DSD models, for both adults and adolescents. The communities recognize blue plated motorbikes and medication packaging and therefore clients fear being labeled as HIV positive in the community. Adolescents in school, informal work sector at market places, and others in community setting are very concerned about any possible breaches of confidentiality. HCWs feel this is why Fast Track is the most preferred approach. With the community approach, there were also concerns about: scheduling and reliability - if a client is not found in the community it delays delivery to other clients that day; fear of COVID-19 risk, and staffing concerns to support community delivery when the health care workers are needed at the facility.

Challenges related to Fast Track were less common, initially there were many concerns about refill queues but the facilities created separate refill benches to address this challenge. Another theme identified by some HCWs was associating DSD models with relaxed adherence among some clients, especially among adolescents. A sense that when clinic appointments are spaced far apart they may feel less need to take their medications every day. It also emerged that some HCWs have experienced some DSD clients with high expectations about getting in and out of the clinic on refill day, which leads to impatience when it takes a little longer than expected.

LUM_HCP: "You know, once you get there and I see you with that envelope, and that blue plate motorbike, automatically I will know that you are taking ARVs because there are people, I will pretend that I am also a member but I want to know what is going on."

RA_HCP: "So the main challenge with the community-based ART distribution, is the issue of stigma and confidentiality, and that is the reason as to why we have almost ¾ of our clients in DFC doing Fast Track."

Recommendations for DSD Clients

Clients are very pleased with DSD, but a few themes emerged for consideration for further improvement, including dedicated DSD clinic days for Fast Track for efficiency, further spacing of appointments to annual. Harmonized refill dates for those in facility-based groups were also suggested to allow for discussion of issues when picking up refills.

<u>HCWs</u>

In regards to Community DSD models, recommendations to help provide ART discretely to mitigate stigma emerged strongly. Recommendations centered on listening to client's voices and needs and responding authentically, not imposing HCW ideas or conveniences on them for community delivery. It was suggested that more attention to finding out what venue in the community might work, for instance a church or nearby medical facility may help. Using couriers was suggested as a way to overcome stigma, prevent extra HCW time in the field, and leverage a business that is experienced in delivery. Consideration of using peer or Community Health Volunteers from the area was also suggested. Currently the vehicles and packaging are very well known as HIV related services, therefore couriers could overcome the vehicle issue and changing up the packaging could address the later.

For Fast Track, longer TCA's emerged as a common theme. HCWs often encounter clients requesting 6month refills or even longer spacing between clinical visits. For instance, either twice annual clinic visits and obtain 6 month refills at the same time or annual visits with twice annual refill visits. This would help those who live distant or have a hard time getting to the clinic. To that end, pharmacies or health centers near clients were also suggested for refill pick up, with us coordinating with the pharmacies. They also advocated for a sufficient supply of drugs, noting that sometimes due to stock clients receive short refill TCA, which isn't what was promised when they entered DSD, however this is unfortunately out of the facilities control. Staggering staff shifts or working extra hours with allowance was also suggested to accommodate clients who need to arrive early or after 5pm.

For both community and facility-based approached, increased staff education on DSD was suggested so they stay abreast of the best ways to deliver the service. On the other side, increased client education to ensure clients remain aware of the importance of visit attendance and adherence was also recommended.