Implementation of HIV/AIDS Differentiated Service Delivery Models and Healthcare Process Outcomes in Siaya County, Kenya: An Observational Assessment

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Executive Summary

With PEPFAR now focused on achieving sustained epidemic control, this calls for a shift in focus from an emergency response to a sustainable health system strengthening approach. With a global shift towards having ART treatment for all HIV-infected individuals and in the context of widespread overcrowding and heavy workloads for healthcare workers in HIV clinics in sub-Saharan Africa (SSA),differentiated care service delivery models (DSD) that customize HIV care to individual client needs are imperative. These differentiated care models look to move stable patients from facility support to community support, ensuring they receive high quality of services while reducing the burden of multiple visits on both the patient and the health system.

The goal of this descriptive evaluation was to provide baseline characterization on DSD implementation in practice at different service delivery levels in Siaya county, Kenya. Specifically, we sought to describe the specific elements in each DSD model, coverage of each model and mix of models as implemented in HIV clinics in Siaya, assess association between i) individual level participation in differentiated care and ii) facility level DSD model coverage with service delivery (quality of care) outcomes and finally, describe efficiencies in service delivery under different DSD approaches from both patient and health worker perspectives.

The evaluation was implemented through a mixed methods approach. Findings from a formative qualitative survey with HIV service delivery implementing partners were used to refine the data collection tools and methods. A health facility survey captured data on facility attributes and DSD model implementation approach. Individual level participation in DSD was obtained by abstracting patient medical charts. To assess efficiencies in service delivery, a time log was used to collect data on patient-provider contact time and patient wait times, both in clinics and during group ART meetings. Finally, qualitative perspectives on DSD efficiencies were obtained from healthcare workers, ART group leaders and health managers through key informant interviews and focus group discussions. This was done over six weeks in Sep-Oct 2019.

Seventy- six facilities were surveyed on facility attributes and DSD model implementation approach. Majority were dispensaries and 46% had between 100 to 500 ART patients. The DSD models described by facilities were multi-month scripting (MMS), Fast track refill (FTR) visits, ART groups and Extended facility hours. MMS was perceived as norm, available in all facilities and often not considered a model of differentiated care. Three quarters (74%) of the clinics reported having extended clinic hours,95% reported offering fast track refill visits while 88% had an ART group (either facility-based [held meetings on facility grounds to avoid stigma in the community] or community based).However, this was discordant from what was observed from

2,053 individual patient records, where DSD participation in ART groups was only 2.4% and only 25% had a fast track refill noted on their chart. In terms of model mix,84% of facilities reported having MMS+FTR+ART groups, yet only 24.2% of the patients participated in at least 2 of the 3 DSD models from their medical records. This could be due to improper documentation. Some models e.g. extended clinic hours are not captured on individual patient records hence coverage cannot be ascertained. It could also be due to limited and varied understanding of various definitions of DSD models. e.g. In smaller facilities, the distinction between a clinical visit and a fast track refill visit was unclear, since the services offered during either type of visit were the same

Individual-level participation was associated with quality of care outcomes.Specifically, patients participating in all three DSD models (MMS+FTR+ART groups) had a 5.1-fold greater likelihood of being classified as having good adherence ($p<0.05$), a 2.2-fold greater likelihood of having a viral load test documented ($p<0.01$), and a 1.8-fold greater likelihood of having an undetectable VL ($p<0.05$), compared to patients with MMS only. There was a trend toward higher likelihood of favorable quality of care outcomes when DSD coverage was highest.

Looking at efficiencies, the median duration of a clinic visit was 68 minutes, with 72% of this time spent waiting. There was wide variation across facilities in the total patient visit duration as well as waiting time. When comparing durations across health facilities, median values for clinical consultation ranged from a high of 10 minutes to a low of 1 minute. Being a county hospital and having more patients on ART was significantly associated with a longer waiting time, while having extended hours was significantly associated with reduced total clinic visit time as well as waiting time. Median duration of group meetings was one hour and 12 min, which is 4 min longer than the median clinic visit time. Given that there is no waiting time in groups, this means group participants spent all their time receiving services. However, group participants noted that they missed out on some services during group meetings which they previously received during clinic visits. e.g. family planning services, blood pressure measurement and nutritional review and counselling. A few groups reported having a common clinical consultation visit during their clinic appointment. i.e. they are all reviewed by the clinician in a single sitting. Documentation on the conduct of a group meeting varied highly and was not standardized.

Qualitatively, different stakeholders perceived advantages of DSD as relating to reductions in facility workload and reducing the number of visits for clients by increasing prescription times for stable patients. Both patients and HCWs felt that DSD gives healthcare workers more time to focus on patients who really need their support. Notably, HCWs mentioned that DSD can help improve patient retention, since reduced visits were a motivation for people to adhere to their

clinic or group appointments, as was the prospect of being dropped from DSD (hence more clinic visits) should they be non-adherent or have unsuppressed viral load. A major concern was the fear of redundancy for HCWs due to reduction in workload.

In conclusion, DSD was positively perceived by patients, healthcare workers and health managers, with wide support. There was a discordance between availability of DSD models and coverage of these methods from individual patient records, a mismatch that can be corrected through better documentation as well as standard definitions of DSD model components, to allow for better comparison across facilities and evaluation of associations between DSD models and service delivery efficiencies as well as quality of care outcomes.

Acknowledgements

This evaluation was made possible by the participation of implementation partners, namely Center for Health Solutions (CHS-Timiza), Siaya County Department of Health HIV Service Delivery Project (NGIMA for Sure) and Kenya Conference of Catholic Bishops, whose officers provided invaluable formative information, participated in training of data collectors, organized logistics at the facility level to ensure data collectors were able to interview the appropriate staff and collect the required data.

We acknowledge the leadership and support by the Siaya county health management team and sub-county officials, who provided feedback in the proposal development phase, enriching the evaluation approach; and who allowed us to access their facilities for this exercise.

We thank the patients, the peer educators and the healthcare workers who participated in this evaluation.

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Acronyms

ART	Antiretroviral Therapy
ARV	Antiretroviral drugs
BMI	Body Mass Index
BP	Blood Pressure
CAG	Community ART Group
CCC	Comprehensive Care Clinic
CHS	Center for Health Solutions
CI	Confidence Interval
DC	Differentiated Care
DSD	Differentiated Service Delivery
ESC	European Society of Cardiology
ESH	European Society of Hypertension
fART	Facility ART Group
FGD	Focus Group Discussion
FP	Family Planning
FTR	Fast Track Refill
GEE	Generalized Estimating Equations
HCW	Health Care Worker
HRH	Human Resources for Health
HRSA	US Health Resources and Services Administration
I-AETC	International AIDS Education and Training Center
IQR	Interquartile Range
IRDO	Impact Research and Development Organization
I-TECH	International Training & Education Center for Health
KCCB	Kenya Conference of Catholic Bishops
KeHIS	Kenya Health Information System (DHIS)
KII	Key Informant Interviews
MMS	Multi month Scripting
MOH	Ministry of Health
NASCOP	National AIDS and STI Control Program
OGAC	US Office of The Global AIDS coordinator
OI	Opportunistic Infection
OR	Odds Ratio
OTZ	Operation Triple Zero
PEPFAR	The President's Emergency Plan For AIDS Relief
PMTCT	Prevention of Maternal To Child transmission
SSA	Sub-Saharan Africa
STI	Sexually Transmitted Infection
TB	Tuberculosis
TCA	To-Come-Again
T-I-M	Time in Motion
TWG	Technical Working Group
VL	Viral Load
WHO	World Health Organization

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Background

While the gains under global support for HIV/AIDS Care and treatment have been tremendous, PEPFAR is now focused on achieving sustained epidemic control[1]. In 2013, PEPFAR aligned its programming with UNAID's 90-90-90 goals (90% of people know their status, 90% of those knowing their status should be on ART (Antiretroviral Therapy) and 90% of those on treatment achieve viral suppression)[2]. In 2015, WHO recommended that all HIV-infected individuals should start ART irrespective of CD4 cell count or clinical presentation. In order to accomplish these goals in the context of widespread overcrowding and heavy workloads for healthcare workers in HIV clinics in sub-Saharan Africa (SSA), innovative and efficient HIV service delivery models became imperative.

Differentiated service delivery (DSD), defined as 'a client-centered approach that simplifies and adapts HIV services across the cascade, in ways that both serve the needs of people living with HIV better and reduce unnecessary burdens on the health system'[3] was endorsed by WHO and other leading global HIV donors in 2016 as an evidence-informed HIV service delivery approach that that relieves pressure on over-burdened health systems in SSA[4],[5]. Customizing HIV care to individual client needs has been shown to improve the quality of HIV care and patient outcomes[6],[7]. Since 2017, several countries in SSA including Kenya, Malawi, Uganda and Zambia have been implementing DSD[8].

One of the main frameworks that informs HIV DSD by Duncombe et al describes DSD as "delivery of the right care at the right frequency to the right individuals by the right care providers in the right location at the right time."9 Elements of DSD models therefore address service intensity, frequency, location and cadre of HCW offering the service, as shown in Fig 1 below.

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[1] PEPFAR, Sustainable HIV Epidemic Control, Pepfar.gov

[2] UNAIDS, 90-90-90 An ambitious treatment targets to help end the AIDS epidemic, Geneva: UNAIDS 2017

[3] Grimsrud A, Bygrave H, Doherty M, Ehrenkranz P, Ellman T, Ferris R, Ford N, Killingo B, Mabote L, Mansell T, Reinisch A. Reimagining HIV service delivery: the role of differentiated care from prevention to suppression. J Int AIDS Soc. 2016;19(1):21484.

[4] WHO (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach. Second edition. Geneva, Switzerland

[5] Duber, H. C., Coates, T. J., Szekeras, G., Kaji, A. H., & Lewis, R. J. (2010). Is there an association between PEPFAR funding and improvement in national health indicators in Africa? A retrospective study. Journal of the International AIDS Society, 13, 21. http://doi.org/10.1186/1758-2652-13-21

[6] Grimsrud A, Bygrave H, Doherty M, Ehrenkranz P, Ellman T, Ferris R, Ford N, Killingo B, Mabote L, Mansell T, Reinisch A. Reimagining HIV service delivery: the role of differentiated care from prevention to suppression. J Int AIDS Soc. 2016;19(1):21484

[7] Prust ML, Banda CK, Nyirenda R, Chimbwandira F, Kalua T, Jahn A, Eliya M, Callahan K, Ehrenkranz P, Prescott MR, McCarthy EA. Multi-month prescriptions, fast-track refills, and community ART groups: results from a process evaluation in Malawi on using differentiated models of care to achieve national HIV treatment goals. J Int AIDS Soc. 2017;20:21650

[8] Roy M, Moore CB, Sikazwe I, Holmes CB. A review of differentiated service delivery for HIV treatment: effectiveness, mechanisms, targeting, and scale. Current HIV/AIDS Reports. 2019;22:1.

[9] Duncombe C, Rosenblum S, Hellmann N, Holmes C, Wilkinson L, Biot M, Bygrave H, Hoos D, Garnett G. Reframing HIV care: putting people at the centre of antiretroviral delivery. Tropical Med Int Health. 2015;20(4):430–47.

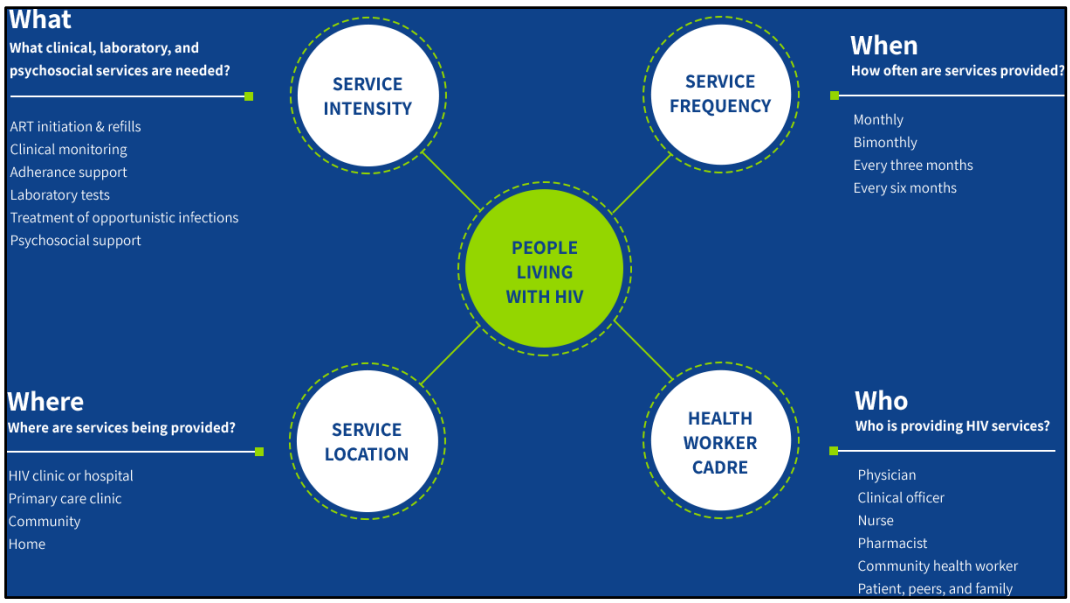


Figure 1:DSD conceptual framework

There are various characterizations of DSD models. The Kenya National DSD Operational guide[10] outlines differential management of patients based on their initial presentation (clinical/immunological status around the time of enrollment) and then once they have been in care for at least 12 months, as shown in Figure 2 below.

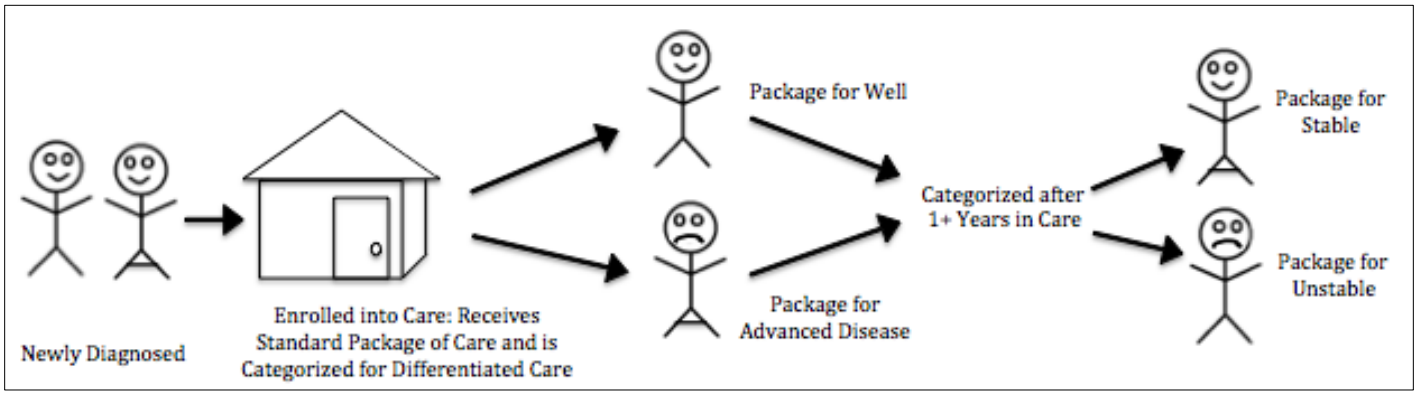


Figure 2:NASCOP's classification for DSD eligibility

This descriptive evaluation focused on characterization of differentiated care among well and stable patients. The DSD models described include:

- Multi-month scripting
- Fast-track refill
- Extended facility hours
- ART group

[10] Ministry of Health, National AIDS and STI Control Program. Differentiated Care: Operational Guide. Nairobi, Kenya: January 2017

Regardless of the service delivery tasks within a DSD model, each model looks to move stable patients from facility support to community support, ensuring they receive high quality of services while reducing the burden of multiple visits on both the patient and the health system.

The goal of this descriptive evaluation was to provide baseline characterization on DSD implementation in practice at different service delivery levels in Siaya county, Kenya.

The specific objectives of the study were:

Objective 1a: To describe the specific elements in each DSD model, coverage of each model and mix of models as implemented in HIV clinics in Siaya county.

Objective 1b: To assess association between i) individual level participation in differentiated care and ii) facility level DSD model coverage with service delivery (quality of care) outcomes.

Objective 2: To describe efficiencies in service delivery under different DSD approaches from both patient and health worker perspectives.

Siaya was selected as the focal county for this evaluation because of interest in describing real-world implementation of DSD within a region of Kenya with a very high HIV burden. The baseline information generated from this evaluation provides a basis for making informed decisions in strengthening implementation of DSD. In addition, this evaluation provides initial evidence of patient experiences of different DSD service delivery points in Kenyan health care facilities at different levels.

Methods

Study Design

This evaluation was observational, utilizing both qualitative and quantitative data (mixed methods), with the qualitative methods used in an exploratory then explanatory sequential approach[11]. (Figure 3)

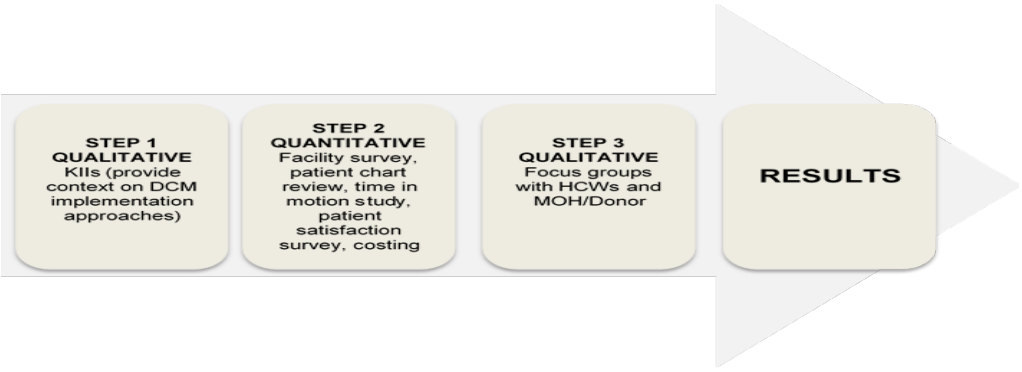


Figure 3: Mixed methods study approach

[11] Kane, H., M. A. Lewis, et al. (2014). "Using qualitative comparative analysis to understand and quantify translation and implementation." Translational Behavioral Medicine 4(2): 201-208.

Study Site

The evaluation was conducted in Siaya County in the Western region of Kenya. Siaya, with a HIV prevalence of 15.3%, is ranked third highest among the 47 counties in Kenya[12] and is one of the priority sub-national units (SNUs) where PEPFAR and the MOH aim to provide scale up of HIV services to saturation in order to achieve HIV epidemic control.

The county has over 150 facilities, of which 137 are supported by PEPFAR to provide HIV services through several implementing partners (IPs). These include Centre for Health Solutions (CHS), Department of Health Siaya County (NGIMA For Sure), Impact Research & Development Organization (IRDO) and Kenya Conference of Catholic Bishops (KCCB).

The health facilities are distributed as shown below:

The distribution of healthcare facilities offering HIV treatment services in Siaya county as at Dec 2018, which formed our sampling frame, are as shown below:

Service Level	**N$^{o/}$**	**%**
Dispensary	79	58
Health Centre	45	33
Sub-county hospital	11	8
County hospital	2	1
TOTAL	137	100

Table 1: Sample frame of CDC-supported facilities offering HIV services in Siaya county

Data Collection

Step 1: Formative Step

Qualitative Stakeholder Engagement Interviews

A meeting with county and sub-county MOH officers and implementing partners in Siaya county was held. The proposed approach, data collection tools and evaluation design were shared with these officers, who then gave their input.

A semi-structured interview guide was used to collect more detailed information on DSD approaches. The respondents were program officers from the implementing partners (IPs). This was used in refining the data collection tools, particularly those targeting community ART groups given contextual knowledge gathered during these interviews

Figure 4: Sub-counties within Siaya county

[12] KENPHIA 2018: Preliminary Results

Step 2: Substantive Data collection

Data was collected over 6 weeks between September 3,2019 and Oct 11, 2019.The data collection approach was aligned to the objectives as follows:

Objective 1A: *To describe the specific elements in each DSD model, coverage of each model and mix of models as implemented in HIV clinics in Siaya county.*

Health Facility Survey: This questionnaire captured data on facility attributes, DSD approaches, and HRH cadre and task mix. The questionnaire was cross sectional (status as at the time of data collection) at the target health facilities. The instrument was based on a customized version of Site Level Health Workforce assessment tool developed by the Office of the United States Global AIDS Coordinator and Health Diplomacy (*OGAC*) HRH TWG. Using this tool, managerial staff at the health facilities and PEPFAR implementing partners were asked questions related to number of each cadre of health workers, HIV specific task allocation, performance management and training of cadres of health workers based at health facilities and communities. The questionnaire was administered by trained data collectors at the sampled health facilities. Respondents were made aware in advance of the dates the data collection team would be visiting the sites, so they could compile the information. The interviews were administered in two parts: the respondent for the first part was typically the facility in charge, as this was geared towards the facility in general. The 2nd respondent was typically someone who worked in comprehensive care center (CCC), mostly the in-charge or their designated respondent. Written informed consent was obtained prior to the interview.
For the questions that required review of records e.g. average patient load per day, the data collectors retrieved the numbers from the registers. Some of these e.g. number of patients currently on ART were confirmed by the data team at I-TECH from the KeHIS.

Objective 1B: *To assess association between i) individual level participation in differentiated care and ii) facility level DSD model coverage with service delivery (quality of care) outcomes*

Patient Chart Review: To assess individual level of participation in DSD, patient level information from their medical records was abstracted. Paper-based records and EMRs were used to derive the list of ART patients who had been active at any point during a defined 12-month period (Oct 2017 through Sep 2018). Being active during the time period meant having received clinical care in the health facility or having received community-based HIV care services at any point during the period. From the list of active patients, a simple random sample was drawn via conventional methods (defining a sampling interval, n, by dividing the total number on the list by the desired sample size of 90 records per site, then identifying a random number between 1 and n as the “starter patient”, then picking the nth patient

from the list and repeating the last step until the sample size is reached). The patient charts, including both paper-based and electronic charts, were used to extract information to the patient chart abstraction tool.

The tool assessed patient demographics; HIV-specific characteristics e.g. duration in care, duration on ART, disclosure status; participation in various DSD models e.g. multi-month scripting, ART group refills and some quality of care (implementation) outcomes e.g. adherence assessment, blood pressure monitoring

Objective 1C: *To describe efficiencies in service delivery under different DSD approaches from both patient and health worker perspectives.*

Clinic Time-in-Motion Assessment: A time log was used to collect data on patient-provider contact time and on patient wait times at sampled health facilities. All patients included in the sample (a target average of 6 per day per site) were informed about the study, and written informed consent was obtained. They were issued with a time slip and simple clock which they carried with them to different service delivery points. At each service delivery point, the service offered, time in and time out were filled, either by the patient or the healthcare provider. The patient returned their completed log to the data collector when they were ready to leave.

Since some patients came in very early before regular operating hours, the data collectors worked collaboratively with the peer mentors in the facility who were on duty in the very early morning hours, and the peer mentors assisted with the process.

The clinic time-in-motion was assessed among all patients and not necessarily those under any DSD model.

Group Time-in-Motion Assessment: Data collectors sat in the ART group meetings in the community (CAGs) and in the facility (fART groups). Liaising with the group leader prior to the meeting, the group leader obtained permission from the group members for the data collector to attend the meeting the following day. During the meeting, data collectors explained the objective of the evaluation and obtained consent from the group members. They then collected demographic information on the group (date formed, number and sex of members). During the meeting, the data collector noted each activity and its duration.

Key Informant Interviews: A semi-structured interview guide was used to collect detailed information on DSD approaches. Respondents included Siaya County health officials and program officers from the implementing partner mechanisms. Participants were purposefully selected with the help of co-investigators to ensure representation of a broad range of perspectives regarding DSD models. implementation in the county. After the interview, interviewers wrote a short interview summary highlighting main themes seen in the interview.

Focus Group Discussions: A semi-structured interview guide was used for focus group discussions with health care workers. Respondents included health care workers of various cadres with involvement in different types of DSD approaches at different levels of health facilities. They also included peer mentors who were largely the ART group leaders. Participants were purposefully selected and grouped with other similar personnel to maximize comfort in sharing ideas (e.g. clinicians, community health workers and volunteers, and health managers). After the discussion, interviewers wrote a short FGD summary highlighting main themes seen in the discussion.
FGD participants received reimbursement of Ksh.500 each for transport.
Quantitative data from both clinic and group time-in-motion assessments was used to assess associations between service delivery efficiencies (time spent receiving service vs waiting) and facility level DSD model mix and coverage.

Data Collectors

Ten data collectors were divided into pairs, forming five dyads. For the first 25 facilities, each dyad visited a site for 5 days, during which they completed the patient satisfaction surveys, time-in-motion log, patient chart review and the facility survey. For the remaining sites, each data collector visited two sites per day for the facility survey.

For the qualitative data collection, there were two data collectors who are well trained in interviewing technique and conducting FGDs, having done similar work in the past within other University of Washington research studies.

Data Collection and Storage

All quantitative data was collected on REDSDap®, using tablets provided by I-TECH. Written consents and any other data collected on paper e.g. total number of patients visiting the CCC on a particular day were stored in a secured cabinet at the Ngima office. These were couriered weekly to the I-TECH offices. For qualitative interviews, with participants' written consent, interviews were audio recorded and transcribed. Audio files and transcripts were stored in secured OneDrive folders. Interview notes

and signed written consent forms were stored in a secured cabinet at the Ngima office. These were couriered weekly to the I-TECH offices.

Data Quality Assurance

To maintain high standards of data quality, multiple checks were built into the electronic versions of the tools e.g. date of diagnosis could not be after date of ART initiation.

For the patient chart abstraction, clinic time-in-motion and patient satisfaction survey, a research assistant in Seattle ran a set number of logic checks specific to each tool. Entries which did not meet the logic checks, missing values and outliers for numerical fields were flagged. These were sent back to the data collectors before they left that facility, for checking and correction. This was done concurrently with data collection.

Data Analysis

Study Measures

Multi-month scripting [MMS]	Patient receives a prescription for several months during their clinic visit
Fast-track refill [FTR]	Patient gets their ART drug refill without necessarily being reviewed by a clinician, following receipt of a multi month prescription. Alternating this with clinic visits allows for adjusted appointment spacing.
Extended clinic hours	HIV clinic operated beyond the standard operating hours. This could be early in the morning (before 8:00 am), later in the evening (after 5:00 pm) or both. It also includes offering services on weekends when the health facility would otherwise be closed.
ART Groups	ARVs dispensed in a group setting. This could be characterized by the venue of the group meeting (facility vs community ART groups) or by the group leadership (HCW vs peer-mentor led). Facility ART groups meet within the facility compound but do not otherwise interact with the health system in any other way during the group meeting.
DSD models	The four DSD models described are: - i) multi-month scripting ii) fast-track refill iii) extended clinic hours iv) ART groups

DSD Coverage	Having MMS only was considered the basic form of DSD model since all facilities reported having MMS. DSD coverage was therefore defined as low, medium or high depending on the proportion of records abstracted that had MMS only as the DSD modality observed in the patient records. ●Low coverage sites were defined as those where the proportion of records with MMS only was greater than the 75th percentile. ●Medium coverage as those where the proportion of records with MMS only was between the 25th and the 75th percentile. ●High coverage as those where the proportion of records with MMS only was below the 25th percentile.
DSD Coverage (binary)	This was defined using the median proportion of individual records with MMS only, hence low coverage facilities had above median proportion of individual records with MMS only and high coverage facilities had below or median proportion of individual records with MMS only.
DSD mix	The various combinations of DSD models as described by the facility or as observed from the individual patient charts.
Quality of Care outcomes	These were related to timeliness of service, completed documentation and patient level outcomes. They included:- I. Level of completeness of documentation at most recent clinic visit for the following parameters: • Weight • BMI • Blood Pressure • Adherence Assessment • STI screening • TB screening • OI screening II. BP monitoring over the last 4 clinic visits III. Adherence assessment over the last 4 clinic visits IV. Viral load suppression over the one year under study review V. Viral load documentation over the one year under study review VI. Recent visit being scheduled or unscheduled

Data Cleaning

For the facility survey, missing or non-logical values were confirmed by calling back the site for clarification. If the site was unreachable, values were treated as missing.

For the patient charts, a lot of missing, duplicate or out-of-order dates were noted for those with multiple clinic and refill visits. These were cleaned out based on chronology i.e. if there were dates for 6 clinic visits but only 4 were valid, the invalid dates were dropped.

For the clinic time-in-motion assessment, data were entered to a spreadsheet. Cases with missing time values for start or end of visit, or for times recorded out of order (i.e. an end time which preceded a start time) were treated as missing data. One clinic was excluded from analyses of overall duration of visits and patient waiting time, because data collectors recorded elapsed time at each service delivery point

but not clock time from the start to the end of the visit. While analyzing the typical duration of service at each service point, we excluded observations where either the starting or ending time was missing or where the duration was estimated as a negative value or as a value exceeding 480 minutes.

Data Analysis

Objective 1a: To describe the specific elements in each DSD model, coverage of each model and mix of models as implemented in HIV clinics in Siaya county.

Facility characteristics were summarized using frequency tables.

DSD models were summarized as present or absent and their frequency described. For each model, descriptive details on how it was offered were summarized. Quantitative data from the group time-in-motion assessments was used to characterize the ART groups. This included date when group was formed, number and sex of members.

Overall patient demographics from the chart abstraction were summarized using medians, interquartile ranges (IQR), and proportions.

Using criteria outlined in the NASCOP Differentiated Care Operational Guide, patients who met certain exclusion criteria but were still in differentiated care were summarized.

Overall and clinic-specific frequency and proportions of various DSD models and final DSD mix observed in all the patient charts from that clinic were summarized.

DSD coverage was described using two-way frequency tables, by facility service level, count of active ART patients and proportion of outpatient visits that were for HIV services.

Objective 1b: To assess association between i) individual level participation in differentiated care and ii) facility level DSD model coverage with service delivery (quality of care) outcomes

Quality of care outcomes were summarized using frequency tables.

i) Association between individual level participation in any DSD model and each quality of care outcome (ii-vi) was assessed using generalized estimating equation (GEE) regression models, which considered the implementation outcomes to be correlated observations which were nested within the health facility.

ii) Facility-level predictors of coverage were assessed using logistic regression. These included: facility service level, count of active ART patients and proportion of outpatient visits that were for HIV services.

Finally, association between facility level coverage and each quality of care outcome was assessed using GEE models.

The GEE models assumed the outcomes to be binary with binomial distribution and used an identity link.

Objective 2: To describe efficiencies in service delivery under different DSD approaches from both patient and health worker perspectives.

From the clinic T-I-M, we summarized the following observations using medians, interquartile ranges (IQR), and frequency tables, both overall and for each clinic.

- total duration of the visit
- the duration spent in clinical activities
- the duration and proportion (%) of total time spent waiting
- total number of service points, or stations, visited within the clinic for each observed patient visit.

For service point-specific analysis, we analyzed data on starting and ending times for each type of service point, or station, within the clinic workflow. We calculated the proportion of all visits which included patient care for each type of service point, then produced descriptive summaries of the typical duration of service at each service point.

Finally, we examined facility-level predictors (facility service level, count of active ART patients and proportion of outpatient visits that were for HIV services) of three efficiency outcomes:

I. total duration of observed patient visit
II. proportion of time spent waiting during observed visit
III. duration of clinical consultation

We generated descriptive summaries of the outcomes by each facility-level predictor.

We also examined associations between facility-level DSD coverage (see description above) and the three efficiency outcomes using GEE regression models. These models considered the observed visits to be correlated observations which were nested within the health facilities. The models assumed the outcomes to be continuous with normal distribution and used an identity link.

From the group T-I-M, each activity's duration was noted and summarized using the median and IQR.

For the health managers, health care workers and patient leaders (peer mentors), audio files from key informant interviews (KII) and focus group discussions (FGD) with healthcare providers and ART group leaders (peer mentors) were transcribed verbatim and translated into English. Transcript files were uploaded into Dedoose qualitative software for coding and analysis.

An initial codebook was developed based on the KII and FGD interview guides. Primary and secondary codes were derived from themes in the guide questions and prompts. The codebook was reviewed by two independent coders prior to transcript review for completeness and relevance to overall study objectives. A deductive coding approach was applied to the initial 4 transcripts (2 KIIs and 2 FGDs) and the codebook was updated iteratively with the coding of these initial transcripts in an inductive manner. Two researchers coded the study transcripts; one researcher was the primary coder for the KIIs and the other was the primary coder for the FGDs. The primary coders coded all transcripts within their category. The secondary coders reviewed a subset of the primary coders' transcripts (2 transcripts of

each type) for code application and coding comprehensiveness. Any disagreement in code application or any coding additions were discussion during a resolution session with the two coders.

A summary table of results was constructed based on the primary themes used to create the codebook. Results are presented by key stakeholder group and data collection method. Representation of key themes specific to each stakeholder group are listed as bullet points in the table with illustrative quotes from the study participants. Bullet points in bold italics represent themes that were mentioned frequently by respondents or stressed as being of particular importance.

Results

Objective 1a: To describe the specific elements in each DSD model, coverage of each model and mix of models as implemented in HIV clinics in Siaya county.

Facility Characteristics

Seventy-six facilities were visited over the six weeks. Their characteristics are as shown in Table 2. A majority of the facilities were dispensaries (61%), while the two county hospitals in Siaya county were also included. They were also proportionally distributed across the six sub-counties, with 49% of the facilities derived from the large sub-counties (Alego Usonga, Bondo) and 7% of the facilities from the smallest sub-county (Ugenya).

From a workload perspective, ambulatory HIV clinic visits made up 11-20% of all outpatient clinic visits for about half of the facilities surveyed (51%). HIV clinic visits represented >40% of all outpatient visits in only four of the facilities surveyed.

Characteristic	**N=76**	**%**
Service Level		
Dispensary	46	61
Health centre	24	32
Sub-county hospital	4	5
County hospital	2	3
Sub-county		
Alego-Usonga	19	25
Bondo	18	24
Gem	13	17
Raieda	11	14
Ugenya	5	7
Ugunja	10	13
Characteristic	N=76	%
Current on ART		
≤100	2	3
101-500	35	46
501-1000	24	31
>1000	15	20

HIV as % of daily workload		
≤10%	13	17
11%-20%	39	51
21-40%	20	27
>40%	4	5
DSD models		
Extended hours		
Yes	56	74
No	20	26
Fast Track Refill		
Yes	72	95
No	4	5
ART Groups		
Facility	5	7
Community	14	18
Both	48	63
None	9	12

Table 2:Demographics of the facilities included in the survey

In terms of DSD models, 56 facilities (74%) offered extended hours for HIV services, 72 facilities (95%) offered fast track refill services, 67 facilities (88%) had ART groups and all (100%) of the facilities reported multi month scripting for ARV prescriptions.

Patient Demographics

From twenty-five (25) facilities, 2,053 patient records of patients on ART were abstracted. On average, eighty-two (82) patient files were reviewed in each facility.

Characteristics of the sampled patients are shown in Table 3. The median age was 41.7 years (Interquartile range [IQR]: 32 – 51 years), with 1,288 (62.7%) being female. Among the females, 77 (6%) were pregnant and 66 (5.1%) were breastfeeding at one point during the period of review, 88 (4.3%) had received cervical cancer screening in the preceding 24 months and only 473 (36.7%) had a family planning method indicated.

The median duration in care since enrollment was 7.2 years (IQR: 4.2 – 9.6 years). At enrollment, 40.9% were in WHO stage I and 34.6% in stage II. Median duration on ART was 6.7 years (IQR: 3.7 – 8.5 years) and median time to ART initiation was 0 weeks (same day) (IQR: 0 – 2 weeks) for those enrolled in or after 2016, when the test and treat guidelines were implemented.

Characteristic	**n or median** (N=2,053)	**% or IQR**
Median (IQR) age in years	41.7	32 - 51
<25	244	11.9%
25-44	1015	49.4%
45-64	675	32.9%

>65	112	5.5%
Missing	7	0.3%
Sex		
Males	765	37.3%
Females	1,288	62.7%
WHO stage at HIV care enrollment		
I	838	40.8%
II	709	34.5%
III	437	21.3%
IV	30	1.5%
Missing	39	1.9%
Duration in Care	7.2	4.2 - 9.6
Duration on ART	6.7	3.7 - 8.5
Time to ART initiation (weeks)		
before 2016 (n=1610)	12	2 - 74
after 2016 (n=443)	0	0 - 2
Facility level		
Dispensary (n=12)	1,017	49.5%
Health centre (n=8)	595	29.0%
Sub-county hospital (n=3)	261	12.7%
County hospital (n=2)	180	8.8%
Subcounty		
Alego-Usonga	503	24.5%
Bondo	645	31.4%
Gem	239	11.6%
Rarieda	179	8.7%
Ugenya	181	8.8%
Ugunja	306	14.9%

Table 3: Demographic characteristics of patients from abstracted medical records

DSD Eligibility

Of the 2,053 patients, 289 (14.5%) met one or more of the five exclusion criteria under the current NASCOP guidelines and were therefore ineligible for differentiated care.

Those who met specific exclusion criteria were as shown in Table 4 below.

Table 4: Patients meeting various exclusion criteria and ineligible for differentiated care

Exclusion Criteria	**#**	**%**
Had an ART change within the year	138	6.7%
Not disclosed their HIV status and/or disclosure status not indicated	135	6.6%
2 viral loads with both being unsuppressed	46	2.2%
On ART for less than 1 year	14	0.7%
Noted concerns on giving longer follow-up duration	217	10.6%

Total patients meeting one or more exclusion criteria	**289**	**14.5%**

However, these patients went on to receive one form or the other of differentiated care and are included in subsequent analysis.

DSD Models

Multi-Month Scripting

All facilities reported having multi-month scripting (MMS). This was seen as a norm, and often not considered a model of differentiated care.

Of the seventy-six facilities, all offered MMS to general adult and pediatric patients, while fourty-two (55%) reported having MMS for key population patients.

Based on responses to the facility survey, the median prescription length was 2 months (IQR:1-3) for general adult population and one month (IQR:1-2 months) for paediatrics and key populations. Of note, prescriptions for pregnant women were reported to be one-month prescriptions in all health facilities.

Fast Track Refill

Seventy-two (95%) of the facilities reported having fast track refill (FTR) services. These were offered to general adult, pediatric and key populations. FTR services started being offered in 2016 in one (1.4%) of the facilities, 2017 in 27 (37.5%) facilities, 2018 in 37 facilities (51.4%) and 2019 in seven (9.7%) facilities. Services reported to be offered during a FTR visit are as shown in Table 5 below.

Table 5: Services offered during a fast track refill visit

Service	**# (%) facilities**
Drug refill	72 (95)
Clinical consultation	27 (36)
Individual counselling by lay counsellor or psychologist or nutritionist	31 (41)
Getting a prescription	36 (47)
Laboratory blood draw	13 (17)
Weighing, BP measurement	34 (45)
Getting a TCA date	43 (57)
Others (TB, STI screening, provision of FP services)	8 (11)

BP = blood pressure; TCA = Next clinic appointment; TB = Tuberculosis; STI = sexually transmitted infections; FP = family planning.

Of note, the distinction between a clinical visit and a fast track visit in small facilities may be limited. The frequency distribution of services provided during an FTR visit did not vary by level of health facility, except for clinical consultation. Dispensaries were more likely to report clinical consultation during an FTR visit compared to health centres and sub-county hospitals. (OR: 3.85, 95% CI: 1.13 -12.1), p-value:0.031)

The cadres of healthcare providers involved in offering services during a fast track refill visit include peer educators (including mentor mothers), nurses, clinical officers, pharmacists and pharmacy technicians, health records officers, adherence and lay counsellors.

From the patient records, there were 513 (25%) with a valid refill visit. The median duration between a refill visit and a clinic visit among these was 85 days [IQR: 77-91].

There are specific NASCOP ART-refill forms for both individual and group refill visits. From qualitative feedback, few of the abstracted patient files had the ART-refill forms completed.

Extended Clinic Hours

Official working hours for out-patient services are 8:00 a.m. through 5:00 p.m. during weekdays.

Fifty-six (74%) of the facilities reported having extended hours (outside of the above) during which they offered HIV-related services for HIV positive patients. This is exclusive of HIV testing, which is offered at any time so long as the facility is open.

The distribution of extended hours by day of the week and whether morning or evening is as shown below in Table 6.

Extended Hours	**n**	**%**
Weekday morning only	10	18%
Weekday evening only	3	5%
Weekday morning & evening only	19	34%
Weekends only (no extended hrs weekday)	12	21%
Both weekdays and weekends	12	21%

Table 6: Extended hours when HIV services are offered

Extended morning hours were largely 7:00 a.m. to 8:00 a.m., although a few facilities (n=8) reported opening at 6:00 am in the morning.

Extended evening hours were largely 5:00 p.m. to 6:00 p.m. although some facilities (n=7) extended till 7:00 p.m.

For the 12 facilities that had extended hours over the weekend only, this was one weekend a month, operating between 8:00 a.m. and 3p.m. and offering *OTZ* (Operation Triple Zero), a package of services for adolescents including individual and group counselling sessions and other fun activities geared towards triple zero: zero new infections, zero missed doses of ART and undetectable viral load.

All the services available for a clinical visit during normal hours were also available during extended hours, including laboratory blood draws for viral load.

For eleven out of twelve of these facilities, they were officially closed during weekends. They only operated one weekend a month to offer *OTZ* services.

Conversely, there were 28 facilities (37%) which opened on weekends but did not offer HIV out-patient services during the weekend.

Presence of extended hours did not vary by facility level, implementing partner or workload.

Community and Facility ART groups

Eighty-eight percent of the facilities reported having one form of ART group or another, as shown in Table 2 above.

The median number of community ART groups (CAGs) attached to a facility were eleven while that of facility ART groups (fART) was eight per facility.

Most ART groups were formed beginning 2018.

Both types of ART groups were for general population adult patients only. There were no ART groups for pediatrics, pregnant women or key population.

Only 42 (2.4%) of patients from 11 facilities were noted to be in facility or community ART groups. These were distributed as shown in Table 7 below:

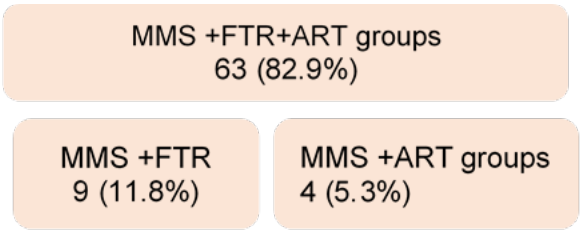
Goup type	**No of patients**	**No of facilities**
CAG -(HCW-led)	12	8
CAG group -(Peer-led)	7	4
fART group -(HCW-led)	19	6
fART group -(Peer-led)	4	2
Grand Total	**42**	**11**

Table 7:Distribution of patients in groups from 25 facilities

They joined the groups between 2018 and 2019. For the one year under review, they had between one and three group refills. In the 19 group meetings that were observed, they were all led by a peer educator

DSD Model Mix

From the facility survey, the distribution of reported DSD model mix across the 76 facilities was as shown in Figure 5 below.



MMS=Multi-month scripting; FTR=Fast Track Refill;
ART=Antiretroviral Therapy Drug Refill groups;

Figure 5: Distribution of differentiated service delivery models mix across all the 76 facilities surveyed

All facilities reported having multi-month scripting (MMS). Sixty-three facilities (82.9%) had ART groups and Fast Track Refill (FTR) in addition to MMS, while 9 facilities had only FTR in addition to

MMS and four facilities (5.3%) had only ART groups in addition to MMS.

This can be contrasted to the DSD combinations observed from the 2,053 patient records as shown in Figure 6 below.

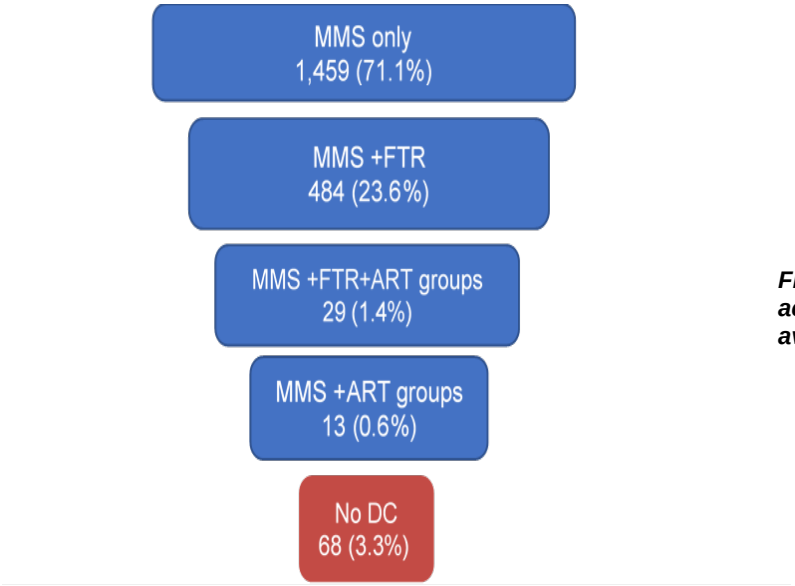


Figure 7a: Distribution of differentiated care DSD models across the patients from 25 facilities (individual level participation)

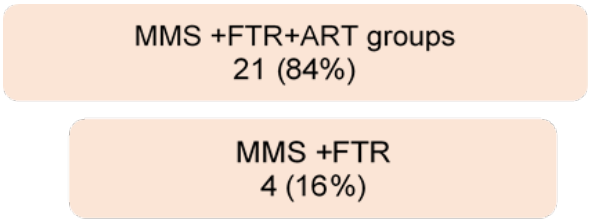


Figure 6b: Distribution of differentiated care DSD models across the patients from 25 facilities (facility level availability)

Of the 2,053 records abstracted, 68 (3.3%) had only one clinic visit and did not have a refill visit recorded during the period of review, and so it was not possible to assess the duration of their prescriptions. These were therefore not considered to have MMS and had no DC model noted.

DSD Coverage

As described in the study measures, extent of coverage was described by categorizing frequency of MMS only, as this was considered the most basic DSD model, since all facilities reported having MMS. DSD coverage of facility-reported DSD combinations was therefore defined as low (high proportion of individual records with MMS only), medium or high (low proportion of individual records with MMS only).For bivariate DSD coverage, this was defined using the median proportion of individual records with MMS only, hence low coverage facilities had above median proportion of individual records with MMS only and high coverage facilities had below or median proportion of individual records with MMS only.

Looking at saturation of various DSD combinations from the individual patient charts from the 25 facilities, the coverage of the various DSD combinations was as shown in Table 8 below

Coverage	MMS+FTR+ART groups	MMS+FTR	Total (%)
Low	7	1	8 (32%)
Medium	8	2	10 (40%)
High	6	1	7 (28%)
Total	**21**	**4**	**25 (100%)**

Table 8: Observed DSD models mix coverage

This can further be characterized as shown in Table 9 below

N=25	**DSD Coverage**		
Characteristic	Low n=8 (%)	Medium n=10 (%)	High n=7 (%)
Service Level			
Dispensary	3 (25)	5 (42)	4 (33)
Health centre	3 (38)	3 (38)	2 (25)
Sub-county hospital	1 (33)	2 (67)	0 (0)
County hospital	1 (50)	0 (0)	1 (50)
Current on ART			
≤100	0 (0)	0 (0)	1(100)
101-500	2 (25)	5 (63)	1 (13)
501-1000	3 (38)	4 (50)	1 (13)
>1000	3 (38)	1(13)	4 (50)
HIV as % of daily workload			
≤10%	3 (75)	0 (0)	1(25)
11%-20%	2 (22)	4 (44)	3 (33)
21-40%	3 (30)	4 (40)	3 (30)
>40%	0 (0)	2 (100)	0 (0)

Table 9:Facility characteristics by DSD coverage

Association between health facility characteristics and DSD Coverage

In bivariate analyses, none of the facility characteristics described above were associated with differentiated care coverage within the facility, as shown in Table 10 below.

		OR (95%CI)
DSD Coverage by facility characteristics (bivariable)		
Level (ref = Dispensary)	Health center	0.6 (0.1, 3.7)
	Sub-county	0.5 (0, 7)
	County	1.0 (0.3, 3.1)
HIV pts as % of daily workload (ref = <=10%)	11-20%	3.7 (0.3, 51.2)
	21-40%	3.0 (0.2, 39.4)
	>40%	-
DSD Coverage by facility characteristics (bivariable)		**OR (95%CI)**
Current on ART	500-1000	1.2 (0.2, 8.7)

(ref = <500)	>1000	2.7 (0.4, 20.2)

Table 10: Bivariate analysis assessing association of DSD coverage with facility characteristics

Objective 1b: To assess association between i) individual level participation in differentiated care and ii) facility level DSD model coverage with service delivery (quality of care) outcomes

Quality of care outcomes

Among the 2,053 records abstracted, service documentation at the most recent clinic visit was as shown in Table 11 below

Service	**Done and documented N (%)**	**Not documented N (%)**	**Missing Data N (%)**
Weight	2025 (99)	28 (1)	0 (0)
BMI	1945 (95)	103 (5)	5 (0)
Blood Pressure	823 (40)	1230 (60)	0 (0)
Adherence Assessment	1922 (94)	131 (6)	5 (0)
STI screening	1864 (91)	181 (9)	8 (0)
TB screening	1604 (78)	226 (11)	223 (11)
OI screening	1386 (67)	652 (32)	15 (1)

Table 11: Services offered in the most recent clinic visit

Quality of care indicators that were assessed included:

- Adherence assessment over time
- Blood pressure monitoring over time
- Viral load suppression over the one year under review
- Recent visit being scheduled
- Having the most recent visit being unscheduled.

A) Adherence assessment over time

Among those with more than one clinic visit, adherence assessment was documented fairly consistently, as shown in Table 12 below.

Adherence	**Most Recent visit N (%)**	**2nd to last visit N (%)**	**3rd to last visit N (%)**	**4th to last visit N (%)**
Documented	1,917 (93)	1,276 (62)	1,407 (69)	1,079 (53)
Undocumented	131 (7)	68 (3)	93 (5)	84 (4)
Missing	5 (0)	709 (35)	553 (27)	890 (43)
TOTAL	2,053	2,053	2,053	2,053

Table 12: Adherence assessment documentation

Among those in whom it was documented, we used the mode across the four visits to determine the average adherence level for each individual. This was noted as good in 1,953 (96%) individuals, fair in 74 (4%) and poor in only 7 (~0%) of the participants.

B) Blood pressure monitoring over time

For the most recent visit, blood pressure was indicated among 823 (40%) of the files abstracted. For this most recent visit, those with hypertension as defined by the European Society of Cardiology and European Society of Hypertension (ESC/ESH) were 64(8%). Males were 26 (41%)

Of all the participants, only 10(0.5%) were indicated to be known hypertensive. Of these, for the most recent clinic visit, only 1 had a normal blood pressure, 6 had uncontrolled hypertension (elevated BP) and 3 did not have the BP recorded.

For up to 4 clinic visits for each individual, on average (mode), 719 (35%) of the visits had a BP measured and recorded.

Among the 42 participants in an ART group, only 9 had a blood pressure reading taken during the last group meeting. None of those known to have hypertension or an elevated BP at the most recent clinic were also in ART groups.

C) Viral load suppression over the one year under review

Of the 2053 participants, 1831(89%) had either the most recent or 2nd last viral load result abstracted falling within the study period. Only 267 (13%) had 2 viral load results within the time period of interest. Viral suppression was as indicated in Table 13 below:

Two viral loads within study period (n=1831)	**Freq (%)**
Suppressed	1670 (91)
Detectable	161(9)
TOTAL	**1831 (100)**

Table 13:Frequency of viral suppression

D) Recent visit being scheduled

This indicator was based on the assumption that participants sticking to scheduled visits are stable and doing well clinically, whereas those who come to the clinic unscheduled have one issue or another that could not wait until their next appointment.

Most recent clinic visit	**Freq (%)**
Scheduled	1,677 (82)
Unscheduled	375 (18)
Missing	1(0)
TOTAL	**2053 (100)**

Table 14: Frequency of the recent visit being scheduled

Associations between quality of care outcomes and individual level participation in differentiated care

There were significant associations between individual-level DSD participation and the QoC outcomes of adherence, having documentation of a viral load test done, and having an undetectable viral load result (Table 15). Specifically, patients participating in all three DSD methods (MMS+FTR+CAG) had a 5.1-fold greater likelihood of being classified as having good adherence ($p<0.05$), a 2.2-fold greater

likelihood of having a viral load test documented (p<0.01), and a 1.8-fold greater likelihood of having an undetectable VL (p<0.05), compared to patients with only MMS. Patients participating only in FTR and CAG, but not in MMS, were less likely to have VL documentation. There was no association between DSD participation and having a blood pressure assessment recorded or having the most recent visit as a scheduled visit.

Table 15: Association between quality of care outcomes and individual level participation in DSD

		OR (95%CI)				
		Adherence	**BP Assessment**	**Undetectable VL**	**Scheduled visit**	**VL documentation**
Individual DSD participation (ref=MMS only)	None	-	1.1 (0.7, 1.7)	3.0 (0.4, 25.0)	1.7 (0.6, 5.5)	0.6 (0.2, 1.7)
	MMS+FTR+CAG	**5.1 (1.3, 19.9)***	1.0 (0.8, 1.2)	**1.8 (1.0, 2.9)***	1.2 (0.8, 1.7)	**2.2 (1.3, 3.8)****
	MMS+FTR	-	1.0 (0.5, 1.9)	0.6 (0.1, 2.7)	1.9 (0.3, 10.2)	0.5 (0.1, 1.6)
	FTR+CAG	0.5 (0.2, 1.1)	1.0 (0.7, 1.2)	1.3 (0.5, 3.3)	1.6 (0.8, 3.4)	**0.4 (0.2, 0.7)****

*<0.05, **<0.01

Associations between quality of care outcomes and facility level DSD coverage

No significant associations between quality of care outcomes and level of DSD coverage at the facility level were observed (Table 16); however, there was a trend toward higher likelihood of favorable QoC outcomes when DSD coverage was highest.

		OR (95%CI)				
		Adherence	**BP Assessment**	**Undetectable VL**	**Scheduled visit**	**VL documentation**
DSD Coverage (ref=low)	Medium	0.5 (0.2, 1.6)	0.3 (0.1, 1.4)	1.1 (0.7, 1.7)	0.7 (0.4, 1.2)	1.3 (0.7, 2.4)
	High	4.3 (0.4, 43.1)	0.4 (0.1, 2.1)	1.1 (0.7, 1.9)	1.2 (0.6, 2.3)	1.9 (0.9, 4.0)

Table 16: Association between quality of care outcomes and facility level DSD coverage

Objective 2: To describe efficiencies in service delivery under different DSD approaches from both patient and health worker perspectives.

DSD Efficiencies: Time spent in the clinic

Overall visit duration

Overall, there were 723 visits observed. Of these, 596 visits (82%) across 24 facilities had complete data on start and end times sufficient to calculate visit duration and waiting times (**Table 17**). Across all clinics, the median duration of a visit was 68 minutes (IQR: 28-104 minutes) and the median wait time was 48 minutes (IQR: 12-85 minutes). The median proportion of time spent in the clinic waiting was 72% overall. The typical patient was seen at 3 service delivery points within the clinic (**Table 17**). Overall,3% of patient visits included service at 1 station, 23% at 2 stations, 39% at 3 stations, 28% at 4 stations, and 6% at 5 stations within the clinic.

The number of observed visits included in the analysis by clinic ranged from 11 to 32 visits. There was wide variation across facilities in the duration of patient visits. The longest median duration, 177 minutes, was observed at facility A, while the shortest median duration, 10 minutes, was observed at facility X. The proportion of time spent waiting was also highly variable, with a high of 89% of time spent waiting for the typical (median) patient at A and F and a low of 10% of ime spent waiting for the typical (median) patient at facility X.

Table 17: Table X: Clinic Time in Motion Results

Facility name	Number of visits observed	Median visit duration (minutes)	IQR visit duration	Median wait time (minutes)	IQR wait time	% time waiting (median)	Median number of stations
Overall	596	68	(28, 104)	48	(12, 85)	72%	3
A	25	177	(161, 201)	153	(142, 177)	89%	4
B	27	145	(108, 167)	121	(81, 145)	80%	4
C	30	134	(118, 164)	99	(73, 119)	69%	4
D	28	95	(75, 126)	74	(52, 99)	78%	3
E	28	94	(70, 166)	69	(54, 139)	80%	3
F	23	85	(69, 136)	70	(60, 118)	89%	4
G	27	84	(53, 148)	72	(34, 128)	79%	4
H	29	83	(64, 104)	64	(37, 92)	83%	3
I	25	77	(71, 120)	67	(50, 104)	85%	4
J	22	76	(45, 97)	64	(34, 87)	81%	1
K	23	75	(39, 80)	47	(17, 63)	62%	4
L	30	61	(17, 89)	38	(5, 77)	77%	3
M	32	60	(42.5, 78)	42	(19, 61)	69%	3
N	24	60	(33.5, 88)	47	(14, 73)	74%	3
O	24	57	(38.5, 93)	48	(23, 83)	87%	2
P	24	50	(37, 73)	34	(13, 52)	70%	3
Q	28	49	(33, 82)	26	(12, 44)	61%	3
R	24	39	(20, 54)	18	(7, 34)	51%	4
S	14	23	(13, 50)	10	(4, 12)	41%	2
T	17	23	(19, 25)	6	(2, 12)	30%	2
U	29	22	(11, 31)	6	(2, 18)	36%	3
V	30	19	(17, 24)	7	(5, 11)	36%	3
W	11	18	(15, 25)	5	(3, 10)	36%	2
X	23	10	(10, 15)	1	(1, 3)	10%	2

Service Point Specific Analyses

Out of the 723 visits, the frequency of visiting specific service delivery points is shown in Table Z. Clinical consultations were the most frequently delivered service, covering 95% of all observed visits. The next most frequent services were triage and pharmacy (56% and 51% of visits, respectively).

Adherence-related services were observed during 41% of visits. A minority of observed visits involved laboratory services (9%) or counseling (7%).

The duration of services for a typical patient was 8 minutes for counseling (IQR: 5-10 minutes), 7 minutes for adherence-related services (IQR: 4-13 minutes), and 5 minutes for clinical consultation (IQR: 4-8 minutes) (Table Z). Triage, pharmacy, laboratory, and appointment management services all typically lasted 3 minutes or less (for the median client). When comparing durations across health facilities, median values for clinical consultation ranged from a high of 10 minutes to a low of 1 minute.

Type of station	Count of visits	% of visits	Count of visits with duration available	Median duration (minutes)	IQR duration (minutes)
Clinical consult	686	95%	670	5	(4, 8)
Triage	407	56%	399	2	(1, 4)
Pharmacy	367	51%	356	3	(2, 4)
Adherence	293	41%	282	7	(4, 13)
Appointment management	184	25%	166	2	(2, 4)
Laboratory	65	9%	65	3	(3, 5)
Counseling	51	7%	50	8	(5, 10)
Other	4	1%	4	22	(12, 39)

Table 18: Number of Service Delivery Points Visited

Association between Health Facility Characteristics and Duration of Patient Visits

The observed median duration of visits and proportion of time spent waiting, by health facility characteristics, are shown in **Table 19**. Total visit time was typically higher in larger facilities which saw a greater number of ART patients, but there was no clear trend or pattern in the relationship between total visit time and the proportion of all outpatients who sought HIV services. Facilities with community or facility ART groups tended to have longer visit times than those without such groups, but those with fast track refill and extended hours had shorter visit times. The relationship between proportion of time spent waiting and the various facility characteristics did not follow a consistent pattern.

In bivariable analysis of the outcome of total visit time, there was a significant association between number of ART patients and visit time, such that facilities with >1,000 active ART patients had visits which were 49.1 minutes longer than facilities with <500 active ART patients (p=0.02) (**Table O**). Facilities with >40% of all outpatients seeking HIV services had visits which were 77.7 minutes shorter than those with <10% of outpatients seeking HIV services (p=0.01). In adjusted analyses, the associations between total visit time and three of the DSD models (presence of community ART group, facility ART group, and extended hours) were statistically significant

In bivariable analysis of the outcome of time spent with a clinician during the visit, there were no significant associations between facility characteristics and the outcome (**Table 20**). In adjusted analyses, none of the DSD models was associated with time spent with clinician. However, there was a significant association between DSD coverage and the outcome (p=0.04).

In terms of the outcome of proportion of time spent waiting (waiting time), the coefficients of the models for this outcome can be interpreted as the absolute percentage point increase or decrease in proportion of time spent waiting during the visit (on a scale of 0 – 100 percent). Both number of active ART patients and proportion of HIV patients among all outpatients were each associated with waiting time in bivariable analyses (**Table 20**). Having a CAG was associated with an increase in waiting time of 19.1 percentage points (p<0.001), while having extended clinic hours was associated with a decrease in waiting time of 28.9 percentage points (p=0.001), in adjusted analyses.

Table 19: Duration of Clinic Visits by Health Facility Characteristics

		Number of observed visits	**Median (minutes)**	**IQR (minutes)**	**% time waiting (median)**
Level	Dispensary	287	50	(19, 97)	73%
	Health center	195	71	(35, 100)	81%
	Sub-county	67	78	(39, 108)	51%
	County	48	82	(70, 124)	55%
Number of active ART patients	<500	171	32	(16, 77)	61%
	500-1000	236	71	(28, 96)	71%
	>1000	166	87	(68, 135)	86%
	unknown	24	39	(20, 54)	79%
% HIV patients among all outpatients per day	<10%	98	74	(42, 139)	42%
	11-20%	166	64	(28, 86)	77%
	21-40%	274	80	(42, 129)	68%
	>40%	59	19	(14, 28)	74%
Community ART group present	No	141	23	(15, 49)	78%
	Yes	456	78	(44, 125)	68%
Facility ART group present	No	176	50	(30, 79)	86%
	Yes	421	74	(26, 127)	69%
Fast Track Refill (FTR) program present	No	205	76	(39, 118)	87%
	Yes	392	61	(25, 96)	62%
Extended HIV clinic hours present	No	52	153	(84, 180)	74%
	Yes	545	63	(25, 95)	78%

Table 20: Time Outcomes by Facility Characteristics and DSD Models

		Total visit time[a]	Clinical visit time[b]	Percent time waiting[a]

Outcomes by facility characteristics (bivariable)[c]				
Level (ref = Dispensary)	Health center	12.7 (-24.7, 50.0)	1.8 (-0.3, 3.9)	10.3 (-4.2, 24.8)
	Sub-county	2.7 (-47.8, 53.2)	-1.5 (-4.5, 1.4)	8.2 (-11.4, 27.8)
	County	30.6 (-28.7, 90.0)	-0.2 (-3.1, 3.4)	**27.3 (4.3, 50.3)***
% HIV (ref = <=10%)	11-20%	-42.9 (-88.1, 2.3)	-1.0 (-4.1, 2.1)	-16.4 (-35.3, 2.5)
	21-40%	-19.6 (-62.2, 23.0)	-1.6 (-4.6, 1.5)	-11.1 (-29.0, 6.7)
	>40%	**-77.7 (-137.3, -18.2)***	-3.9 (-7.9, 0.1)	**-38.9 (-63.7, -14.0)****
ART cat (ref = <500)	500-1000	21.3 (-14.2, 56.7)	1.1 (-0.9, 3.1)	**14.9 (0.3, 29.5)***
	>1000	**49.1 (9.7, 88.4)***	-1.2 (-3.3, 1.0)	**25.6 (9.4, 41.8)****
Outcomes by DSD model (adjusted for facility characteristics)[d]				
Community ART group		**38.2 (10.8, 65.6)****	-0.3 (-2.1, 1.4)	**19.1 (8.8, 29.4)*****
Facility ART group		**29.4 (0.6, 58.1)***	-1.0 (-2.7, 0.7)	0.2 (-12.7, 13.2)
Fast track refill		-6.4 (-34.2, 21.3)	0.0 (-1.6, 1.5)	0.7 (-10.6, 12.0)
Extended hours		**-95.6 (-131.0, -60.2)*****	-0.2 (-3.2, 2.8)	**-28.9 (-46.8, -11.1)****

*p<0.05 ; **p<0.01 ; ***p<0.001
a N=573 client visits ; b N=648 client visits ; c Generalized estimating equations models for association between each facility characteristic and each time outcome (bivariable models); d Generalized estimating equations models for association between each DSD model and each time outcome, after adjustment for facility characteristics (facility level, number of ART visits, proportion of HIV patients among all outpatient clients)

DSD Efficiencies: Time spent at group meetings

Nineteen community groups were observed between Sep 4th and Oct 4th 2019. Group size at enrollment ranged from six to 15 participants, with a median of eight participants per group, while median group attendance on that particular day was 7. Meeting duration ranged from 33 minutes to two hours and seven minutes, with a median duration of one hour and 12 minutes. Groups reported being formed between March 2018 and September 2019. The members' year of diagnosis ranged from 2002 to 2018. 69% of the members were female, and all groups had both males and females.

Group activities fell into five categories: administrative, counselling, discussion, ART and Q&A as shown in Table 21 below. The administrative category included introductions, general housekeeping, election of leaders, naming of the group and formation of group policies. In some cases, introductions included overviews by peer educators on topics including adherence, viral load, drug and substance abuse and the groups' various projects. All nineteen groups carried out administrative activities, and spent a median of eight minutes, and up to 35 minutes, on these activities. Fourteen of the groups (70%) engaged in counselling, which included adherence counseling. Groups varied in how much time they dedicated to counselling. The mean duration of counseling was 14 minutes, but the time spend ranged from two minutes to one hour. Only 6 (30%) of groups (6) dedicated time to discussion, which included sharing of challenges and encouragement from members. The median duration of discussions

was 30 minutes, though time spend ranged from 14 minutes to one hour and 14 minutes. Ninety percent of groups (18) dedicated time to distribution and refills of ART. Some groups took participants' blood pressure and one group also spent time listening to the remarks of a pharmaceutical technician. The median duration of time dedicated to ART was 13 minutes, and no groups spent more than 33 minutes. Twenty-five percent of groups (5) included Q&A in their sessions, allowing participants time to address their concerns and ask questions. This included questions about viral load and side effects from medications. Groups spent a median of 14 minutes, and time spent ranged from six to 49 minutes.

Table 21:Characteristics and Duration of Groups

Overall	Number of groups	Median	IQR	Min, Max
Duration of group meetings (minutes)	19 (100%)	72	36	33, 127
Number of enrollees per group	19 (100%)	8	4	6, 15
Number of participants per group observed	19 (100%)	7	3	5, 15
Activity Specific				
Administrative duration (minutes)	19 (100%)	8	10	1, 35
Counselling duration (minutes)	14 (70%)	14	11	2, 60
Discussion duration (minutes)	6 (30%)	30	15	14, 74
ART dispensing duration (minutes)	18 (90%)	13	5	5, 33
Q&A duration (minutes)	5 (25%)	14	0	6, 49

Perspectives on Differentiated Service Delivery

Differentiated Care/Differentiated Service Delivery Meaning

When participants were asked "what does differentiated care (DC) mean to you?," their responses indicated a fairly consistent understanding of what it meant, focusing on the client-centered nature of the approach. Most HCWs responded that it was the classification of patients into different care trajectories based on stable versus unstable designation. As one HCW put it, "[DSD] is a model of categorizing our HIV positive patients according to their adherence and clinical status." Peer Educators referred to it as care in the community, not just the health care facilities. One Peer Educator explained "Differentiated care is putting clients in different levels…it also gives us an easy time because when we are given the drugs the clinician tells us that we are doing well and gives us drugs for longer periods, so we don't have to come to the facility as often. It also saves time and also saves the cost of transportation when the drugs are brought to the community." While HCWs focused on the classifications of patients, Peer Educators focused more on the length of time between visits. Additionally, both groups commented on how DSD has saved them time and allowed them to focus on the clients most in need of care.

Compared to health workers on the ground who focused more on the implications for individual clients, high level stake holders and implementers had more of a 'birds eye' systems view of DSD.

Stakeholders focused on reductions in facility workload, as well as reducing the number of visits for clients by increasing prescription times for stable patients. One key stakeholder stated “it is aimed at reducing the workload in the facility; and two, it is aimed at reducing the frequent visits made by the client. So it is also something that is advantageous to the client.” Implementers spoke about categorizing patients, tailored services and the options of ART models provide to clients. According to one implementer, “Clients are categorized into stable and unstable clients where the stable clients are clients who have been on ART for at least one year, they don't have any other major clinical condition that make/warrant them to be coming to the facility every now and then. So these stable clients are given models of ART” to choose from.

Overall, all participants had a positive view of DSD, and were in agreement that DSD is a client-centered approach with a myriad of benefits for patients and health systems alike.

Successes and challenges of differentiated care

The information received about differentiated care in Siaya County was generally positive. The participants felt that, overall, the models have been beneficial to patients, yet there were also some challenges to the program.

Participants noted many advantages from DSD. The most commonly mentioned positive outcome was that DSD reduced the workload for health care workers while enabling them to still provide appropriate care to the patient. As one peer educator explained, *“*I have seen benefits to the clinicians. It gives them an easy time, by reducing their workload, and at the same time the patients get the chance to come for their medication or the same is taken to them at other places. This gives them a bit of room.” An HCW shared the impact on their workload: “I really think DSD has lessened the work, because for our case here we used to see many clients - like in a day, we would book up to 150 clients - but right now we are seeing around 50 and if we spread that to all the clinicians, I think it is now easier for us as clinicians.”

DSD also gives healthcare workers more time to focus on patients who really need their support. It has helped improve the quality of care and time health care workers have to focus on unstable clients. An HCW stated “It is giving us an easy time as healthcare workers to mainly focus on those unstable clients who really need our care,” while stable clients who don’t have issues are placed “in DSD rather than the unstable who really needs close attention of the healthcare provider.” A Peer Educator explained the need for the DSD system because “where patients are few they receive quality services, but when they are many the doctor will be overwhelmed, so sometimes he can forget to ask the patient what his problem was.”

Most notably, many participants also mentioned that that DSD can help improve patient retention, making it easier for patients to stay in care. Some health care workers explained that their patients

were motivated to be adherent because they were now in community groups, and the groups hold community members accountable: “I think when they [patients] are in the community groups, they motivate each other, and when one has not picked his or her drugs, I think either of them or the members will remind him or her.” In addition, patients were aware if they were not adherent they would no longer qualify for DSD. A Peer Educator noted the benefit of clients beginning this process when they are stable: “The longer TCAs motivates the client because one is put on it when they are stable and so encourages the client to continue taking good care of themselves to maintain that.” Another Peer Educator noticed “defaulting has gone down significantly and this is what usually causes a lot of work.”

Healthcare workers and patients also reported a reduction in stigma. According to an HCW, *“*We can be in a home or family where no one has disclosed their status to each other, and now when [clients] are all categorized and put in a group, I think disclosure will be higher and reduce stigma.” A peer educator added “[DSD] reduces stigma. There are those who had been taking medication for long but were never comfortable but as we continued in the group, the members became more comfortable and had no reason to keep their status a secret.” At the same time, some health care workers have mentioned that some patients miss their appointments because they have still have drugs and don’t think they need to come back for their clinic visits: *“*Most clients on DSD tend to miss their clinic appointments. When you are putting them on DSD we normally tell them, "You are stable," like you don’t have any factors, so they tend to relax. When coming for the refill, most of them don't come back. They tell you "I still have drugs at home" and that is why I didn't come for my appointment date.” A stakeholder echoed this sentiment *“*It can also lead to them not really adhering to because some of these patients require a lot of reminders and support, which if they do not really get then it is easier for them to stop…”

Additionally, there are challenges with supply chain (drugs, drug bags, forms) and having enough supplies to fully implement DSD. An HCW explained, “Shortage of drugs - sometimes we get less drugs and so the client will not get the full package and so they are given what is available and asked to come for more later which sometimes can also be challenging.”

One surprising outcome that emerged was that the HCWs feared losing their jobs due to reduction in workload. Some commented that they no longer had enough to do at the facilities. An HCW explained: “…but people will also lose their jobs, because if you were able to have 500 clients in a month and you are now to see 200 in a month, sincerely some [healthcare workers] will go home.” A Peer Educator added “Because of differentiated care, the [few] patients who come on a regular basis, the staff numbers are reduced, therefore employment opportunities are reduced, and others are laid off. So this will be a challenge… which shows that the effects of differentiated care are good on one hand but negative on the other.”

Some healthcare workers worried that patients would not report opportunistic infections in time, and that patients don't contact their clinician when needed. An HCW discussed how this was difficult to track; "another challenge that I'd say is that it takes time for the healthcare worker to know if a patient does not come to report that they have an opportunistic infection, by the time you detect it might be too late." A Peer Educator found DSD also impacted communications with medical staff: "I feel that it hinders contact between me and my clinician."

Overall, most study participants found the benefits of DSD outweighed the disadvantages. This data offers insight into areas that could be addressed to further improve implementation of DSD.

Shifting the workload from the facility to the community

Implementation of DSD shifts the bulk of workload from healthcare providers at facilities to community support professionals, such as adherence counselors and ART group leaders. With this approach, healthcare providers are seeing fewer clients and able to spend more time with those who need them, while adherence counselors and peer educators are spending more time managing larger caseloads and increased travel time. One HCW remarked that now a healthcare provider "has enough time, in that he doesn't rush compared to when he had like 70 a day. It eases the strain for the health worker." In comparison, ART group leaders, who "are now overwhelmed because you find that there is one CAG group leader who has several groups, a scenario whereby she has to visit maybe this group in the morning then the other group" according to one Peer Educator, who also notes that as a result "the CAG group leader [now] fails at times." Another Peer Educator worries about this workload increasing exponentially if DSD is successful in suppressing more people "because the [ART] groups to be met will increase per month as long as the suppression rate goes down, and viral load goes down so the groups increase. Despite delivering the medication, [the leader] must meet them even at the facility, since each has one peer counselor selected to do this."

Stakeholders and implementers acknowledged this shift, however they seemed to focus more on the need for fewer clinicians. One Implementer stated "we are highly likely to reconsider the number of clinicians who have been seeing clients at the facility…because there will be less clients to see." Another implementer stated simply that now they see "less burn outs." One key stakeholder mentioned that now staff are being redistributed: "clinical officers…where we have less work now they can be spread to help another person. Same even [for] adherence counselors." While there is an awareness of the shift, there was not discussion of how to ease the burden on community-based workers, or oversight put into place to ensure that CAG group leader continues to be successful in this system.

Improved use of time and quality of care

Typically, DSD has resulted in care providers spending an increased amount of time with patient who need care. HCWs generally felt this was a more efficient system, and improved the quality of care

provided: “Initially when we used to have so many patients we would rush so that we don't [leave] patients waiting…but now that we have a few patients…There are patients that have issues that need time, there are those who just need a few minutes to clear them. So we have enough time for these patients who have got issues.” Similarly, adherence counselors have more time to provide better care with their patient load decreased. A Peer Educator further explained the “services provided are of good quality, and the time is good, since even among those who come with high viral load, they are not as many as before, so the adherence counselor can speak to the patients in detail, until a solution is found. Not like it used to be with the high viral load clinic, which was full from wall to wall, and the adherence counselor had little time for each since there were 70. ”

Respondents also indicated that patients were more engaged because they are involved in choosing their own model of care, often resulting in improved adherence. As one implementer explained, DSD allows “the client [the opportunity] to choose a model of their preference. I think it gives the healthcare worker now that easy time of dealing with the clients by not choosing for them what to do which they are likely not to adhere to,” adding “we've never had enough resources in this sector, never, and so with the DSD I think we'll now be able to balance with the little that we have to ensure that whatever little we have, we are able to efficiently use it to provide services to clients.”

Improved adherence

Respondents indicated that they felt that DSD improved retention for most patients. Patients who need care get better care with shorter wait times, and patients who can be supported in the community no longer need to go to the facility. This both increases adherence and reduces the workload for care providers. An implementer explained “before we used to have a lot of missed appointments or retention issues because the clinics were crowded because you'd see all patients. But…since we categorize the patients out, retention has improved. Even the patients are happy with the service, they are able to re-schedule their appointments, and they are able to just seek the services that suit them.” Patients also benefit from peer support that holds community members accountable. One HCW explained “when they [patients] are in the community groups, they motivate each other, and when one has not picked his or her drugs…the members will remind him or her.”

Respondents indicated that DSD is in demand for clients who qualify. According to one HCW, “from the information we get from patients, most of them want to be given drugs for longer TCAs and when we interact with them we are able to give them information as to why they have to quality, we have to give them DSD; and if they mess in terms of maybe they are not adhering well to their medication, they are not keeping clinic appointments then they will be disqualified from DSD.”-

Though adherence is improved for many clients, some patients with longer TCAs do forget about their appointments, which can lead to non-adherence without reminders. A key stakeholder explained “it can

also lead to them not really adhering too because some of these patients require a lot of reminders and support, which if they do not really get then it is easier for them to stop."

Patient perspective (from group T-I-M)

Overall, reports suggested that the meetings provided value to group members. In response to a question about the benefits of the groups, one respondent noted "members were very happy to form a group rather than to be treated as individuals, as they encourage each other and every member agreed that none will leave the group." Group members reported that receiving ART through the group is convenient, time-saving, economical (didn't need to pay for transport to the facility), helps generate income, builds community with fellow patients, reduces overall trips to the facility, decreases stigma, reduces defaulting, provides education, provides counselling and boosts morale. One respondent listed the three main benefits of the group, stating that it is "1) time-saving, 2) convenient for those who go to work [and] 3) members encourage each other." It was noted that several of the groups are new, thus more time was dedicated to administrative activities such as naming the group and electing leaders. In 16 out 20 groups, participants saw the clinician individually. The four remaining groups saw the clinician as a group, for reasons that included saving time, reducing the burden on health workers, reducing stigma, opportunity for learning, increasing adherence and reducing defaulting. Several groups noted how appreciative they were of the current support provided.

Additional services participants would like to receive as part of the group include condom distribution and family planning, vitals checks, counselling, nutritional services, distribution of water guards and nets, refreshments, transport allowances, financial support or capital for income generation activities, watches to help them take their medication on time and malarial treatment. Two respondents raised the issues of cost and difficulty of transport for group leaders.

Key recommendations to optimize implementation from the qualitative interviews

Participants were enthusiastic about the DSD program, and all felt it benefitted the clients and the health system. They were also able to provide an important perspective on barriers to optimal implementation and key recommendations to improve the program. Suggestions for systemic improvements included implementation of an IT system to track patients across facilities, better alerts and reminders for clients who do not have frequent appointments, improved sample transport to Nairobi, customized guidelines at the county level and improvements to supply chain management of ARTs, drug bags for community distribution, and printed copies of required forms. There were also suggestions for improvements to education, including opportunities to educate patients about the DSD program, and additional training for peer educators.

There is a need for increased support and staffing for community-level workers, who currently have a heavy load that is likely to increase as more and more patients are suppressed. As one Peer Educator put it, “I think there is really need of recruiting more CAG group leaders and training them, so that they can curb the workload that is increasing.” For ART group leaders, there were requests for increased funding and support, including improved transportation (motorcycles instead of bicycles) for group leaders required to travel far distances, especially during the rainy season. Because DSD has been so popular and yielded good results, there were requests were also made to expand the eligibility criteria for clients to include different cohorts by age and gender and reduce the cut off age from 18 to 15 years old, as well as make special considerations for key populations and increase the overall number of facilities offering DSD.

Discussion

DSD Model Mix & Coverage

Discordance between availability of DSD models in a facility and individual participation

From the survey, many facilities reported having a varied mix of DSD models (ART groups, fast track refill) present but in many cases, the evidence of clients receiving the range of DSD services showed low coverage. This could be due to improper documentation, as sites reported not having the ART refill forms for documenting fast track refill visits. However, in other sites, the forms and registers prescribed by NASCOP were present but not filled as required.

Specific to ART groups, many of them reported being formed around the time of the assessment. This could explain the disparity in coverage – 84% of facilities reported having groups yet only 44% of them had patients whose charts indicated them being in a group and even in these, the individual participation in ART groups was quite low (42/2053 patients). We also observed the discordance in what was reported at facility level and what was observed in practice: while facilities reported having HCW-led ART groups, all the 19 group meetings we observed were led by peer educators. Further attention to application of DSD models in practice for eligible clients who prefer these models is needed.

Limited and varied understanding of various definitions of DSD models

In smaller facilities, the distinction between a clinical visit and a fast track refill visit was unclear, since the services offered during either type of visit were the same. Sites reported implementing MMS yet from individual patient records, there were no fast track refill visits in-between clinic visits where the patient interacted with the clinician. This means that perhaps some fast track refill visits were marked as clinic visits. The service scope definition and documentation of a fast track refill visit therefore needs to be better outlined.

Challenges observed with specific DSD models include

- MMS – For women in PMTCT, they were reported to be on MMS yet their prescription length was one month.
- Extended hours
  - While this was reported from the facility survey, time of service is not documented on patient records. It was therefore not possible to estimate coverage of this DSD element. At the facility level, having extended hours was associated with reduced waiting time. Given this, further characterization of services offered during extended hours (which services, which staff offering them, proportion of patients receiving services) would be important.
  - Having extended hours was a staff initiative. There was therefore a wide range of variation in terms of extended hours and services available during these hours. e.g. some facilities were open during the weekend but didn't offer HIV services while others were closed for the weekend but were open to offer OTZ services one weekend a month.

With poor documentation and varied definitions/understanding, it is difficult to characterize the DSD models that patients participate in or compare model mix across facilities.

Association between DSD models and Quality of Care

Consistent documentation for most of the essential services like weight and adherence assessment was high (62%-99%). However, it was less than optimal for BP monitoring (40%).

A model mix combining all the DSD models (MMS+FTR+CAG) was significantly associated with better quality of care outcomes (adherence, undetectable viral load, consistent viral load documentation) compared to having MMS only. Given the observational, cross-sectional nature of this study, it is impossible to know the direction of causality in this relationship: whether participation in the full array of DSD models improved adherence and viral suppression, or whether clients who were allowed to participate in these DSD methods were patients who were most stable and healthy and therefore likely to have favourable QoC outcomes. .

Despite lack of statistical significance, high DSD coverage at the facility level was consistently associated with higher odds of having a positive quality of care indicator, compared to low DSD coverage (Table GG). The fact that we observed significant associations between individual-level participation in DSD and QoC outcomes, but not between facility-level level of DSD coverage and these outcomes suggests that DSD did not result in a dramatic overall transformation of health services quality such that QoC results for all patients would be universally improved based on practice transformation (e.g. channelling health work time and focus toward unstable patients). Alternatively, the lack of statistical significance could be explained by heterogeneity in definition and classification of

various DSD models even within the low, medium, and high coverage groupings. This bias was absent in DSD models which were well defined, and which were assessed at facility level and not at patient level e.g. extended hours. This model was associated with an overall shorter clinic visit and seen to be associated with shorter clinic visits and a decrease in waiting time of 28.9 percentage points, a highly significant result in adjusted analyses.

DSD efficiencies: Time spent at the clinic

With a median visit duration of 68 minutes, 72% of this time was spent waiting. This varied highly by facility. With all these facilities reporting implementation of some DSD model mix, there may be room to improve efficiency in service delivery.

Longest time spent at counselling (8 min), followed by adherence counselling (7 min) while clinical consult was 5 min and pharmacy (3 min). Given that a lot of what is being done at the clinic is counselling, more efficient ways of doing this could be explored.

Factors associated with a shorter visit included having fewer ART patients and having extended hours. Streamlined extended hours could be explored as a way of maximizing efficiency during a clinic visit. Further stratification of clinic visit time by time of day could be useful in characterizing hours when patient load is highest and wait times longest, so that staffing can be re-organized to match need.

DSD efficiencies: Time spent in an ART group

At facility level, ART groups were described based on the location of the group meetings. i.e .facility ART groups congregated on facility grounds while community ART groups met somewhere in the community. This is a slight variation of the standard community vs HCW-led ART group nomenclature. Median duration of group meetings was one hour and 12 min, which is 4 min longer than the median clinic visit time. Given that there is no waiting time in groups, this means group participants spent all their time receiving services in contrast to 28% of the time spent receiving services during a clinic visit. Patients receiving ART through the group reported it as convenient, time-saving, economical (didn't need to pay for transport to the facility), builds community with fellow patients, reduces overall trips to the facility.

Of note, there was no standard documentation on how an ART group meeting was conducted. There were ART refill forms and the leader took attendance. The rest of the documentation e.g. meeting deliberations, specific issues of concern for the whole group discussed during the meeting e.g. at the time, patients were raising concerns over the switch to Dolutegravir, were not captured.

The format for conducting an ART group meeting was also not clear. While all the groups had ART refill and adherence counselling, some spent more time discussing social issues while other spent more time discussing health-related issues.

A few groups reported having a common clinical consultation visit. i.e. they are all reviewed by the clinician in a single sitting. This is a novel DSD element that can be further explored for efficiency.

Limitations

We were unable to use viral suppression as a quality of care outcome in the manner outlined in the national HIV treatment guidelines i.e. two viral load tests within 12 months. This is because many viral load dates were not within the specified time period of interest. We tried to confirm the dates and values from the national viral load database, but for the same individual(s) matched by clinic ID, the date and viral load results values in the viral load data base were completely incongruent with records found at the facility level. E.g. a patient could have results in the clinic file as “undetectable” but for the same date in the national VL database, the result would have detectable copies/ml.

For the clinic time in motion, it was not possible to distinguish between a clinic visit and a fast track refill visit for better characterization.

Some of the ART groups reported to be in existence were formed around the time of the evaluation. Some reported never having met in the past and being convened on the day of the data collectors’ visit.

Given the heterogeneity in classification of various DSD models, the qualitative perceived benefits of DSD models described by patients, healthcare providers and health managers may not have been fully reflected in the associations between participation and coverage with quality of care outcomes. The cross-sectional nature of our evaluation did not also allow us to observe the before and after the DSD model implementation.

Conclusion

Qualitative responses from health workers and patients indicated wide support and perceived value of DSD services. While most facilities reported offering a full range of DSD services, the level of coverage of these services within their client populations was low and varied widely. However, participation in as many DSD models as eligible was associated with better quality of care outcomes, including viral suppression. There was a highly significant association between facilities offering extended hours and reduced time for patient visits, suggesting this is a key DSD model for more widespread implementation. Concerningly, facilities with community or facility ART groups had longer visit times, suggesting optimization of the operations of these groups is needed, as well as further evaluation at individual patient level to probe this in detail. Further attention to optimizing DSD participation and to ensuring strong quality of care among both clients participating and not participating in DSD is needed.