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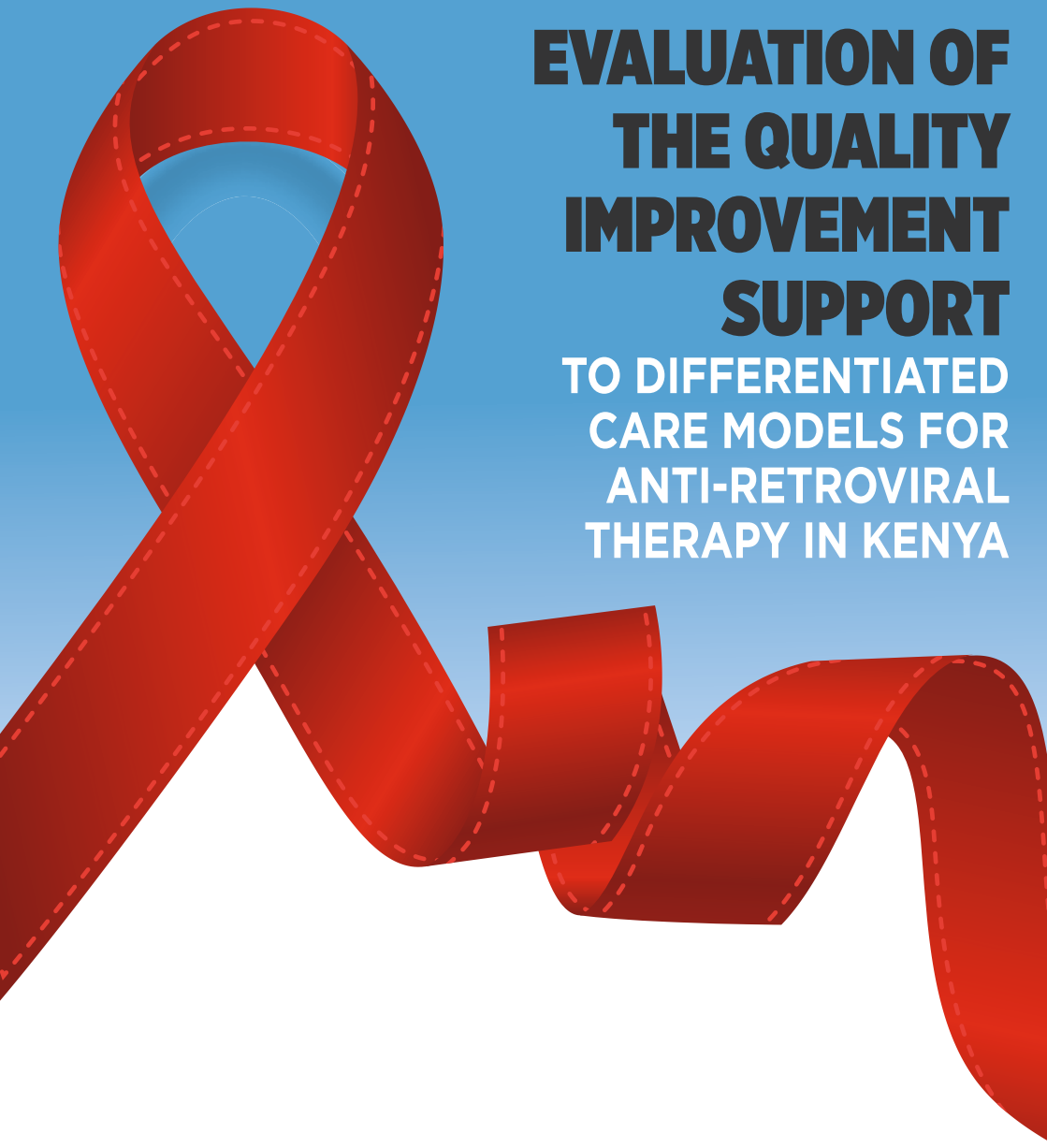

EVALUATION OF THE QUALITY IMPROVEMENT SUPPORT

TO DIFFERENTIATED CARE MODELS FOR ANTI-RETROVIRAL THERAPY IN KENYA

EVALUATION OF THE QUALITY IMPROVEMENT SUPPORT TO DIFFERENTIATED CARE MODELS FOR ANTI-RETROVIRAL THERAPY IN KENYA

Ministry of Health, Kenya

In collaboration with

Global Fund to Fight AIDS, TB and Malaria

And

International Decision Support Initiative (iDSI)

Project Period: March 2019–September 2019

Funded by: Global Fund HIV Grant:

KEN-H-TNT 2018-20

and the Department for International Development (DFID Supplement to iDSI2).

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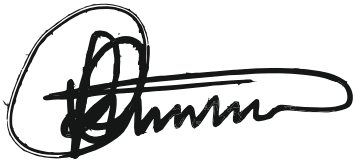
FOREWORD

The Ministry of Health greatly expanded the ART program over the years. This expansion created constraints and limitations in the health system to adequately serve the increasing numbers of PLHIVs in the health facilities. The National Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya – 2016 Edition introduced Differentiated Care Service (DSD) delivery for implementation in the country. DSD is a client-centred approach that simplifies and adapts HIV services across the clinical cascade to reflect the needs of the various groups of PLHIV while reducing unnecessary burdens on the health system. Through DSD, the health system can refocus resources to those most in need.

NASCOP through Global Fund support implemented the program quality efficiency project in 70 health facilities across 7 counties. The aim of the project was to integrate DSD along the cascade of HIV care using Quality Improvement (QI) approach, to measure the impact in terms of improvement of indicators along the HIV cascade and to estimate the cost efficiency of implemented approaches along the cascade of HIV care. The evaluation of this project was undertaken to determine the program efficiencies in service delivery, estimate the resource requirements for each service delivery model, and assess the impact of DSD implementation with QI approach on patient health outcomes and satisfaction. The PQE intervention sites were compared to facilities that implemented differentiated service delivery approach in absence of structured QI support.

This report is intended for use by all policy makers, facility teams and all the stakeholders to improve the quality of service delivery process and patient outcomes. Lessons learnt can be



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ACKNOWLEDGEMENTS

The development of this report was done through collaborative efforts from different institutions including Ministry of Health led by Division of National AIDS and STI Control Programme (NASCOP), National AIDS Control Council (NACC) & MOH-Central Planning and Project Monitoring Department, Imperial College of London and the Global Fund.

I take this opportunity to appreciate the officers at NASCOP who participated in the development of the study protocol, data collection, data analysis, report writing and finalization of this report. A special compliment to Dr Maureen Kimani, Dr Valerie Obare, Milcah Chepkorir and the PQE team Maureen Inimah, Sewe Nicholas and Mburu Muiyoro for coordination during study implementation. In addition, our gratitude goes to Regina Ombam, Bernard Lukoba, Peter Kinuthia (all of NACC) and David Njuguna (MOH) who supported the costing component.
Special thanks to our team of consultants and partners: Dr Y ling Chi, Dr Lumbwe Chola, Dr Peter Memiah and Dr Sarah Asiimwe for the technical support during study implementation and finalization of the report.

Lastly, I acknowledge with gratitude the financial and technical support to undertake this study from The Global Fund and the Department for International Development (DFID Supplement to iDSI2).

Dr Catherine Ngugi
Head: Division of National AIDS/STI Control Program

EXECUTIVE SUMMARY

Background: In 2016, the Ministry of Health released comprehensive guidelines on the use of antiretroviral drugs for treating and preventing HIV in Kenya. One of the key highlights in the guidelines was the introduction of differentiated care models (DC) for clients on anti-retroviral therapy (ART). DC is a patient-centred approach the goal of which is to provide services based on individual needs of clients. In addition, one of the widely discussed goals of DC is to improve efficiency in resource use at the clinic level, thereby reducing the average cost per client. Some authors have discussed how DC could solve the crisis in treatment financing for HIV. However, DC requires up-front investments, e.g. to categorize clients or to track clinical appointments. Given these constraints, there is limited evidence on widespread, intensity, or completeness of implementation of DC guidelines on the ground in Kenya.

The National AIDS and STI Control Program piloted a Quality Improvement (QI) programme to explicitly support DC implementation (DC+QI) in 7 counties in Kenya with support of the Global Fund to fight against AIDS, TB and Malaria. This research sought to establish how the implementation of DC affects processes of care at facility level, patient outcomes and the average cost for treating and care for HIV per client per year in DC+QI compared to DC alone.

Methods: This study relied on a comparison between patient, provider and cost outcomes between intervention sites and control sites (i.e. non-intervention) using statistical tests to estimate significance. Intervention sites were coupled with control sites using propensity score matching and nearest neighbour based on observable baseline characteristics. In this study,1412 patients and 56 health providers were interviewed. In addition, activity-based costing (time driven) was conducted in 30 facilities in 13 counties in Kenya to estimate costs.

Results: The study shows significant positive associations between DC+QI and a range of patient health outcomes (e.g. satisfaction, viral load, self-reported health, experience of care). For example, viral suppression (usually considered the gold standard when it comes to evaluating HIV interventions) was 89.4% in control sites versus 92.7% in intervention sites. On the other hand, we found no significant difference between intervention and control site on other variables, such as provider and patient knowledge or provider satisfaction. The costs associated with QI implementation were typically small (cost estimate was KES 516 per patient per year), the great majority of those costs associated with administration costs and intervention costs (e.g. learning sessions and coaching).

Conclusions: Across the world, DC pathways have been implemented, in line with global guidelines (as issued by the WHO). However, the evidence on the extent of the guideline implementation in non-trial settings on the ground is limited and evidence on cost is spare. This research will provide valuable impacts on DC implementation, contribution of QI to DC implementation in Kenya and other settings, both on the value to patients and on its costs.

ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
BMI	Body Mass Index
DC	Differentiated Care
GF	Global Fund
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
KES	Kenyan Shillings
MoH	Ministry of Health
NACC	National AIDS Control Council
NASCOP	National AIDS/STI Control Program
PDSA	Plan-Do-Study-Act
PI	Principal Investigator
PICO	Population, Intervention, Comparison, Outcomes
PLHIV	People Living with HIV
PQE	Program Quality and Efficiency
QI	Quality Improvement
STI	Sexually Transmitted Infections
TNT	The National Treasury
USAID	United States Agency for International Development

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INSTITUTIONAL RESPONSIBILITIES

National AIDS and STI Control Program (NASCOP)
NASCOP led the development of the study protocol, data collection instruments, on the ground data collection, data analysis, report writing, and manuscript writing. They were also responsible for communication and collaboration with partner organizations and dissemination of the findings.

National AIDS Control Council (NACC)
NACC supported the protocol development, training of research assistants, data analysis as well as report and manuscript writing.

The Global Fund to Fight against AIDS, TB and Malaria (henceforth 'the Global Fund')
The Global Fund co-funded the study. The Country team provided support during protocol development, training of research assistants, data collection, data analysis and report and manuscript writing.

Imperial College London as part of the international Decision Support Initiative
Imperial College London (ICL) worked closely with NASCOP to support the development of the protocol, survey instruments and provided support in the training of research assistants, data collection, data analysis and report writing.

Dr. Peter Memiah (University of Maryland) was one of the three consultants for this study. He worked with the study team and NASCOP to review the protocol, survey instruments, and was involved in data collection, data analysis and report writing specifically in relation to the Patient and Provider Data.

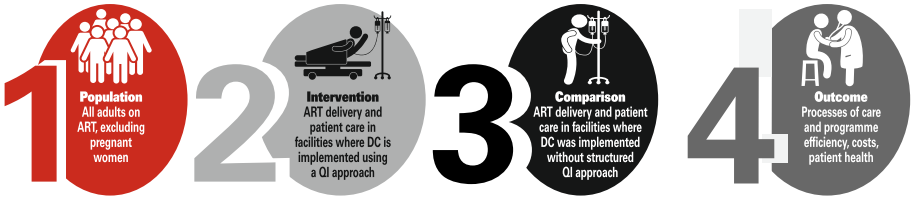
All investigators and organizations shared responsibility for the ethical oversight of this research.

Investigator Roles
Principal Investigators (PIs) were responsible for guiding conception, coordination and oversight of protocol development, project design, project funding/implementation, and data collection, analysis, and dissemination. They maintained overall responsibility for conducting the survey. Co-investigators were involved in project conception, coordination, project design, project implementation, data collection analysis, and dissemination. All investigators, consultant and organizations shared responsibility for the ethical oversight of this research.

Conflict of interest statement
Participating investigators reported no conflicts of interest in the conduct of this study.

Funding
This study was jointly funded by the Global Fund HIV Grant- KEN-H-TNT 2018-2021 and the UK Department for International Development (DFID Supplement to iDSI2).

BACKGROUND



In 2016, the Ministry of Health issued comprehensive guidelines on the use of Antiretroviral drugs for treating and preventing HIV in Kenya. One of its key highlights was the introduction of differentiated care (DC) models (also known as differentiated service delivery) for patients on anti-retroviral therapy (ART). DC is a patient-centered approach, the goal of which is to provide services based on individual needs of patients (Ministry of Health, National AIDS and STI Control Program, 2016). Subsequently an operational guide with step-by-step guidance on implementing DC in facilities was released in January 2017 (Ministry of Health, National AIDS and STI Control Program, 2017). The overall aim is to improve quality of care) and treatment outcomes for the patients. Due to its importance, the DC strategy was maintained in the recent update of the Guidelines on Use of Antiretroviral drugs for Treating and Preventing HIV in Kenya in 2018.

With increasing numbers of people living with HIV (PLHIV) on treatment and scarce resources to support the health system, DC offers an opportunity to use the limited resources more efficiently while at the same time tailoring care and follow-up services to groups of patients that are most at need. DC requires up-front investments to categorize patients based on clinical status, track clinical appointments, re-design patient flow and ART delivery in accordance with the needs of patients. Given these processes, there is limited evidence on extent of coverage, intensity, or completeness of implementation of DC guidelines on the ground in Kenya.

Box 1. PICO summary	
Population	All adults (>19 years old) on ART (newly initiated ART patients (<12m on treatment), ART patients (>12m), stable and unstable) ; excluding pregnant women
Intervention	ART delivery and patient care in facilities where DC is implemented using a QI approach
Comparison	ART delivery and patient care in facilities where DC was implemented without structured QI approach
Outcome	processes of care and programme efficiency, costs, patient health

The National AIDS and STI Control Program (NASCOP), with support from the Global Fund to fight against AIDS, Tuberculosis and Malaria (henceforth referred to as 'the Global Fund'), piloted a Quality Improvement (QI) programme to understand whether implementation of DC could be improved by using quality improvement methods and supervisory mechanisms in 7 counties in Kenya. The approach was tailored to the needs of each facility, intended to support staff on the ground during implementation with scaling up DC. This study sought to establish how the intervention; DC supplemented with a QI approach; compared to an unsupervised implementation of DC. A series of outcomes (described in the next section) ranging from practice of care, provider and patient experience, cost and programme efficiency were considered for this study.

OBJECTIVES OF THE STUDY

» **THE MAIN OBJECTIVES OF THIS WORK WERE:**

01 To evaluate the program efficiencies in service delivery in intervention and control sites.

02 To evaluate the patient and provider costs in intervention and control sites

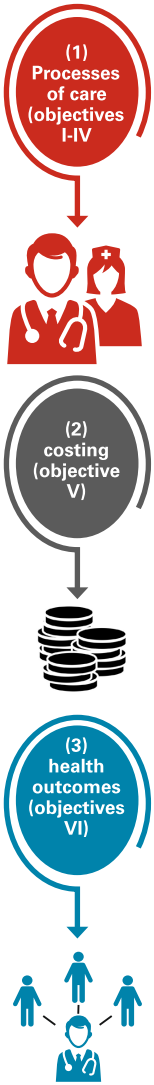
03 To determine health outcomes and level of patient satisfaction in the intervention and control sites

Those objectives were further broken down into the following questions:

- To evaluate the patient process maps in the intervention and control sites
- To determine linkage to care and timely ART initiation in intervention and control sites
- To evaluate patient and provider experience and satisfaction index for DC in intervention and control sites.
- To determine patient and provider knowledge on national guidelines relating to DC in the intervention and control sites
- To determine the average cost of ART delivery and care in the intervention and control sites.
- To determine health outcomes (including viral suppression) among the patients in the intervention and control sites.

DESCRIPTION OF THE WORK PACKAGES

A framework with a set of outcomes of interest was developed to address the above specific objectives and sub-objectives, through literature review and discussions with NASCOP (see Annex 1). This served as the basis for organizing the work in three work packages (WP) to provide a comprehensive reviews of the intervention: (i) processes of care (objectives I-IV), (ii) costing (objective V), (iii) health outcomes (objectives VI). In totality, these WPs provided a comprehensive picture of the quality of care and costs in facilities supported by DC+QI approach compared to facilities where DC alone was implemented.



Work Package 1 (WP1): Processes of care and programme efficiency

The first hypothesis was that DC+QI led to better processes of care by; training healthcare providers on DC guidelines, supporting DC implementation in the facilities and also identifying gaps in the care pathways or quality of care. To test this hypothesis WP1 compared the difference between intervention and control sites on the following areas:

- Patient journey (process maps) at the time of visit
- Timely linkage to care and ART initiation
- Patient and provider experience and satisfaction
- Patient and provider knowledge of national guidelines

Work Package 2 (WP2): Estimating the patient and provider costs of care

The second hypothesis was that DC implementation would result in efficiencies that free-up resources at the facility level, which can in turn be made available to patients who need them the most. QI helps facilities to be more efficient in their delivery of DC through better understanding of processes of care and testing changes. that increase value and eliminate non-value-added activities; thereby potentially reducing the cost per patient.

Relating to those hypotheses, the aim of WP2 was to understand and estimate the resource requirements of service delivery for HIV clients. Time Driven Activity-Based Costing (TD-ABC) was used to estimates of the average cost of ART delivery and care per patient per year (ppy) in facilities where DC+QI was implemented vs control facilities (DC alone). In addition, ingredients-based cost analysis was used to estimate costs of QI, HIV testing and ART.

Work Package 3 (WP3): Patient health outcomes

The final hypothesis was that, correct DC implementation would reduce the frequency of visits for stable patients, without negative impacts on the care received and outcomes for this category of patients. Concurrently, the unstable patients would benefit from increased follow-up, counselling and clinical examinations..

To test this hypothesis, WP3 documented the impact of DC+QI on patient health status. In WP3, incidence of reported opportunistic infections, viral suppression and quality of life measures were included.

DESCRIPTION OF THE INTERVENTION

» DIFFERENTIATED CARE (DC)

DC intends to reshape patient flow in the facility and to reallocate resources from stable patients to those most in need (unstable or new patients presenting advanced disease); thereby potentially reducing the average cost per patient and improving quality of care by tailoring services to patients more closely. It is also an added opportunity to build capacity of service providers on patient-centered care. According to the 2017 Differentiated Care Tool Guide, there are two main categories of patients:

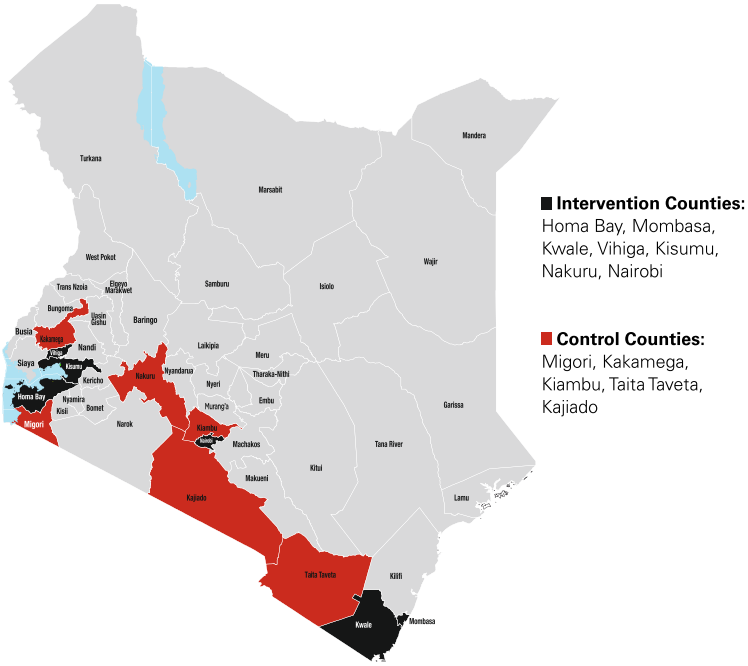
- patients who have been on ART for more than 12 months and are stable,
- patients who have been on ART for more than 12 months and are unstable.

On average, stable patients will have two clinical consultation reviews and two ARV refills (direct ART pick up without clinical consultation review) in a given year. This model is aimed at reducing patients waiting time at the facility and reducing unnecessary consultations for physicians. Unstable patients are followed-up with a clinician every 1-3 months, depending on their needs and do not have a direct ARV pick-up from a pharmacist or designated person. In addition, efforts are put to expand the range of services offered to unstable patients to improve adherence or follow-up.

» THE INTERVENTION: DC WITH QUALITY IMPROVEMENT

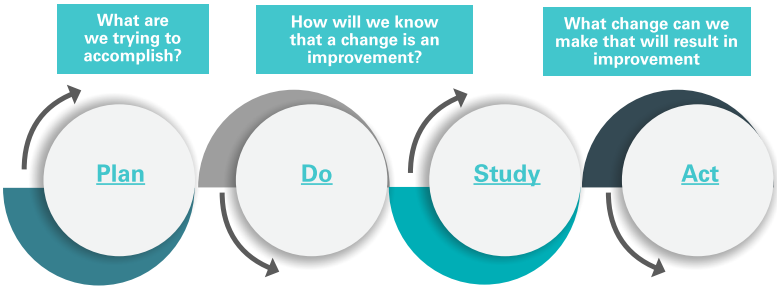
The Program Quality and Efficiency team based at NASCOP supported seven counties (Homa Bay, Mombasa, Kwale, Vihiga, Kisumu, Nakuru and Nairobi) to implement DC with a QI approach in 70 facilities. Five (5) counties (Migori, Kakamega, Kiambu, Taita Taveta and Kajiado) were selected as control counties based on the following criteria: same geographic region, similar HIV burden as measured by HIV prevalence rates and have similar viral load outcomes. Figure 1 provides the location of the intervention and control counties.

Figure 1 Map indicating the Intervention and control counties.



In intervention counties, DC+QI followed the Improvement Collaborative approach developed by the Institute for Healthcare Improvement, which integrates elements of traditional health programming (standards, training, job aids, equipment, and supplies) with modern QI elements (team work, process analysis, monitoring of results, client satisfaction) (Institute for Healthcare Improvement, 2003). This results in a dynamic learning system where teams from different sites collaborate to share and rapidly scale up strategies for improving quality and efficiency of health services in a targeted technical area with the broad purpose of increasing value to the patient. The model for improvement asks the following three questions:

Figure 2 ***the Plan-Do-Study-Act (PDSA) cycle***



The QI model utilizes the Plan-Do-Study-Act (PDSA) cycle:

- Step 1: Plan—Plan the test or observation, including a plan for collecting data
- Step 2: Do—Try out the test on a small scale
- Step 3: Study—Set aside time to analyse the data and study the results
- Step 4: Act—Refine the change, based on what was learned from the test

PDSA helps testing tailored response and change in real work setting. In addition to PDSA, the QI approach applied to DC in this context also includes shared learning across different facilities to promote rapid dissemination of successful practices (USAID, 2008; Institute for Healthcare Improvement, 2003).

The PQE project was implemented from December 2017 to May 2019 as shown in Figure 3.

At the national level, a team was formed to support training and project implementation. At the county and sub-county levels, key health workers were identified and trained as QI coaches to support implementation. The role of the QI coaches was to review facility performance and work plans, support facility staff review priority gaps, and document their QI processes as they implemented DC. In each facility, QI teams were formed from existing personnel, to collect baseline data, set and monitor performance targets to address service delivery gaps with regards to HIV services and improve process flow. The practical Handbook, and ART and DC guidelines served as the basis for DC+QI implementation (Ministry of Health, National AIDS and STI Control Program, 2016; Ministry of Health, National AIDS and STI Control Program, 2017).

The project was organized around learning sessions (four over the course of project implementation) and action periods.

- *Learning sessions* were workshops which drew participants from the 70 sites to learn about QI and DC and engage in the process of measurement of improvement, and also to share experiences, challenges and successes in implementing the differentiated care approach.
- *Action period* was the period in between learning sessions; facility level QI teams implemented changes to processes and measured the impact of those changes on the outcomes of interest. During those periods, facility QI teams met regularly (weekly or bi-weekly), documented their processes and submitted progress reports to the QI coaches. In addition, coaching visits (with team members from NASCOP, county and sub-county coaches) were organised on a monthly basis during action periods. Coaching visits entailed on job training, mentorship on the process of improvement and identification of activities required to maximize efficiencies to achieve better patient outcomes.

At the national level, a team was formed to support training and project implementation. At the county and sub-county levels, key health workers were identified and trained as QI coaches to support implementation. The role of the QI coaches was to review facility performance and work plans, support facility staff review priority gaps, and document their QI processes as they implemented DC. In each facility, QI teams were formed from existing personnel, to collect baseline data, set and monitor performance targets to address service delivery gaps with regards to HIV services and improve process flow. The practical Handbook, and ART and DC guidelines served as the basis for DC+QI implementation (Ministry of Health, National AIDS and STI Control Program, 2016; Ministry of Health, National AIDS and STI Control Program, 2017).

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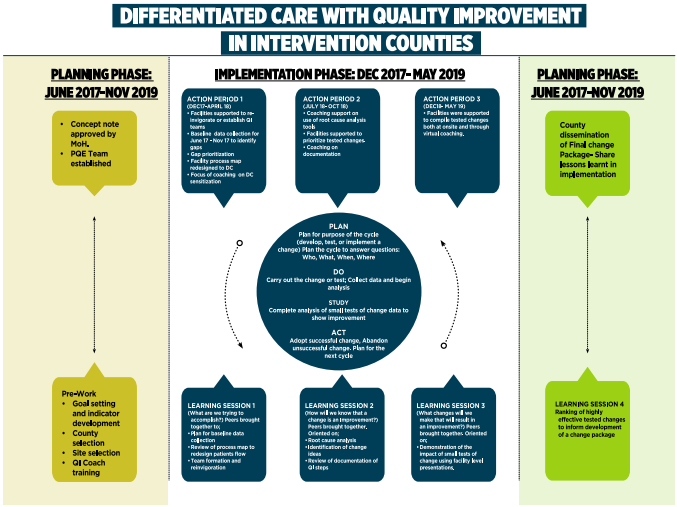
Action periods are the times between learning sessions, during which facility level QI teams implement changes to processes and measure the impact of those changes on the outcomes of interest. During those periods, facility QI teams met regularly (weekly or bi-weekly). They also documented their processes and submitted progress reports to the QI coaches. In addition, coaching visits (with team members from NASCOP, county and sub-county coaches) were organised on a monthly basis during action periods.

The intervention also introduced the philosophy of process improvement in facilities, encouraging on the job training and education in service organization and redesign, understanding processes and activities required to maximize efficiencies in the health care system while focusing on client needs to achieve better patient outcomes.

The intervention was implemented from December 2017 to May 2019. The project implementation timeline is shown in Figure 3.

Figure 3 Summary of DC+QI Implementation in Kenya.



METHODS

Matching Characteristics :Intervention and Control Sites

- Client was enrolled in a facility (intervention or control)
- Client was aged 20 years or older
- Client was not pregnant or expecting
- Client had been on ART for more than six months

Matching Characteristics :Intervention and Control Sites

- Facility level
- County characteristics
- Proportion of patients registered at the facility with a viral load test recorded in the most recent year

Sources

- Patient survey, chart abstraction and time and motion study
- Provider survey
- Facility costing tools

STUDY POPULATION

The study subjects[1] were split in the following categories:

1. Clients on ART[2]: the eligibility criteria were as follows (i) client was enrolled in a facility (intervention or control), (ii) was aged 20 years or older, (iii) was not pregnant or expecting, (iv) had been on ART for more than six months.
2. Providers of ART services (who spent at least 50% of their working time in the CCC or providing care for HIV positive clients)
3. Health facilities

STUDY SITES

This study compared intervention and control sites, which were matched using propensity score matching based on the following pre-intervention (i.e. June 2017) characteristics:

- Facility level (that is level II, III, or IV facility).
- County characteristics (epidemiological profile)
- Number of patients on ART registered at the facility
- Proportion of patients registered at the facility with a viral load test recorded in the most recent year

Propensity score matching ensures that the intervention sites and control sites present similar characteristics pre-intervention; in other words, that they were comparable before DC+QI was implemented.

All 70 intervention sites were considered for matching with a total of 193 potential candidate control sites (in the five control counties). The nearest neighbour matching method was used to match each intervention site with three control sites. Consequently, the program used their knowledge of the sites to pick the best match out of the three. Only the best 15 matches were considered for the study. A list of all sites included in this study can be found in Appendix 2.

DATA SOURCES

This study relied on the following data sources:

» PATIENT SURVEY, CHART ABSTRACTION AND TIME AND MOTION STUDY

A comprehensive patient survey was administered to 1,419 participants[3] randomly sampled[4] from facilities. The patient survey was split in the following sections: (i) personal information, (ii) HIV status, (iii) incurred expenses, (iv) satisfaction and knowledge, (v) health status. Information on treatment regimens, last weight and height check, viral load and CD4 test results were extracted from the Green Cards (the medical file equivalent in use for clients on ART) of all respondents to the study.

---

1 This research was subject to ethics approval by AMREF, Kenya, and received approval on May 10, 2019 (see reference AMREF-ESRC P624/2019). Informed consent was obtained from all participants to the study (patients and providers). The informed consent covered the purpose of the study, risks, benefits, cost to the participant and assurance of confidentiality.

2 Eligibility criteria is based on the 2018 treatment guidelines on differentiated care

Data collection

- **All data was collected between May-June 2019 under the supervision of NASCOP, and with the support of NACC, the Global Fund and the International Decision Support Initiative**
- **All data was collected from facilities, except for information on overheads, drug and commodity prices and costing of QI**

In addition, a time and motion survey was conducted on a subsample of 223 patients selected for the survey participants. The aim was to observe and record the time spent by an individual patient at every service delivery in the care pathway. The time and motion study was also a significant part of the time-driven activity based costing.

» PROVIDER SURVEY

56 health providers were interviewed across 30 facilities. The survey consisted of the following parts: (i) personal information, (ii) job satisfaction, (iii) knowledge, (iv) QI activities (this was only collected in intervention sites). All health providers identified as providing care for HIV clients for 50% or more of their time were interviewed.

» FACILITY COSTING TOOLS[5]:

Data were collected from 30 facilities using three sets of tools

- Process mapping (and time and motion study): this was done to map out the steps that form the process of care at the facility level and make an inventory of resources used at each step.
- Facility questionnaire: this enumerated the total health facility resources used in the health facility.
- Costing of QI: this was done through a review of the book of accounts held by Kenya Red Cross.

DATA COLLECTION

All data was collected between May-June 2019 under the supervision of NASCOP, and with the support of NACC, the Global Fund and the International Decision Support Initiative (at Imperial College London). Data collection was organized exactly two years after the implementation of DC+QI started.

All data was collected from facilities, except for information on overheads, drug and commodity prices and costing of QI.

» COSTING METHODS

TD-ABC was used for estimating costs of facility visits because it makes it possible to capture the fine differences in processes of care and is considered more accurate than other forms of activity-based costing. Accuracy here refers to how close the estimates are to the true costs (Keel et al., 2017). Patient costs which were not within the remit of the health system perspective were also measured and are presented separately in this report. Those mainly included direct costs paid by the patient such as transportation, lab tests or accommodation (if relevant) and did not include foregone income.

» STATISTICAL ANALYSIS

This report uses two main methods to estimate the differences in outcomes between intervention and control (i.e. non-intervention) sites across the different work packages.

Descriptive statistics and outcomes from the patient and provider survey were compared using means and proportions combined with a t-test or a Chi^2 test (based on whether or not the outcome under consideration is a continuous or a binary variable) to measure significance. Data were analysed using

STATA 14 (Texas Corporation). All statistical tests were two-sided. A p-value inferior to 0.05 indicates a difference between the control and the intervention sites significant at the 5% level. A p-value inferior to 0.01 corresponds to a highly statistically significant difference (at the 1% level). For work package 2, cost estimates were compared nominatively between intervention and control sites.

LIMITATIONS

The intervention was not randomized, which could have been problematic:

- If intervention sites volunteered to participate to the intervention despite not being eligible for the intervention
- If sites, once selected to participate to the intervention, declined to participate

However, there were no reports of such kind. Intervention sites were selected based on pre-defined characteristics, and no site declined to participate upon selection. To ensure that sites in the intervention and control arm are comparable, we employed a procedure called matching (see the section on site selection).

This study also estimated the average outcome difference between intervention and control sites, solely based on one end-point data collection. There was no baseline data, thus despite the matching, there could be pre-existing differences between sites that were not accounted for. Because the evaluation relied on a single end-point observation, it was not possible to detect the true statistical impact of DC+QI. The estimates presented in this report are associations between the outcomes under consideration and the intervention.

Another limitation to note was the presence of missing data in the time and motion survey. In some facilities, not all categories of patients were surveyed (e.g. only stable visits were observed). In addition, when patients were observed, times for some services were not appropriately reported due to the enumerators z not collecting sufficiently granular observations for times in each step. In those two instances, data was imputed for the missing observation based on the average time, per patient category, for the missing step. For imputation, in order not to create an artificial difference between intervention and control sites, the average for all facilities was used, regardless of their intervention status. This means that if a bias occurs from the imputation method, then it is likely that we under-estimate the difference between intervention and control sites (downward), rather than over-estimate. This means those estimates are conservative.

Finally, specific to the calculation of quality of life scores from EQ5D (see WP3), Kenya does not have a 5 level (5L) value set so the Zimbabwe crosswalk value set was used instead. The Zimbabwe value set was used because Zimbabwe as a country has more in common with Kenya than other countries with values sets (it is the only value set available for the region). Despite the similarities between the two countries there may still be a margin of error in the results as a result of using the Zimbabwean value set instead of a Kenya value set (if it existed).

RESULTS

DESCRIPTIVE STATISTICS (PATIENT AND PROVIDER SAMPLE)

» PATIENT CHARACTERISTICS

A summary of demographic characteristics for patients is shown in Table 1. A total of 1,419 patients responded to the survey. 55.1% of respondents were interviewed in intervention sites (44.9% in control sites). In Table 1, the first column relates to the total sample and the subsequent columns to the patients surveyed in control and intervention sites.

1,419
The total number of patients who responded to the survey.

30
Facilities surveyed

Table 1 Demographic characteristics of Patients

	Total (N=1419)	Control (n=637)	Intervention (n=782)	P-value
Gender				**0.205**
Female	62.7%	64.5%	61.3%	
Male	37.3%	35.5%	38.7%	
Marital status				**0.043**
Married	62.8%	64.8%	61.1%	
Separated	8.2%	5.7%	10.2%	
Single	9.9%	10%	9.7%	
Widowed	19%	19.3%	18.8%	
Other	0.1%	0.2%	0.1%	
Household size				**0.016**
(mean number of people)	4.93	4.80	5.11	
Employment status				**0.874**
Not employed	26.6%	26.8%	26.5%	
Employed	73.4%	73.2%	73.5%	
Average monthly wage (in KES)				**<0.001**
Below 10000	63.7%	73.8%	55.0%	
10001-29999	25.2%	19.1%	30.5%	
30000- 49999	6.5%	3.8%	8.8%	
50000-79999	1.9%	1.6%	2.1%	
80000-119999	1.1%	0.5%	1.7%	
120000-149999	0.3%	0.0%	0.5%	
150000-199999	0.1%	0.3%	0.0%	
200000 and above	0.1%	0.0%	0.2%	
Disclosure of status to family				**0.141**
No	4.0%	4.9%	3.3%	
Yes	96.0%	95.1%	96.7%	
Distance facility-home				**<0.001**
< 5Km	44.9%	53.9%	37.6%	
5-10 KM	16.4%	17.5%	15.6%	

	Total (N=1419)	Control (n=637)	Intervention (n=782)	P-value
11 + KM	38.7%	28.6%	46.8%	
BMI Category				**0.22**
Low BMI (Malnourished)	8.7%	9.0%	8.4%	
Normal	58%	60.3%	56.1%	
Pre-Obesity	22%	21.4%	22.5%	
Obesity Class I	8.8%	7.3%	10%	
Obesity Class III	2.5%	1.9%	2.9%	

Generally, the control and intervention groups were similar in terms of gender and employment status. There was no statistical difference between control and intervention sites in patients' gender or age. Most patients (62.8%) were married. The proportion of patients who reported to be separated or single was higher in the intervention group. More than half of the patients (53.4%) were from households with 5 or more members, with roughly the same proportions at control and intervention sites.

Most of the respondents were employed (73.4%). More than half of the employed respondents (63.7%) reported earning wages less than 10,000 KES per month. It is worth noting that there was a significant difference in earnings between control and intervention sites (73.8% versus 55.0% reported earning less than 10,000 KES/month), even when excluding the Nairobi area1.

The rate of disclosure of HIV status within the family was very high (96%), with no significant difference between control and intervention sites. A higher proportion of patients in control sites (53.9%) were seen at facilities within 5km of their home, compared to 37.6% of patients from intervention sites. Conversely, a higher proportion of patients from intervention sites received care at facilities that were 11km or more from their home (28.6% versus 46.8%).

62.8% of the patients who responded were married

73.4% of the patients who responded were employed

96% The rate of disclosure of HIV status within the family

1 *An additional analysis was conducted to test whether the difference in earnings was significant when excluding Nairobi. The rationale for this was that earnings in Nairobi are considered typically high compared to other Kenyan counties. The county match for Nairobi was Kiambu, which has a much lower GDP per capita. However, this additional analysis showed that the difference remained significant, although the difference between intervention and control sites was smaller.*

» PROVIDER CHARACTERISTICS

56 providers were interviewed for this study (27 in control and 29 in intervention sites). The demographic characteristics of the sample of providers is shown in Table 2.

56
The total number of providers who responded to the survey.

96.6%
of the providers have served at a facility for over a year

37.5%
of the providers only attend to people living with HIV

Table 2 ***Demographic characteristics of providers***

	Total (N=56)	Control (n=27)	Intervention (n=29)	P Value
Gender				
Female	57.1%	55.6%	58.6%	0.817
Male	42.9%	44.4%	41.4%	
Cadre				
Clinical officer	53.6%	55.6%	51.7%	0.393
Nurse	8.9%	7.4%	10.3%	
Pharmacist	5.4%	11.1%		
Pharmaceutical technician	12.4%	14.8%	10.3%	
HRIO/Data Clerk	1.8%		3.4%	
Nutritionist	1.8%		3.4%	
Specify Other	16.1%	11.1%	20.7%	
Duration of service at facility				
Over A Year	94.6%	92.6%	96.6%	0.511
Under A Year	5.4%	7.4%	3.4%	
Average hours worked in this facility				
Day: Median (Range)	8(7-10)	8(7 - 10)	8(8 - 9)	0.16
Month: Median (Range)	20(6-30)	20(12 - 30)	20(6 - 26)	0.23
Attend to people only living with HIV				
Yes	37.5%	22.2%	51.7%	0.023
No, I see other patients	62.5%	77.8%	48.3%	

A higher proportion of the sample were women (57.1% in total sample) both in the intervention and control sites. More than half of providers (53.6%) were clinical officers (no significant difference between the intervention and control sites). Nearly all providers (94.6%) had worked in their facility for more than one year and providers in control and intervention sites had similar level of working experience.

Providers reported working a median of eight hours per day and 20 days per month, which did not vary significantly between control and intervention sites (p=0.16). However, there was a significant difference in care assignments between sites: 77.8% of providers in control sites provide services to patients other than PLHIV, while the majority of providers (51.7%) from intervention sites only provided services to PLHIV.

WORK PACKAGE 1: PROCESSES OF CARE AND PROGRAMME EFFICIENCY

» PATIENT PATHWAY

Process maps drawn at the facility level differed significantly from one facility to another, even when considering a given patient group. The figures below depict, however, a 'typical' pathway at the facility level for the three categories of patients.

Patient pathways summary

Figure 4 ***Process step for unstable client***

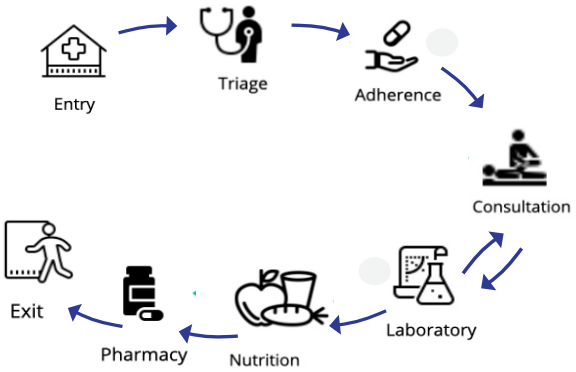


Figure 5 ***Process step for stable client during six monthly clinic review***

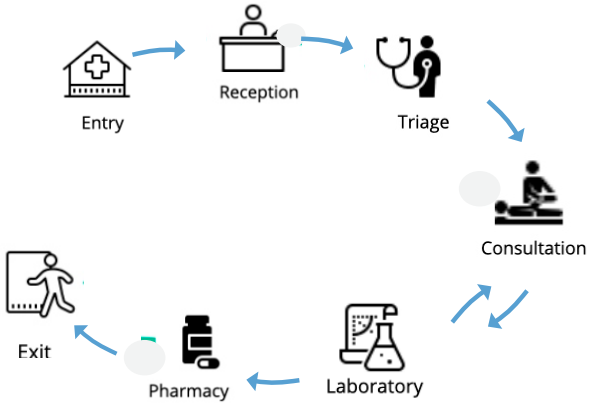
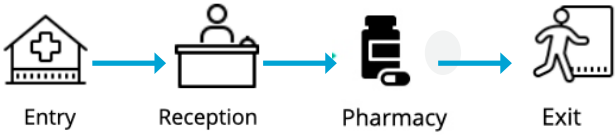
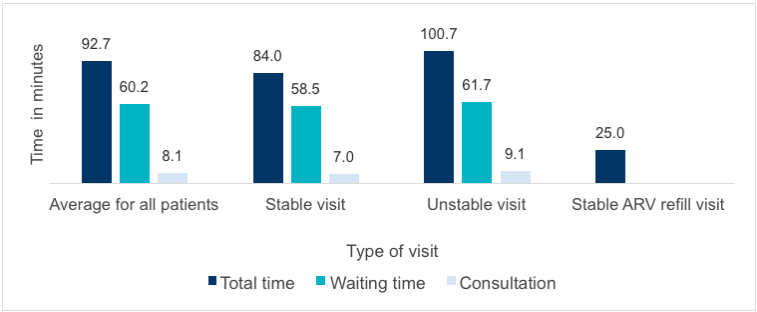


Figure 6 ***Process steps for stable client during drug pick up***



A summary of total times is shown on Figure 5 below. The average total time spent at the clinic was 84.0 minutes for stable patients and 100.7 minutes for unstable patients. The difference in total time can be justified by higher waiting times, as well as higher consultation time for unstable patients. Total times were, on average, much higher for visits that contained a clinical appointment compared to drug pick-up (92.6 minutes versus 25.0 minutes).

Figure 7 ***Summary of process times by type of visit, in minutes***



Total and waiting times in low volume facilities (with fewer than 1000 patients on ART registered at the clinic) were much lower than in high volume facilities: on average, those were respectively 76.13 minutes versus 107.06 minutes. Times spent in the consultation room were also higher in low-volume facilities compared to high volumes (9.86 minutes versus 6.6 minutes). In one high-volume facility, the average waiting time was 198.5 minutes, in other words over three hours.

Figure 8 ***Average process times in minutes, by patient volume (all facilities)***

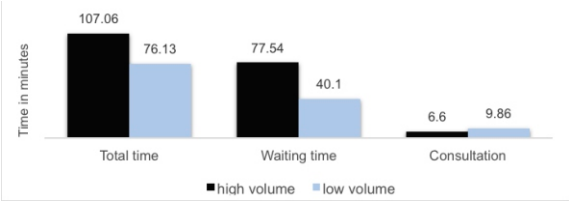


Table 3 compares the average times in intervention and control sites. On average, patients in intervention facilities spent less time at the clinic compared to control sites, due to lower time spent on waiting bays (56.1 minutes versus 63.7).

Table 3 ***Average time per step by intervention status, in minutes***

Process	Total	Intervention	Control
Adherence	11.29	10.34	12.43
Consultation	8.09	7.95	8.21
Laboratory	6.08	5.92	6.24
Nutrition	15.49	15.81	15.21
Pharmacy	3.82	3.38	4.14
Reception	2.46	2.72	2.13
Records	2.05	2.6	1.7
Triage	2.83	3.31	2.43
Total time	92.66	89.94	95
Waiting Bay	60.15	56.08	63.69

NB: only visits for stable and unstable patients were considered for the above calculation, drug pick-up was excluded from this analysis.

» LINKAGE TO CARE AND TIMELY ART INITIATION

Linkage of patients into care is a critical step in ensuring successful treatment outcomes. Patients should be enrolled at the facility within 90 days and initiated on ART within 14 days at the latest.

***Table 4** Time taken to ART initiation and Enrolment in 2017*

	Total (N=165)	Control (n=69)	Intervention (n=96)	p Value
Time taken to ART initiation 2017				**0.141**
Within 14 Days	86.7%	81.7%	90%	
After 14 Days	13.3%	18.3%	10%	
Time taken to ART initiation 2017 median days (range)	**0 (0-515)**	**0 (0-121)**	**0 (0-515)**	**0.07**
	Total (N=192)	**Control (n=81)**	**Intervention (n=111)**	
HIV Diagnosis to Enrolment 2017				**0.882**
Within 90 Days	94.7%	95%	94.4%	
After 90 Days	5.3%	5%	5.6%	
HIV Diagnosis to Enrolment 2017 median days (range)	**0(0-375)**	**0(0-316)**	**0(0-375)**	**0.1**

NB. The sample size for this analysis is lower because we only included patients enrolled after June 2017 in this analysis. We did not include patients enrolled before 2017 because QI+DC was not yet implemented as to test out differences from the program implementation perspective.

Table 4 presents two measures of time, from HIV diagnosis, patient enrolment at the facility to initiation of ART. On these two measures, there was no significant difference between the control and intervention sites, although 8.3% more patients were linked to care and initiated on ART within two weeks in intervention compared to control sites (difference not significant[2]). The proportion of patients initiated on ART late (after 14 days) was 10% in intervention sites versus 18.3% in control sites. There was no difference in median time to enrolment after HIV diagnosis (0 days).

2 *In this analysis, low sample size might explain lack of statistical power.*

» PATIENT AND PROVIDER KNOWLEDGE ON NATIONAL GUIDELINES RELATING TO DIFFERENTIATED CARE

Patient

The patients' knowledge of ART and HIV improves treatment ownership and has been positively associated with greater adherence to ART and management of adverse events (Terblanche & Stellenberg, 2014; Agu, Oparah, & Ochei, 2012). For the purpose of this study, patient knowledge was measured based on the questions presented in Table 5.

***Table 5** Patient Knowledge, by intervention status*

	Total (N=1419)	Control (n=637)	Intervention (n=782)	p-value
Have you completed a 6 month period of Isoniazid Preventive Therapy or IPT?				**0.482**
No	13.7%	13%	14.3%	
Yes	86.3%	87%	85.7%	
Do you know when your next appointment will be after today?				**0.509**
No	1.1%	1.3%	0.9%	
Yes	98.9%	98.7%	99.1%	
Do you know what will happen during your next appointment?				**<0.001**
No	17.8%	26.1%	11.0%	
Yes	82.2%	73.9%	89.0%	
How often should you receive a viral load test?				**0.849**
Answered Incorrectly	81.9%	82.1%	81.7%	
Answered Correctly	18.1%	17.9%	18.3%	
What do you do if you have forgotten your medication? (n=703)				**<0.001**
Answered correctly	65.4%	58.7%	70.6%	
Answered wrong	24.6%	41.3%	29.4%	

A greater proportion of clients reported knowing what will happen in the next appointment in intervention compared to control sites ($p<0.001$). Almost all patients were aware, on the exit interview, about when their next appointment would be after the observed visit (98.9%). There was a significant difference and higher proportion of patients (70.6%) in intervention sites who answered correctly to what they would do if they forgot their medication ($p<0.001$)

Provider knowledge

Given the important role of health care providers in HIV care, from HIV diagnosis to adherence preparation and treatment follow-up, identifying knowledge gaps and training providers to efficiently manage their work tasks is of utmost importance for a successful ART program in the public health sector.

Table 6 ***Provider knowledge score, by intervention status***

	Total (N=56)	Control (n=27)	Intervention (n=29)	p-value
Knowledge Score				**0.745**
No knowledge	5.4%	7.4%	3.4%	
Poor knowledge	23.2%	29.6%	17.2%	
Average knowledge	41.1%	37.0%	44.8%	
Good knowledge	26.8%	22.2%	31.0%	
Very good knowledge	3.6%	3.7%	3.4%	

There was no significant difference in knowledge (based on this score) between intervention and control sites. However, the proportion of providers scoring no knowledge was lower in intervention sites and the percentage of providers scoring good knowledge was 31.0% in intervention sites compared to 22.2% in control sites (although differences in distribution is not significant).

» PATIENT AND PROVIDER EXPERIENCE AND SATISFACTION

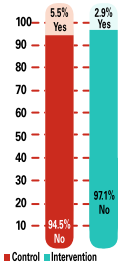
Patient experience and satisfaction

Patient satisfaction is often measured as part of a project evaluation. Table 7 summarises outcomes of patient experience.

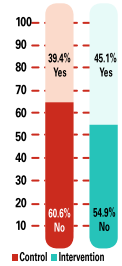
Table 7 ***Summary of patient experience, by intervention status***

	Total (N=1419)	Control (n=637)	Intervention (n=782)	P-value
Hospitalisation in relation to HIV infection in the last 6 months				**0.016**
No	95.9%	94.5%	97.1%	
Yes	4.1%	5.5%	2.9%	
Blood pressure measurement in the last year				**0.003**
No	43.9%	48.2%	40.4%	
Yes	56.1%	51.8%	59.6%	
Cervical Screening in the past year				**0.077**
No	57.4%	60.6%	54.7%	
Yes	42.6%	39.4%	45.3%	

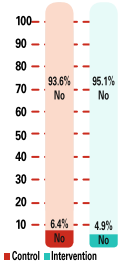
Hospitalisation in relation to HIV infection in the last 6 months



Cervical Screening in the past year



Whether was able to see a clinician on visit



	Total (N=1419)	Control (n=637)	Intervention (n=782)	P-value
Whether was able to see a clinician on visit				**0.198**
No	5.6%	6.4%	4.9%	
Yes	94.4%	93.6%	95.1%	
was able to get: Consultation				**0.003**
No	3.9%	5.5%	2.5%	
Yes	96.1%	94.5%	97.5%	
was able to get: Lab services				**0.773**
No	45.0%	44.5%	45.5%	
Yes	55.0%	55.5%	54.5%	
was able to get: Nutrition Services				**<0.001**
No	73.7%	66.7%	81.9%	
Yes	26.3%	33.3%	18.1%	
was able to get: Drug pick up				**0.82**
No	0.9%	0.8%	0.9%	
Yes	99.1%	99.2%	99.1%	
was able to get: Adherence Counselling				**<0.001**
No	49.2%	66.7%	33.9%	
Yes	50.8%	33.3%	41.2%	
Ever been a fast-track client?				**0.366**
Don't know	0.2%	0.5%		
No	96.4%	96.5%	96.4%	
Yes	3.3%	3.1%	3.6%	
Would recommend fast track models to other stable patients?				**<0.001**
Don't know	2.4%	5.0%	1.0%	
No	5.2%	10.0%	2.8%	
Yes	92.4%	85.0%	96.2%	

NB. Sample size varies in this table. Sample size total was 1419, but for the availability of services, depending on what type of services were sought by clients on the day of their visit, the sample is lower. For instance, if a patient did not need adherence counselling on the day of the interview, then their answers were recorded as N/A or missing.

There were several significant differences in patient experience between intervention and control sites. 5.5% of patients in control sites reported having been hospitalized in relation to their HIV infection in the last six months, compared to 2.3% in intervention sites (p=0.016). A higher proportion of patients in intervention sites (59.6%) reported having had their blood pressure taken in comparison to (51.8%) in control sites (p = 0.003). A higher proportion of patients in intervention sites reported having been able to get a consultation to control sites (95.1% versus 93.7%) (p <0.001). However, a higher proportion of patients in control sites reported having been able to receive nutritional services (33.3% versus 18.1%) (p<0.001). Finally, 95.2% of patients interviewed were willing to recommend fast-track models of care in the intervention group compared to 85.0% in the control group (p<0.001).

Satisfaction was measured using a standard Likert scale (six-point scale from Extremely Satisfied to extremely dissatisfied) along several dimensions of care. Table 8 shows the results for the overall satisfaction score, as well as satisfaction along individual items. Respondents reported on average high satisfaction across all domains. The lowest satisfaction was reported for the waiting times (how long you waited to see the clinician) which received on average 4.69/6.

***Table 8** Patient experience and satisfaction scores (mean score), by intervention status*

	Total (N=1419)	Control (n=637)	Intervention (n=782)	p-value
How long you waited to see the clinician	4.69	4.59	4.77	<0.001
Convenience of the time of appointment	5.39	5.32	5.45	0.04
Time spent with the clinician	5.49	5.46	5.52	0.08
Observation of privacy clinician	5.51	5.44	5.56	0.005
The clinician approach towards you	5.57	5.57	5.59	0.33
Explanation of what was done to you	5.50	5.50	5.49	0.66
Technical skills of the clinician	5.55	5.56	5.55	0.64
Drug availability	5.67	5.73	5.61	0.99
visit overall	5.41	5.37	5.47	0.98
Generated score (average)	5.42	5.40	5.43	0.21

NB: Generated average score is calculated as the mean from all the other scores

Patients in intervention sites reported to be more satisfied with the waiting times, convenience of appointment, time spent with the clinician (during the consultation) and observation of privacy compared to control sites (all p<0.10). However, satisfaction was rated equally across control and intervention sites on a number of variables, including the overall score.

Provider satisfaction

Studies have shown that provider satisfaction has been positively associated with greater quality of care, care safety, diligence, relationship with patients (Casalino & Crosson, 2015; Dewa, Loong, Bonato, & Trojanowski, 2017; Tumiel-Berhalter & Watkins, 2006).

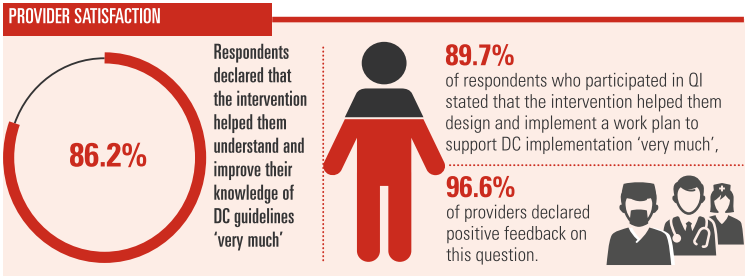
Table 9 ***Provider satisfaction score (mean score), by intervention status***

	Total (N=1419)	Control (n=637)	Intervention (n=782)	p-value
Work environment	4.25	4.30	4.21	0.61
Atmosphere at work	4.46	4.59	4.34	0.76
Hospital Administration support	4.59	4.48	4.69	0.26
Remuneration/pay	3.42	3.48	3.38	0.60
Hours worked	4.77	4.67	4.86	0.28
Autonomy (Independence to do your work)	5.07	5.14	5.00	0.69
Compatibility of professional and personal life	4.84	4.63	5.03	0.13
Overall satisfaction with your job	4.84	4.67	5.00	0.12
Generated score (average)	4.53	4.49	4.56	0.378

NB: Generated average score is calculated as the mean from all the other scores

Satisfaction was generally high for both control and intervention groups. However, satisfaction was found the lowest for pay and the work environment. There were no significant differences in the satisfaction scores for any of the queried domains between intervention and control sites.

In addition, opinions and satisfaction about the participation to QI was evaluated in intervention sites. 86.2% of respondents declared that the intervention helped them understand and improve their knowledge of DC guidelines 'very much'. 89.7% of respondents who participated in QI stated that the intervention helped them design and implement a work plan to support DC implementation 'very much', overall 96.6% of providers declared positive feedback on this question.



WORK PACKAGE 2: COSTING

» COST OF AN UNSTABLE PATIENT CLINICAL VISIT

Table 10 Unit costs of unstable client visits for intervention and control facilities shows the estimated unit costs for unstable client visits 14 intervention and 15 control sites. The average cost of the unstable client visit across all 29 facilities (combining intervention and non-intervention sites) was KES 996 with a median of KES 858. In intervention sites, the highest unit cost was recorded in Mbaghathi Hospital (KES 1,672) and the lowest was recorded in Muhoroni (KES 642). This is compared to a highest cost of KES 2,374 in Mwatate and lowest of KES 471 in Bushiri for control facilities.

On average, costs of unstable visits were higher in control sites. The average cost in control facilities was KES 1,105 compared to KES 983.76 in intervention sites.

On average, costs of unstable visits were higher in control sites.

Control Facilities
KES 1,105

Intervention Sites
KES 983.76

Table 10 ***Unit costs of unstable client visits for intervention and control facilities***

Intervention	Cost (KES)	Overhead	Composition Space and equipment	Personnel
Ahero	819.99	38%	6%	56%
Ganjoni	733.71	30%	18%	52%
Ipali	500.05	17%	17%	67%
Kinondo kwetu	1,433.04	18%	7%	76%
Kisumu	936.14	42%	17%	40%
Kombewa	1,366.88	41%	10%	49%
Kuresoi	846.11	29%	26%	45%
Lumumba	1,041.28	38%	20%	42%
Mbagathi	1,671.99	15%	14%	72%
Mbale	669.88	32%	10%	58%
Miriu	778.17	48%	17%	35%
Msambweni	1,397.05	10%	75%	15%
Muhoroni	642.04	18%	38%	44%
Pumwani	936.34	44%	19%	37%
Average	983.76	30%	21%	49%
Control				
Awendo	1,147.18	40%	13%	47%
Bushiri	470.78	23%	12%	65%
Kajiado	532.78	16%	16%	69%
Kiambu	876.43	39%	15%	46%
Macalder	673.80	34%	16%	50%

Intervention	Cost (KES)	Overhead	Composition Space and equipment	Personnel
Migori	627.75	18%	30%	51%
Muhuru	835.83	26%	40%	33%
Mwatate	2,373.97	43%	20%	37%
Rongo	1,167.27	34%	23%	43%
Ruiru	673.32	40%	11%	50%
St. Camilus Karungu	964.92	34%	11%	55%
St. Joseph Taita Taveta	1,141.41	24%	12%	64%
Taita Taveta	2,249.78	34%	13%	53%
Kambiri	522.00	19%	11%	70%
Shitswitswi	858.08	37%	21%	42%
Average	1,007.69	31%	18%	52%
All facilities				
Average	1105.40	30%	19%	50%
Median	858.08			

On average, cost per stable visit was lower in intervention sites compared to control sit:

» COST OF STABLE 6-MONTH REVIEW

Table 11 Unit costs of stable client 6-month visits for intervention and control facilities presents the unit costs for stable client visits 13 intervention and 14 control facilities). The average cost of the stable client 6-month visit across all 27 facilities was KES 642 with a median of KES 622.

Mbagathi had the highest cost (KES 1,231) and Kinondo Kwetu recorded the lowest cost (KES 230) among intervention sites. Taita Taveta (KES 1,657) had the highest cost and Kajiado (KES 227) had the lowest among control sites.

On average, cost per stable visit was lower in intervention sites compared to control site: The average cost per stable visit was KES 702 (27% overhead, 16% space and equipment, 48% personnel) in control sites, compared to KES 578 in intervention sites (31% overhead, 23% space and equipment, 46% personnel).

***Table 11** Unit costs of stable client 6-month visits for intervention and control facilities*

	Cost (KES)	Composition		
Intervention sites		**Overhead**	**Space and equipment**	**Personnel**
Ganjoni	349.32	27%	15%	58%
Ipali	439.76	17%	16%	67%
Kinondo kwetu	229.91	50%	25%	25%
Kisumu	980.06	42%	21%	37%

	Cost (KES)	Composition		
Intervention sites		**Overhead**	**Space and equipment**	**Personnel**
Kombewa	455.26	33%	8%	59%
Kuresoi	425.77	32%	13%	55%
Lumumba	520.87	31%	24%	45%
Mbagathi	1,230.65	16%	17%	67%
Mbale	594.65	32%	11%	58%
Miriu	645.82	51%	18%	31%
Msambweni	373.33	11%	86%	3%
Muhoroni	622.13	20%	32%	48%
Pumwani	643.41	41%	17%	41%
Average	577.76	31%	23%	46%
Control				
Awendo	857.62	35%	12%	53%
Bushiri	296.07	24%	11%	66%
Kajiado	227.12	17%	20%	64%
Kiambu	921.85	42%	15%	43%
Macalder	814.59	36%	15%	49%
MIGORI	290.32	16%	20%	64%
Muhuru	807.91	26%	41%	33%
Mwatate	1,131.48	34%	28%	37%
Ruiru	291.23	42%	12%	46%
St. Camilus Karungu	580.44	31%	12%	57%
St. Joseph Taita Taveta	657.41	18%	14%	68%
Taita Taveta	1,656.91	32%	16%	53%
Kambiri	509.62	6%	3%	22%
Shitswitswi	790.73	17%	10%	21%
Average	702.38	27%	16%	48%
All facilities				
Average	642.38	29%	20%	47%
Median	622.13			

On average, ARV pick-up costs were higher in intervention than control sites

Control Facilities
KES 207

Intervention Sites
KES 243

» COST OF FAST-TRACK ARV PICK-UP

Data were collected in 13 out of 30 facilities3 (Table 12 Unit costs of stable client drug pick up in intervention and control facilities). Across all sites, the average cost of an ARV pick-up was KES 230, with a median of KES 170. The highest cost in intervention sites was KES 496 (Mbagathi) compared to KES 602 (Taita Taveta) in control sites.

On average, ARV pick-up costs were higher in intervention (KES 243) than control sites (KES 207).

***Table 12** Unit costs of stable client drug pick up in intervention and control facilities*

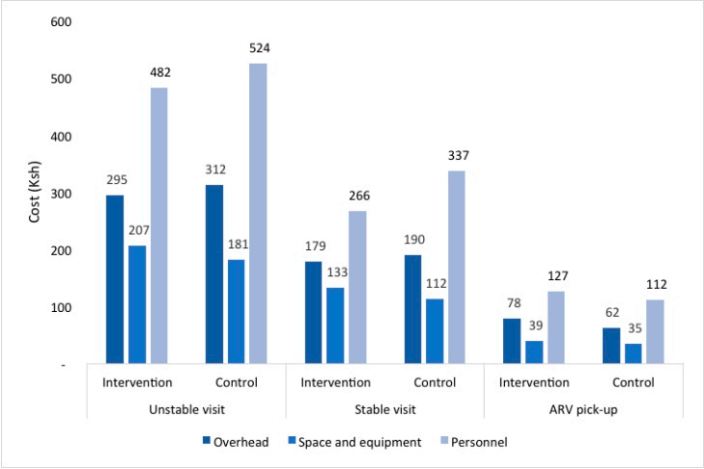
	Cost (KES)	Composition		
Intervention sites		**Overhead**	**Space and equipment**	**Personnel**
Ekwanda	257.17	12%	36%	52%
Ganjoni	356.83	23%	14%	63%
Kisumu	131.38	39%	20%	40%
Kombewa	275.53	30%	4%	66%
Lumumba	97.48	59%	10%	31%
Mbagathi	495.66	10%	16%	74%
Miriu	169.95	47%	11%	41%
Pumwani	162.86	34%	19%	47%
Average	243.36	32%	16%	52%
Control sites				
Migori	159.46	14%	12%	74%
Muhuru	196.26	47%	28%	25%
Taita Taveta	602.27	33%	8%	59%
Kambiri	8.80	28%	27%	46%
Shitswitswi	70.87	27%	9%	64%
Average	207.53	30%	17%	54%
All sites	**KES**	**Overhead**	**Space and equipment**	**Personnel**
Average	229.58	31%	16%	53%
Median	169.95			

3 *This is a limitation as enumerators did not observe fast track patients in many facilities, despite implementing fast-tracking. It is worth noting that two sites in the control counties did not implement DC guidelines at all (e.g. no categorisation and no fast tracking)*

» SUMMARY COMPARISON OF UNIT COSTS FOR ALL VISITS

Figure 6 illustrates the unit costs across all facilities in control and intervention sites for all three types of visits. Costs were generally higher for unstable visits in both control and intervention sites, and lowest for the ARV pick-up. Cost of unstable patient visits were approximately 60% on average higher than costs of stable 6 month reviews. The cost of ARV pick-up visits was more than four lower than the cost of a stable 6 month review. The difference in costs was attributed to the time that patients spent at the facility (in the entire patient pathway). Personnel costs contributed most (approximately 50%) to unit costs for all types of visits.

Figure 6 ***Breakdown of costs (KES) per type of visit (all facilities)***



» DRUG COSTS

Costs of drugs were calculated separately and not included in the cost visits presented in Table 10, 11 and 12. This was done because we were unable to collect this data during fieldwork, for instance, drug regimens were not appropriately recorded. To fill this data gap, we use the reference price to estimate average drugs costs for first and second line regimens (shown on Table 13 Average drugs costs (KES) for first- and second-line regiments). The costs were calculated for an average patient, regardless of whether they were in intervention or control sites. The estimated average cost per patient per day was KES 23 for first line and KES 74 for second line regimens. We estimated that the annual regimen cost would be KES 8,295 and KES 26,916, respectively for first- and second-line regimens.

Table 13 ***Average drugs costs (KES) for first- and second-line regiments***

ARV Regimen	Cost Per Day	Cost Per Month	Cost Per Year
First Line	23	682	8,295
Second Line	74	2,212	26,916

COST OF TESTS

KES 22,821
Estimated the cost of laboratory tests for an unstable patient

KES 10,000
Estimated the cost of laboratory tests for a stable patient

» ESTIMATING COST OF HIV TESTS

Similar to drug costs, the cost of HIV tests was not appropriately recorded during data collection. As a result, the government reference price was used to estimate the cost of tests, taking into account all consumables and requirements. We estimated the cost of laboratory tests for an unstable patient to be KES 22,821 per year, compared to KES 10,000 for a stable patient (Table 14 Number of tests and cost per year per HIV patient).

Table 14 ***Number of tests and cost per year per HIV patient***

	Number of test	Cost of test	Unstable patient	Stable patient
Baseline tests				
HIV confirmatory test	1	121	121	
CD4 Test	1	2,500	2,500	
Serum Cryptococcal Antigen (sCrAg) test	1	200	200	
Viral load	2	10,000	20,000	
Routine test (Annual)				
Viral load monitoring	1	10,000		10,000
Total cost of tests per patient per year			**22,821**	**10,000**

TOTAL COST

KES 100M
Estimated total cost of implementing the QI intervention for the 2 years project duration

18%
Start-up cost

39%
Administration cost

43%
Intervention costs

» AVERAGE COSTS OF THE QUALITY IMPROVEMENT INTERVENTION

A final cost component estimated for this report is the cost of QI implementation. Those costs are accrued at the national level (e.g. organization of coaching sessions) and costs incurred at the facility level for intervention sites only. The total cost of implementing the QI intervention was estimated to be KES 100 million for the duration of the project (2 years). The total cost comprised of three categories – Start-up (18%), Administration (39%) and Intervention costs (43%). More than 50% of intervention costs were spent on learning sessions.

Table 15 ***Total costs (KES) of the QI intervention for the project duration of 2 years***

Cost category	Cost (KES)	% of total costs
Start-up	17,883,197.00	18%
Administration and overhead	39,398,865.32	39%
Intervention costs	42,836,192.70	43%
• Coaching sessions	15,393,861.82	
• Learning sessions	24,421,781.60	
• QI coaches training	3,020,549.28	
Total costs	**100,118,255.02**	

Personnel costs accounted for 70% of all costs over the project duration (data not shown in table). Given a total number of 96,946 patients across the 70 intervention sites, the cost of PQE per patient (beneficiary) was KES 1,032.72 over a period of two years; or KES 516 per year.

UNSTABLE PATIENT

KES 8,843
The annual cost of clinical visits on first line treatment

KES 39,959
The total cost of drugs and tests per year

STABLE PATIENT

KES 1,744
The annual cost of clinical visits

KES 20,115
The total cost of drugs and tests per year

» AVERAGE COST FOR ART PER PATIENT YEAR

We estimated the cost of treating one patient per year by adding up the cost of visits, drugs and laboratory tests for stable and unstable patients (Table 16 Annual costs (KES) per patient (by patient type)). The cost for stable patients combined the 6-month visit and ARV pick up.4

Unstable patients

The guideline states that unstable patients should be seen once every 1-3 months, in other words, between 4 to 12 per year. We approximated that unstable patients would have 8 visits in a year. The annual cost of clinical visits for an unstable patient on first line treatment is thus KES 8,843 on average (combining intervention and control sites). Adding the cost of drugs and tests, the total cost per year for an unstable patient is KES 39,959. The annual cost per patient in control sites is KES39,178 compared to KES38,986 in intervention facilities, a difference of KES191 (or 2% of control costs).

Stable patients

Stable patients have a clinic review every 6 months in addition to the ART pick up if on the fast track model. This adds up to a total of 4 visits to the facility (2 clinical visits and 2 drug refill visit). The total cost of visits for the year is KES 1,744 (both intervention and control). When costs of drugs and tests are added, the annual cost in control sites are KES20,115 compared to KES19,937 in intervention sites.

***Table 16** Annual costs (KES) per patient (by patient type)*

Unstable patient	Visit	Drugs	Tests	Total
Intervention	7,870	8,295	22,821	38,986
Control	8,062	8,295	22,821	39,178
All	8,843	8,295	22,821	39,959
Stable patient				
Intervention	1,642	8,295	10,000	19,937
Control	1,820	8,295	10,000	20,115
All	**1,744**	**8,295**	**10,000**	**20,039**

NB. Costs showing for only patients on first line drugs costs.

» ANNUAL COST OF HIV TREATMENT WITH QI

When the cost of QI is added to the cost of HIV treatment, the Kenyan government would expect to spend and additional KES 516 per patient per year; i.e. taking intervention facilities costs, an average of KES 40,475 for unstable patients and KES 20,555 per year for stable patients on first line treatment.

4 *Once again, the number of visits was not well recorded in the survey. This means the number of visits was estimated from the guideline and expert consultation (see below).*

WORK PACKAGE 3: PATIENT HEALTH OUTCOMES

» OPPORTUNISTIC INFECTIONS

All PLHIV are at risk of acquiring opportunistic infections (OIs). OIs reduce patients' quality of life and have been shown to be predictive of increased risk of death, independent of CD4 T-cell count (Chaisson, Gallant, Keruly, & Moore, 1998; Osmond, et al., 1999). OIs tend to occur when patients fail treatment (poor adherence or unresponsive to their regimen) or/and do not observe measures to reduce OIs (e.g. Cotrimoxazole Preventive Therapy -CPT-) (Ministry of Health, 2016)

Table 17 ***Self-reported opportunistic infections, by intervention status***

	Total (N=1419)	Control (n=637)	Intervention (n=782)	P Value
Last year: TB				**0.020**
No	97%	96%	98%	
Yes	3%	4%	2%	
Last year: pneumonia				**0.072**
No	97%	96%	98%	
Yes	3%	4%	2%	
Last year: skin infection				**0.556**
No	95%	95%	96%	
Yes	5%	5%	4%	
Last year: any OIs				**0.042**
No	90%	88%	91%	
Yes	10%	12%	9%	

The vast majority of patients did not encounter opportunistic infections in the last year (90%). A greater percentage of patients in the control group reported having had TB (4%) ($p<0.05$), pneumonia (4%) ($p<0.10$) or any other OI (12%) than patients in the intervention group ($p<0.05$).

» VIRAL SUPPRESSION

Viral load test is the gold standard measure in HIV treatment monitoring. It indicates adherence and treatment efficacy as well as diagnosing treatment failure (Roberts, Cohn, Bonner, & Hargreaves).

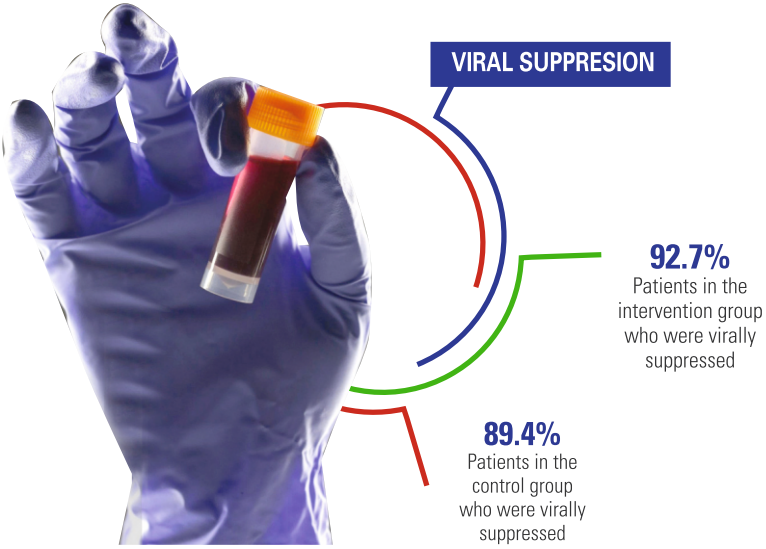
In this study, we collected data on whether the patient was virally suppressed (defined as less than 1000 copies per mL) from patient green cards. In the total sample, 88.6% of clients were reported as being virally suppressed in their last viral load test. The testing rate was high: 88.6% of clients had a viral load test recorded in the last year (as per the clinical guideline) and 94.7% had a viral load test recorded in the last year and a half.

***Table 18** Viral Suppression, by intervention status*

	Total (N=1378)	Control (n=615)	Intervention (n=773)	p Value
Viral Suppression				**0.017**
No	8.8%	10.6%	7.2%	
Yes	91.2%	89.4%	92.7%	

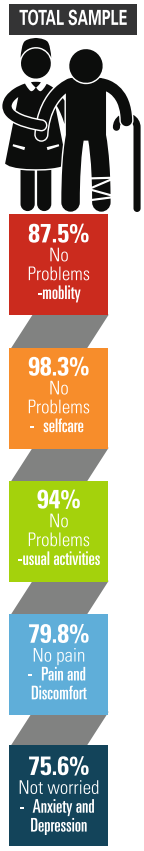
NB: only patients who had a record of a viral load were included in this analysis. As a result, the sample size is of 1378.

Although a high percentage of patients were generally virally suppressed in both groups, patients in the intervention group were more likely to be virally suppressed (92.7%) than those in the control group (89.4%) ($p<0.05$).



» QUALITY OF LIFE (EQ5D)

With PLHIV on ART living longer lives, studies are increasingly using measures of health-related quality of life (QoL) in addition to mortality and viral suppression. A QoL intends to capture all 'aspects of self perceived well being that are related to, or affected by the presence of a disease or treatment'. Typically, a QoL will intend to capture how one feels across physical, mental and social domains of health (Ebrahim, 1995). Viral load gives very valuable information about how successful ART is to patients and of transmission reduction. However, PLHIV may experience other problems, either as a direct consequence of HIV or as a side effect to ART. This is where the QoL, used in conjunction to viral load information, can provide a more complete picture of patient health. QoLs are almost always self-reported: a patient is presented with a set of questions, which helps eliciting how they feel, at a certain point of time (typically the time of the interview). They fill out the questionnaire on their own, or with the support of a research staff/enumerator (e.g. if the person is illiterate).



There is no standard means of measuring QoL in HIV patients, which is in itself interesting given that QoLs are used widely in other disease areas. In this study, we use E5QD, developed by EuroQoL. It is a generic QoL measure, which means it has not been developed specifically for PLHIV, but for the general population. However, EQ5D is a widely validated tool and has been used across all health research, it is also the most widely used generic measure of QoL in HIV research. EQ5D aims at describing the health states along 5 dimensions (see table 19). The answers provided by individuals to each question are compiled together to form health states, which is then used to derive a quality of life score. The score is comprised between 0 and 1, with 1 representing the best health. Annex 4 gives a short description of how those health states and quality of life scores are calculated. In addition, description of the health states is accompanied with a Visual Analogue Scale (EQ5D VAS) which is used to mark one's health status from 0-100 (worst health you can imagine – best health you can imagine).

Table 19 ***Severity levels for EQ5D, by intervention status***

		Total (N=1419)	Control (n=637)	Intervention (n=782)	P-Value
Mobility	No problems	87.5%	85.1%	89.4%	0.101
	Slight problems	8.2%	9.1%	7.4%	
	Moderate problems	3.7%	5.0%	2.7%	
	Severe Problems	0.4%	0.5%	0.4	
	Unable to walk	0.2%	0.3%	0.1%	
Self care	No problems	98.3%	98.3%	98.3%	0.679
	Slight problems	0.9%	0.6%	1.0%	
	Moderate problems	0.6%	0.8%	0.5%	
	Severe Problems	0.1%	0.2%	0.0%	
	Unable to wash or dress self	0.1%	0.2%	0.1%	
Usual activities	No problems	94.0%	91.7%	95.9%	0.013
	Slight problems	4.0%	5.2%	2.9%	
	Moderate problems	1.4%	2.2%	0.7%	
	Severe Problems	0.4%	0.6%	0.1%	
	Unable to do usual activities	0.3%	0.3%	0.3%	

		Total (N=1419)	Control (n=637)	Intervention (n=782)	P-Value
Pain and Discomfort	No pain	79.8%	74.4%	84.3%	0.000
	Slight problems	14.7%	18.7%	11.4%	
	Moderate pain	4.1%	5.5%	2.9%	
	Severe Pain	1.2%	1.3%	1.2%	
	Extreme pain	0.2%	0.2%	0.3%	
Anxiety and Depression	Not worried	75.6%	77.4%	74.0%	0.604
	Slight worried	18.2%	16.3%	19.7%	
	Moderate worried	4.5%	4.6%	4.5%	
	Severe worried	1.3%	1.3%	1.3%	
	Extremely worried	0.5%	0.5%	0.5%	

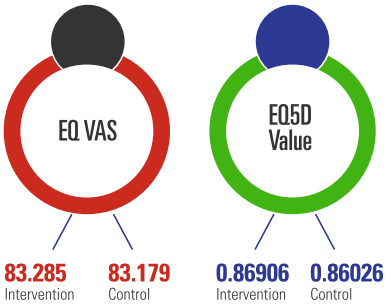
The health status rating by the patients in the five dimensions of the EQ5D instrument was high in both the intervention and control groups. A higher proportion of patients in the intervention group stated having no problems in all dimensions compared to their counter parts in the control group ($p<0.05$). For instance, on pain and discomfort, 84.3% of patients reported no pain in intervention sites, compared to 74.4% in control sites. There was no significant difference between intervention and control group in other dimensions.

***Table 20** Mean quality of life and EQ VAS score by intervention*

	Control (n=637)	Intervention (n=782)	P-value
EQ5D Value	0.86026	0.86906	0.0036
EQ VAS	83.179	83.285	0.4482

In addition, there was a significant difference in the calculated EQ5D score between intervention and control sites ($p<0.01$). The mean score in control site was 0.86 compared to 0.87 in intervention sites ($p<0.01$).

There was no difference in the VAS score; however, participants rated their health scores as being high in both groups.



DISCUSSION

DC models were initially developed as a means to address suboptimal long-term retention in HIV care, and to better meet patient needs while ensuring efficient use of resources. The models themselves are designed to streamline care along the HIV care cascade and range from individual to group-based models and facility to community-based health delivery systems. However, much remains to be understood about how well DC has been scaled up nationally, and how the implementation of a QI approach can support the delivery of DC on the ground. Our study provides evidence on the implementation of DC and the DC+QI model and providing future directions for scaling up DC+QI.

In this report, we investigated the associations between the intervention and a range of outcomes from patient reported outcomes, costing to provider satisfaction. Those study outcome variables for this study were identified using a theory of change and conceptual framework tailored to the intervention. To our knowledge, it is unique in that it provides a complete picture of DC+QI implementation from the health systems, client and provider perspective. Despite the empirical challenges, the methods employed in this research have allowed us to extract robust associations between the intervention and the outcomes under consideration.

We discuss the results and lessons learnt according to each study objectives.

TO EVALUATE THE PATIENT PROCESS MAPS IN THE INTERVENTION AND CONTROL SITES

First of all, consideration of patient process maps in intervention and control sites allowed us to provide an up-to-date picture of the processes of care at the facility level, regardless of the intervention status. It is worth noting that there was a variation in processes by facility. Interestingly, some facilities accommodated their opening times (e.g. earlier opening times for ARV pick-up) and differentiated clinic days as part of DC implementation (e.g. stable patient day). This was observed across both intervention and control sites. Another common theme was the length of waiting times, especially in some high-volume facilities (defined as facilities with over 1000 ART clients registered).

In one facility, waiting times averaged three hours. Time spent on seeking services was low (e.g. time spent in the consultation room was on average 8.1 minutes compared to on average 92.65 minutes spent in total at the clinic). Waiting times in intervention sites seemed to be lower than in control sites. It is worth noting that ARV pick-ups involved fewer steps and led to considerable time gains for both patients and efficient use of facility resources: total time was on average 25.0 minutes for a drug-pick up.

Longer waiting times were observed in control facilities.

TO DETERMINE LINKAGE TO CARE AND TIMELY ART INITIATION AT THE INTERVENTION AND CONTROL SITES

Timely linkage to care and initiation to ART are associated with optimal patient outcomes. We found no significant difference between control and intervention sites on timely initiation and linkage to care. Furthermore over 90% of clients were enrolled into care and 85% initiated on ART within the recommended time by the guidelines; and a great proportion of those patients were enrolled and linked to care within the same day.

TO EVALUATE PATIENT AND PROVIDER EXPERIENCE AND SATISFACTION IN THE INTERVENTION AND CONTROL SITES.

Patient experience is an important parameter to assess the quality of health care delivery, alongside more traditional health outcomes and quality measures. Patients in intervention sites experienced lower hospitalisation rates (in relation to their HIV infection), and were more likely to have had a blood pressure measurement in the last year. In addition, a higher proportion of patients were able to get the services they needed on the day of the visit, although nutrition and laboratory services availability (on the day of the visit) was rated lower than in control sites. The reason for this latter result will need to be investigated. However, overall, those results are consistent with other results discussed in later sections on patient health. More consistent approaches to screening for blood pressure may also be indicative of greater adherence to clinical guidelines following training on new guidelines, and perhaps greater monitoring of patient health; which could, in turn, lead to clinicians, at the CCC levels, identifying and addressing problems early and avoiding hospital admission. However, the data collected within this survey does not allow us to test out whether this is hypothesis is true.

The overall satisfaction across the sample was high. Patients were most satisfied with drug availability, and less so with waiting times, which scored 4.6 out of 6 points on average for the total sample. This is consistent with the findings from the time and motion study, which highlighted long waiting times, sometimes averaging over three hours in facilities.

We found significant positive difference between intervention status and satisfaction with care in the following dimensions: waiting times, convenience of the appointment, time spent with the clinician and observation of privacy. There was no significant difference in some dimensions, including technical skills of the clinician. There could have been expectations that the intervention improved the technical skills. However, satisfaction was already very high on those dimensions, and there might have been a ceiling effect from the Likert scale. Moreover, while the intervention did seek to improve provider knowledge of the guideline, we found no statistical difference in knowledge between intervention and control; which may also explain the lack of results along those dimensions.

Relating to satisfaction, the study showed majority of patients from intervention sites also sought services from facilities that were over 11km from their homes as compared to control sites who covered

a shorter distance from home to facility. The choice of a facility for health services may be dependent on history of patient treatment, patient perception of quality of services, stigma and access to mode of transport to the health facility (among other factors). The willingness to travel further distance may be associated with perception of higher quality of care in intervention sites.

Provider satisfaction was also measured in this survey using a similar approach to patient knowledge. There was no significant difference between intervention and control sites on the satisfaction ranking, for any of the dimensions considered. It is worth noting that the overall satisfaction with the job was higher in intervention compared to control (5.0/6 compared to 4.7/6, no significant). Questions submitted to intervention sites only found very high levels of satisfaction with participating to the intervention: 89.7% of respondents stated that the intervention helped them design and implement a work plan to support DC implementation 'very much'.

TO DETERMINE PATIENT AND PROVIDER KNOWLEDGE ON NATIONAL GUIDELINES RELATING TO DIFFERENTIATED CARE IN THE INTERVENTION AND CONTROL SITES

In this study, patient and provider knowledge is assessed using a series of questions pertaining to practice of care. Patient knowledge was measured alongside two main measures about what to do in the event of a missed pill and their self-reported knowledge about what will happen in the next appointment. The proportion of clients reporting to know what will happen in the next appointment was higher in intervention sites (89.0% compared to 73.9%). This is in line with other studies that have indicated that quality improvement increases knowledge of the patients/people involves (Wagner, Mugo, & Bluemer-Miroite, 2017). The study could not find any difference in knowledge between health care providers in the intervention and control sites.

TO DETERMINE THE AVERAGE COST OF ART DELIVERY AND CARE IN THE INTERVENTION AND CONTROL SITES.

TThe study estimated the costs of providing HIV services to patients from the perspective of the Kenyan government. Overall, costs were lower in both intervention and control sites for the ARV pick-up compared to the other types of visits. The cost of stable visits were much lower than those for unstable visits. This follows because as shown, stable patients spent significantly less time in facilities than unstable patients; and more importantly, the ARV pick-up model had much fewer steps, thus used up fewer resources and was relatively cheaper to administer (than the clinic visits). Thus, the Kenyan government should ensure that more patients that are stable are put on the fast-track ART pick up model, as this is would potentially be cost-saving with minimal or even positive impact on the quality of care .

As expected, the main cost-driver in service delivery was personnel, but we estimated higher than anticipated overhead costs. It is worth noting that these were not collected at the facility during data collection, as these costs are typically incurred by the central administration. We thus used a 'secondary' estimate based on the MOH annual budget, which could have slightly overestimated the costs.

The costs of stable and unstable patient visits were lower for intervention sites on average, however,

control sites had lower unit costs for the ARV pick-up visit. We estimated that the annual cost of treating a patient was approximately KES40,000 for unstable and KES20,000 for stable patients; the difference between intervention and control sites being the cost of a visit.

We found that QI could be implemented at a relatively low cost: KES 516 per patient per year, approximately 1% of the cost of an unstable visit for a patient on first line ARV treatment. We cannot say whether this is ultimately affordable to the government, but a decision to implement QI nationally could be made by weighing the benefits against the costs. Further, intervention costs could reduce significantly at scale.

TO DETERMINE HEALTH AMONG THE PATIENTS IN THE INTERVENTION AND CONTROL SITES

The intervention placed a lot of emphasis on both aspects of quality improvement, and correct implementation of the DC guidelines: providers were trained on the guidelines, to identify quality gaps in relation to correct guideline implementation (for DC and the new guidelines in general), and coached by QI experts at all levels (sub-county and national level). In some facilities, better categorization systems in patients were put in place, which also included color coding for patient files to indicate the need for follow-up, listing of clients on a regular basis for laboratory testing, and improvement in appointment booking and tracking systems (NASCOP, 2019).

Those processes supported better patient follow-up and identification of possible issues with medication or health issues early on, which were then addressed using different mechanisms, including follow-up calls, reminders, use of community support groups or the use of community health workers to address knowledge gaps. For those reasons, patient health outcomes are the primary metric of success for the evaluation of the intervention.

The intervention was positively associated with viral suppression and quality of life, and also associated to lower reporting of opportunistic infections (in particular, tuberculosis). Viral suppression rates in the entire sample was high (above 90% of patient surveyed), but it was higher in intervention sites (92.7%) compared to control sites (89.4%). Note here that viral suppression rate was only calculated based on clients who had a recent documented viral load test in the patient charts (97% of patients in the sample).

The viral suppression rate may be lower as viral load test results were not documented for 3% of the sample. This result is consistent with the results on opportunistic infections and on QoL. A generic QoL measure was introduced to measure patient's (self-reported) well-being and level of functioning. This constituted a novel attempt to introduce a measure to complement the interpretation of viral load, by providing a more complete picture of patients' health states along dimensions that are typically important to individuals.

Although the majority of patients in both intervention and control group reported not having any problems in all dimensions, there was a greater proportion of the patients reporting no problems in the intervention group than the control group in usual activities and pain and discomfort. There was also a significant difference in EQ5D score between the intervention and control group.

Box 2 Considerations for future research and possible scale-up

1. This evaluation has found significant positive associations between DC+QI and a range of patient outcomes (satisfaction, viral load, self-reported health etc.). On the other hand, we found no significant difference between intervention and control site on other variables, such as provider and patient knowledge or provider satisfaction.

2. Some patient outcomes, such as satisfaction rates across different domains, were high in both intervention and control sites.

3. There was variation in implementation of DC guidelines in majority of facilities, including intervention sites based on factors such as level of facility and volume of patients enrolled in the facility. Further research to standardize the application of the guidelines or tailor the intervention towards further training to minimize this variation could be envisaged. In addition, tailoring DC implementation to different characteristics of the facility may also be beneficial to patient care, and future work should seek to understand how to develop appropriate DC/DC+QI models to accommodate different characteristics (volume of patients, integration of CCC within the facility, level of facility, health workforce etc.).

4. Average waiting times in facilities remain high in both intervention and control sites. Further research or support can be directed towards understanding the reasons and reducing those, particularly in high volume facilities. Greater efforts to implement DC, in particular fast-tracking of drug pick up, could help reduce waiting times, as well as efficiency in the use of resources.

5. Relating to the above, future work to improve scheduling appointments (and increase adherence) should be undertaken: learning from the facility innovations on the use of differentiated care days, mobile text messaging, reminder devices etc.

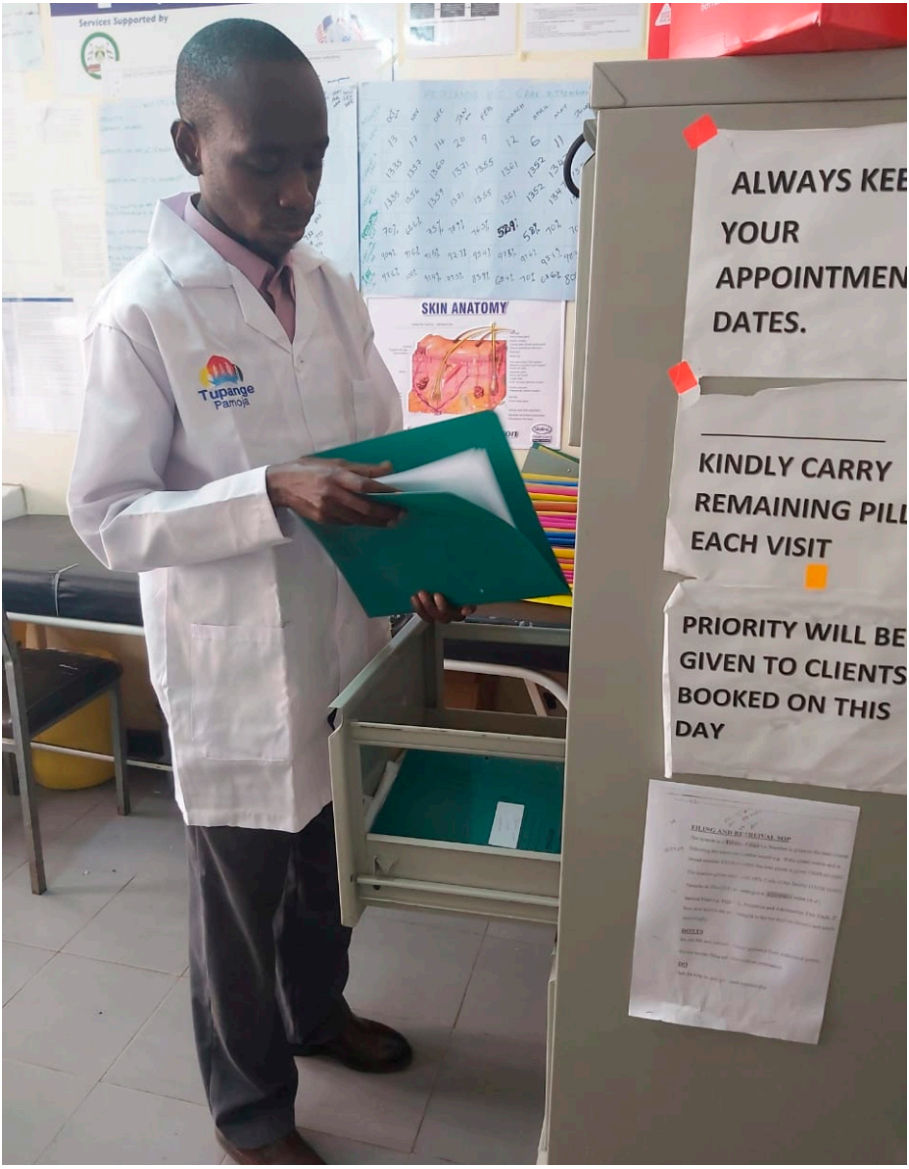
6. Unstable visits costs were much higher than stable visits costs. Costs of ARV pick-ups were the lowest, which suggests that appropriate implementation of DC guidelines would reduce costs of ART provision overall.

7. The cost of the intervention (DC+QI) appear to translate into gains for patients and facilities. As a result, we consider thatscale-up should be envisaged to other parts of the country as the cost analysis shows that those gains would be realised with marginal increases in resources (subject to a budget impact analysis). A complete cost effectiveness analysis should be carried out to determine whether the intervention is cost effective in the Kenyan context.

8. If scale-up is envisaged, reducing intervention costs through virtual platforms e.g. ECHO and training options should be explored.

9. With the scale up of electronic medical records, national and sub-national levels can now conduct routine data reviews and analyses that facilitate understanding of the net effects of DC and DC+QI – this should be explored to follow from this analysis.

CONCLUSION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In this study, we described DC+QI in detail and the processes and our findings from this evaluation are able to provide information on whether this effort has improved quality, access, adherence, outcomes; as well as identifying the cost implications of the intervention. To this end, we created a framework to identify relevant outcomes, and compared intervention to control facilities. The control group consisted in facilities implementing DC without the QI approach. It is worth noting that facilities in the control group did receive some form of supervision, especially at the onset when the new guidelines were launched. The objective of the study was to understand how intervention facilities compared to control facilities on a number of outcomes.

The results indicate that DC+QI was associated with significant level of improvements along several measures, particularly when it comes to patient outcomes. Unfortunately, the evaluation was not sufficiently detailed to explore how some processes of care (e.g. scheduling of appointments, frequency of visits or processes of care within the visits) affected the patient health outcomes. This question could be the topic of further exploration beyond this report. However, the emerging findings when it comes to health outcomes is consistent with results across the entire report (higher satisfaction levels for patients on some dimensions, lower hospitalization rates and report of OIs, higher patient knowledge). In addition, those findings are also in line with anecdotal reports at the facility level. In one facility, viral suppression rate was monitored throughout the entire length of the intervention and was well below the national average/target at baseline (72%) and improved to 89.7% at the end point evaluation (between June 2017-May 2019) (NASCOP, 2019). Some facilities reported that the intervention not only supported them in redesigning care pathways to match more closely clinical guidelines, but also strengthened the use of their own data to monitor patient health (including the use of electronic medical records) and improved collaboration at the facility level (NASCOP, 2019).

It is likely that beyond DC implementation, the intervention influenced a number of aspects of quality of care at the facility level. Despite the initial focus on the DC and the new guidelines (in which DC was the most prominent feature), some facilities developed and implemented change ideas on dimensions that were not specific to DC. For instance, some facilities included some extra activities to increase retention to care, especially where loss to follow-up was perceived as a challenge. This is an important point and an important thread throughout the evaluation: the positive associations found with the interventions may be the product of both a more thorough adherence to DC guidelines, but also to creating a broader QI environment at the facility level, which was one of the primary objectives of the study. It is likely that those positive associations stem from the holistic approach to QI implemented as part of the intervention, which was developed into a multi-pronged set of activities at the facility level. This is, again, confirmed with staff reports or presentations delivered as part of the intervention.

There are clear indications that DC has a positive impact on resource use from the government/payer's perspective. Patients on the fast-track model spent much less time in the facility and thereby used up fewer resources. The costs of clinic visits were lower for stable than unstable patients, because much less time was spent in consultations and other steps of the care pathway. We recommend that a scale up of the DC+QI would thus be beneficial and the cost-analysis indicates that this would be relatively inexpensive compared to the overall costs of ART provision.

Beyond the intervention, this evaluation also contributed to the state of knowledge on the implementation of DC in Kenya and, more broadly, HIV care. First of all, the time and motion survey identified a lot of variation of processes at the facility level, as well as processing times. Very long waiting times and short

consultation times (especially in in high volume facilities) are important lessons for the HIV program as a whole, and should be addressed as a matter of urgency through future pragmatic research. For instance, several facilities implemented differentiated days (e.g. for stable and unstable patients) or very early opening times for drug pickups. Additional research (including qualitative) should seek to understand whether those adjustments made at the facility level supported the implementation of DC and helped streamline patient flow and reduce waiting times, especially in larger facilities where waiting times were the highest. Moreover, additional work could help identify whether different components of DC are more relevant given facility set ups (e.g. high volume versus low volume). As found in the time and motion study, care processes and efficiencies are very different depending on the volume of patients registered at the facility level. This research could make use of the expansion of electronic medical records in CCCs, which should allow the HIV programmes to conduct routine data reviews and analyses. Finally, this study also has implications about how a QI approach can support delivery of services, perhaps for other parts of the HIV care cascade or for other non-HIV services. The approach to QI implementation led to local problem diagnosis, peer learning, and implementation of solutions to change the care pathway. We find differences in quality of care beyond DC implementation in this study.

As stated in earlier, this present work suffers from several limitations. The lack of baseline data means that no trends could be identified, and the study used bivariate comparisons to the difference between the control and intervention facilities. It is worth noting that we attempted to control for some source of confounders by using matching. In addition, facilities that were selected for the intervention were, on average, lower performers within their counties. It is reflected in the data we used in the matching process, which showed, for instance, much lower testing rates at baseline in intervention facilities. For this reason, it is unlikely that the positive associations found in this report can be attributed to pre-existing high performance in the intervention sites compared to the control sites, which would not be attributable to the intervention. However, given the research constraints, we refrained from using the word impact in this report. More robust analyses can be conducted to improve the estimates, for instance, by using multivariable models to control for remaining differences in observable characteristics at the patient level (e.g. control for differences in case mix for age, income or education).

In addition, data imputation and extrapolation, despite being common (especially in costing studies), were also applied in this research and may have had an impact on the robustness of the results. Such transformations are discussed openly earlier in the methods section and supplementation information can be provided on request. It is also worth noting that a lot of clients, in the evaluation, were transitioning to a new first line treatment (DTG was introduced in 2018), which means that the proportion of patients considered unstable was inflated compared to other contexts.

In the cost analysis, some data were not available at the facility level, hence we had to use data from other sources and make imputations. Data on overhead costs were estimated from the MOH budget; costs of drugs and laboratory tests estimated using a different methodology to costs of visits, because data were not sufficiently available at the health facility. There is thus some uncertainty about the true estimates of some of the costs in this study.

Despite those limitations, this evaluation provides an interesting picture of the possible associations between the intervention and quality improvement at the facility level (on DC implementation or on quality of care more broadly), and provides evidence on potential support measures to DC implementation in Kenya and across the world.

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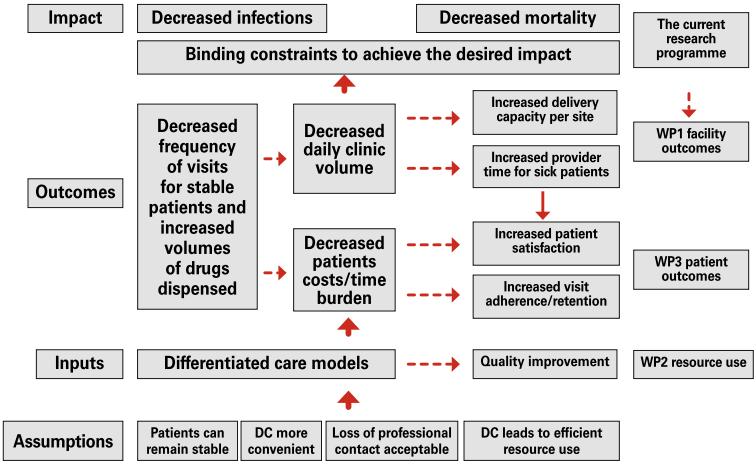
ANNEXES

ANNEX 1. FRAMEWORK FOR THE RESEARCH



ANNEX 2. LIST OF EVALUATION SITES AND THE NUMBER OF PARTICIPANTS PER SITE

County	Name of Facility (project sites)
Intervention sites	
Homabay	Miriu health centre
Kisumu	Muhoroni subcounty hospital
Kisumu	Ahero subcounty hospital
Kisumu	Lumumba subcounty hospital
Kisumu	Kombewa subcounty hospital
Kisumu	Kisumu county hospital
Kwale	Kwale county referral hospital
Kwale	Kinondu kwetu health centre
Mombasa	Ganjoni subcounty hospital
Nairobi	Pumwani maternity hospital
Nairobi	Mbagathi county hospital
Nakuru	Kuresoi subcounty hospital
Vihiga	Ipali Health Centre
Vihiga	Mbale rural training centre
Vihiga	Ekwanda health centre

County	Name of Facility (project sites)
Control sites	
Kajiado	Kitengela medical services
Kakamega	Kambiri Health centre
Kakamega	Bushiri health centre
Kakamega	Shitsitswi health centre
Kiambu	Ruiru subcounty hospital
Kiambu	Kiambu county hospital
Migori	Macalder subcounty hospital
Migori	Rongo subcounty hospital
Migori	Awendo subcounty hospital
Migori	St Camilus Karungu
Migori	Muhuru subcounty hospital
Migori	Migori county hospital
Taita Taveta	Taveta subcounty hospital
Taita Taveta	Mwatate subcounty hospital
Taita Taveta	St Joseph shelter of hope

ANNEX 3. COSTING METHODS

The objective was to estimate the total and average costs of implementing the QI project in health facilities in Kenya. The following research question was specified by the HIV programme during initial consultation to frame the research: "What are the costs of introducing a quality improvement programme to support health facilities in Kenya with implementing differentiated care models for ART?"

PERSPECTIVE: The perspective chosen for this analysis was the health system perspective, meaning that only costs borne by the project were considered. Patient costs were collected but included as a separate analysis.

TIME HORIZON: The time horizon was 2 years, the duration of the QI project.

METHODOLOGY: The study used a combination of top-down and bottom-up ingredients methods to identify resource use and estimate programme costs. Top-down costing was applied to expenditure data, focusing on the PQE books of accounts to capture all financial outlays. This was supplemented by an ingredients approach, which helped to identify all resources that were not reflect in the accounts.

The study applied activity-based costing, with the resources allocated to the following cost-centres (Figure 2):

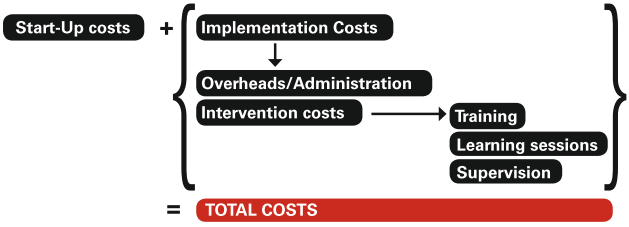
1) Start-up costs - These were costs that were incurred when setting up the project and included protocol development, initial meetings to create awareness among participating facilities, workshops and planning meetings, any initial training. Start-up costs were treated as a capital item with useful life equivalent to the duration of the project.

2) Implementation costs - These were the costs of running the project, which were into: a) general administrative and overhead costs, and b) QI intervention costs.

3) Administrative costs - The administrative costs were the day-to-day costs incurred in running the project. These included rentals, communication, water, electricity. The costs related to project management were included in admin costs: salaries for project staff such as drivers, the project manager and other support staff.

4) Intervention costs - The intervention costs included any expenses incurred at the facility level, such as purchase of computers, transportation, meetings and workshops, training, any outreach programmes. These were apportioned according to three project activities: training, learning sessions and supervision.

Framework for QI costing



Costs were categorised as recurrent and capital costs. Capital costs were those with a useful life of more than one year. Recurrent costs were those incurred regularly and repeatedly, such as personnel time, fuel, etc. Both financial and economic costs were estimated. Financial costs were direct expenditure outlays that did not take into account opportunity costs. Economic costs reflected opportunity costs e.g. volunteer time.

Treatment of costs

1) Discounting. Costs were discounted to reflect the depreciation of value over time. We used a rate of 3% to discount all costs.

2) Annuitization of capital costs was done to reflect the annual value of capital outlays. The annual financial cost of capital items wascalculated using a straight line depreciation method, where the total cost of an item is divided by its useful life years. The annual economic cost of capital items was calculated using the discount rate.

Data sources

Cost data were collected from the project books of accounts. Clarification was sought from project personnel where necessary to understand the allocation of costs. A data extraction sheet was used to collect data from the accounts. Outcomes data were collected from project reports. These included the number of facilities where the intervention was deployed, number of health workers trained in QI methods, and the potential number of patients who benefited from the QI intervention.

Analysis

The data were entered into a costing template in Microsoft Excel for analysis. The costing template was based on Figure 1. All costs were collected and analysed in Kenya Shillings (KES). The year 2018 was taken as the base year for costing.

Costs were summed up by main costing category (or activity) to get the total QI costs by activity. We then estimated the average costs per facility, number of health workers trained and number of ART patients reached. The latter was proposed since patients were the ultimate beneficiaries of the QI initiative.

ANNEX 4. CALCULATION OF THE QUALITY OF LIFE SCORES BASED ON THE EQ5D HEALTH STATES

We followed the process described below to calculate the average quality of life of patients in the intervention and control groups.

Step one: Administration of the EQ5D 5L questionnaire

The process started with the administration of an EQ5D 5L questionnaire to each patient. An EQ-5D-5L questionnaire describes the health states comprising 5 dimensions ('5D'), that is; mobility; self-care; usual activities; pain/discomfort and anxiety/depression. When administered to a person or patient, the person or patient rates his/her state of health based on a 5-point scale. Each of the five dimensions is rated by a 5-point rating scale according to level of severity.

The five levels ('5L') of severity are: Level 1: no problems; Level 2: slight problems; Level 3: moderate problems; Level 4: severe problems; Level 5: extreme problems. For each dimension, one level of severity is chosen that best describes the state of the person or patient answering the questionnaire. This provides a 1-digit number for each dimension. The digits for the 5 dimensions can be combined in a 5-digit code describing the person's health state. The health states can range from 11111 (best state of health) to 55555 (worst state of health). Each patient was answered the questionnaire and rates his or her health state. The resultant is the patient's health state stated as five digits corresponding to the how he/she rated his/her health in each of the five dimensions.

Step two: conversion of the EQ 5D 5L health states to quality of life weight

Each EQ 5D 5L health state corresponds to a specific single utility or quality of life weight in a given value set. So EQ-5D-5L health states were converted into a single index 'utility' or quality of life weight using a relevant value set. Because Kenya does not have a recognized value set for EQ 5D 5L nor 3L, an alternative value set had to be used to calculate the quality of life weight of each patient based on the EQ 5D 5L health state of the patient. The best alternative was the Zimbabwe crosswalk value set.

A "crosswalk" value set is a value set that has been developed, based on the existing EQ 5D 3L value set, to be used to estimate the quality of life weights of EQ 5D 5L health states. Since value sets are generated from usually public preferences where people in a specific area or country are asked to rate given health states using different valuation methods like time-trade off (TTO)1.This indicates that preferences may vary between places/countries as illustrated by Gerlinger et al.2 Therefore, a value of a country with similar characteristics can be used as an alternative. In this case, Kenya and Zimbabwe have similarities making it suitable to use the Zimbabwe value set in the calculation of the quality of life weights or health utility index for a Kenyan population/person/patient. The quality of life weight was calculated for each patient in both intervention and control groups by matching the patient's health state with the respective quality of life weight in the Zimbabwe crosswalk value set. The sum of the quality of life weights in the intervention and control group was got and mean quality of life weight was calculated for the intervention and control groups to enable comparison.

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2 *C. Gerlinger et al., "Comparing the EQ-5D-5L utility index based on value sets of different countries: Impact on the interpretation of clinical study results 11 Medical and Health Sciences 1117 Public Health and Health Services," BMC Research Notes, vol. 12, no. 1, Jan. 2019.*

MINISTRY OF HEALTH