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MINISTRY OF HEALTH

EVALUATION REPORT

Evaluating the Impact of COVID-19 on HIV Prevention, Care and Treatment Service delivery, and Outcomes in Nyandarua,Nyeri, and Murang'a Counties of Kenya

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DISCLAIMER

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

EXECUTIVE SUMMARY

Background

Several international and national guidelines for example, World Health Organization (WHO), US Centers for Disease Control and Prevention (CDC) i.e. Ministry of Health/National AIDS and STI control program (NASCOP) exist that address HIV testing and linkage services including self-testing to facilitate achievement of the first 90 target, later revised to the current first 95 target. A defined standard package of care for persons living with HIV (PLHIV), issued by NASCOP, was adopted including universal access to antiretroviral therapy (ART) for children, adolescents, and adults to support the achievement of the second 90 target. The guidance also included innovative patient-centered models to support adherence and retention, such as differentiated care approaches at the facility and community level to support the achievement of the third 90 targets.

WHO first declared COVID-19 to be a public health emergency of international concern on January 30, 2020 and subsequently declared it a pandemic on March 11, 2020. Kenya reported its first case of COVID-19 on March 13, 2020. However, not much is known about the impact of the COVID-19 pandemic on the implementation of HIV prevention, care and treatment interventions in resource-limited settings, particularly in Nyeri, Murang'a, and Nyandarua counties of the central region in Kenya where the CHS Tegemeza Plus project was implemented. This evaluation sought to document and assess the impact of COVID-19 and COVID-19 mitigation measures on various public health interventions and strategies employed along the 90-90-90 cascade of identification, antiretroviral treatment and viral suppression, and other patient outcomes in the three counties supported by CHS Tegemeza Plus.

Methods

The purpose of this evaluation was to utilize routinely collected health facility data as well as administrative information to identify and document sustainable interventions for HIV epidemic control in CHS Tegemeza Plus project-supported health facilities in Nyeri, Murang'a, and Nyandarua counties in the context of a pandemic. Descriptive, bivariate and regression analyses were done to document the impact of COVID-19 on HIV testing, gender based violence (GBV), Tuberculosis testing plus treatment, pre exposure prophylaxis (PrEP), and outcomes of patients on ART including viral suppression, mortality, and loss to follow up (LTFU).

Key Findings

Viral Load Suppression

There was no major impact of COVID-19 on viral suppression among clients given the higher suppression rates during the COVID-19 period. This could be due to the systems and strategies that were put in place to ensure close monitoring of clients. The systems and strategies included: rapid scale-up of ART optimization for eligible clients being switched to newer drugs such as Tenofovir (TDF) and Dolutegravir (DTG) which are associated with faster achievement of viral suppression as well as sustained suppression due to their higher genetic barrier for mutations.

Lost to Follow-up

The LTFU incidence remained lower during the COVID-19 period compared to the pre-COVID-19 period against the expectation. The program made changes to programming to accommodate clients who had difficulty accessing care in a timely and usual way. The Ministry of Health through NASCOP issued temporary guidance authorizing issuance of up to 3 months of ART to all PLHIV on care irrespective of criteria such as viral load. This measure was designed to limit the number of visits to health facilities for these patients ostensibly to reduce the risk of transmission of COVID-19 in the clinic setting.

Learners living with HIV may be stigmatized due to repeated absenteeism from class to attending clinic appointments because they have not disclosed their status to the school administration. The choice between seeking health services and provision of food for their families creates a barrier to access to ART. Further, movement from one region to another seeking casual labor and employment due to the pandemic may have made some cease to access care and treatment services. Movement due to socio-economic instability may also have increased the loss to follow up rates but the program strategies were robust enough to keep the rate as low as possible.

Mortality

The risk of mortality was lower during the COVID-19 period compared to the pre-COVID-19 period. This could be due to strategies aimed at retaining clients and ensuring that they receive good care even during the pandemic.

Tuberculosis

There was significant decrease in reported Tuberculosis (TB) cases and number of patients completing TB treatment during the COVID-19 period compared to the pre-COVID-19 period. However, good treatment and monitoring strategies employed ensured that mortality and LTFU was minimized. Also ensuring that treatment failure and incomplete treatment numbers remained relatively similar before and after the COVID-19 period. The treatment success rate decreased at the start of the COVID-19 period but remained steady thereafter.

KEY CONSIDERATIONS

In the event of a similar challenge in the future, like COVID-19, which affected HIV service provision at the facilities we propose the following measures for consideration.

1. Targeted HIV self-test kit distribution in the community to have people continue accessing HIV testing services without necessarily coming to the health facilities.
2. Doing more targeted testing, like index testing both at the facility and in the community, prioritizes individuals at higher risk of HIV, and is likely to identify HIV positive cases. In addition, optimize structured rescreening among newly enrolled, high viral load (HVL), prevention of mother to child transmission of HIV (PMTCT) and adolescent and young people during their clinic visits to identify more eligible sexual contacts for testing.
3. Reorganizing patient flow at the outpatient department (OPD) to allow eligibility screening which is key in identifying HIV cases. To reduce time spent between a client and provider (which made facilities revise policies to alleviate congestion at OPDs), there is a need to revise eligibility screening criteria to have an only key question which capture risk patterns or HIV-related symptoms thus making the screening process faster. This coupled with social distancing and use of personal protective equipment (PPE) like face masks by the HIV testing service (HTS) providers will have HTS services continue as usual.
4. Proper utilization of electronic HTS system (eHTS) to provide real time data for HTS, helping monitor HTS trends and institution of immediate action plans.
5. Improvement of appointment management system through use of electronic medical records (EMR) system, and incorporation of the patient appointment reminder system in the existing appointment diary and defaulter tracing register.
6. Development and roll-out of a national individualized case management system across all the HIV positive populations.
7. Child and adolescent-responsive HIV service delivery through strategies such as a standard operating procedure (SOP) defining the school engagement program at both national and county levels as well as rollout of the NASCOP learners living with HIV in basic learning institution guide.
8. More engagement of the orphaned and vulnerable children (OVC) partners to support children and adolescents living with HIV (CALHIV) adherence activities such as tracing loss to follow up (LTFU), directly observed therapy (DOT)/case management, home visits, and school engagement activities.
9. Interruption in treatment (IIT) characterization helps tailor individualized adherence and continuity in care interventions.
10. SOP to define structured pre-exposure prophylaxis (PrEP) and gender based violence (GBV) demand creation activities that include key messages targeting specific populations at both health and community level.
11. Nationally defined and adopted PrEP and GBV functional inter and intra-facility referral system.

12. National police, judicial and provincial administration training curriculum in GBV matters
13. A guide that defines peer to peer learning approach across PrEP and GBV service delivery cascade.
14. Adoption of a tiered GBV service delivery model that will categorize facilities into different tiers based on their capacity to offer different services with a clear referral system in place.
15. To achieve eMTCT, continued collaboration with different stakeholders working with adolescents may continue to prevent teenage pregnancies and avert possible HIV infections.
16. Adoption of a new system of working on a rotational basis by Health care providers working in maternal, newborn and child health (MNCH) department as opposed to existing work schedules of working from Monday to Friday. This may minimize exposure at the workplace while ensuring uninterrupted service provision in antenatal care (ANC) testing, prompt linkage, and ART initiation for those testing positive.
17. Counties to introduce viral load testing facilities within counties to avoid over dependence on testing laboratories in Nairobi using existing point of care machines like GeneXpert testing machines.

LESSONS LEARNT

The lessons learned during service provision by TEGEMEZA Plus project during this COVID-19 pandemic included the following:

1. Without OPD workload screening for HTS eligibility, there will be missed opportunities for HIV-case identification.
2. With paralyzed HIV testing at OPD, targeted HTS (self and index testing), both at the facility and the and at community, can help identify HIV positive individuals .
3. Client-centered services such as bookings, use of technology to support adherence (pre-calls, Ushauri messaging, virtual counseling and support, and video DOT, case management and risk of default screening are vital in improving viral suppression and continuity in care.
4. Structured patient education through treatment literacy, one on one counseling and positive health dignity and prevention (PHDP) messaging is a key strategy to improve continuity in care and patient outcomes
5. Interruption in treatment characterization for individualized client care that will minimize interruption in treatment
6. Multi-month dispensing for all age groups including unstable clients minimizes interruption in treatment
7. The listed strategies if implemented with fidelity improves viral suppression and minimizes interruption in treatment among CALHIVs. They include physical/virtual DOT, video DOT (NimeCONFIRM), caregiver engagement, School engagement, clinical Orphans and Vulnerable Children (OVC) integration, OTZ (Operation Tripple Zeroe), PAMA.
8. Facilitated case management by adolescent mentors and champions is a sure way of achieving re-suppression and sustained suppression among CALHIV.
9. Active involvement of the CHMT in PrEP and GBV integration agenda to improve progress towards successful PrEP and GBV integration in other service delivery points that is vital sustainability of the services.
10. Structured demand creation activities that includes key messages targeting specific populations at both health facility and community levels are key to increased uptake of PrEP and GBV services.
11. Daily and weekly monitoring of PrEP and GBV performance to enable one to timely identification of performance gaps and challenges and put immediate remedial measures in place.
12. Functional inter and intra facility referral system minimizes missed opportunities in PrEP and GBV service provision.
13. Peer led approach for PrEP demand creation and follow up with specific messaging leads to increased PrEP uptake among the key population
14. Fast tracking of PrEP clients and offering PrEP in a safe space is vital to the increased uptake among special populations such as key population (KP), adolescent girls and young women (AGYW) and pregnant and breastfeeding women (PBFW).

15. GBV multi-sectoral engagement is critical in offering comprehensive GBV services to survivors and it leads to ownership and sustainability.
16. To sustain efforts made towards eMTCT, health facilities should adopt flexi working hours to ensure uninterrupted service provision within the MNCH department.
17. To achieve eMTCT, there is need for continued collaborative efforts by different stakeholders to ensure AGYW attend schools, economically empowered among others to reduce the high rates of teenage pregnancies as was experienced during the COVID-19 period (this led to a surge in HIV infections among the AGYW). This will promote subsequent reduction in HIV infections among this vulnerable group.
18. Counties to introduce point of care viral load testing facilities within counties to avoid over dependence on testing laboratories in Nairobi to minimize testing interruptions in a lockdown.

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ACRONYMS

ABC	Abacavir	HRIO	Health Records Information Officer
ADT	ARV dispensing tool	HTS	HIV testing services
AES	Advanced Encryption Standard	HVL	High Viral Load
AGYW	Adolescent Girls and Young Women	IIT	Interruptions in treatment
AIDS	Acquired immune deficiency syndrome	IPD	In-Patient Department
ANC	Antenatal care	IQR	Interquartile Interval/Range
ANC	Antenatal Care	IRB	Institutional review Board
aPNS	assisted Partner Notification Services	KENPHIA	Kenya Population-based HIV Impact Assessment
ART	Antiretroviral therapy	KP	Key Population
ARV	Antiretroviral (drugs)	LTFU	Loss to follow up
aSHR	Adjusted Sub Hazard Ratio	M&E	Monitoring and Evaluation
AYP	Adolescents and Young People	MNCH	Maternal Newborn and Child Health
AZT	Azidothymidine	MOH	Ministry of Health
BMI	body mass index	NACC	National AIDS Control Council
CALHIVs	Children and Adolescents living with HIV	NASCOP	National AIDS and STI Control Program
CASCO	County AIDS and STI Coordinator	NTLD	National Tuberculosis, Leprosy and Lung Disease
CBO	Community-Based Organizations	OPD	Our-Patient Department
CCC	Comprehensive Care Clinic	OTZ	Operation Triple Zero
CDC	Centre for Disease Control and prevention	PAMA	Papa and mama
CHMT	County Health Management Team	PBFW	Pregnant and Breast Feeding Women
CHS	Centre for Health Solutions	PEPFAR	President's Emergency Plan for AIDS Relief
CHV	Community Health Volunteers	PI	Principal Investigator

CSO	Civil Society Organizations	PLHIV	People living with HIV
D4T	Stavudine	PMTCT	Prevention of Mother to Child Transmission of HIV
DHIS	District Health Information System	PPE	Personal Protetcive Equipment
DHIS2	District Health Information Soft-ware-version2	PrEP	Pre-Exposure Prophylaxis
	Directly Observed Therapy	SOP	standard operating procedures
DOTs	Directly Observed Therapy	SOP	Standard Operating Procedures
DTG	Dolutegravir	TB	Tuberculosis
EMR	Electronic Medical Records	TDF	Tenofovir disoproxil fumarate
GBV	Gender Based Violence	TLD	Tenofovir, Lamivudine, and Do-lutegravir
HCW	Health Care Worker	UNAIDS	The Joint United Nations Pro-gramme on HIV/AIDS
HIV	Human Immunodeficiency virus	WHO	World Health Organization

INTRODUCTION

1. BACKGROUND

The global Human Immunodeficiency Virus (HIV) response has been boosted by the Joint United Nations Program on HIV/AIDS (UNAIDS) fast-track approach towards epidemic control by 2030. The aim is to incrementally avert 17.6 million HIV infections and 10.8 million AIDS-related deaths between 2016 and 2030. Due to the global scale-up of antiretroviral therapy (ART) coverage, there was a 48% global decline in AIDS-related deaths from a peak of 1.9 Million deaths in 2005 (UNAIDS, 2017). Eastern Africa regions achieved up to 60% ART coverage (from 24% in 2010) (UNAIDS, 2017).

Close to the start of the evaluation period, Kenya had the fourth-largest HIV epidemic in Africa with adult prevalence of 6% among ages 15 – 49 (NACC, 2014) and an estimated 1.5 million PLHIV in 2015. The estimated annual incident infections were over 71,000 among adults and 6,600 among children (NACC, 2016). More recent data from Kenya Population-based HIV Impact Assessment (KENPHIA) 2018 survey estimates the annual incidence of HIV among adults at 36,000, (NASCOP, 2020). The new infections were predominantly sexually transmitted (93.7%) among adults mostly affecting heterosexual couples in unions, key populations, and young women aged 15-24 years (44%, 30%, and 21% respectively; NASCOP 2015). Data from Kenya HIV Estimates Report, 2018, indicated a reduction to 28% in new HIV infections among young women aged 15 – 24 years out of all adults (NACC, 2018). HIV-related mortality was estimated at 29% of total deaths in the country and 12.6% of deaths in Nairobi based on a mortuary surveillance study (NASCOP, 2016). The latest HIV prevalence data in the evaluation period from the Kenya Population-based HIV Impact Assessment (KENPHIA) survey conducted in 2018 estimated that there were 1.3 million PLHIV and an estimated adult prevalence of 4.9% (NASCOP, 2019).

Kenya adopted the UNAIDS 90-90-90 global treatment targets in 2015 to ensure that 90 percent of people living with HIV are diagnosed, 90 percent of those diagnosed are on antiretroviral therapy and 90 percent of people on ART are virally suppressed by 2020 (UNAIDS, 2014). In the same year, emphasis on a data-driven approach led to the development and utilization of county HIV profiles to guide implementation (NACC, 2014). Over 900,000 PHLIV had been initiated on lifesaving ART with a treatment gap of 40% by the end of 2015. Kenya adopted the World Health Organization's (WHO) test and start guidelines in 2016 to reach all patients requiring ART (NASCOP, 2016).

These guidelines address HIV testing and linkage services including self-testing to facilitate the achievement of the first 90 targets. Defined standard package of care for PLHIV was adopted including universal access to ART for children, adolescents, and adults to support the achievement of the second 90 target. The guidance also included patient-centered models to support adherence and retention, such as differentiated care approaches at facility and community levels to support the achievement of the third 90 target (NASCOP, 2016). In 2014, these global treatment targets were updated to 95-95-95 by The Joint United Nations Programme on HIV/AIDS (UNAIDS) with the aim to diagnose 95% of all HIV-positive individuals, provide antiretroviral therapy (ART) for 95% of those diagnosed and achieve viral suppression for 95% of those treated by 2030 (UNAIDS, 2014).

COVID-19 was declared a global pandemic on March 11, 2020, by Tedros Adhanom Ghebreyesus, Director-General of WHO following the alarming levels of spread and severity of the outbreak outside of China where the first case was reported in early 2020 (WHO, 2020). Most countries in including Kenya are struggling with a lack of capacity and resources. In Kenya, the pandemic was declared when the first case of the virus was confirmed on March 12, 2020 (Ministry of Health, 2020). Measures including restriction of movement, gathering, and curfews among others were put in place to further stem the spread of the virus. We anticipate negative impacts on resource availability and efficient provision of HIV testing, care, and treatment services in Central Kenya counties. It would be important to take stock of this impact on our prevention (testing), care and treatment services as well as outcomes for learning and also future planning. We also anticipate the implementation of bidirectional screening for TB and COVID-19 given the pandemic context and especially to offer a level of guarantee for an effective response to COVID-19 while ensuring that TB services at our clinics, especially TB case-finding, are maintained.

However, not much is known about the effects of COVID-19 on the implementation of these HIV interventions in resource limited settings in Nyeri, Murang'a, and Nyandarua counties of Kenya where the CHS Tegemeza Plus project was implemented. This evaluation seeks to document and assess the impact of COVID-19 on various public health interventions and strategies employed along the 95-95-95 cascade of identification, antiretroviral treatment and viral suppression, and other patient outcomes in the three counties supported by CHS Tegemeza Plus. Progress toward HIV epidemic control was documented through assessment of HIV positivity rates, HIV treatment outcomes as well as the institutionalization of structural interventions within the counties.

2. JUSTIFICATION FOR EVALUATION

The purpose of this evaluation was to utilize routinely collected health facility information to identify and document effects of COVID-19 on the sustainable interventions for HIV epidemic control in CHS Tegemeza Plus project-supported health facilities in Nyeri, Murang'a, and Nyandarua counties. Understanding results from this evaluation using routine program data will provide useful information to evaluate the changes in program implementation during COVID-19 period and inform future project strategies in readiness for similar challenges. Country and county strategies on handling COVID-19 challenges may also benefit from this information. In addition, it will contribute to the body of knowledge on sustainable and comprehensive HIV prevention, care and treatment programs in the COVID-19 era.

3. STAKEHOLDER ENGAGEMENT

The key stakeholders included County Health Management Teams (CHMT) in Murang'a, Nyandarua, and Nyeri, National AIDS and STI Control Program (NASCOP), NTLD-Program, the MOH, the CDC, clients, the general public, healthcare workers, and community gate-keepers/key informants, CHS Tegemeza Plus, and other programs working to identify more HIV/TB cases, put them on treatment, and improve their treatment outcomes. MOH, through the various County MOH heads was sought

to provide authorization to undertake the evaluation activities. The key stakeholders were involved in the evaluation process as much as possible from conception with evaluation protocol input and reviews. We also leveraged on the existing relationships between the stakeholders and the Tegemeza Plus Project in obtaining data during the evaluations. Some of the stakeholders were directly involved in the planning, execution, and dissemination plans of evaluation findings.

4. INTENDED/POTENTIAL USE OF EVALUATION FINDINGS

Evaluation findings will be used to review project performance towards achieving the goal of epidemic control despite the COVID-19 pandemic challenges. Findings will also be disseminated as presentations to local and international audiences; and abstracts, as well as manuscripts will be developed for possible publication in peer-reviewed journals. Evaluation findings will also be used to inform and contribute to policy development and review at county and country-level aimed at HIV epidemic control. The final evaluation report is in alignment with the PEPFAR Evaluation Standards of Practice requirements and will be posted (in English) on a publicly accessible website within 90 days of report CDC clearance.

5. GOAL AND OBJECTIVE

The goal of this evaluation was to assess the impact of COVID-19 on HIV service delivery and outcomes across the various program areas at Tegemeza Plus Project supported health facilities in Central Kenya between October 2017 and December 2021.

Evaluation Objective

To evaluate impact of COVID-19 on HIV service delivery and outcomes across the various program areas including HIV testing services, PMTCT, Viral load testing, TB, GBV, PrEP, and ART outcomes.

METHODS

1. METHODOLOGY AND DESIGN

The design used in the evaluation was-cross-sectional. We only used quantitative data collection methods. Both prospective and retrospective routinely collected program data and patient cohort data were used for the evaluation. Clients data as available for the evaluation were restricted to those seen between 1st October 2017 and 30th December 2021. The pre-COVID-19 period was defined as the time between October 2017 and February 2020 while COVID-19 period was defined as the time between March 2020 and December 2021. The evaluation type, design, data collection, data sources, as well as the indicators are elaborated in the evaluation matrix (Appendix 1A).

2. POPULATION

Clients accessing HIV treatment services from the 87 CHS-supported sites in Murang'a, Nyandarua, and Nyeri counties within central Kenya.

Eligibility: All clients accessing HIV services or PLHIV enrolled in the 87 Tegemeza Plus project supported health facilities at the time of evaluation were eligible for inclusion.

3. SAMPLING METHODOLOGY

The evaluation used routine HIV care and treatment data, so no clients were recruited directly. All clients who had received services at CHS Tegemeza Plus project supported facilities whose data was available in the electronic medical record systems and registers and meeting inclusion criteria were included and therefore sampling procedures to determine the sample size were not anticipated. We included data on all HIV tests done and data from new and continuing clients accessing HIV care and treatment services at the 87 CHS Tegemeza Plus supported sites within the project period, and meeting the inclusion criteria.

4. DATA COLLECTION, DATA MANAGEMENT, AND ANALYSIS

Data Collection

Data was captured through the national MOH system as well as other supplementary systems. The primary source of data included: Comprehensive care clinic (CCC) patient card, Tuberculosis (TB) screening tools, Pre and ART registers, daily activity registers, HIV testing and counseling register and viral load sample collection register, viral load register, ANC register, TB register, GBV registers, and PrEP registers. The above source documents which are Ministry of Health (MOH) tools used to collect patient information and are filled by service providers either real-time or after the patient has left. Data aggregated from these tools are reported to the MOH through reporting tools such as MOH 711, MOH 731 and MOH 717 which are hybrid (exist in both paper and updated electronic copies). These reports are entered into a national web-based reporting system called District Health Information System 2 (DHIS2).

The data systems (both electronic and paper based) capture patient level data and makes it easier for service providers to access all information regarding a patient for decision-making. CHS works closely with data clerks and health records and information officers (HRIOs) at the facility level by

doing routine and non-routine data collection and entry to ensure that the medical records were up to date and that the data meets set data quality standards including accuracy, validity, reliability, completeness and relevance. The EMR is updated real-time during a client encounter (for facilities that are point of care) or shortly thereafter for EMR sites that are not point of care. EMR data is uploaded to the National Data Warehouse weekly/monthly. These systems have patient-level data and were customized to provide various MOH reports. At the site-level, the EMR systems are used to assess patient outcomes, manage appointments and track performance in accordance with the national guidelines. Individual level data were extracted directly from Kenya EMR using structured query language (SQL) scripts. Only data managers had passwords to access the databases. All the individual patient identifiers were removed before analysis.

Data Management and Storage

The evaluation and data management team loaded all the data into a customized Microsoft Access database for cleaning and validation. All data were anonymized by the data manager to remove all identifiable information such as names, patient IDs, location, etc. before exporting to Stata version 17 software. No individual patient identifiers were included in the analysis datasets. All electronic routine patient data in the EMRs will be retained for continual use during patient follow-up care and treatment as they formed a useful part of clients' history. All the other non-routine data electronic files were destroyed by running permanent deletion software 'Active Eraser' on the computers, flash, and hard drives to prevent data recovery of the same. All data will be stored in encrypted folders in a password-protected computer accessible to the study data management team only. Real-time data backups of electronic patient records in the Kenya EMR electronic medical record system were set up on the CHS data servers by the data manager and information technology manager. All other electronic data were regularly and securely backed up by the data manager on the CHS servers. Data is owned jointly by the Ministry of Health and CHS, with use and release determined by applicable Ministry of Health, CDC and CHS policies. The principal investigator is responsible for ensuring adherence to data integrity to prevent inadvertent access to study data. Data sources are provided in Appendix 1B.

Statistical Analysis

Baseline characteristics of clients were determined. Mean (standard deviation), median (interquartile interval [iqi]) and counts (proportions) descriptive statistics were used as appropriate. Temporal quarterly trends in HIV testing numbers, PMTCT and, GBV, PrEP were assessed for overall and also by age category and sex. Non parametric test of trend (Jonckheere-Terpstra Test) was done on quarterly project totals on key HIV testing, PMTCT, viral load, data outputs and outcomes since start of project in October 2017 to December 2021. Logistic regression analyses were done to assess the effect of COVID-19 on viral suppression (viral load <1000 copies per ml) among clients on ART reporting the adjusted Odds Ratios [aOR] (95% confidence intervals (CI)). Competing risk regression analyses were done to assess the impact of COVID-19 on LTFU, (mortality or transfer out outcome were the two competing events for LTFU since they were no longer at risk of being LTFU). Similar competing risk regression analyses were done to assess the effect of COVID-19 on mortality, (LTFU or transfer out outcomes were the two competing events for mortality since they were no longer at risk of mortality at the censoring date). Flexible parametric competing-risks model using a direct likelihood approach

for the cause-specific cumulative incidence function was used (Mozumder et al, 2017). The cumulative incidence function (CIF) plots and sub-distribution hazard ratios (SHR 95% confidence intervals (CI)) were presented for LTFU and mortality outcomes. Complete case analysis was used given the large number of observations and little to missing data on all the key variables used. All statistical tests were evaluated at the 5% level of significance. All regression analyses done at the project level, adjusted for clustering (at the facility level) and reported robust standard errors. Statistical analysis for quantitative data was done using Stata software version 17 (Stata Corp, College Station, TX).

Training

The principal investigators ensured that all key staff involved in the evaluation were trained on human subjects' protections. The evaluations manager, and evaluations advisor (analyst) had training on data protection, good clinical practice (GCP), and information security including file encryption and protection systems. All the investigators had undergone research ethics training and were certified.

Evaluation Limitations

The evaluation relied on routinely collected facility data which had some missing data, and may have had incorrect values captured. Some clients that were recorded as having incomplete or missing outcomes were most probably enrolled in or provided treatment at other facilities in or out of the region. We were unable to obtain sufficiently complete data on some variables such as weight and height; therefore, BMI was not included in the analyses among other variables not collected that may have introduced some bias. However, given the large numbers we believe the statistical inferences will be largely valid. We would like to highlight the limitations of the evaluation design which is not an experimental and acknowledge there were other activities during the period. To account for changes in aggregate quarterly data we used a non-linear trend approach looking at the trends over several quarterly time points using the Jonckheere Terpstra approach to assess for any nonlinear trend which is ordered in either direction. If we had an increase in the numbers and a sudden change in direction then we may hypothesize that there was a change related to COVID in the absence of a reasonable explanation. For the individual-level data, we were able to adjust for some patient-level characteristics while trying to estimate the effect of COVID on the treatment outcomes.

ETHICAL CONSIDERATIONS

All the data proposed to be used in this cohort reporting is routinely collected in the support and delivery of medical services. Each client was assigned a unique identifier in the access database and confidentiality was ensured by stripping patient medical information of names and other personal identifiers by the data manager during analysis dataset preparation. All data used were coded using unique database identifiers to safeguard patient details. Results were reported in aggregate without referencing patient details. Analysis of this medical data will provide information that is beneficial in guiding patient management and improving outcomes among HIV positive clients.

The evaluation protocol was reviewed in accordance with the U.S. Centers for Disease Control and Prevention (CDC) human research protection procedures and determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes. Local approval for the evaluation was obtained from Kenyatta National Hospital - University of Nairobi (KNH-UoN) Ethics Review Committee (approval number P686-2-2017).

FINDINGS

1. HTS TRENDS

HIV testing of clients

The total number of HIV tests done in between October 2017 and December 2021 in the 3 counties was 1,293,116 tests. Murang'a County had the highest number of tests done 682,453. There was a significant non-linear trend (P-value <0.001) showing a marked decrease in the project's total number of tests from October to December of 2017. This is partly as result of programs emphasis and mentorship on testing efficiency which reduced numbers tested in 2018 and peaking in April to June of 2019 after which there was a steady decline, especially during the COVID-19 period as shown in Table 1 and Figure 1. Similar trends are seen among the age categories and sex as shown in Figure 2 and Figure 3.

Table 1 HTS samples tested, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

County				
County	Murang'a County	Nyandarua County	Nyeri County	Total*
Year-Quarter				
2017 Oct-Dec (q4)	32020	5244	17041	54305
2018 Jan-Mar (q1)	70696	13973	39766	124435
2018 Apr-Jun (q2)	76478	12279	33037	121794
2018 Jul-Sep (q3)	62640	10314	30684	103638
2018 Oct-Dec (q4)	51886	11073	32151	95110
2019 Jan-Mar (q1)	62473	16545	42462	121480
2019 Apr-Jun (q2)	72064	19701	51444	143209
2019 Jul-Sep (q3)	53627	15891	44387	113905
2019 Oct-Dec (q4)	30775	9384	27619	67778
2020 Jan-Mar (q1)	25445	12314	22956	60715
2020 Apr-Jun (q2)	17903	9075	15222	42200
2020 Jul-Sep (q3)	21555	9015	17190	47760
2020 Oct-Dec (q4)	24705	5172	16720	46597
2021 Jan-Mar (q1)	26034	6426	18777	51237
2021 Apr-Jun (q2)	18389	4329	13752	36470
2021 Jul-Sep (q3)	18249	4014	13770	36033
2021 Oct-Dec (q4)	17514	-	8936	26450
Total	682453	164749	445914	1293116
*Jonckheere-Terpstra test for time ordered overall decrease in numbers, P-value <0.001				

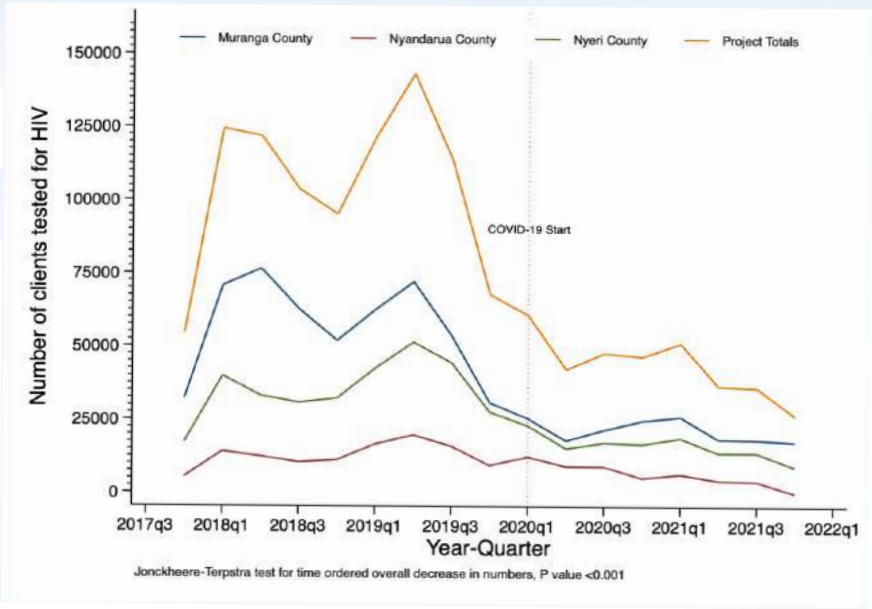

Figure 1 HTS samples tested, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

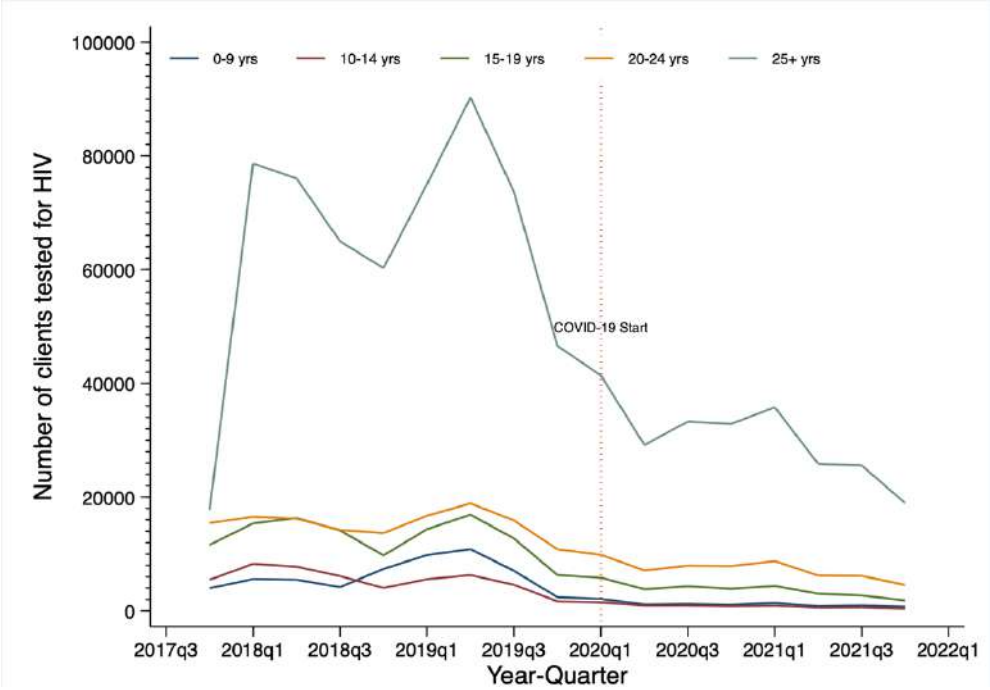

Figure 2 HTS samples tested by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

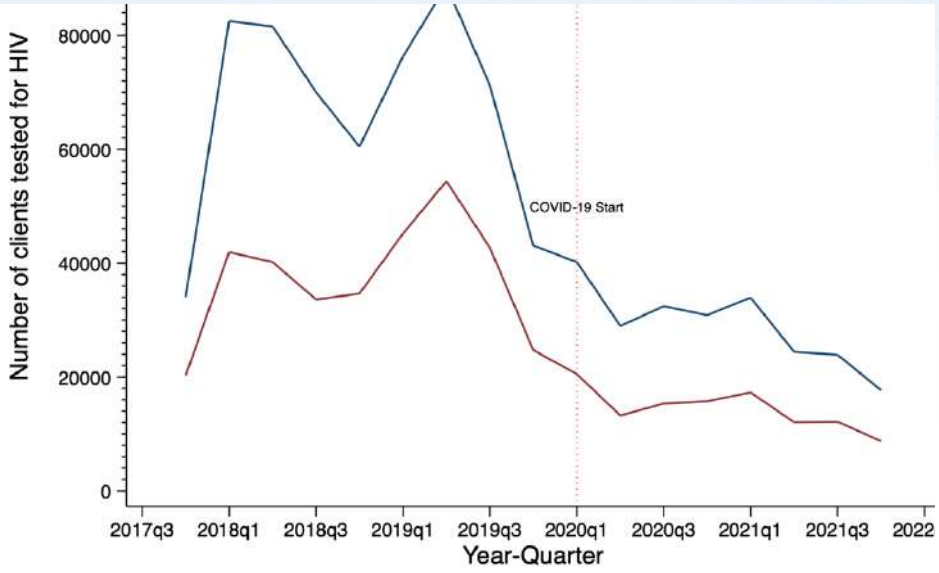

Figure 3 HTS samples tested by sex, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

HIV positive clients

The total number of HIV positive clients in the 3 counties was 12,428. Murang'a County had the highest number of HIV positive clients identified from all the tests done (n= 5,156). Results did not indicate a significant non-linear trend (P-value 0.271) for a marked increase or decrease in the project total number of HIV positive clients identified from October to December of 2017. However, the results show some decline in the number of positive tests overall, in Nyeri and Murang'a counties, during the COVID-19 period as shown in Table 2 and Figure 4. Results by age and gender show a similar trend in clients identified pre and during COVID-19 period (Figure 5 and 6 respectively).

Table 2 HIV positive clients, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

County	Murang'a County	Nyandarua County	Nyeri County	Total*
Year-Quarter	n (%)	n (%)	n (%)	n (%)
2017 Oct-Dec (q4)	109 (0.3%)	42 (0.8%)	89 (0.5%)	240 (0.4%)
2018 Jan-Mar (q1)	420 (0.6%)	151 (1.1%)	311 (0.8%)	882 (0.7%)
2018 Apr-Jun (q2)	409 (0.5%)	123 (1.0%)	305 (0.9%)	837 (0.7%)
2018 Jul-Sep (q3)	323 (0.5%)	121 (1.2%)	310 (1.0%)	754 (0.7%)
2018 Oct-Dec (q4)	266 (0.5%)	133 (1.2%)	276 (0.9%)	675 (0.7%)
2019 Jan-Mar (q1)	338 (0.5%)	148 (0.9%)	316 (0.7%)	802 (0.7%)
2019 Apr-Jun (q2)	392 (0.5%)	168 (0.9%)	425 (0.8%)	985 (0.7%)
2019 Jul-Sep (q3)	370 (0.7%)	216 (1.4%)	493 (1.1%)	1079 (0.9%)
2019 Oct-Dec (q4)	260 (0.8%)	195 (2.1%)	442 (1.6%)	897 (1.3%)
2020 Jan-Mar (q1)	269 (1.1%)	190 (1.5%)	341 (1.5%)	800 (1.3%)
2020 Apr-Jun (q2)	195 (1.1%)	132 (1.5%)	265 (1.7%)	592 (1.4%)
2020 Jul-Sep (q3)	212 (1.0%)	130 (1.4%)	265 (1.5%)	607 (1.3%)
2020 Oct-Dec (q4)	334 (1.4%)	105 (2.0%)	255 (1.5%)	694 (1.5%)
2021 Jan-Mar (q1)	403 (1.5%)	126 (2.0%)	271 (1.4%)	800 (1.6%)
2021 Apr-Jun (q2)	268 (1.5%)	95 (2.2%)	260 (1.9%)	623 (1.7%)

2021 Jul-Sep (q3)	286 (1.6%)	84 (2.1%)	236 (1.7%)	606 (1.7%)
2021 Oct-Dec (q4)	302 (1.7%)	-	253 (2.8%)	555 (2.1%)
Total	5156 (0.8%)	2159 (1.3%)	5113 (1.1%)	12428 (1.0%)

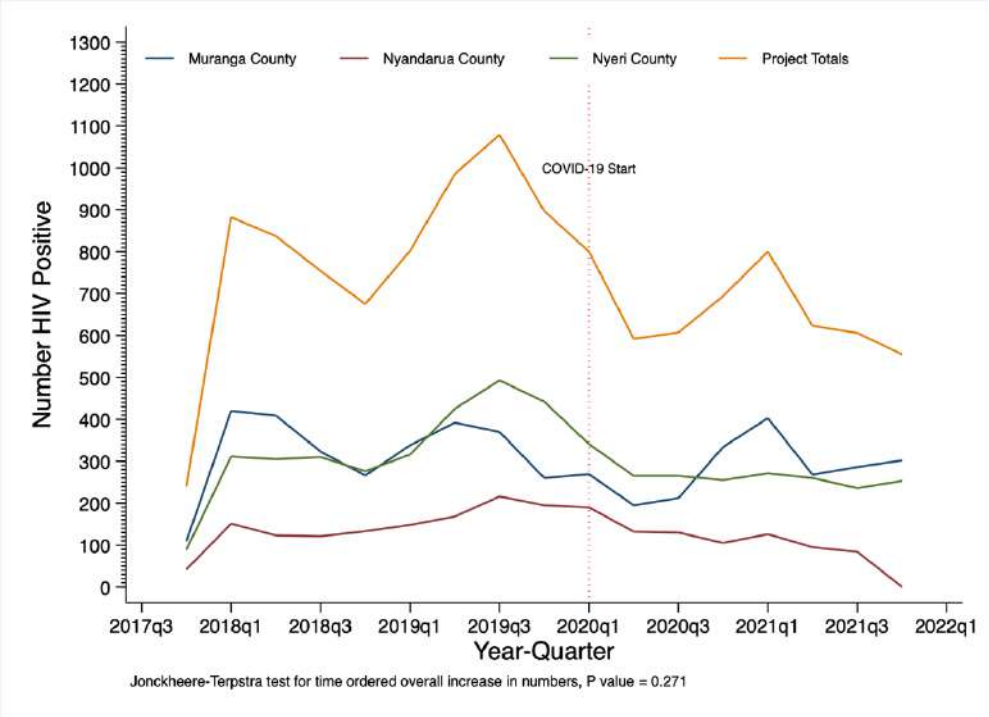

Figure 4 HIV positive, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

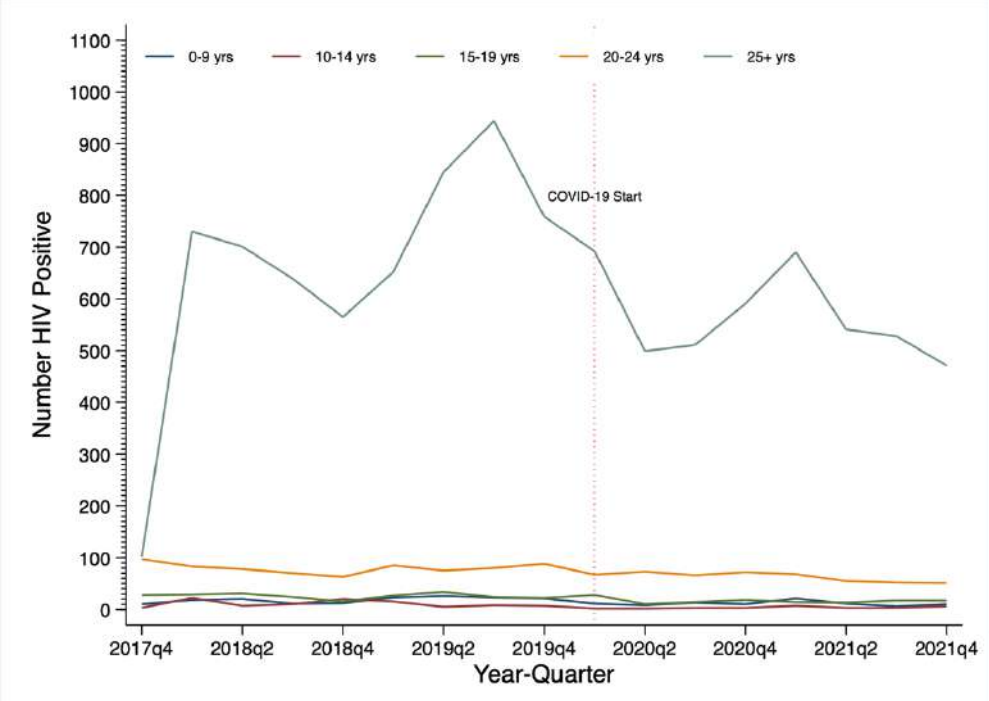

Figure 5 HIV positive by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

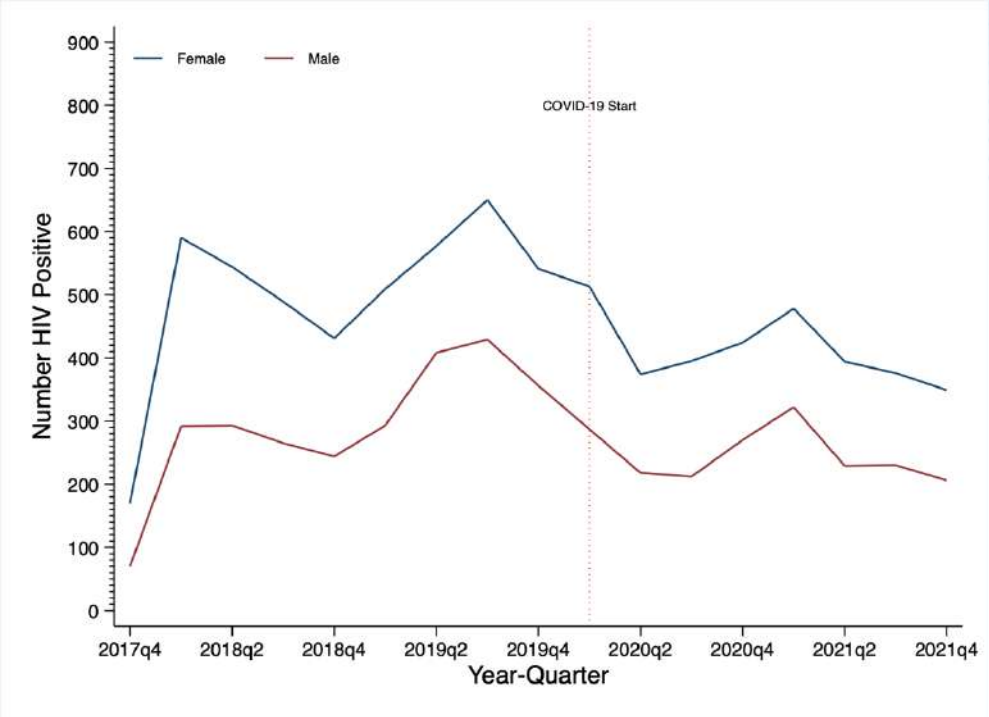

Figure 6 HIV positive by sex, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

2. VIRAL LOAD TRENDS

Viral Load Trends among HIV positive clients

The total number of viral load test was 321,957 and with a majority, 299,211 (92.9%), having a suppressed viral load result. Nyeri County had the highest number of viral of tests done as shown in Figure 7. Overall there was a significant non-linear trend (P-value <0.001) indicating a marked increase in the number of viral load tests from October to December of 2018 and peaking in January to March of 2021 and thereafter a steady decline in the numbers during the COVID-19 period with a large final drop in October to December of 2021 as shown in the Table 3 and Figure 7 and 8. The proportion of clients with suppressed viral load trends after July to September of 2018 remained relatively similar pre and during the COVID-19 pandemic period as shown in Figure 9.

Table 3 Viral Load Trends among HIV positive clients, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

County	VL <1000 Copies/mL	Total number of Viral Loads*
Year-Quarter	n (%)	
2017 Oct-Dec (q4)	3619 (54.6%)	6633
2018 Jan-Mar (q1)	5374 (69.4%)	7741
2018 Apr-Jun (q2)	6166 (70.2%)	8781
2018 Jul-Sep (q3)	5226 (65.3%)	7999
2018 Oct-Dec (q4)	15426 (93.7%)	16470
2019 Jan-Mar (q1)	17917 (94.6%)	18931
2019 Apr-Jun (q2)	19344 (94.7%)	20416
2019 Jul-Sep (q3)	20230 (95.6%)	21152

2019 Oct-Dec (q4)	22781 (95.4%)	23888
2020 Jan-Mar (q1)	22946 (95.9%)	23924
2020 Apr-Jun (q2)	22066 (96.1%)	22970
2020 Jul-Sep (q3)	22758 (96.4%)	23611
2020 Oct-Dec (q4)	30261 (96.8%)	31274
2021 Jan-Mar (q1)	30166 (97.0%)	31104
2021 Apr-Jun (q2)	26670 (96.5%)	27638
2021 Jul-Sep (q3)	18298 (96.2%)	19023
2021 Oct-Dec (q4)	9963 (95.8%)	10402
Total	299211 (92.9%)	321957
*Jonckheere-Terpstra test for time ordered overall increase in numbers, P-value <0.001		

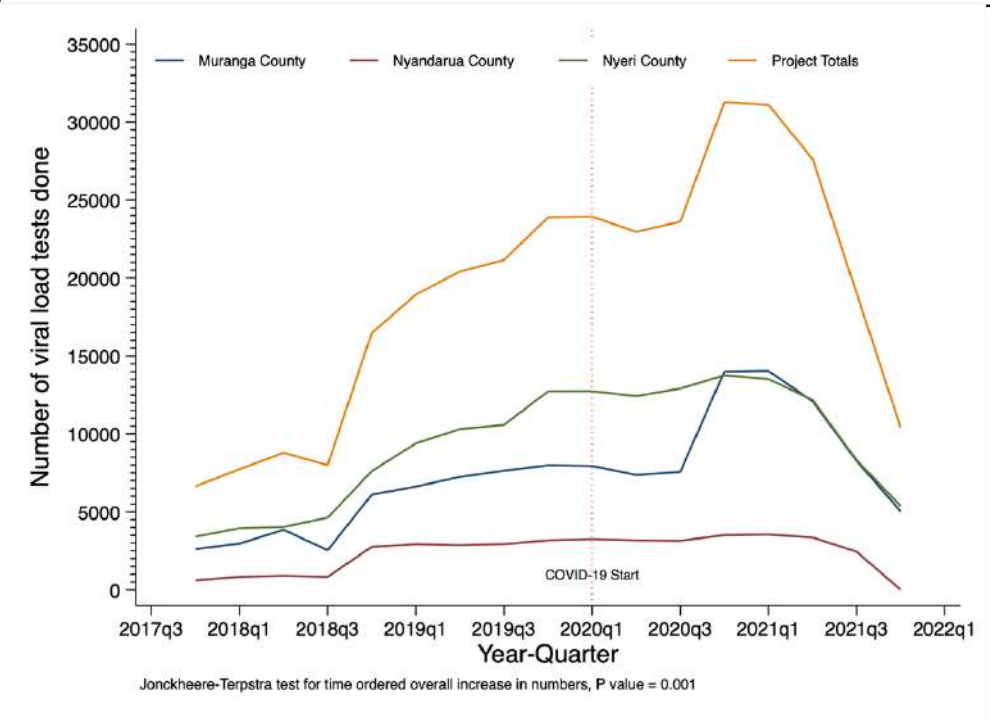

Figure 7 Viral load trends among HIV positive clients, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

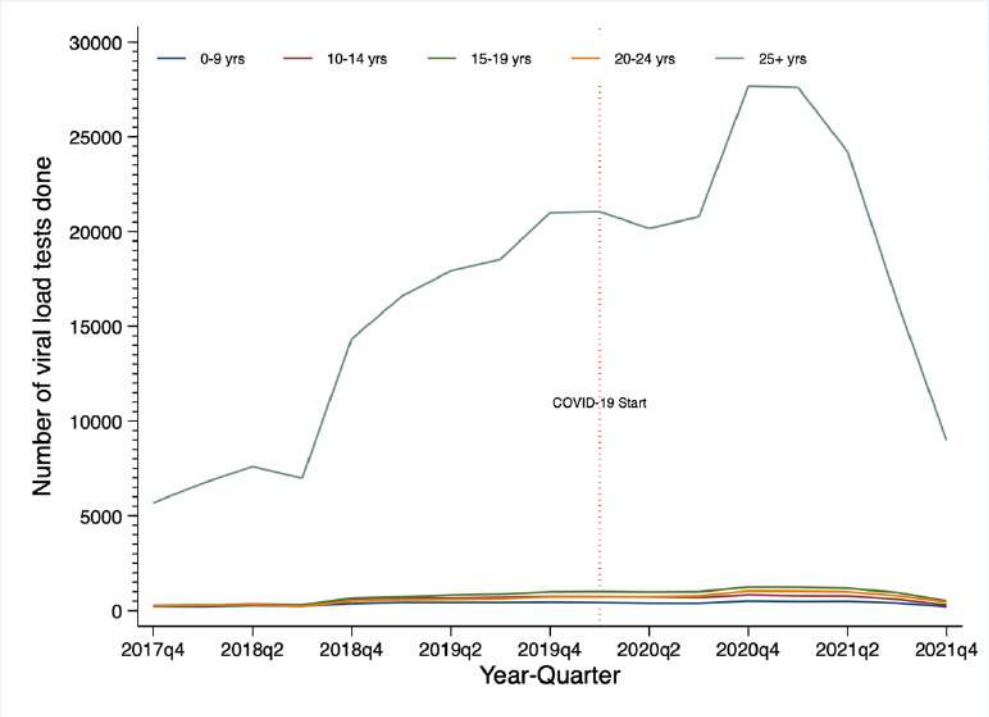

Figure 8 Viral load trends by age, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

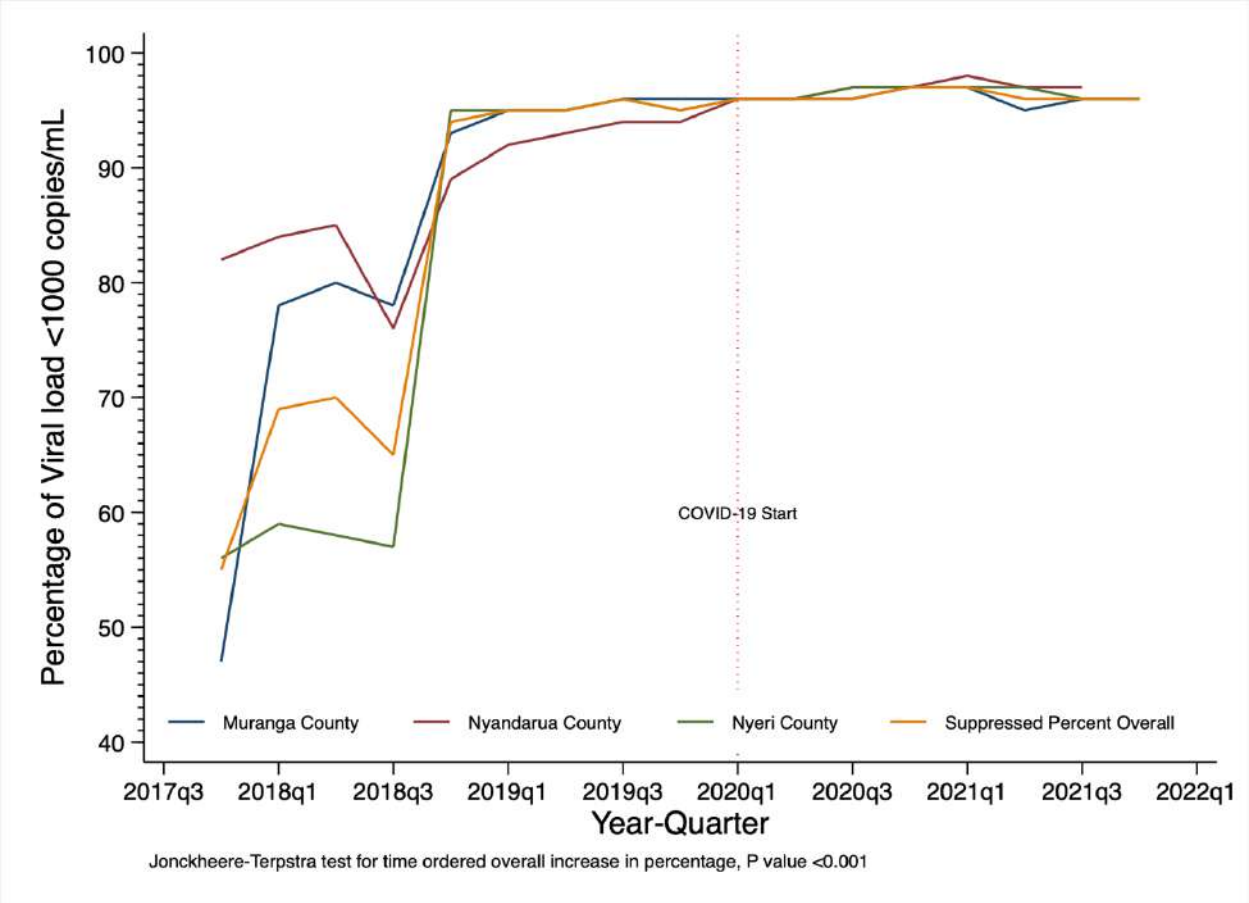

Figure 9 Suppressed Viral load trends, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

2. PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV TRENDS

Antenatal Care Clients seen

The total number of antenatal care clients served at facilities in the 3 counties was 115,367. Overall, Murang'a County had the highest number of antenatal care clients (n= 51,373), with results showing an increase in the number of tests between January to March of 2018 all the way to July to September of 2021. A significant non-linear trend (P-value = 0.023) indicated a marked increase in the project total number of clients seen overall. The trends show a drop in the numbers at the start of the COVID-19 period for 3 consecutive quarters as shown in Table 4 and Figure 10.

Table 4 Antenatal Care Clients seen, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

	County			
	Murang'a County	Nyandarua County	Nyeri County	Total*
Year-Quarter				
2017 Oct-Dec (q4)	1065	466	1114	2645
2018 Jan-Mar (q1)	2963	1211	2941	7115
2018 Apr-Jun (q2)	2681	1202	2768	6651
2018 Jul-Sep (q3)	2623	1120	2684	6427
2018 Oct-Dec (q4)	2431	1046	2372	5849
2019 Jan-Mar (q1)	2885	1282	2806	6973
2019 Apr-Jun (q2)	2735	1186	2677	6598
2019 Jul-Sep (q3)	2902	1231	2790	6923
2019 Oct-Dec (q4)	2292	1080	2597	5969
2020 Jan-Mar (q1)	2831	1334	3231	7396
2020 Apr-Jun (q2)	2697	1249	2973	6919
2020 Jul-Sep (q3)	2532	1236	3025	6793
2020 Oct-Dec (q4)	3886	896	2704	7486
2021 Jan-Mar (q1)	4582	1310	3016	8908
2021 Apr-Jun (q2)	4315	1331	2970	8616
2021 Jul-Sep (q3)	4000	1194	2622	7816
2021 Oct-Dec (q4)	3953	0	2330	6283
Total	51373	18374	45620	115367
*Jonckheere-Terpstra test for time ordered overall increase in numbers, P-value 0.023				

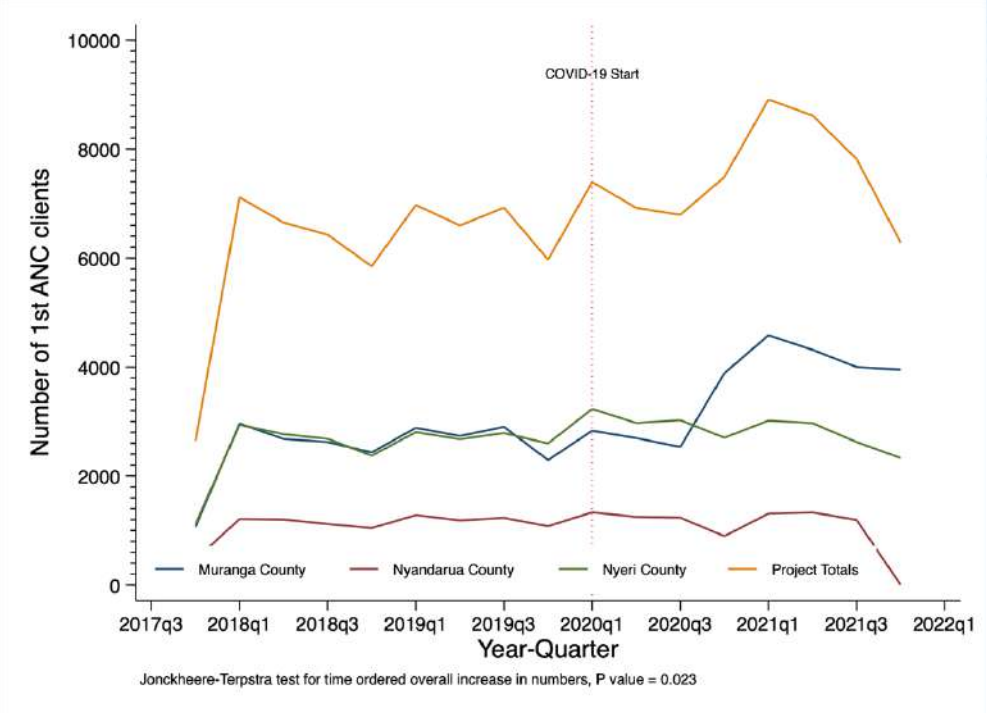

Figure 10 Antenatal Care Clients seen, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Known HIV Positive clients at first Antenatal Care visit

The project total number of known HIV positive clients at first antenatal care visit in the 3 counties was 2,312. Nyeri County had the highest number of clients, n=1,005. There was a significant non-linear trend (P-value = 0.006) indicating a marked increase in the project total numbers over time. However, during the COVID-19 period there seems to be a steady decline from January to March of 2021 to October to December of 2021 as shown in Figure 11.

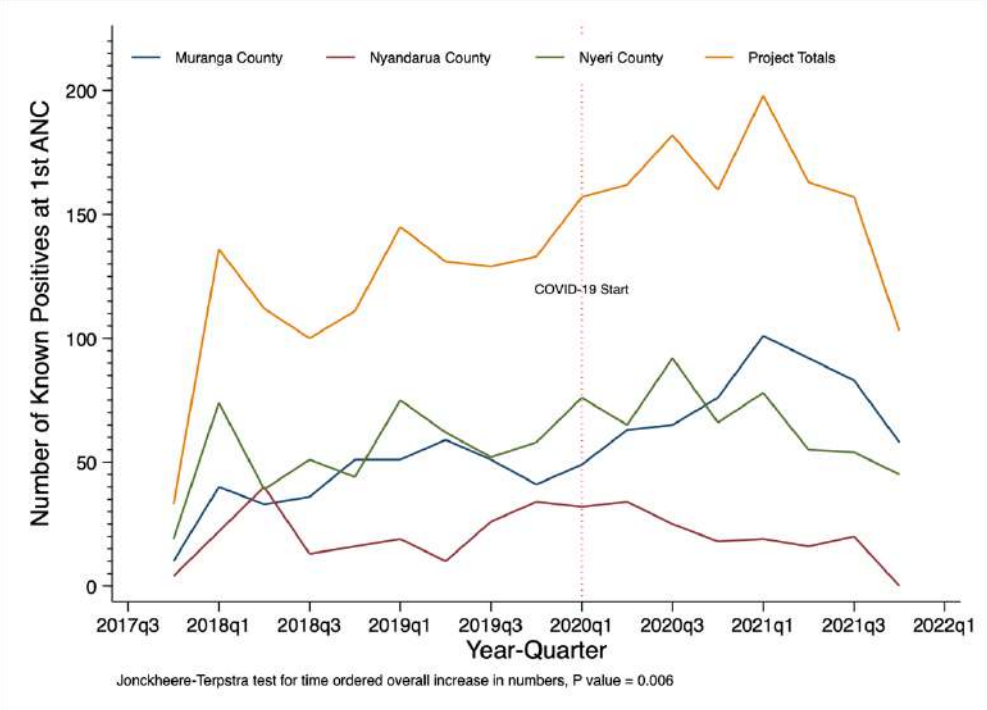

Figure 11 Known HIV Positive clients at first Antenatal Care visit, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Clients tested at first Antenatal Care visit

The project total number of clients tested in the 3 counties was 111,771. Murang'a County had the highest number of clients tested (n= 49,918). Results indicated a significant non-linear trend (P-value 0.025) indicating a marked overall increase in the number of clients tested (Table 5). The results also show an immediate decline in the numbers at the start of the COVID-19 period and in two subsequent quarters, then the numbers went up and dropped steadily again as shown in Figure 12.

Table 5 Clients tested at first Antenatal Care visit, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

County				
	Murang'a County	Nyandarua County	Nyeri County	Total*
Year-Quarter				
2017 Oct-Dec (q4)	1055	462	1078	2595
2018 Jan-Mar (q1)	2835	1154	2795	6784
2018 Apr-Jun (q2)	2572	1126	2648	6346
2018 Jul-Sep (q3)	2520	1073	2549	6142
2018 Oct-Dec (q4)	2380	1030	2328	5738
2019 Jan-Mar (q1)	2834	1263	2731	6828
2019 Apr-Jun (q2)	2676	1176	2615	6467
2019 Jul-Sep (q3)	2851	1205	2738	6794
2019 Oct-Dec (q4)	2252	1046	2539	5837
2020 Jan-Mar (q1)	2782	1302	3155	7239
2020 Apr-Jun (q2)	2634	1215	2908	6757
2020 Jul-Sep (q3)	2467	1211	2933	6611
2020 Oct-Dec (q4)	3810	878	2638	7326
2021 Jan-Mar (q1)	4481	1291	2938	8710
2021 Apr-Jun (q2)	3985	1128	2884	7997
2021 Jul-Sep (q3)	3891	1022	2554	7467
2021 Oct-Dec (q4)	3893	0	2240	6133
Total	49918	17582	44271	111771
*Jonckheere-Terpstra test for time ordered overall increase in numbers, P-value 0.025				

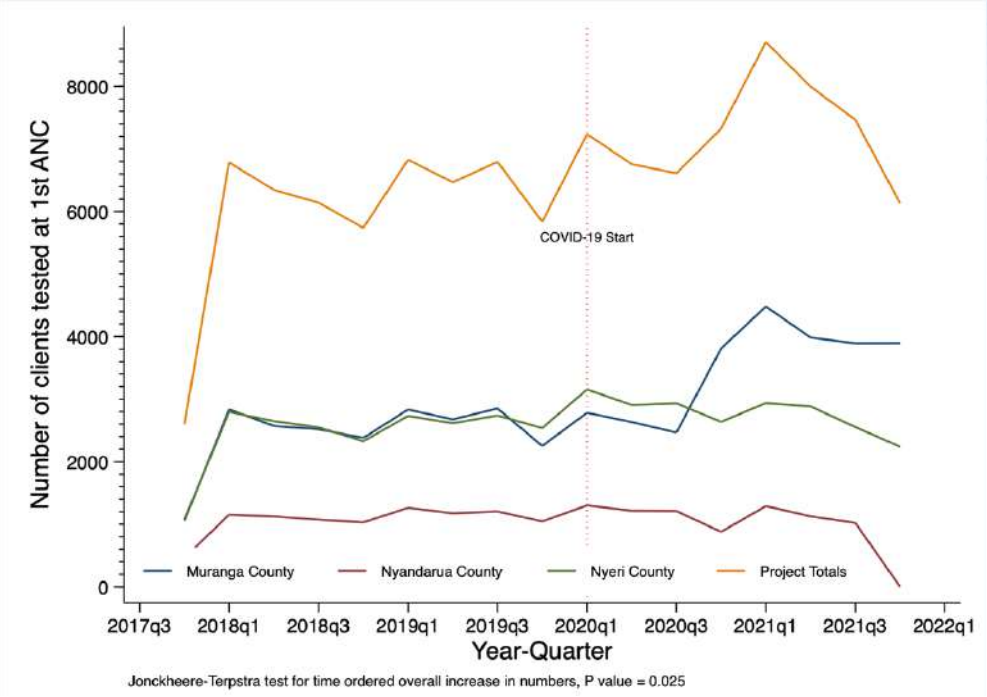

Figure 12 Number of clients tested at 1st Antenatal Care visit, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

New HIV positive clients at first Antenatal Care visit

The project total number of clients with HIV positive results at first antenatal care visit in the 3 counties was 927. Nyeri county had the highest number of clients with HIV positive test results from all the tests done, n=401. There was no significant non-linear trend (P-value = 0.203) in an increase or decrease in numbers as shown in Figure 13. There was an upsurge during the COVID-19 period in new HIV positive clients among age groups 15-19 years and 20-24 years between January to March of 2020 and July to September of 2020. Overall trends in the new positives remained relatively similar pre and during the COVID-19 period among the other age categories as shown in Figure 14.

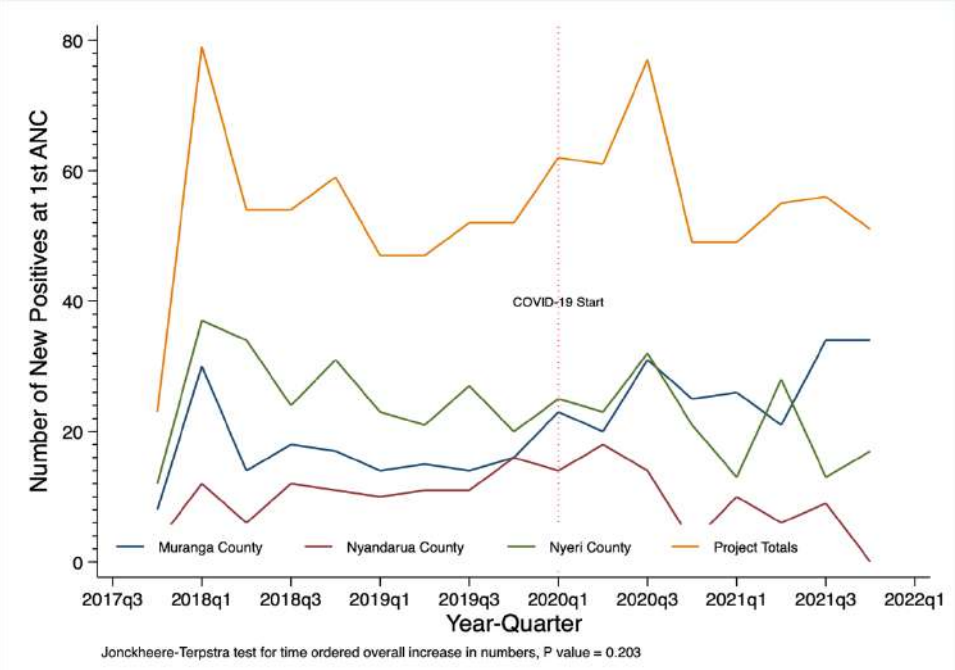

Figure 13 New HIV positive clients at first Antenatal Care visit, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

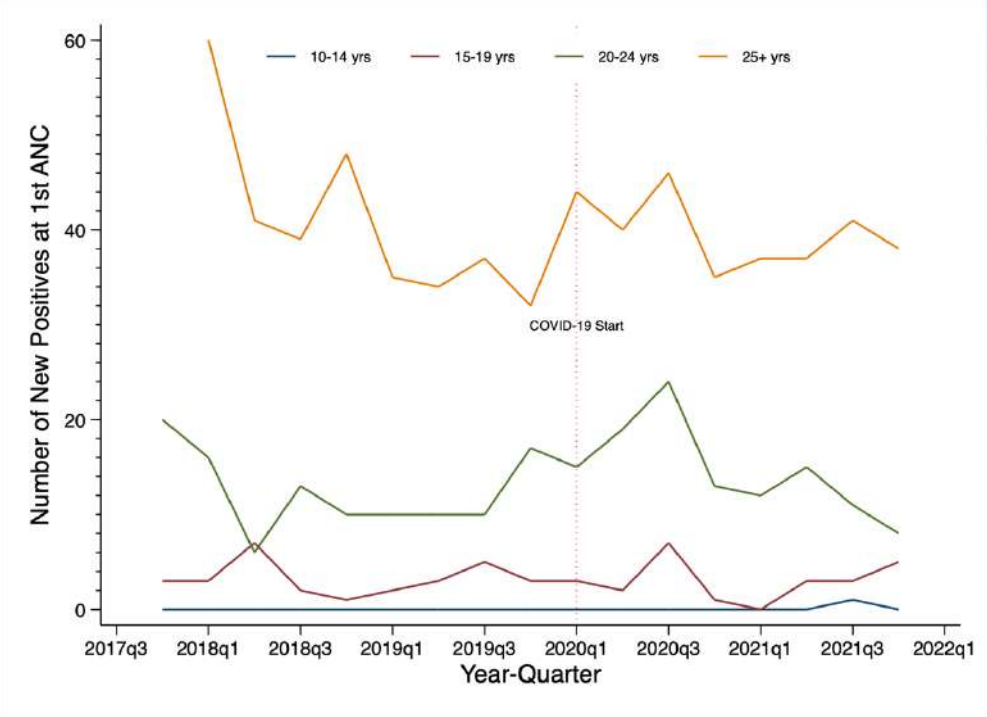

Figure 14 New HIV positive clients at first Antenatal Care visit by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

3. PRE-EXPOSURE PROPHYLAXIS

Number of new pre-exposure prophylaxis clients

The total number of new clients initiated on pre-exposure prophylaxis in the 3 counties was n= 5,798 as shown in Table 6. Murang'a county had the highest number of new clients initiated on pre-exposure prophylaxis, n=3,138. There was a significant non-linear trend (P-value <0.001) indicating a marked increase in the number of new pre-exposure prophylaxis clients overall. The numbers dropped immediately after the start of the COVID-19 period but then increased sharply from April to June of 2020 and peaked in July to September of 2021 as shown in Figure 15. The general trends by age indicated a spike in clients aged 25 years and above during the COVID-19 period (Figure 16). More females than men newly initiated pre-exposure prophylaxis during the COVID-19 period (Figure 17).

Table 6 Number of new pre-exposure prophylaxis clients, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

	County			
	Murang'a County	Nyandarua County	Nyeri County	Total*
Year-Quarter				
2017 Oct-Dec (q4)	13	0	7	20
2018 Jan-Mar (q1)	53	2	43	98
2018 Apr-Jun (q2)	65	7	32	104
2018 Jul-Sep (q3)	34	2	43	79

2018 Oct-Dec (q4)	0	0	0	0
2019 Jan-Mar (q1)	84	18	103	205
2019 Apr-Jun (q2)	0	0	0	0
2019 Jul-Sep (q3)	85	14	94	193
2019 Oct-Dec (q4)	0	0	0	0
2020 Jan-Mar (q1)	180	37	128	345
2020 Apr-Jun (q2)	0	0	0	0
2020 Jul-Sep (q3)	269	151	260	680
2020 Oct-Dec (q4)	152	50	145	347
2021 Jan-Mar (q1)	358	113	288	759
2021 Apr-Jun (q2)	452	94	326	872
2021 Jul-Sep (q3)	719	58	332	1109
2021 Oct-Dec (q4)	674	0	313	987
Total	3138	546	2114	5798
*Jonckheere-Terpstra test for time ordered an overall increase in numbers, P-value <0.001				

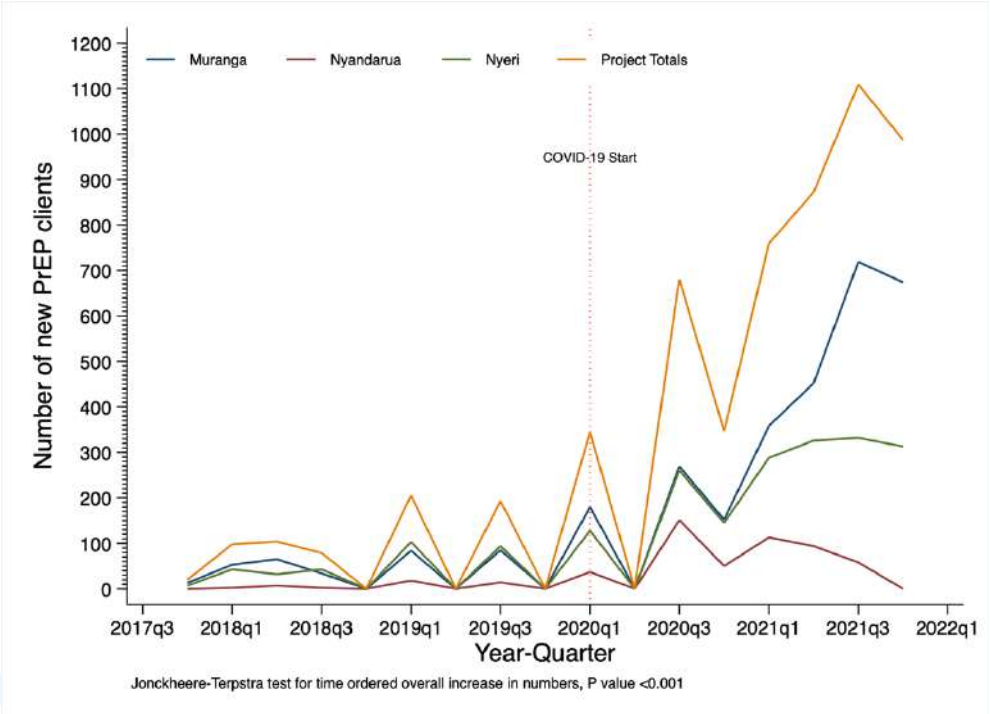

Figure 15 Number of new pre-exposure prophylaxis clients, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

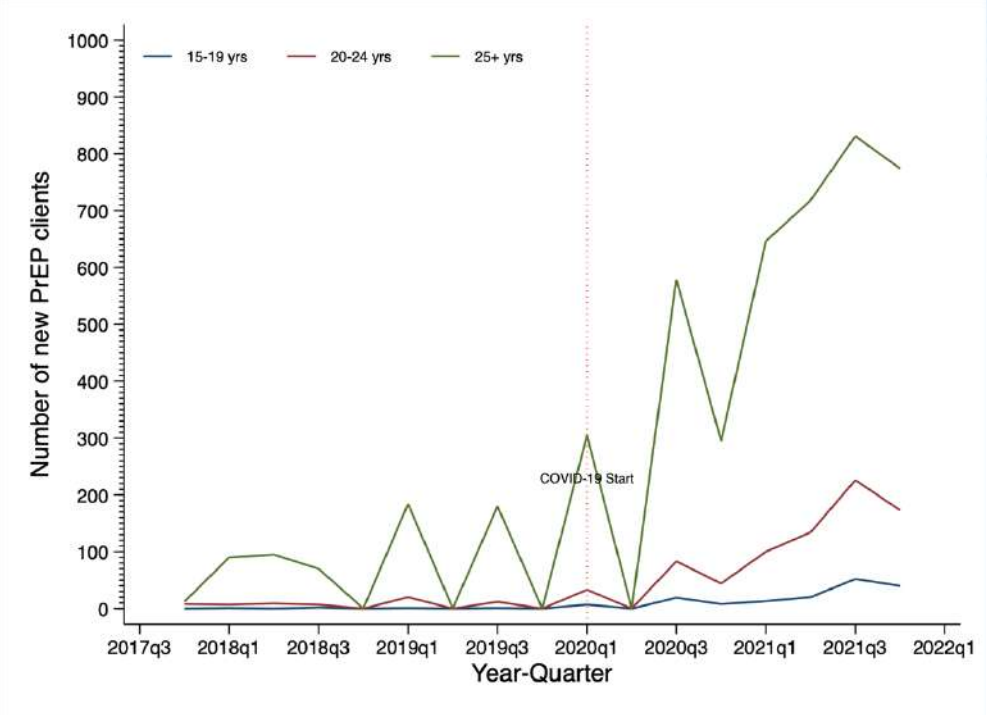

Figure 16 Number of new pre-exposure prophylaxis clients by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

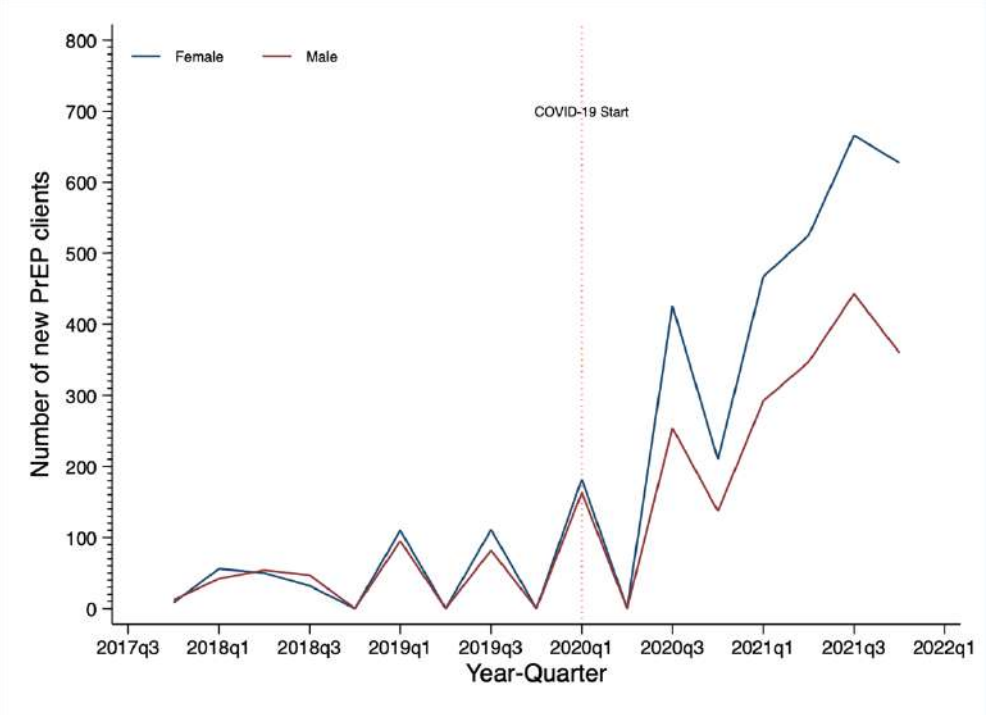

Figure 17 Number of new pre-exposure prophylaxis clients by sex, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

4. GENDER-BASED VIOLENCE

Number of Sexual Violence Cases reported

The number of sexual violence cases reported in the 3 counties was 2,686. Overall, Nyeri county had the highest number of cases reported, n= 1,363. A significant non-linear trend (P-value < 0.001) indicated a marked increase in the overall project total number of cases. Overall, results show an increase in the cases of sexual violence during the COVID-19 period compared to the period before as shown in Table 7 and Figure 18. There was a noticeable increase in the cases among those aged 50 years and above during the COVID-19 period (Figure 19). The number of cases among females increased markedly during the COVID-19 period compared to the period before (Figure 20).

Table 7 Number of Sexual Violence Cases reported, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

County				
Indicator	Murang'a	Nyandarua	Nyeri	Total*
2019	86	112	275	473
2020	224	168	558	950
2021	491	242	530	1263
Total	801	522	1363	2686

*Jonckheere-Terpstra test for time ordered overall increase in numbers, P-value <0.001

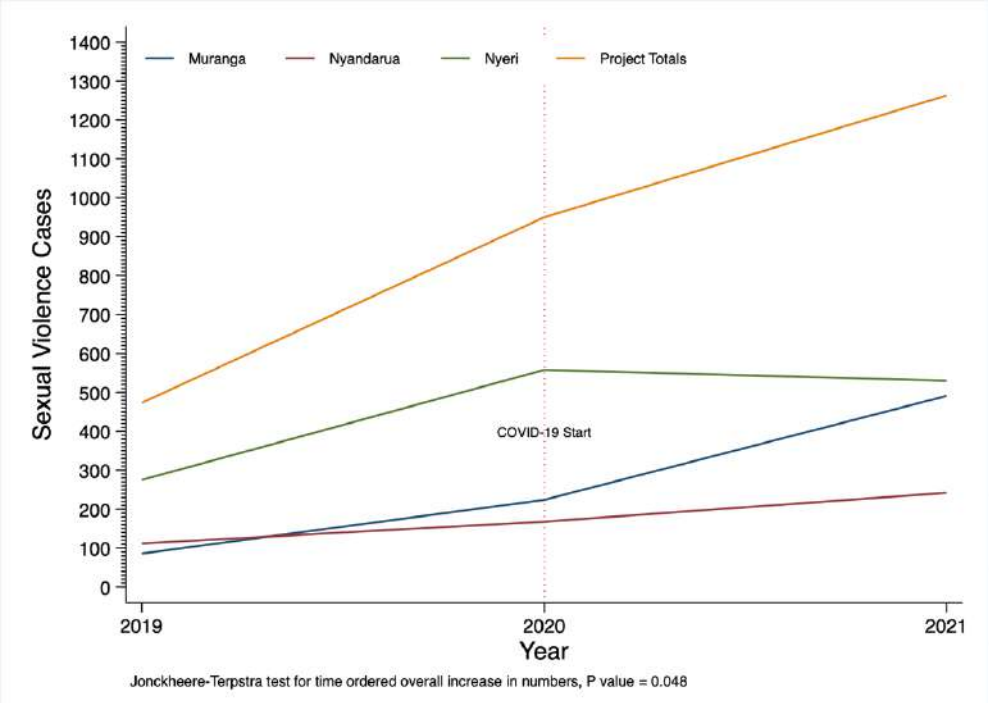

Figure 18 Number of Sexual Violence Cases reported, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

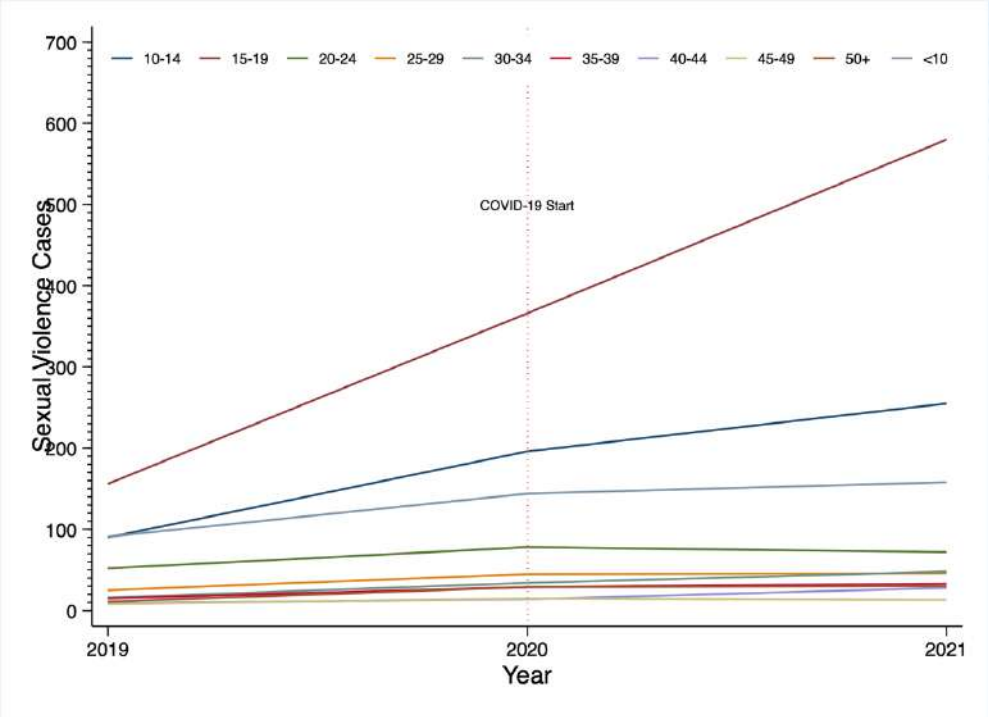

Figure 19 Number of Sexual Violence Cases reported by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

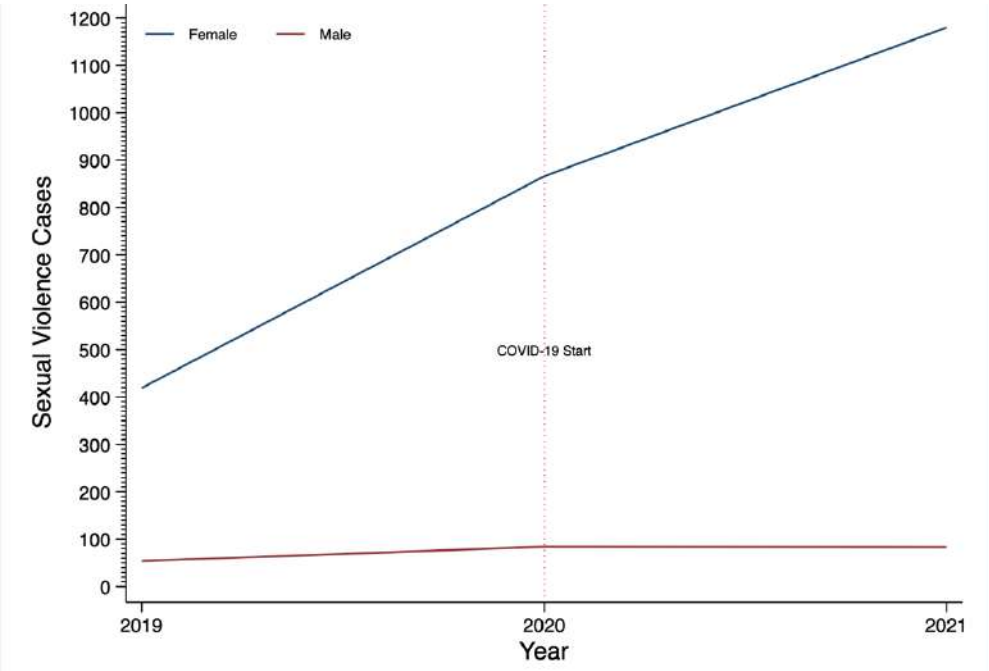

Figure 20 Number of Sexual Violence Cases reported by sex, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Number of Physical and (or) Emotional Violence Cases reported

The number of physical and (or) emotional violence cases reported in the 3 counties was 18,301. Overall, Nyeri county had the highest number of cases reported, n= 8,765. A significant non-linear trend (P-value < 0.001) indicated a sharp increase in the overall project total number of physical and (or) emotional violence cases during the COVID-19 period compared to the period before as shown in Table 8 and Figure 21. There was a noticeable increase in the cases among those aged 50 years and above during the COVID-19 period (Figure 22). The number of cases among females increased markedly compared to an increase among males during the COVID-19 period in comparison to the period before (Figure 23).

Table 8 Number of Physical and (or) Emotional Violence Cases reported, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

	County			
Indicator	Murang'a	Nyandarua	Nyeri	Total*
2019	118	20	131	269
2020	997	488	523	2008
2021	6523	1390	8111	16024
Total	7638	1898	8765	18301

*Jonckheere-Terpstra test for time ordered an overall increase in numbers, P-value <0.001

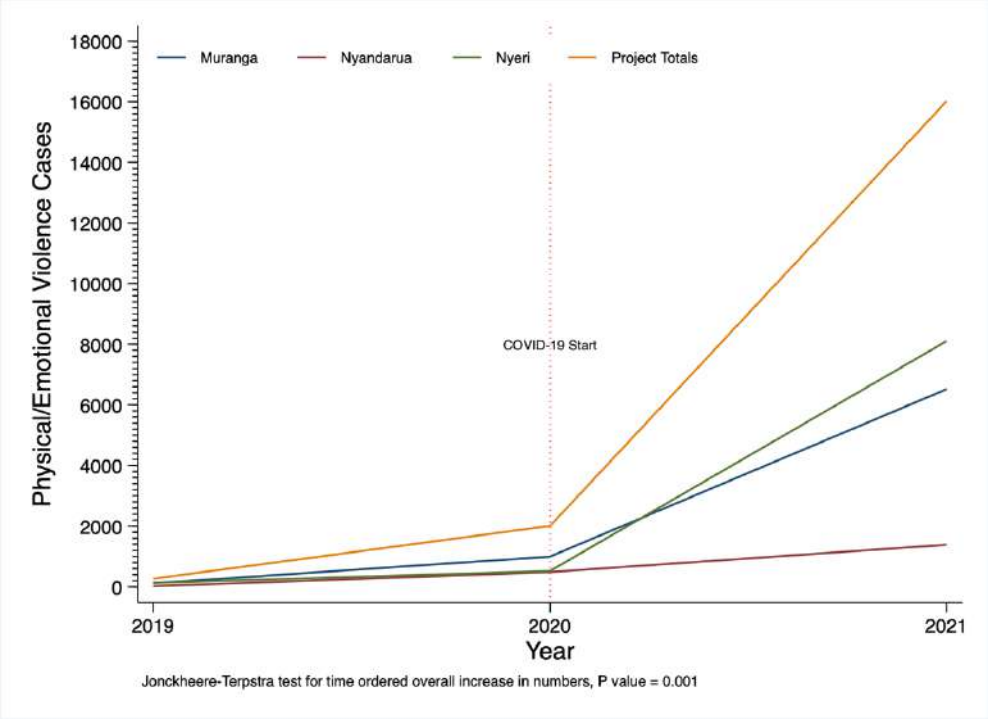

Figure 21 Number of Physical and (or) Emotional Violence Cases reported, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

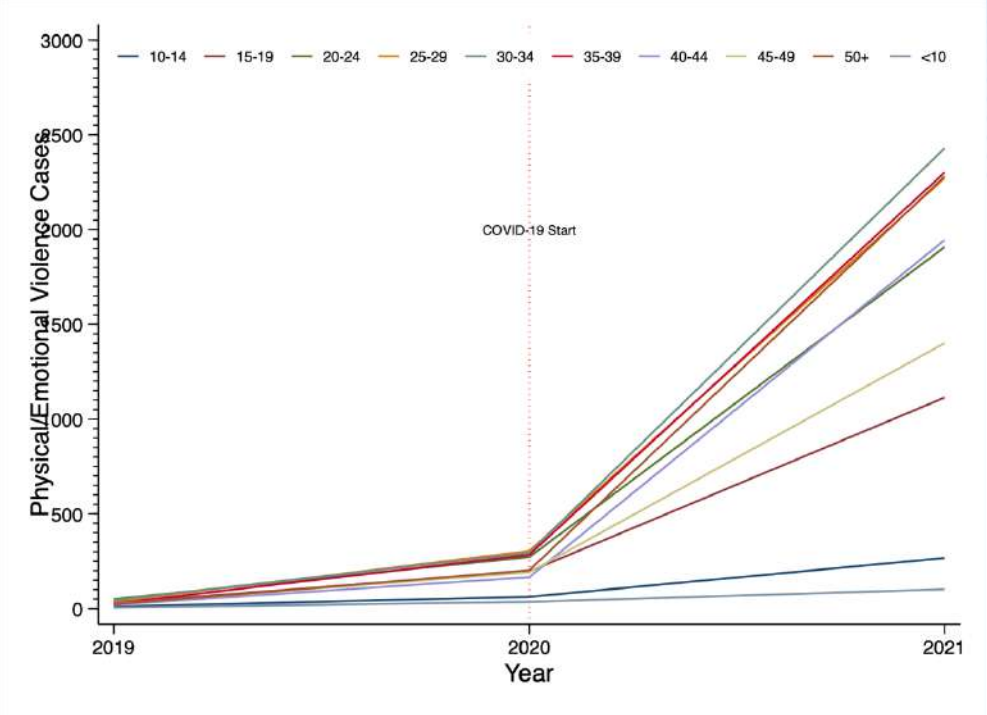

Figure 22 Number of Physical and (or) Emotional Violence Cases reported by age category, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

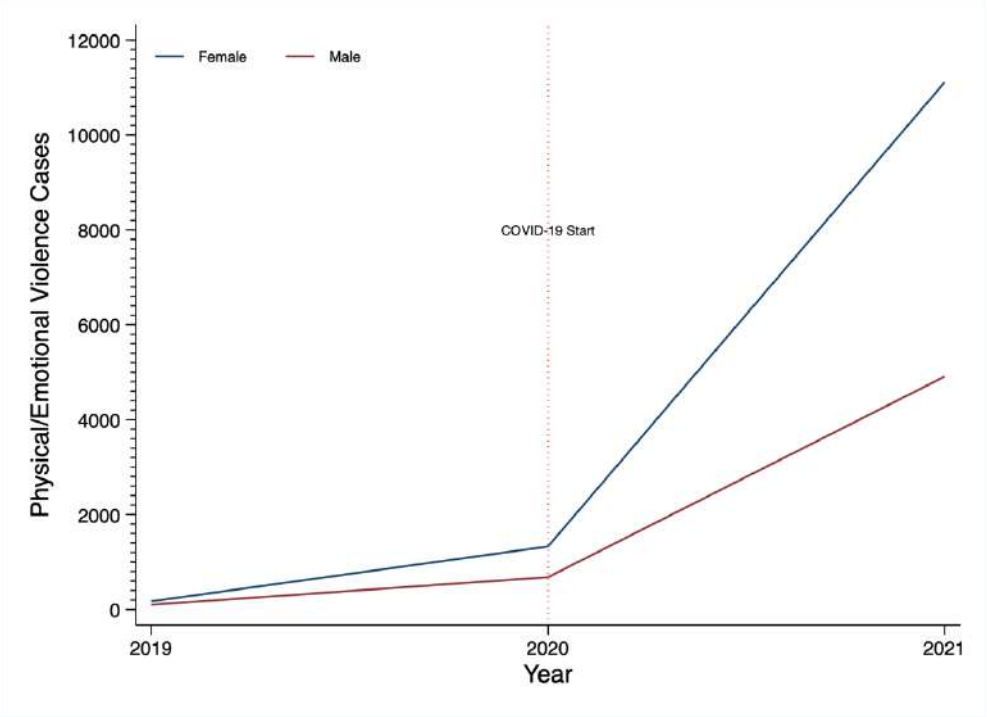

Figure 23 Number of Physical and (or) Emotional Violence Cases reported by sex, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

5. TUBERCULOSIS

Tuberculosis Cases

The number of tuberculosis cases reported in the 3 counties was 11,971. Overall, Murang'a county had the highest number of cases reported, n= 548. Overall, results show a decrease in TB cases during the COVID-19 period compared to the period before as shown in Figure 24. However, it was a non-significant non-linear trend in reduction of cases (P-value 0.185).

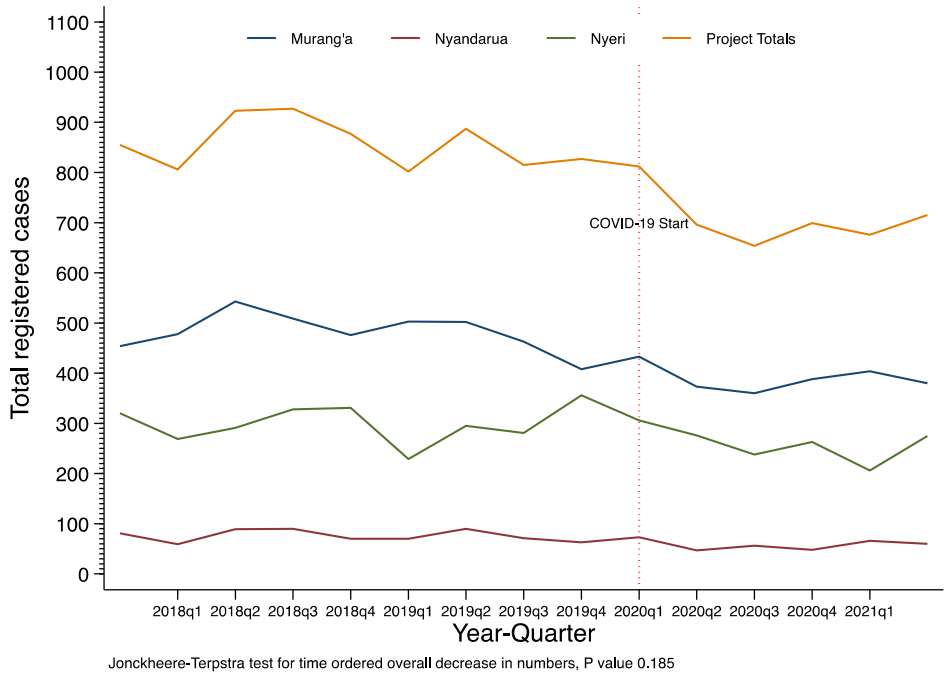

Figure 24 Number of registered TB cases, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Completion of TB Treatment

The number of patients who completed TB treatment in the 3 counties was 5,465. Overall, Murang'a county had the highest number of patients, n= 2,908. There is a sharp decline in the numbers at the start of the COVID-19 period. A significant non-linear trend (P-value = 0.037) indicated a marked decrease in the overall project total number of patients who completed TB treatment as shown in Figure 25.

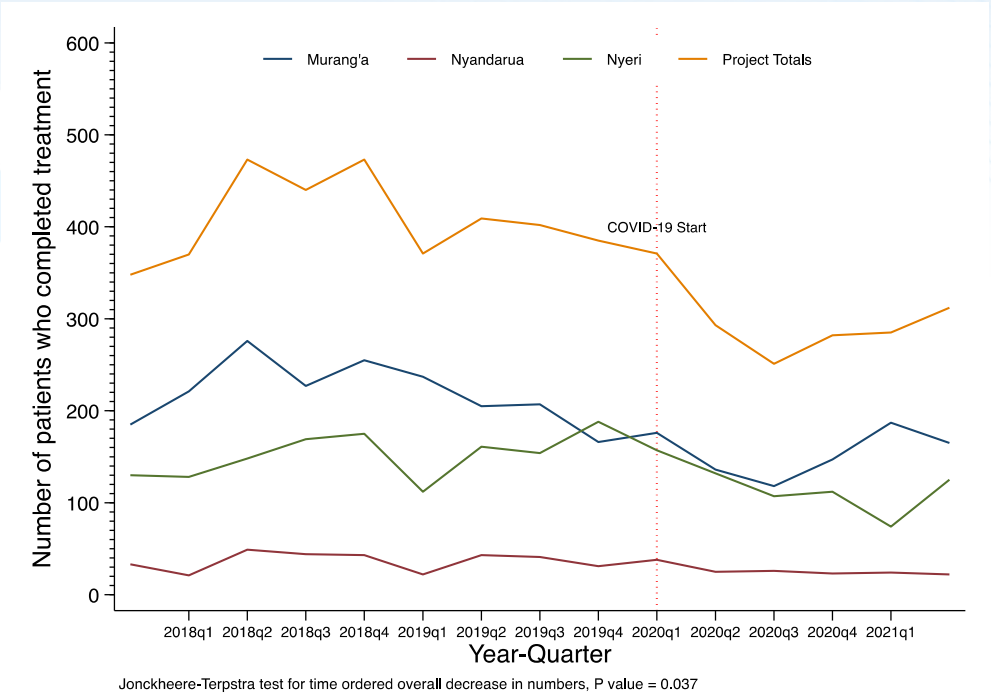

Figure 25 Number of patients who completed TB treatment, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

TB Treatment Success Rate

Results shown in Figure 26 indicate a non-significant non-linear decrease in the percentage treatment success rate at the start of the COVID-19 period (P-value = 0.539). The rate remains stable up to December of 2020.

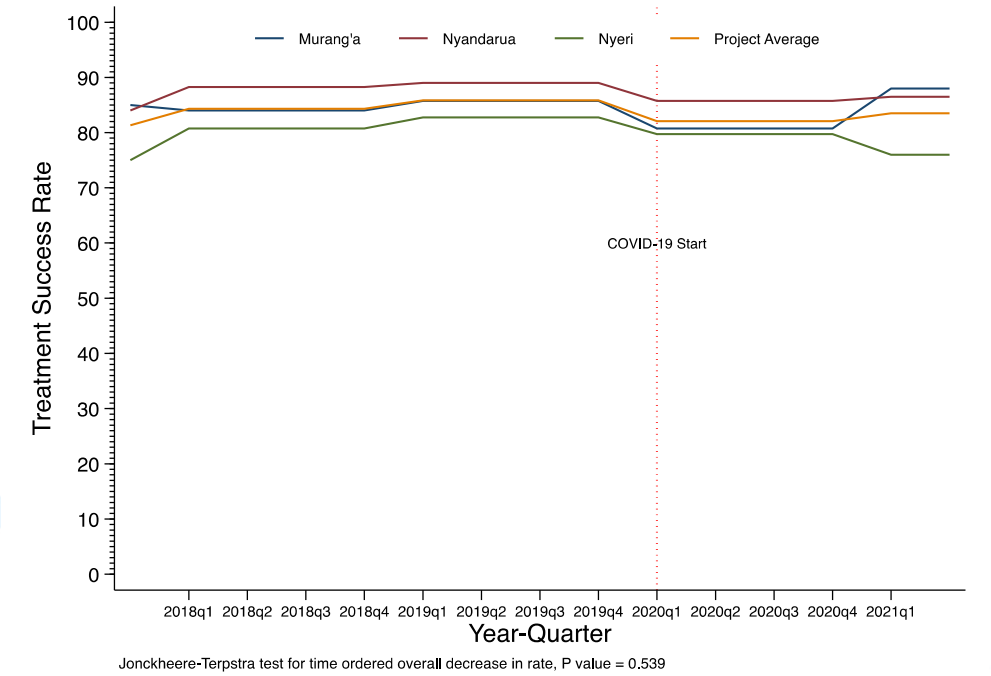

Figure 26 TB treatment success rate (%), Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Other TB treatment outcomes

Results show non-significant increase in the death cases around the start of the COVID-19 period (P-value = 0.225). Conversely, there was a significant decrease in LTFU cases around the start of the COVID-19 period (P-value = 0.048). The trends in patients who had treatment failure or moved to category 4 (MT4) were relatively similar before and after start of the COVID-19 period as shown in Figure 27.

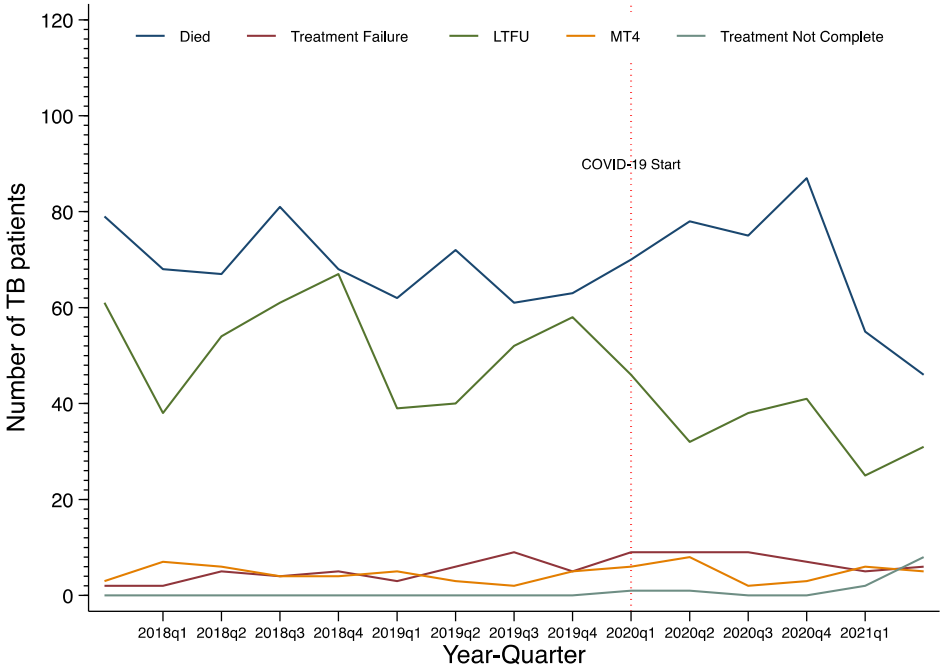

Figure 27 Other TB treatment outcomes, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 - December 2021

Characteristics of HIV positive clients on ART with viral load outcomes

The number of clients with a current viral load was 23,371 (8,270 pre-COVID-19 and 15,101 during the COVID-19 period). The mean client age was 37.2 years (SD= 15.16) with 6,313 (27.0%) aged 35-44 years and 6,975 (29.8%) aged 45-54 years. Most, 15,853 (67.8%), were female and, less than half, 9,379 (40.1%), married. The highest number of clients, 9,245 (39.6%), had a normal weight. A majority, 21,732 (93.0%) and 17,910 (76.6%) had suppressed viral loads and WHO stage I at ART initiation respectively. A majority, 22,599 (97.1%), had been on ART and for an overall median of 85.67 months (IQR: 49.15; 127.38). Most, 13,858 (59.4%), were on TDF-based regimens at ART initiation. The majority, 21,222 (90.9%), are currently on TDF-based regimens. The majority, 22,235 (95.1%), of the HIV clients had suppressed viral loads.

Impact of COVID-19 on viral suppression among HIV positive clients on ART

On univariable logistic regression analysis, there was 14% higher odds (non-significant) of having viral suppression among clients in the COVID-19 period compared to the pre-COVID-19 period, 1.14 (95% CI: 0.83 - 1.57), P-value = 0.422.

On multivariable logistic regression analysis, there was 12% higher odds (non-significant) of having viral suppression among clients in the COVID-19 period compared to the pre-COVID-19 period after adjusting for their age category, sex, marital status, BMI, baseline viral suppression and WHO stage,

time on ART, initial and current core regimen, 1.14 (95% CI: 0.83 - 1.49), P-value = 0.460 as shown in Table 9.

Table 9 Impact of COVID-19 on viral suppression among HIV positive clients on ART, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 to December 2021

Current Viral Suppression	<1000 copies/ml	>=1000 copies/ml	Univariable Model		Multivariable Model	
n (%)	22235 (95.1)	1136 (4.9)	OR (95% CI)	P-value	OR (95% CI)	P-value
Evaluation Period, n (%)						
Pre-COVID-19 Period	7786 (35.0)	484 (42.6)	Reference		Reference	
COVID-19 Period	14449 (65.0)	652 (57.4)	1.14 (0.83 - 1.57)	0.422	1.12 (0.83 - 1.49)	0.460
Age Category, n (%)						
0-9yrs	281 (1.3)	45 (4.0)	Reference		Reference	
10-14	471 (2.1)	31 (2.7)	2.43 (1.44 - 4.11)	0.001	1.15 (0.51 - 2.62)	0.737
15-19	712 (3.2)	86 (7.6)	1.33 (0.86 - 2.05)	0.203	0.49 (0.23 - 1.03)	0.061
20-24	757 (3.4)	109 (9.6)	1.11 (0.74 - 1.66)	0.605	0.45 (0.23 - 0.89)	0.022
25-34	2526 (11.4)	175 (15.4)	2.31 (1.64 - 3.26)	<0.001	0.44 (0.20 - 0.97)	0.042
35-44	6003 (27.0)	310 (27.3)	3.10 (2.19 - 4.40)	<0.001	0.56 (0.24 - 1.29)	0.175
45-54	6742 (30.3)	233 (20.5)	4.63 (2.96 - 7.26)	<0.001	0.65 (0.24 - 1.74)	0.390
55-64	3512 (15.8)	115 (10.1)	4.89 (3.31 - 7.24)	<0.001	0.60 (0.25 - 1.47)	0.264
65+	1227 (5.5)	32 (2.8)	6.14 (3.61 - 10.44)	<0.001	0.67 (0.26 - 1.72)	0.402
Sex, n (%)						
M	7111 (32.0)	407 (35.8)	Reference		Reference	
F	15124 (68.0)	729 (64.2)	1.12 (0.98 - 1.28)	0.093	1.09 (0.96 - 1.25)	0.183
Marital Status, n (%)						
Divorced/Separated	2694 (12.1)	125 (11.0)	Reference		Reference	
Married	9015 (40.5)	364 (32.0)	1.15 (0.86 - 1.54)	0.353	1.02 (0.76 - 1.37)	0.896
Never married	5311 (23.9)	399 (35.1)	0.62 (0.48 - 0.79)	<0.001	0.86 (0.63 - 1.17)	0.333
Polygamous	827 (3.7)	27 (2.4)	1.42 (0.89 - 2.28)	0.144	1.18 (0.67 - 2.07)	0.577
Unknown	2110 (9.5)	152 (13.4)	0.64 (0.52 - 0.80)	<0.001	0.88 (0.64 - 1.21)	0.428
Widowed	2278 (10.2)	69 (6.1)	1.53 (1.15 - 2.05)	0.004	1.23 (0.87 - 1.74)	0.245

BMI Category, n (%)						
Underweight	4187 (18.8)	236 (20.8)	Reference		Reference	
Normal weight	8778 (39.5)	467 (41.1)	1.06 (0.93 - 1.20)	0.379	1.13 (0.94 - 1.36)	0.201
Overweight	3878 (17.4)	179 (15.8)	1.22 (1.01 - 1.47)	0.037	1.33 (1.05 - 1.69)	0.016
Obese	1897 (8.5)	90 (7.9)	1.19 (0.91 - 1.55)	0.202	1.41 (0.94 - 2.11)	0.097
Not Indicated	3495 (15.7)	164 (14.4)	1.20 (0.97 - 1.49)	0.100	1.37 (1.08 - 1.73)	0.010
Baseline Viral Suppression, n (%)						
>=1000 copies/ml	874 (3.9)	754 (66.4)	Reference		Reference	
<1000 copies/ml	21352 (96.0)	380 (33.5)	48.47 (38.04 - 61.77)	<0.001	37.59 (29.31 - 48.20)	<0.001
No Baseline VL	9 (0.0)	2 (0.2)	3.88 (1.40 - 10.73)	0.009	4.07 (2.02 - 8.22)	<0.001
Baseline WHO stage, n (%)						
Stage I	17147 (77.1)	763 (67.2)	4.58 (2.54 - 8.27)	<0.001	3.54 (1.70 - 7.40)	0.001
Stage II	2796 (12.6)	154 (13.6)	3.70 (2.26 - 6.08)	<0.001	3.29 (1.78 - 6.10)	<0.001
Stage III	1510 (6.8)	139 (12.2)	2.22 (1.37 - 3.59)	0.001	2.15 (1.17 - 3.95)	0.013
Stage IV	152 (0.7)	31 (2.7)			Reference	
Unstaged	630 (2.8)	49 (4.3)	2.62 (1.35 - 5.10)	0.005	2.11 (0.99 - 4.50)	0.053
Time on ART, n (%)						
0-6 months	301 (1.4)	36 (3.2)	Reference		Reference	
7-12 months	303 (1.4)	36 (3.2)	1.01 (0.59 - 1.72)	0.981	0.99 (0.66 - 1.49)	0.974
>12 months	21543 (97.3)	1056 (93.6)	2.44 (1.47 - 4.04)	0.001	2.13 (1.58 - 2.86)	<0.001
Initial Core Regimen, n (%)						
ABC Based, n (%)	2984 (13.4)	216 (19.0)	Reference		Reference	
AZT Based, n (%)	997 (4.5)	144 (12.7)	0.50 (0.40 - 0.63)	<0.001	0.70 (0.46 - 1.06)	0.094
D4T Based, n (%)	3352 (15.1)	106 (9.3)	2.29 (1.73 - 3.02)	<0.001	1.72 (1.26 - 2.33)	0.001
TDF Based, n (%)	13252 (59.7)	606 (53.4)	1.58 (1.36 - 1.85)	<0.001	1.06 (0.85 - 1.32)	0.621
Other, n (%)	1621 (7.3)	62 (5.5)	1.89 (1.41 - 2.55)	<0.001	1.55 (0.98 - 2.47)	0.063

Current Core Regimen, n (%)						
ABC Based, n (%)	878 (4.0)	245 (21.6)	Reference		Reference	
AZT Based, n (%)	774 (3.5)	114 (10.1)	1.89 (1.57 - 2.29)	<0.001	1.32 (0.92 - 1.90)	0.131
TDF Based, n (%)	20462 (92.1)	760 (67.0)	7.51 (6.62 - 8.53)	<0.001	2.11 (1.64 - 2.71)	<0.001
Other, n (%)	94 (0.4)	15 (1.3)	1.75 (1.02 - 3.00)	0.042	0.47 (0.22 - 0.97)	0.041

Characteristics of HIV Positive Clients on ART with retention outcomes

A total of 38,056 clients on ART were included in the analysis (13,448 pre-COVID-19 and 24,608 during the COVID-19 period). The mean client age was 42.58 years (SD= 14.11). Most, 6,313 (27.0%) 6,975 (29.8%) were aged 35-44 years and 45-54 years, respectively. Most, 25,324 (66.5%), were female, and less than half, 14,917 (39.2%), were married. Less than half of the clients, 14,961 (39.3%), had a normal weight. A majority, 32,174 (85.0%), had been on ART for more than 12 months and an overall median of 74.59 months (IQR: 30.69; 122.33). Most, 13,858 (59.4), were on TDF-based regimens at ART initiation. A majority, 34,792 (91.5%), were on TDF-based regimens as their current regimen as shown in Table 10.

Retention outcomes among HIV positive clients on ART

Overall, 29,296 (77.0%) were alive and active in care, 6,716 (17.6%) transferred-out of care to other facilities, 774 (2.0%) were LTFU and 1,270 (3.3%) had died as shown in Table 10. There was a higher number of deaths, and LTFU in the pre-COVID-19 period compared to the COVID-19 period.

Table 10 Characteristics of HIV Positive Clients on ART with retention outcomes, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 to December 2021

Treatment Outcome	Total	Alive	Died	Lost to follow up	Transferred out
n (%)	38056 (100.0)	29296 (77.0)	1270 (3.3)	774 (2.0)	6716 (17.6)
Age , mean (sd)	42.58 (14.11)	43.81 (14.01)	45.02 (14.24)	38.13 (12.47)	37.25 (13.32)
Age Category, n (%)					
0-9yrs	567 (1.5)	378 (1.3)	18 (1.4)	16 (2.1)	155 (2.3)
10-14	728 (1.9)	587 (2.0)	11 (0.9)	8 (1.0)	122 (1.8)
15-19	1296 (3.4)	1005 (3.4)	24 (1.9)	21 (2.7)	246 (3.7)
20-24	1800 (4.7)	1122 (3.8)	40 (3.2)	58 (7.5)	580 (8.7)
25-34	5327 (14.0)	3312 (11.3)	154 (12.1)	189 (24.5)	1672 (25.0)
35-44	10373 (27.3)	7737 (26.4)	395 (31.2)	249 (32.2)	1992 (29.8)
45-54	10738 (28.2)	8957 (30.6)	317 (25.0)	165 (21.3)	1299 (19.4)
55-64	5332 (14.0)	4632 (15.8)	191 (15.1)	56 (7.2)	453 (6.8)
65+	1861 (4.9)	1566 (5.3)	118 (9.3)	11 (1.4)	166 (2.5)

Adult Category, n (%)					
Child	1295 (3.4)	965 (3.3)	29 (2.3)	24 (3.1)	277 (4.1)
Adult	36727 (96.6)	28331 (96.7)	1239 (97.7)	749 (96.9)	6408 (95.9)
Sex, n (%)					
Female	25324 (66.5)	19564 (66.8)	648 (51.0)	453 (58.5)	4659 (69.4)
Male	12732 (33.5)	9732 (33.2)	622 (49.0)	321 (41.5)	2057 (30.6)
Marital Status, n (%)					
Divorced/Separated	4731 (12.4)	3663 (12.5)	190 (15.0)	101 (13.0)	777 (11.6)
Married	14917 (39.2)	11591 (39.6)	432 (34.0)	289 (37.3)	2605 (38.8)
Never married	9310 (24.5)	6785 (23.2)	307 (24.2)	244 (31.5)	1974 (29.4)
Polygamous	1768 (4.6)	1467 (5.0)	43 (3.4)	29 (3.7)	229 (3.4)
Unknown	3828 (10.1)	2817 (9.6)	156 (12.3)	74 (9.6)	781 (11.6)
Widowed	3502 (9.2)	2973 (10.1)	142 (11.2)	37 (4.8)	350 (5.2)
BMI Category, n (%)					
Underweight	7660 (20.1)	5962 (20.4)	277 (21.8)	158 (20.4)	1263 (18.8)
Normal weight	14961 (39.3)	11505 (39.3)	473 (37.2)	303 (39.1)	2680 (39.9)
Overweight	6306 (16.6)	4885 (16.7)	214 (16.9)	120 (15.5)	1087 (16.2)
Obese	3236 (8.5)	2471 (8.4)	103 (8.1)	54 (7.0)	608 (9.1)
Not Indicated	5893 (15.5)	4473 (15.3)	203 (16.0)	139 (18.0)	1078 (16.1)
Baseline Viral Suppression, n (%)					
>=1000 copies/ml	1870 (4.9)	1317 (4.5)	104 (8.2)	55 (7.1)	394 (5.9)
<1000 copies/ml	25763 (67.7)	21889 (74.7)	386 (30.4)	311 (40.2)	3177 (47.3)
No Baseline VL	10423 (27.4)	6090 (20.8)	780 (61.4)	408 (52.7)	3145 (46.8)
Current Viral suppression, n (%)					
<1000 copies/ml	22235 (58.4)	18816 (64.2)	337 (26.5)	291 (37.6)	2791 (41.6)
>=1000 copies/ml	1136 (3.0)	689 (2.4)	93 (7.3)	40 (5.2)	314 (4.7)
No VL done	14685 (38.6)	9791 (33.4)	840 (66.1)	443 (57.2)	3611 (53.8)
Baseline WHO stage, n (%)					
Stage I	27036 (71.0)	21452 (73.2)	525 (41.3)	466 (60.2)	4593 (68.4)
Stage II	3908 (10.3)	2728 (9.3)	213 (16.8)	131 (16.9)	836 (12.4)
Stage III	2354 (6.2)	1457 (5.0)	255 (20.1)	102 (13.2)	540 (8.0)
Stage IV	281 (0.7)	151 (0.5)	60 (4.7)	15 (1.9)	55 (0.8)
Unstaged	4477 (11.8)	3508 (12.0)	217 (17.1)	60 (7.8)	692 (10.3)
Time on ART (months), median (IQR)	74.59 (30.69; 122.33)	85.90 (45.74; 132.16)	9.95 (0.52; 74.46)	26.72 (1.54; 80.56)	20.85 (1.84; 79.85)

Time on ART, n (%)					
0-6 months	4550 (12.0)	1261 (4.3)	584 (46.6)	275 (36.0)	2430 (36.7)
7-12 months	1130 (3.0)	644 (2.2)	62 (4.9)	31 (4.1)	393 (5.9)
>12 months	32174 (85.0)	27314 (93.5)	608 (48.5)	457 (59.9)	3795 (57.3)
Initial Core Regimen, n (%)					
ABC Based	4775 (12.6)	3941 (13.5)	116 (9.2)	67 (8.7)	651 (9.7)
AZT Based	1722 (4.5)	1336 (4.6)	33 (2.6)	27 (3.5)	326 (4.9)
D4T Based	5187 (13.6)	4550 (15.5)	133 (10.6)	34 (4.4)	470 (7.0)
TDF Based	24039 (63.2)	17530 (59.9)	927 (73.6)	611 (79.1)	4971 (74.3)
Other	2284 (6.0)	1931 (6.6)	51 (4.0)	33 (4.3)	269 (4.0)
Current Core Regimen, n (%)					
ABC Based	1624 (4.3)	1164 (4.0)	70 (5.6)	34 (4.4)	356 (5.3)
AZT Based	1340 (3.5)	940 (3.2)	75 (6.0)	26 (3.4)	299 (4.5)
TDF Based	34792 (91.5)	27103 (92.5)	1073 (85.2)	697 (90.4)	5919 (88.5)
Other	251 (0.7)	81 (0.3)	41 (3.3)	14 (1.8)	115 (1.7)
Period, n (%)					
Pre-COVID-19 Period	13448 (35.3)	8282 (28.3)	887 (69.8)	407 (52.6)	3872 (57.7)
COVID-19 Period	24608 (64.7)	21014 (71.7)	383 (30.2)	367 (47.4)	2844 (42.3)

Impact of COVID-19 on loss to follow up (LTFU) among HIV positive clients on ART

On univariable analysis, the COVID-19 period had a lower risk of being LTFU compared to the pre-COVID-19 period without statistical significance, SHR = 0.62(95% CI: 0.38 – 1.03) as shown in Table 11. The cumulative incidence plot over time in months since initiating ART also showed a higher proportion of clients LTFU in the pre-COVID-19 period compared to the COVID-19 period (Figure 28). On multivariable analysis, there was a lower risk of being LTFU (non-significant) compared to the pre-COVID-19 period, adjusting for age category, sex, marital status, BMI, current viral suppression, baseline WHO stage, and current core regimen, aSHR = 0.50 (95% CI: 0.24 - 1.05), P-value = 0.068 (Table 11).

Table 11 Association of COVID-19 period with loss to follow up (LTFU) among HIV positive clients on ART, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 to December 2021

	Univariable		Multivariable	
	sHR (95% CI)	P-value	sHR (95% CI)	P-value
Evaluation Period				
Pre-COVID-19 Period	Ref		Ref	
COVID-19 Period	0.62 (0.38 - 1.03)	0.064	0.64 (0.34 - 1.22)	0.177
Age Category				
0-9yrs	7.55 (3.34 - 17.06)	<0.001	2.71 (1.01 - 7.33)	0.049

10-14	2.16 (0.82 - 5.68)	0.118	1.36 (0.70 - 2.63)	0.363
15-19	2.46 (1.13 - 5.38)	0.024	1.33 (0.76 - 2.31)	0.317
20-24	5.27 (2.65 - 10.48)	<0.001	1.75 (1.04 - 2.94)	0.036
25-34	8.28 (4.36 - 15.72)	<0.001	2.69 (1.71 - 4.23)	<0.001
35-44	5.36 (2.85 - 10.11)	<0.001	1.89 (1.24 - 2.89)	0.003
45-54	2.58 (1.36 - 4.90)	0.004	1.27 (0.96 - 1.67)	0.092
55-64	1.71 (0.87 - 3.39)	0.121	1.14 (0.83 - 1.56)	0.425
65+	Ref		Ref	
Sex				
Female	Ref		Ref	
Male	1.39 (1.19 - 1.63)	<0.001	1.11 (0.86 - 1.42)	0.427
Marital Status				
Divorced/Separated	Ref		Ref	
Married	0.84 (0.62 - 1.14)	0.259	0.91 (0.67 - 1.23)	0.541
Never married	1.16 (0.89 - 1.51)	0.282	0.98 (0.69 - 1.39)	0.919
Polygamous	0.69 (0.48 - 1.00)	0.048	0.76 (0.52 - 1.12)	0.169
Unknown	0.88 (0.61 - 1.26)	0.476	0.83 (0.54 - 1.27)	0.388
Widowed	0.41 (0.26 - 0.64)	<0.001	0.81 (0.56 - 1.17)	0.263
BMI Category				
Underweight	Ref		Ref	
Normal weight	1.04 (0.77 - 1.40)	0.812	1.05 (0.83 - 1.35)	0.675
Overweight	1.07 (0.80 - 1.42)	0.662	1.10 (0.86 - 1.42)	0.457
Obese	0.95 (0.64 - 1.40)	0.799	1.07 (0.76 - 1.52)	0.69
Not Indicated	1.20 (0.86 - 1.67)	0.286	1.16 (0.87 - 1.55)	0.313
Current Viral Suppression				
>=1000 copies/ml	Ref		Ref	
<1000 copies/ml	2.64 (1.91 - 3.65)	<0.001	1.55 (0.92 - 2.60)	0.099
No Current VL	1.93 (1.09 - 3.43)	0.025	1.75 (1.20 - 2.55)	0.004
Baseline WHO stage				
Stage I	Ref		Ref	
Stage II	1.76 (1.03 - 3.02)	0.039	1.31 (0.82 - 2.09)	0.251
Stage III	2.24 (1.26 - 3.98)	0.006	1.41 (0.79 - 2.53)	0.245
Stage IV	3.07 (1.62 - 5.83)	0.001	1.83 (0.68 - 4.92)	0.23
Unstaged	0.53 (0.26 - 1.09)	0.085	0.49 (0.19 - 1.26)	0.137
Current Core Regimen				
ABC Based				

AZT Based	1.24 (1.07 - 1.44)	0.005	1.10 (0.58 - 2.05)	0.777
TDF Based	0.82 (0.71 - 0.95)	0.007	1.12 (0.82 - 1.52)	0.49
Other	2.06 (1.61 - 2.64)	<0.001	1.36 (0.64 - 2.86)	0.423

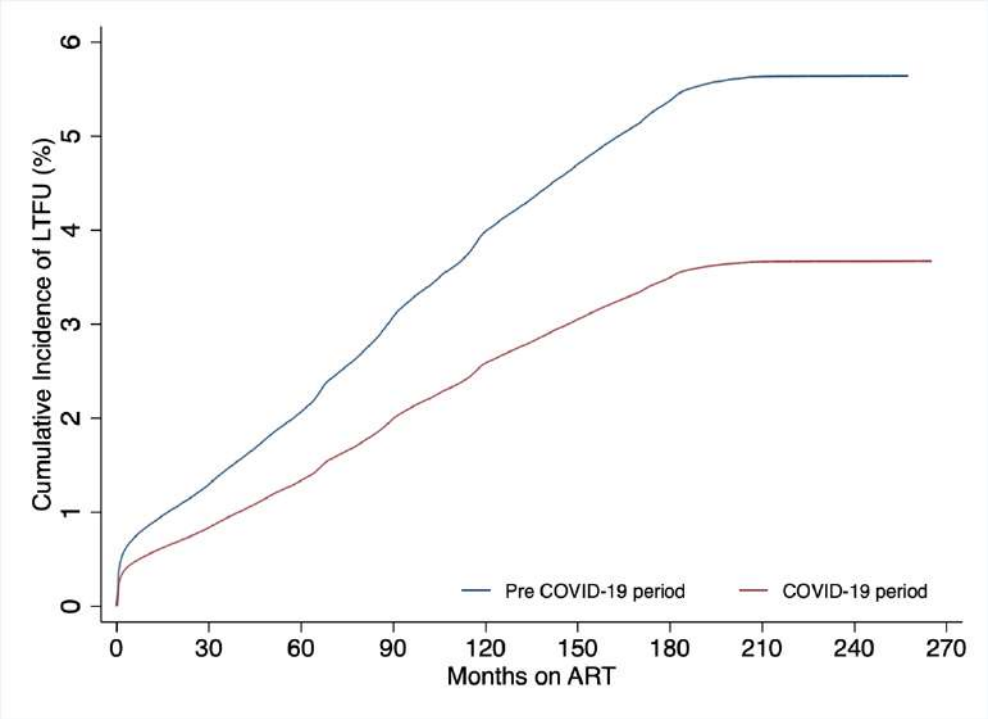

Figure 28 Cumulative incidence of loss to follow up (LTFU) by COVID-19 period among HIV positive clients on ART, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 to December 2021

Impact of COVID-19 on mortality among HIV positive clients on ART

On univariable analysis, the COVID-19 period had a significantly lower risk of mortality compared to the pre-COVID-19 period, SHR = 0.23 (95% CI: 0.14 – 0.38) as shown in Table 12. The trends proportion of clients LTFU over time in months since initiating ART indicated higher mortality proportions in the pre-COVID-19 period as shown in the cumulative incidence plot (Figure 29). On multivariable analysis, there was still a lower risk of being LTFU (non-significant) compared to the pre-COVID-19 period, adjusting for age category, sex, marital status, BMI, current viral suppression, baseline WHO stage, and current core regimen, aSHR = 0.50 (95% CI: 0.24 - 1.05), P-value = 0.068 (Table 12).

Table 12 Association of COVID-19 period with mortality among HIV positive clients on ART, Tegemeza Plus Project in Murang'a, Nyandarua, and Nyeri, October 2017 to December 2021

	Univariable		Multivariable	
Outcome: Mortality	SHR (95% CI)	P-value	SHR (95% CI)	P-value
Evaluation Period				
Pre-COVID-19 Period	Ref		Ref	
COVID-19 Period	0.23 (0.14 - 0.38)	<0.001	0.50 (0.24 - 1.05)	0.068

Age Category				
0-9yrs	0.63 (0.37 - 1.08)	0.093	0.65 (0.29 - 1.46)	0.301
10-14	0.24 (0.12 - 0.47)	<0.001	0.62 (0.34 - 1.12)	0.11
15-19	0.26 (0.16 - 0.42)	<0.001	0.61 (0.36 - 1.03)	0.064
20-24	0.30 (0.20 - 0.45)	<0.001	0.56 (0.34 - 0.93)	0.024
25-34	0.53 (0.41 - 0.68)	<0.001	0.87 (0.56 - 1.35)	0.529
35-44	0.64 (0.52 - 0.79)	<0.001	1.00 (0.79 - 1.26)	0.999
45-54	0.42 (0.33 - 0.52)	<0.001	0.74 (0.54 - 1.00)	0.053
55-64	0.52 (0.41 - 0.65)	<0.001	0.76 (0.56 - 1.04)	0.082
65+	Ref		Ref	
Sex				
Female	Ref		Ref	
Male	1.85 (1.64 - 2.09)	<0.001	1.21 (1.06 - 1.39)	0.005
Marital Status				
Divorced/Separated	Ref		Ref	
Married	0.70 (0.56 - 0.87)	0.001	0.85 (0.68 - 1.07)	0.177
Never married	0.79 (0.65 - 0.95)	0.014	0.97 (0.78 - 1.20)	0.756
Polygamous	0.58 (0.33 - 1.01)	0.054	0.75 (0.41 - 1.36)	0.343
Unknown	0.95 (0.76 - 1.19)	0.668	1.00 (0.73 - 1.37)	0.993
Widowed	0.94 (0.71 - 1.26)	0.685	0.93 (0.72 - 1.21)	0.58
BMI Category				
Underweight	Ref		Ref	
Normal weight	0.87 (0.73 - 1.03)	0.111	0.97 (0.82 - 1.15)	0.75
Overweight	0.93 (0.78 - 1.10)	0.385	1.07 (0.89 - 1.29)	0.456
Obese	0.81 (0.62 - 1.06)	0.132	1.01 (0.79 - 1.29)	0.938
Not Indicated	0.91 (0.75 - 1.09)	0.304	1.05 (0.88 - 1.26)	0.56
Current Viral Suppression				
>=1000 copies/ml	Ref		Ref	
<1000 copies/ml	5.49 (4.37 - 6.91)	<0.001	2.22 (1.35 - 3.65)	0.002
No Current VL	3.25 (2.25 - 4.70)	<0.001	2.12 (1.18 - 3.81)	0.012
Baseline WHO stage				
Stage I	Ref		Ref	
Stage II	2.68 (1.43 - 5.02)	0.002	1.37 (0.78 - 2.42)	0.275
Stage III	4.62 (2.82 - 7.56)	<0.001	1.77 (1.04 - 3.02)	0.036
Stage IV	9.89 (4.69 - 20.87)	<0.001	3.24 (1.29 - 8.12)	0.012
Unstaged	2.14 (1.45 - 3.17)	<0.001	0.66 (0.36 - 1.19)	0.168

Current Core Regimen				
ABC Based				
AZT Based	1.05 (0.63 - 1.76)	0.844	1.58 (0.92 - 2.71)	0.095
TDF Based	0.93 (0.65 - 1.32)	0.673	0.92 (0.64 - 1.33)	0.65
Other	2.32 (1.41 - 3.82)	0.001	2.02 (1.05 - 3.89)	0.036

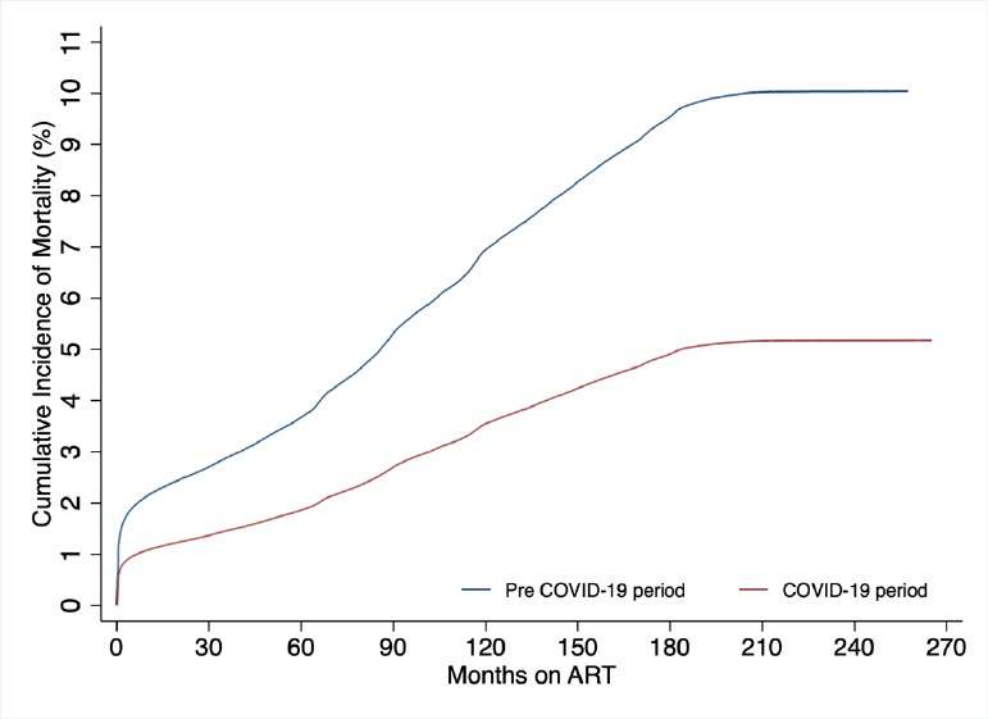

Figure 29 Association of COVID-19 period with mortality among HIV positive clients on ART, October 2017 to December 2021

INTERPRETATION OF FINDINGS

The following were the key findings:

1. COVID-19 IMPACT ON HTS SERVICE DELIVERY

To achieve universal HIV testing, the World Health Organization (WHO) and the Kenyan Government through the Ministry of Health recommend provider initiated testing and counselling (PITC) to all patients 13-64 years who present to health facilities, but on an 'opt-out' basis 1. (WHO, 2007), (NASCOP, 2010), and (Branson et al, 2006). Despite this recommendation, HIV-infected patients continue to be diagnosed late, at an advanced disease stage despite visiting the facility severally (Alisha et al, 2016) and (Avery et al, 2012). This late diagnosis is due to missed opportunities whereby clients present to the facility seeking health services but due to some barriers are not offered HIV screening and testing.

The coronavirus disease (COVID-19) pandemic was associated with severe disruptions in health care services in central Kenya. In HIV Testing Services (HTS), disruptions included reduced outpatient departments' workload, reassignment of HTS screening points to COVID-19 screening points, staff reductions caused by sick leave, lock-downs affecting HTS providers' mobility to workplaces, and clients' mobility to hospitals, facility policy revisions to alleviate congestion at the facility level affecting OPD patient flow and in-person HIV testing services, among others. This led to missed opportunities in HTS with a reduction in the proportion of workload screened for HTS, suspension of HTS eligibility screening as a process to identify the eligible for testing, reduction in numbers tested for HIV (both patients and non-patients/voluntary testers) and consequently number identified as HIV positive. Due to COVID-19 interruptions, the program had a 30% reduction in numbers tested for HIV in April to June of 2020, with Nyeri, Murang'a, and Nyandarua having a 34%, 30%, and 26% drop in numbers tested respectively. In terms of HIV case identification, the program had an overall drop of 26%. Nyandarua was the worst affected with a 31% reduction in HIV case identification, while Murang'a and Nyeri had a 28% and 22% reduction in HIV cases identified.

The program instituted some mitigation measures to cope with these COVID-19 interruptions. Such included procurement of 14 HTS screening booths to replace HTS screening points converted to COVID-19 screening points in 16 high and mid-volume facilities. HTS providers focused on HIVST kits distribution in the community to improve access to testing. Further, more HTS providers' workforce was redeployed to doing index testing at the CCC and community, helping decongest the OPDs and continue identifying HIV positive cases. The program engaged County and facility management teams to allow HTS screening and testing at OPD as long as the COVID-19 protocols were observed, like screening clients one at a time, and strict wearing of masks, among others. These mitigation measures, coupled with a reduction in new COVID-19 cases led to a slight improvement in HTS numbers in July to September of 2020. The program had a 13% increase in numbers tested for HIV. Murang'a and Nyeri had a 20% and 13% increase in numbers tested with Nyandarua on the other hand having a 0.6% decrease in numbers tested. In terms of HIV case identification, the program had a 2.5% increase in HIV cases identified. Murang'a had a 9% increase in HIV cases while Nyandarua had a 1.5% decrease in HIV cases. Nyeri did not have a substantial change in HIV cases from April to June of 2020 and July to September of 2020.

2. COVID-19 IMPACT ON VIRAL LOAD TESTING

Although COVID 19 pandemic has been associated with severe disruptions in health care services in Kenya. There was a steady improvement in viral load samples collected over the various quarters from January to March of 2019 18,931 samples to 31,104 samples in January to March of 202. A significant positive upward trend in terms of viral load sample collection was noted from January to March of 2020 whereby 23,924 samples were collected to 31,274 samples collected in October to December of 2020. However, in the year 2020, after the detection of the 1st case of COVID in March, movement restrictions and lockdown measures were instilled from April 2020 to July 2020, a dip in the number of viral load samples during that quarter is evident. Consequently, there was a significant decline in the number of viral load samples collected from 31,104 samples collected in January to March of 2021 to 10,402 samples collected in October to December of 2021 because sample transport to the testing laboratory in Nairobi was a challenge due to lock-down related barriers installed at routes leading into Nairobi city where the main testing laboratories are located. Over time county governments for Murang'a, Nyeri and Nyandarua were to seek permission for vehicle transporting samples to access barriers to transport samples to Nairobi. We resumed normal operations after receiving access to the testing laboratory. Even though there was a drop, it's also important to interpret this in light of the country-wide viral load commodity stock outs that occurred between April 2021 to mid-January 2022. During the COVID-19 period, there was routine shipping of viral load samples to Nairobi with measures put in place to ensure all eligible patients' samples were collected and samples shipped. Murang'a, Nyeri, and Nyandarua were not among fully locked counties (with no movement in or out) therefore at the minimum patients were able to travel to seek medical services.

Despite COVID 19 pandemic, there was a steady improvement in viral suppression from a low of 94.7% in April to June of 2019 to a high of 97% in January to March of 2021. A dip from 97% in 2021 January to March of to 95.8% in October to December of 2021 was realized and this is attributable to suppression rates of specific sub-population that do not represent the entire PLHIV population. In addition, this was a result of fewer samples eligible for analysis.

3. COVID-19 IMPACT ON PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV

The global community has committed to eliminating mother-to-child transmission of HIV. The initiative focuses on a harmonized approach to improving health outcomes for mothers and children. To achieve universal elimination, timely and comprehensive antenatal care services are critical for the health of women and their unborn babies. This allows for early detection and linkage to the treatment of those who test positive for HIV thereby reducing the risk of transmission. Tegemeza plus provides a quality PMTCT standard package of care that includes among others HIV testing, linkage, and timely ART initiation.

The coronavirus disease (COVID-19) pandemic was associated with severe disruptions in health care services in Central Kenya. The interruptions affected ANC attendance as patients kept away from hospitals due to fear of transmission, staff number reductions due to sick leave, the restricted movement that particularly affected Murang'a County, in facility patient flow policy revisions that disrupted client flow consequently affecting service provision such as HIV testing uptake leading to

missed opportunities in testing. A decline in ANC attendance was noted in April to June and July to September of 2020 compared to January to March of 2020. There was an upsurge in HIV positive cases identified among AGYW during the COVID period. AGYW face a substantially higher risk of infection than their male counterparts due to factors such as gender-based violence, lack of economic and educational empowerment, and inadequate access to sexual and reproductive health services (SRH). The prolonged school closure during the COVID-19 period may have exposed AGYWs to the factors enumerated.

The program put in measures to ensure MCH service provision continued amidst the pandemic by ensuring that the ANC department was operational by having a nurse and HTS provider available throughout the week. Arrangements were also made between the CCC and PMTCT clinic staff, to ensure that neither of the clinics was left unattended to ensure 100% linkage of clients and timely initiation of ART. This saw an increase in ANC attendance and testing from July to September of 2020 and January to March of 2021. All of the new positives identified were linked to treatment. An increase in KPs at 1st ANC is seen in April to June 2020 and July to September 2020 and an increase in new positives in July to September of 2020 despite the COVID disruptions.

4. COVID-19 IMPACT ON HIV PRE-EXPOSURE PROPHYLAXIS

The World Health Organization issued a strong recommendation for oral PrEP, a highly potent HIV prevention intervention that has the potential to reduce HIV incidence markedly if used effectively (WHO, 2016). However, PrEP scale-up had been suboptimal across the country and in central Kenya region counties. PrEP uptake in sub populations especially AGYWs has remained sub-optimal. AGYW, 15-24 years account for 68% of young people in Eastern and Southern Africa who are living with HIV. This subpopulation is twice as likely as their male peers to acquire HIV infection and in 2020, they accounted for 26% of new HIV infections in the region. According to Kenya AIDS Strategic Framework, they accounted for 30% of new HIV infections in Kenya, recording a prevalence of 1.96% (NACC, 2021). A study done in 21 PEPFAR-funded Countries showed a 157% increase in PrEP uptake during the COVID19 period with increased uptake among AGYWs and Key Populations at 159% and 170% respectively (Michael K. et.al, 2022). Muhula et.al, (2021) study reported a 24% PrEP uptake increase among people from the Kibera informal settlement and COVID19 hotspot Counties during the first wave of the pandemic. This trend was also witnessed in the three Counties supported by the Tegemeza Plus project after posting a 245% and 836% increase in 2020 and 2021 respectively from what was reported in 2019. The following measures were put in place as a mitigation measure against COVID19: (1) Intensified CMEs, mentorship and peer to peer learning focusing on PrEP eligibility screening and referral for initiation, (2) Demand creation activities including virtual awareness creation, (3) Peer-led approach for PrEP follow up and demand creation with a focus among the Key population (4) Multi-month dispensing to ease the burden of visiting hospitals monthly, (5) Decentralization of PrEP service delivery among the Key Population, (6) County led PrEP integration in other service delivery points, and (7) Functional inter and intra-referral systems within the health facilities and the community.

5. COVID-19 IMPACT ON GENDER-BASED VIOLENCE

Gender-based violence (GBV) has negatively affected progress towards achieving the 95-95-95 HIV cascade in Kenya. GBV is a global crisis that thrives on other crises and it threatens the health and human rights of the survivors. The COVID-19 pandemic necessitated isolation and social distancing, leading to escalated GBV cases due to economic disruptions, and social and travel restrictions. It is estimated that 1 in every 2 women reported to have or knew someone who had experienced a form of violence since the onset of COVID-19 (UN Women, 2021). A third of all the reported crimes during the pandemic were related to sexual violence (Anna, & Maniza, 2020). An estimated 27.6% AGYWs were affected by intimate partner violence (IPV) at some point during the pandemic (Decker e.t. al, 2021) in addition to increasing trends in teenage pregnancies.

Tegemeza Plus reported an upward trend in GBV case identification in all the three supported Counties. There was a 101% and 167% increase in sexual violence reported cases in 2020 and 2021 respectively. The project also reported a tremendous increase in physical and emotional violence with a 646% and 5857% increase in 2020 and 2021 respectively from what was reported before the onset of COVID-19. Some of the interventions that led to this increased case reporting were: (1) Capacity building service providers through mentorship and LIVEs training, (2) Adoption of a multisectoral approach with the active involvement of community stakeholders and gatekeepers in case identification and referral, (3) Structured demand creation activities at health facility and community level, (4) Integration of GBV screening at all service delivery points within the health facilities, (5) Establishment of a functional referral system that includes referral directory, tools, and register, and (6) Strengthening GBV committees within the health facilities and County multi-sectoral GBV TWG leading ownership and sustainability.

6. COVID-19 IMPACT ON TUBERCULOSIS

The COVID-19 pandemic has had devastating effects on every aspect of global health, but tuberculosis services have been disproportionately affected. Provisional data compiled by the World Health Organization (WHO) from 84 countries indicates that an estimated 1.4 million fewer people received care for tuberculosis (TB) in 2020 than in 2019 - a reduction of 21% from 2019 (WHO, 2020). WHO projects that these COVID-19 related disruptions in access to TB care caused significant additional TB deaths.

Kenya has experienced similar effects and in Central Kenya where Tegemeza Plus implemented a HIV/TB program where overall, there was a decrease in TB cases across the 3 supported counties of Murang'a, Nyeri and Nyandarua. This could be attributed to Stigma and fear of quarantine by cough patients that led to overall poor patient turnout at the health facilities thus low TB screening coverage. There was also disruption of the GeneXpert laboratory networks that may have led to sub-optimal identification of bacteriologically confirmed TB cases occasioned by disruption in public transportation affecting both patient access and the sputum sample human courier part of the laboratory networking.

The TB treatment completion rates dipped below the national average of 90% at the onset of COVID 19 due to barriers in accessing services, and a slight increase in TB case fatality rates and defaulter rates. However, this did not significantly lower the overall treatment success rates. To mitigate these;

the program introduced a model to improve on TB case identification that could be termed as a best practice where an ACF champion role was introduced in high volume sites. One of the HTS providers was re-assigned a role to dedicate effort in improving quality of TB screening and coverage at the OPD settings. This increased case finding by over 30% in the implementing sites. To improve treatment completion rates, the project instituted measures including active defaulter tracing through phone calls to return patients to care and linking patients to nearest facilities for treatment. Providers were also sensitized on TB differentiated service delivery models that provided longer prescriptions as per revised guidelines and use of existing HIV virtual adherence models to improve adherence and retention. Use of motorbikes to transport sputum samples to hubs for analysis was strengthened and this improved GeneXpert utilization and bacteriological diagnosis which also eliminated the challenges experience by human courier system. Tegemeza was an early adopter of conducting TB mortality audits using the national tools and data analyzed was used to provide mentorship on strategies to mitigate TB related deaths.

Tegemeza plus in collaboration with NLTP has spearheaded the development of TB-COVID bi-direction screening guidelines that will be disseminated nationally and could result in an increase in case identification and outcomes for both infectious diseases.

7. ANTIRETROVIRAL THERAPY TREATMENT OUTCOMES

Viral Load Suppression

There was no major impact of COVID-19 on viral suppression among clients given the higher suppression rates during the COVID-19 period This could be due to the systems and strategies that were put in place to ensure close monitoring of clients. The systems and strategies included: ART optimization for eligible clients being switched to newer and more efficacious drugs such as Tenofovir (TDF) and Dolutegravir (DTG) which are associated with the faster achievement of viral suppression as well as sustained suppression due to their higher genetic barrier. There was also optimization of individualized client-centered services by use of technology to support adherence (virtual counseling/support, virtual/video DOT-NimeCONFIRM), case management, structured patient literacy, psychosocial support groups, and multi-month prescription for all age groups. Nita-Re-Suppress initiative that involves enhanced adherence counseling (EAC), case management, DOT management, home visits, viremia clinics, and support groups led to improved re-suppression rates among clients failing on treatment.

Evidence-based medication adherence interventions such as OTZ and PAMA highly contributed to good adherence among the CALHIVs. The project also facilitated adolescent mentors and champions to case manage adolescents with suspected treatment failure and possible adherence issues. There was a scale-up of caregiver engagement and clinical OVC integration that ensured adherence monitoring at the community level, and enhancement of school engagement activities through multisectoral engagement was done. A standardized disclosure approach was implemented that led to improved disclosure rates among children and adolescents that facilitated adherence leading to good viral suppression. Linkage to other community support systems such as the children's department, rescue centres, and children homes were also strengthened.

Interruption in Treatment (IIT)

The IIT incidence remained lower during the COVID-19 period compared to the pre-COVID-19 period against the expectation. The program had to make some changes to programming to accommodate clients who had difficulty accessing care in a timely and usual way. The changes included implementation of the NASCOP patient movement standard operating procedures (SOP) with fidelity, strict implementation of the patient reminder system that included pre-calls, Ushauri and text messaging, and virtual counseling and follow up. Risk of default screening and IIT characterization was done with appropriate remedial measures in place that included case loading, treatment budding, and structured treatment literacy which prevented IIT among many clients. Multi-month prescriptions were also extended to unstable populations such as children, adolescents, and PMTCT mothers with babies above 12 months old to ensure continuity in treatment. School-going children and adolescents were booked over the school holidays which facilitated better appointment keeping. An initiative dubbed "Return the lost" was adopted whereby the health facility partnered with the community health strategy to physically trace the clients who had interrupted treatment and could not be reached on phone.

Mortality

The risk of mortality was lower during the COVID-19 period compared to the pre-COVID-19 period. This could be due to strategies aimed at retaining clients and ensuring that they receive good care even during the pandemic. Also, coupled with strategic changes in programming during the COVID-19 period to maintain and improve ART treatment outcomes led to a lower incidence of mortality.

CONCLUSION

Overall, COVID-19 had a negative effect on care and treatment where facilities experienced reduced patient clinic attendance due to lockdowns, economic downturns, closure of hospital departments when health care workers were infected by COVID-19, and fear of infection with COVID-19 among clients. There was a significant negative effect on the project's total number of HIV tests done due to COVID-19. However, there was no significant change in the project's total number of HIV positive cases. Changes in programming and interventions during the COVID period ensured that gains made in HTS eligibility screening to identify those at significant risk of HIV infection, yield in both numbers tested and number HIV positive were maintained or improved upon. There are strategies that worked towards improving the project's treatment growth included use of technology to support adherence, IIT characterization and putting in place facility specific remedial measures, modification of the MMS criteria to suit unstable clients with no adherence issues and implementation of the return to care initiative. Strategies towards improving viral suppression among the HIV positive clients included switching to optimal regimens, individualized client-centered services, use of technology to support adherence, Nita-Suppress initiative, evidence-based medication adherence interventions, structured disclosure approach, caregiver and school engagement, OVC clinical integration, and linkage to other community support systems.

KEY CONSIDERATIONS

In the event of a similar challenge in the future, like COVID-19, which affected HIV service provision at the facilities we propose the following measures for consideration.

1. Targeted HIV self-test kit distribution in the community to have people continue accessing HIV testing services without necessarily coming to the health facilities.
2. Doing more targeted testing, like index testing both at the facility and in the community, prioritizes individuals at higher risk of HIV, and is likely to identify HIV positive cases. In addition, optimize structured rescreening among newly enrolled, HVL, PMTCT and adolescent and young people during their clinic visits to identify more eligible sexual contacts for testing.
3. Reorganizing patient flow at the OPD to allow eligibility screening which is key in identifying HIV cases. To reduce time spent between a client and provider (which made facilities revise policies to alleviate congestion at OPDs), there is a need to revise eligibility screening criteria to have an only key question which capture risk patterns or HIV-related symptoms thus making the screening process faster. This coupled with social distancing and use of PPEs like face masks by the HTS providers will have HTS services continue as near normal.
4. Proper utilization of eHTS to provide real time data for HTS, helping monitor HTS trends and institution of immediate action plans.
5. Improvement of appointment management system through use of EMR system, and incorporation of the patient appointment reminder system in the existing appointment diary and defaulter tracing register.
6. Development and roll-out of a national individualized case management system across all the HIV positive populations.
7. Child and adolescent-responsive HIV service delivery through strategies such as a standard operating procedure (SOP) defining the school engagement program at both national and county levels as well as rollout of the NASCOP learners living with HIV in basic learning institution guide.
8. More engagement of the OVC partners to support CALHIV adherence activities such as tracing LTFU, DOT/case management, home visits, and school engagement activities.
9. Interruption in treatment characterization helps offer individualized adherence and continuity in care interventions.
10. SOP to define structured PrEP and GBV demand creation activities that include key messages targeting specific populations at both health and community level.
11. Nationally defined and adopted PrEP and GBV functional inter and intra-referral system.
12. National police, judicial and provincial administration training curriculum in GBV matters
13. A guide that defines peer to peer learning approach across PrEP and GBV service delivery cascade.
14. Adoption of a tiered GBV service delivery model that will categorize facilities into different tiers based on their capacity to offer different services with a clear referral system in place.

15. To achieve eMTCT, continued collaboration with different stakeholders working with adolescents may continue to prevent teenage pregnancies and avert possible HIV infections.
16. Health care providers working in MNCH department may benefit with adopting a new system of working on a rotational basis as opposed to existing work schedules of working from Monday to Friday. This will minimize exposure at the workplace while ensuring uninterrupted service provision in ANC testing, prompt linkage, and ART initiation for those testing positive.
17. Counties to introduce viral load testing facilities within counties to avoid over dependence on testing laboratories in Nairobi using existing point of care machines like GeneXpert testing machines.

LESSONS LEARNT

The lessons learned during service provision by TEGEMEZA Plus project during this COVID-19 pandemic included the following:

1. Without OPD workload screening for HTS eligibility, there will be HIV-case identification missed opportunities.
2. With paralyzed testing at OPD, targeted HTS self and index testing, both at the facility and the and at community, can help identify HIV positive cases.
3. Client-centered services such as bookings, use of technology to support adherence (pre calls, Ushauri messaging, virtual counseling and support, and video DOT), case management and risk of default screening are vital in improving viral suppression and continuity in care.
4. Structured patient education through treatment literacy, one on one counseling and PHDP messaging is a key strategy to improve continuity in care and patient outcomes
5. Interruption in treatment characterization for individualized client care that will minimize interruption in treatment
6. MMS for all age groups including unstable clients minimizes interruption in treatment
7. The listed strategies if implemented with fidelity improves viral suppression and minimizes interruption in treatment among CALHIVs. They include physical/virtual DOTs, video DOTs (NimeCONFIRM), caregiver engagement, School engagement, clinical OVC integration, OTZ, PAMA.
8. Facilitated case management by adolescent mentors and champions is a sure way of achieving re-suppression and sustained suppression among CALHIV.
9. Active involvement of the CHMT in PrEP and GBV integration agenda to improve progress towards successful PrEP and GBV integration in other service delivery points that is vital sustainability of the services.
10. Structured demand creation activities that includes key messages targeting specific populations at both health facility and community levels are key to increased uptake of PrEP and GBV services.
11. Daily and weekly monitoring of PrEP and GBV performance to enable one to timely identification of performance gaps and challenges and put immediate remedial measures in place.
12. Functional inter and intra referral system minimizes missed opportunities in PrEP and GBV service provision.
13. Peer led approach for PrEP demand creation and follow up with specific messaging leads to increased PrEP uptake among the key population
14. Fast tracking of PrEP clients and offering PrEP in a safe space is vital to the increased uptake among special populations such as KP, AGYW and PBFW.
15. GBV multi sectoral engagement is critical in offering comprehensive GBV services to survivors and it leads to ownership and sustainability.
16. To sustain efforts made towards eMTCT, health facilities adoption of flexi working hours may ensure uninterrupted service provision within the MNCH department.

17. To achieve eMTCT, continued collaborative efforts by different stakeholders to ensure AGYW attend schools, economically empowered among others may reduce the high rates of teenage pregnancies as was experienced during the COVID-19 period (this led to a surge in HIV infections among the AGYW). This will promote subsequent reduction in HIV infections among this vulnerable group.
18. Counties to introduce viral load testing facilities within counties to avoid over dependence on testing laboratories in Nairobi to minimize interruptions in a lockdown.

DISSEMINATION OF FINDINGS

Evaluation findings will be disseminated to all key stakeholders including the CHMTs, NASCOP, NTLD-Program, the MOH, CDC, and the public through dissemination meetings or scientific forums. In addition, selected findings will be disseminated through publications in peer-reviewed, open-source journals. Finally, CHS will publish the findings in internal newsletters and organizational websites for access by the public. All stakeholders will be involved in the dissemination of the evaluations results at different levels. The evaluations report will be presented to CDC as part of its reporting requirements. The final evaluation report is in alignment with the PEPFAR Evaluation Standards of Practice requirements and will be posted (in English) on a publicly-accessible website within 90 days of report clearance. Only de-identified individual patient-level data will be released according to the CDC data policy on a limited release approved by CDC, CHS program, and data team. A reasonable request for the individual patient-level data can be made to the Chief Executive Officer through the email address; info@chskenya.org. All the other aggregate data used was under general release to the public.

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APPENDIX

1A Matrix with the indicator and data source details

Indicator/ Variables	Data source	Data Source Type
• HIV testing coverage: Number of eligible clients tested for HIV in Out-patient department (OPD) and in-patient department (IPD) • PMTCT: ANC registers • GBV: GBV registers • PrEP: Oral PrEP register • Patient characteristics and ART treatment outcomes: Proportion of PLWHIV initiated on ART • Proportion of clients achieving viral suppression Variables: Age, Gender, Marital Status, Height/Weight, Initial HIV Status, Baseline and follow-up Viral Load, Enrolment into care, and Retention outcomes (Death, LTFU, Transfer Out, Retained), If on HAART, Follow-up Viral Load.	• MOH 362 HTS register • MOH 731 Monthly report summary • HTS eligibility screening tool • Point of service testing reports • Family and partner testing register Treatment preparation register, ART register, Cohort analysis registers, Viral load register, Electronic medical records, Mortality audit minutes, defaulter tracking registers, MOH 257 (HIV Care Patient Card) GBV registers PrEP registers	• Both paper and electronic

1B Data Sources and documents list

1. PrEP Clinical Encounter form
2. Antenatal Care Register
3. Defaulter tracing register
4. DSTB-TB4-Register
5. eHTS AfyaSTAT
6. Green card MOH 257
7. High Viral load follow-up Register
8. HIV mortality audit form
9. HIV Testing Service and Counseling Register
10. HIV Testing Service Eligibility screening register
11. HIV Testing Service Register MOH 362
12. KenyaEMR
13. Monthly Report Summary MOH 731
14. Partner Notification Services Register
15. Post Rape Care form MOH 363
16. PrEP Clinical Encounter card
17. PrEP Register
18. SGBV Register MOH 365
19. Treatment Preparation Register

Centre for Health Solutions - Kenya

Preferred Partner for Health Solutions

4th Floor, CVS Plaza, Kasuku Lane, Off Lenana Road
P.O Box 23248-00100 Nairobi
Tel: 0724 710 077
www. chskenya.org