



## Evaluation Report

# Analysis of Tuberculosis Case Finding Strategies, Tuberculosis Preventive Therapy Uptake, and Tuberculosis Treatment Outcomes Among Clients in General Outpatient Setting and People Living with HIV in Siaya County, Kenya

Version 2.1

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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

Kenya ranks 10<sup>th</sup> out of the 22 countries with the highest tuberculosis (TB) burden globally. The high prevalence of Human Immunodeficiency Virus (HIV) in Kenya is a major contributing factor to TB incidence. Siaya County is among the ten highest burden TB counties in Kenya. According to the National TB and Leprosy Annual Report of 2019, there were a total of 2,268 TB cases (773 new bacteriologically confirmed, 875 new clinically diagnosed, 152 previously treated, 269 extrapulmonary TB, and 199 TB among children) in Siaya County, of which 55.1% were TB/HIV co-infected. The county was among the five counties in Kenya with the highest burden of HIV according to the National Aids Control Council (NACC) report of 2018 and is home to an estimated 123,106 people living with HIV (PLHIV) or 8.2% of all PLHIV in Kenya.

**Evaluation purpose and goal:** This evaluation used routinely collected health facility and patient-level data to document the implementation of intensified case finding (ICF) for TB among PLHIV and active case finding (ACF) of TB within outpatient department (OPD) settings in Siaya County. This evaluation was conducted to provide information that could be used at county and national-level to support TB control and improve service delivery, and in addition, to contribute to the body of knowledge on sustainable interventions for TB control in resource-limited settings. The goal of was to evaluate the implementation of and outcomes associated with, TB Case Finding, Isoniazid preventive therapy (IPT) and TB treatment across 119 health facilities supported by CHS Shinda Project in Siaya County, Kenya.

### Methods

Routinely collected health facility data on ACF, ICF, IPT and TB treatment from all patients at the 119 CHS-supported sites were included in the analyses. Data were drawn from electronic and/or paper-based records and databases. In this pre- and post-intervention design, outcomes were evaluated at baseline (October 2016-September 2018) prior to intensified case finding (ICF) for TB among PLHIV and active case finding (ACF) of TB within outpatient department (OPD) settings in Siaya County intervention implementation and compared to post-intervention endline period (October 2018 – September 2020). Retrospective data from these two periods were used for the evaluation. Routinely collected data and outcomes of interest from all clients seeking outpatient

services and all PLHIV enrolled and accessing HIV treatment services from the 119 CHS-supported sites were included in the evaluation. Descriptive, bivariate, and multivariable regression analyses were conducted to assess patient characteristics and outcomes, and the effectiveness of various implementation models.

## **Key Findings**

### Active Case Finding in Outpatient Clinics

1. The vast majority (99.7%) of clients accessing the OPD during the study period were screened for TB
2. Most of patients screened through ACF were in Kenya Essential Package of Health (KEPH) level 3 facilities.
3. The availability of diagnostic methods such as Chest X-ray and GeneXpert enabled TB diagnosis in both evaluation periods.
4. A significantly greater proportion of clients screened at endline had presumptive TB as compared to those screened at baseline period (18.0% vs. 16.3%; p-value<0.001).
5. ACF increased the number of presumptive TB cases identified by 7.7%, which translated to a concomitant 44.3% increase in TB cases diagnosed.
6. The TB identification rate increased from 15 to 22 per 1,000 clients screened

### Intensified Case Finding among PLHIV

1. TB screening coverage among PLHIV accessing care was high (97%) across the study period
2. There was a significant increase in the number of presumptive TB cases identified among PLHIV at the endline compared to baseline (16.6% vs. 5.7%; p-value<0.001).
3. TB identification rate increased from 31 to 40 per 1,000 clients screened (29% increase in the rate of TB case identification per 1,000 clients screened)
4. More adult females were screened in ICF, consistent with the demographic distribution of PLHIV.

### Tuberculosis Preventive Therapy

1. IPT initiation significantly increased in the end line period (89.7%) compared to the baseline (78.9%).
2. IPT completion rate was better in clients who have been on ART longer than 6 months.
3. In the multivariable analysis factors associated with non-completion of IPT included being from Alego Usonga [aOR = 1.40 (95% CI 1.02-1.94)], Bondo [aOR= 2.57(95% CI (1.93-3.45)], and Ugenya [aOR= 3.25 (95% CI (2.31-4.61)] sub-counties compared to Rarieda Sub-county, on ART for six months or less [aOR= 2.09 (95% CI 1.72-2.54)], age-group 20-24 years [aOR= 1.66 (95% CI 1.06-2.65) compared to age-group 0-9 years, and those not virally suppressed at IPT initiation compared to those who had viral suppression [aOR= 0.70(95% CI 0.53-0.92)].

### Tuberculosis Treatment Outcomes

1. Treatment success (treatment completion and cure rates) was better at endline (83.1%) compared to baseline (78.6%).
2. Better treatment outcomes were also recorded among patients whose treatment was started in KEPH level 3 (health centers and sub-county hospitals) and KEPH level 2 (Dispensaries). The majority of TB deaths, lost to follow-up (LTFU) and transfers out occurred in KEPH level 4 health facilities (County hospitals), and this was statistically significant.
3. Female clients, those with pulmonary TB and those who were underweight had better treatment completion outcomes.
4. Within Siaya county, there were variations in treatment success rates amongst the Sub-counties; Alego Usonga Sub-county had a significantly lower treatment completion rates compared to other Sub-counties.

### Lessons Learnt

1. TB diagnosis support through the use of GeneXpert and Chest X-ray improves the diagnosis of TB among the presumptive TB cases.
2. Early detection of TB among patients in the general out-patient improves TB treatment outcomes.

3. Involvement of sensitized and mentored HTS providers in TB screening as first level screeners minimizes missed opportunities for TB presumptive case identification.
4. Utilization of ACF stamps for non-comprehensive care centre (CCC) departments that have not integrated TB screening questions in electronic medical records (EMR) or patient cards helps to reduce any missed opportunities.
5. Involvement of the mentored community antiretroviral therapy (ART) treatment supporters in screening for TB for Differentiated Service Delivery (DSD) clients helps in improving case finding.
6. Utilization of the modified TB diary to monitor appointment and sputum follow-up helps to track defaulters and improving appointment keeping resulting in better treatment success rate (TSR) and cure rate.
7. Active engagement of the County Tuberculosis and Leprosy coordinator (CTLC) and Subcounty Tuberculosis and Leprosy coordinator (SCTLC) to support in follow up of clients transferred out helps to improve documentation of treatment outcomes resulting in improvement of TSR.
8. The introduction and regular utilization of a TB dashboard to monitor TB/HIV performance during site mentorship and review of performance has improved the quality of care for TB patients.
9. Utilization of EMR to monitor patient level data has helped improve IPT uptake and completion rates.
10. Integration of TB/HIV services helps improve IPT completion among the PLHIV through synchronizing appointment dates and prompt tracing of missed appointments.
11. Leveraging on existing structures (using peer educators, appointment management systems, treatment literacy groups, psychosocial support groups (PSSG) and CHS retention action plan) to support in follow-up of LTFU clients on TB and IPT medications has led to better outcomes.
12. Integration of TB screening questions in the ART distribution forms and TB screening in the HTS, OPD, and inpatient department (IPD) screening registers helps to minimize missed opportunities for TB screening.

## Key Considerations

1. We suggest scaling up the incorporation of standardized TB screening processes into routine HIV testing services (HTS) in public health facilities in order to improve TB case identification.
2. We propose the revision of other service delivery registers to incorporate TB screening and outcomes as institutionalized in the HTS register.
3. Conduct continuous sensitization and re-sensitization of health care workers on importance of IPT among PLHIV, and to improve the quality of TB screening.
4. Consider broader adoption of the following strategies to avoid missed opportunities for TB screening: Conduct routine TB screening among differentiated service delivery (DSD) clients in community antiretroviral groups (CAGs) and facility antiretroviral groups (FAGs), and incorporate standardized TB screening tool into the ART distribution forms either through placement of a stamp (as done in this evaluation) or adoption of revised tools.
5. Monitor the process and provide a forum for sharing the best practices to be scaled up through regular focused ACF/ICF, IPT and TB treatment performance review meetings at facility multidisciplinary team (MDT), program level and County technical working group (TWG)
6. Support ongoing integration of TB and HIV services to enable prompt follow up and better IPT completion rates.
7. Inclusion of reasons for not completing/stopping IPT in the electronic medical records;— this information helps to identify gaps and design strategies to improve IPT completion.
8. Develop interventions to support completion of IPT among ages 15–24 years. The interventions may be guided by qualitative assessments of facilitators and barriers to IPT completion.
9. Cross learning opportunities among regions may be promoted to facilitate adoption of best practices to improve TB treatment outcomes
10. Quality of care at KEPH level 3 health facilities could be replicated in lower KEPH level health facilities to improve treatment outcomes.
11. Factors leading to poor outcomes at KEPH level 4 health facilities need to be further studied to inform and improve programming at this level.
12. Special interventions targeting men to improve adherence to treatment and ultimately favorable TB treatment outcomes needs to be explored and developed.

13. Special care, which can include more frequent follow ups for clients with extrapulmonary TB (EPTB), could be considered as a means to improve patient outcomes.

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## ACRONYMS

ACF	Active Case Finding	IPT	Isoniazid Preventive Therapy
AIDS	Acquired Immune Deficiency Syndrome	LTFU	Lost to follow up
ART	Antiretroviral Therapy	MDR-TB	Multi-Drug Resistant Tuberculosis
CCC	Comprehensive care clinic	MOH	Ministry of Health
CDC	US Centers for Disease Control and Prevention	M&E	Monitoring and Evaluation
CHMT	County Health Management Team	MNCH	Maternal Neonatal and Child Health
CHS	Centre for Health Solutions – Kenya	NACC	National AIDS Control Council
CXR	Chest X-Ray	NASCOP	National AIDS and STI Control Program
DSD	Differentiated service delivery	NTLD-Program	National Tuberculosis, Leprosy and Lung Disease Program
DR	Drug Resistant	OPD	Outpatient Department
EMR	Electronic Medical Records	PI	Principal Investigator
EPTB	Extra Pulmonary Tuberculosis	PLHIV	People Living with HIV
HIV	Human Immunodeficiency Virus	TSR	Treatment success rate
SCTLC/CTLC	County/Subcounty TB and Leprosy coordinator	PLHIV	People Living with HIV
SCHMT	Sub County Health Management Team	TB	Tuberculosis
ICF	Intensified Case Finding	TIBU	Treatment Information Basic Unit
IPD	Inpatient Department	WHO	World Health Organization

## DEFINITION OF TERMS

TB screening- A client will be considered to have received routine TB screening if they were screened for TB during their last clinical encounter at baseline and/or end line period.

ACF-Active case finding is systematic screening of clients accessing the health facilities for TB symptoms.

ICF-Intensive case finding is the systematic screening of TB symptoms among PLHIV clients.

Positive TB screen- A client is considered to have a positive TB screen if he has any of the 4 cardinal symptoms of TB: Cough, night sweats, fever or weight loss/failure to thrive for children.

Presumptive TB clients TB diagnosis – A client who had a positive TB screening outcome before and again presents with signs and symptoms suggestive of TB at any given time in the baseline or the endline period.

Workload – A Cumulative number of clients who had at least one clinical encounter in CHS Shinda supported health facilities at baseline or end line period.

TB Preventive therapy: refers to treatment given to vulnerable clients who have no TB symptoms to prevent them from acquiring TB.

TB screening- A client will be considered to have received routine TB screening if they were screened for TB during their last clinical encounter at baseline and/or end line period.

# INTRODUCTION

## 1. BACKGROUND

Recent estimates of the global tuberculosis (TB) epidemic (WHO, 2019) suggests a higher burden than previously estimated. In 2019, the World Health Organization (WHO) reported 10 million incident TB cases globally, with the majority (56%) occurring among men as compared to women (32%) and children (12%). Among TB-infected persons, 8.2% were people living with human immunodeficiency virus (HIV) (PLHIV). In the same year, TB was among the top ten causes of death worldwide resulting in 1.2 million deaths (1).

Among PLHIV, TB remains a leading cause of death, accounting for one in every three acquired immunodeficiency syndrome (AIDS)-related deaths globally (1). Overall, there was a 14% reduction in TB-related deaths among PLHIV between 2015 and 2019(2). However, six out of every ten TB cases among PLHIV were undiagnosed or untreated, resulting in 0.4 million deaths in 2015 (2).

Countries in Africa bear a substantial proportion of the global burden of TB and HIV. In 2016, countries in eastern and southern Africa accounted for 52% of all PLHIV, and 43% of all new HIV infections globally (3). Approximately 25% of all incident TB cases in 2019 occurred in countries in Africa, where the annual TB case detection rate (281 cases per 100,000) is twice the global average (133 per 100,000). African countries also account for 74% of the global burden of TB/HIV coinfection (4). Inequalities in access to TB diagnosis and treatment in African countries are reflected in high TB case fatality rates (20%) (WHO, 2016) and sub-optimal treatment success rates (48%) among those with multi-drug resistant TB (MDR-TB). Access to care for TB is further hampered by limited resources—in 2015 the Africa regions had the largest funding gap for TB control estimated at 0.4 billion United States dollars in 2015 (4).

Kenya is listed among the 30 high-burden countries that contribute approximately 85% of incident TB cases, TB/HIV co-infections and incident MDR-TB cases globally (3,4) .

Kenya also has the fourth-largest HIV epidemic in Africa with an estimated 1.5 million PLHIV in 2017 and a HIV prevalence of 4.9% (5). In 2019, the Kenya Ministry of Health (MOH) was notified of 86,385 TB cases, which were mostly pulmonary TB (83%), and disproportionately affected men (65%). During this period the country experienced a slight decline in TB/HIV co-infection rates from

28% in 2018 to 26% in 2019 attributed to effective integration of TB/HIV services. Siaya County is among the ten-highest burden TB counties in Kenya. According to the National TB and Leprosy Annual Report of 2019 there were a total of 2,268 TB cases in 2019 and 2,319 in 2018; TB/HIV coinfection decreased from 62.7% in 2016 to 55.1%, but remains high(6). The report also indicated that in 2019, 98% of TB patients received an HIV test and 96% of persons with TB/HIV co-infection were initiated on antiretroviral therapy (ART) in the county. Despite the gains made in reducing HIV-associated TB in the country, 40% of TB cases (in the general population) remained undiagnosed and therefore untreated and potentially infectious (5,7,8).

Passive TB case finding requires that affected individuals are aware of their symptoms, have access to health facilities, and are evaluated by health workers or volunteers who recognize the symptoms of TB and who have access to a reliable laboratory remains the predominant approach in Kenya. Active case finding (ACF), on the other hand, is predominantly healthcare provider-initiated, and involves the systematic screening of persons for TB among people seeking health care for a variety of reasons, including those who may have TB but are unaware of the symptoms, or do not perceive TB symptoms as a problem warranting medical attention (5,9). In 2016, the Kenyan National Tuberculosis, Leprosy and Lung Disease (NTLD) Program developed and rolled out the Kenya ACF Toolkit, which provides guidance and recommendations for implementing TB ACF in Kenya (6); however, roll out of ACF was suboptimal in most counties.

The NTLD-Program in line with WHO has recommended the use of GeneXpert as a first test for TB diagnosis for patients screening positive for TB symptoms (10).

The 2013 WHO guidelines on systematic screening for active TB recommended the implementation of ACF through symptomatic screening aimed at early diagnosis of TB. Symptomatic screening interventions are recommended at all service delivery points, including among PLHIV and contacts (15).

The End TB strategy highlights monitoring and evaluation of TB patients' treatment outcomes as a fundamental part in the treatment and prevention of TB. TB treatment outcomes can be categorized as successful (treatment completed or cured), unsuccessful (defaulted, lost to follow up, treatment failure/developing drug resistance (DR)) or death. WHO recommends a treatment success rate of at least 90% for all persons diagnosed with TB and initiated on TB treatment services (1). When the CHS Shinda project began in October 2016, there was a global decline in treatment success rates from 86% in 2014 to 83% in 2017 (11). A systematic review and meta-analysis of 31 published studies from

seven countries in three regions within Sub Saharan Africa found a pooled treatment success rate (TSR) of 76% among adult bacteriologically-confirmed pulmonary TB patients, which is far below both the WHO recommendation for TSR and the global TSR of 83% (12). Routinely collected program data from the 119 health facilities supported by CHS Shinda indicated a cure rate of 72.6% in October of 2017. Certain factors have been linked to unfavourable treatment outcomes. A retrospective cohort study conducted in Nigeria involving children with TB, found that re-treatment cases, having a positive smear at the second month of follow-up, smear-negative after 2 months of treatment, pulmonary TB (PTB), and being male were associated with unfavourable TB treatment outcomes (13). Another study found that male gender, having a negative smear result at diagnosis, being HIV positive, and being a retreatment case was associated with unfavourable treatment outcomes (14).

Isoniazid is one of the drugs used to prevent TB. In 2018, WHO added other regimens for TB Preventive Treatment (TPT) and recommends successful completion to prevent of active TB among PLHIV (1). The benefits of IPT in these populations have been well documented in the literature (2–5). A randomized controlled trial in Africa has shown that IPT results in a significant reduction in death independent of ART(6).

In 2009, Kenya adopted the WHO three I's (IPT, intensified case finding (ICF) for active TB, and TB Infection Control (IC),) and included 2 more interventions; Immediate ART Therapy and Integration of TB and HIV- collectively dubbed the five I's (7). WHO issued the first policy statement that recognized the efficacy of management of latent TB infection among PLHIV with IPT in 1993 and recommended implementation in 1998 and this was adopted by Kenya for rollout from 2015.

## 2. JUSTIFICATION FOR EVALUATION

This evaluation was conducted in Siaya County in western Kenya. Siaya County is among the ten high-burden TB counties in Kenya. According to the National TB and Leprosy Annual Report of 2019 there were a total of 2,268 cases (773 new bacteriologically confirmed, 875 new clinically diagnosed, 152 previously treated, 269 extra PTB (EPTB), and 199 TB among children) with a TB/HIV coinfection of 55.1% (6). The County also ranks fourth among five counties with a high burden of HIV and is home to an estimated 123,106 PLHIV or 8.2% of all PLHIV in Kenya (5). In 2015, the HIV prevalence was estimated at 24.8% (15). Since county-level TB prevalence data is not routinely available, a cross-sectional survey conducted in the Karemo Division in Siaya County showed that

out of 5,004 adolescents enrolled, 1,960 (39.2%) were identified with suspected TB, including 1,544 with a positive Mantoux test (prevalence 1,544/4,808, 32.1%), 515 with symptoms suggestive of TB (10.3%), and 144 (2.9%) with household TB contact (10). These findings suggest the importance of case finding interventions to identify any potentially missed TB cases in Siaya County (16). As Siaya county was also among the first in the country to implement IPT guidelines in 2018, there was an emerging need to assess outcomes of this initiative.

This evaluation primarily utilized routinely collected health facility and patient-level data to document the implementation of TB ICF among PLHIV and ACF within outpatient settings, as well as implementation of IPT among PLHIV. Understanding results from such interventions will provide useful information to guide current and future program design and implementation, and inform project strategies. This evaluation also provides insights that could be used at county and national-level to support TB control. In addition, it contributes to the body of knowledge on sustainable interventions for TB control in resource-limited settings.

### **3. STAKEHOLDER ENGAGEMENT**

The key stakeholders included Siaya County and Sub-County Health Management Teams (CHMT & SCHMT), National AIDS and STI Control Program (NASCOP), National Tuberculosis, Leprosy and Lung Diseases Program (NTLD), the Ministry of Health (MOH), the US Centers for Disease Control and Prevention (CDC) Kenya, clients/, healthcare workers, community gate-keepers/key informants, CHS Shinda, and other implementing partners working in Siaya County to identify TB cases, put them on treatment, and improve their treatment outcomes. The MOH, through the Siaya County Department of Health, was engaged to provide authorization to undertake the evaluation activities. The key stakeholders were involved in the evaluation process by seeking input at every stage of the evaluation from planning, execution, and ultimately the dissemination plans of findings.

### **4. INTENDED/POTENTIAL USE OF EVALUATION FINDINGS**

Evaluation findings may be used to inform interventions to support TB case finding, IPT and TB treatment, among PLHIV and in the general population. Findings will also be disseminated as presentations to local and international audiences, abstracts, and manuscripts for publication in peer-reviewed journals. Evaluation findings will be used at county level to improve TB case finding and TB

treatment outcomes and these findings shall be cascaded to National level and may contribute to policy and guideline revisions. As per the EPMP regulations the report has to be publicly available via a url within 90 days of release.

## 5. GOALS AND OBJECTIVES

The goal of this evaluation was to evaluate the implementation of, and outcomes associated with, TB ICF and ACF, IPT and TB treatment across 119 health facilities supported by CHS Shinda Project in Siaya County, Kenya between October 2016 and September 2020.

### Objectives:

1. To determine the extent to which TB ACF efforts in the outpatient settings affected TB case finding at CHS Shinda supported health facilities comparing the baseline (October 2016 - September 2018) and end line period (October 2018 – September 2020).
2. To determine the extent to which TB ICF efforts in the HIV clinics among PLHIV affected TB case finding at CHS Shinda supported health facilities comparing baseline period and end line period
3. To determine the effect of various project implementation interventions on TB treatment outcomes in CHS Shinda supported health facilities.
4. To determine the effect of various project implementation interventions on outcomes of IPT among PLHIV initiated on IPT in CHS Shinda supported health facilities.

### Evaluation questions:

1. What is the coverage of TB screening among clients attending the Outpatient Department (OPD) and HIV clinic settings?
2. What were the outcomes of TB screening in the general outpatient client population (ACF) and PLHIV in the HIV clinics (ICF)?
3. What were the outcomes of IPT among clients with known HIV-positive status in the endline period compared to the baseline period?

4. What client and facility level factors were associated with outcomes of interest including completion of IPT, TB diagnosis and completion of TB treatment?

## METHODS

### 1. INTERVENTION

According to the Directly Observed Therapy (DOTS) Expansion Working Group, under the overall auspices of the Stop TB partnership findings (2009) the evaluation of a framework for identification of relevant entry points for improved early case detection, and reduced delayed treatment were highlighted as in Figure 1 below.

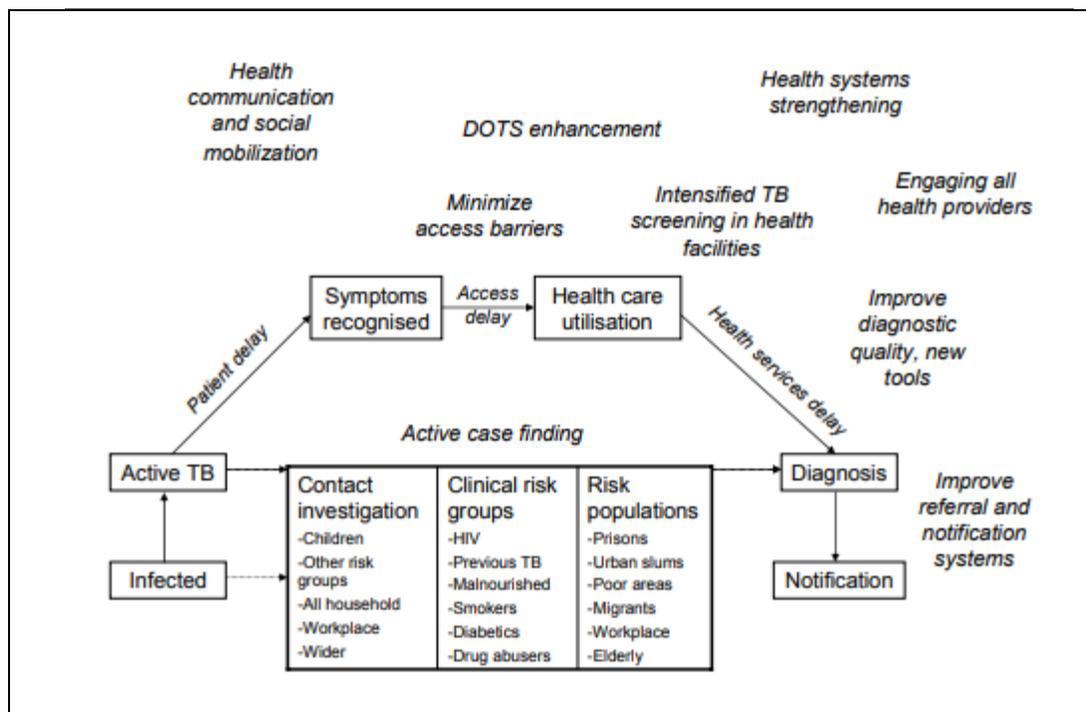


Figure 1. A framework for analysis and action to improve early case detection

The upper part of Figure 1 represents “passive case finding” whereby patients recognize symptoms and seek care in the health facility showing a pathway to diagnosis and treatment. The lower part of Figure 1 depicts the pathway for ACF, implying actions to screen high-risk groups who may not actively seek healthcare due to TB symptoms. This involves active symptom screening by healthcare

workers. ACF may also include screening of high-risk groups. The latter type of screening among people who actively seek care in a health facility, though not for TB symptoms, conceptually falls somewhere between “passive” and “active” case finding.

### Facility Processes for TB Active Case Finding in Outpatient department

The processes involved in TB ACF at CHS Shinda supported health facilities were as outlined in Figure 2 below.

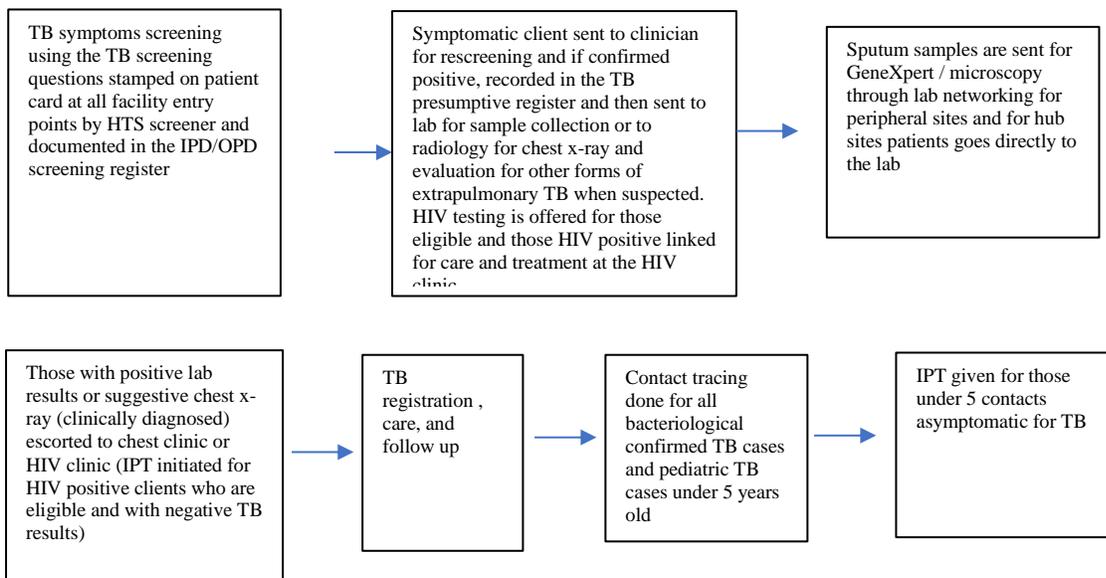


Figure 2. Active Case Finding process

### Facility process for TB Intensified Case Finding among PLHIV

The processes involved in TB ICF at CHS Shinda supported health facilities were as outlined in Figure 3 below.

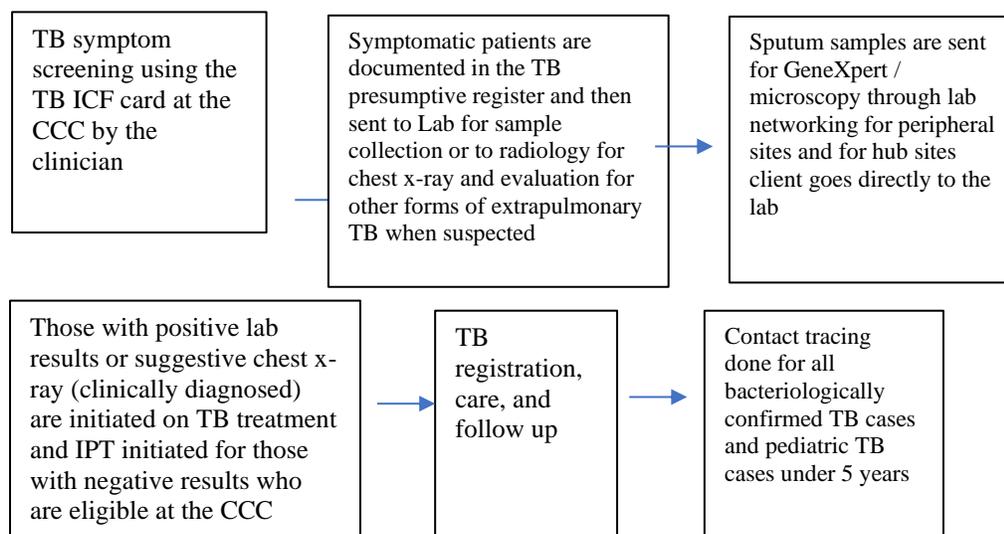


Figure 3. Intensified Case Finding process

To support TB screening for non CCC clients, the program modified the HTS screening register to include TB screening and procured ACF stamps engraved with TB screening questions.

Bidirectional screening for TB symptoms and HIV testing eligibility by HTS providers targeted all patients at facility entry points with results documented in the OPD/IPD screening register. Those identified to be presumptive for TB were sent to the clinician for rescreening and documentation in the presumptive register prior to laboratory or radiology investigation. Clinicians were also able to screen patients suspected for EPTB and refer appropriately for further evaluation.

At the CCC department all the clients were screened using the ICF questions at every visit by the clinician and all presumptive cases referred for investigation. For CCC clients on differentiated service delivery, community ART treatment supporters were mentored on TB screening and they conducted TB screening during drug distribution using the modified ART distribution form that has

integrated TB screening questions while for Fast track CCC clients TB screening is done at the dispensing service point.

ACF/ICF implementation was monitored on a weekly basis at Sub-county level and monthly at program level and challenges and gaps identified during reviews were addressed. The program also initiated a TB dashboard to monitor periodic TB indicators performance which was accessible to the staff for monitoring progress and for use to conduct site level mentorship. Involvement of the facility health management team and having an ACF focal person at facility level to spearhead ACF activities also contributed to improved TB case identification. Facility ACF leads and health management teams monitored ACF activities and facilitated quarterly continuous medical education (CME) to support implementation.

To improve TSR, CHS Shinda initiated continuous quality improvement (CQI) projects to monitor and improve treatment outcomes at all 119 supported health facilities. Program and health facility staff were mentored on correct documentation and reporting of treatment outcomes in the TB4 registers which was monitored every month. A modified TB diary was used to monitor appointments complementing existing structures for prevention and management of TB defaulters and interruptions in treatment. County and Sub-county TB and Leprosy Coordinators (CTLTC and SCTLTC) and technical officers supported follow up of all transfer out clients. Monthly tracking of sputum follow-ups for bacteriologically confirmed TB clients eligible at month 2, 5 and 6 was also done. The project implemented TB mortality audits and reviews and gaps noted led to remedial interventions, discussed with the health facilities. DOTS were utilized especially for DR-TB patients with the support of health care workers. Concurrent HIV and TB treatment literacy sessions were offered to patients to improve their adherence to treatment.

To improve IPT initiation and outcomes, CHS Shinda program ensured that the IPT policy in the National HIV guideline which supports screening and initiation of IPT for all eligible PLHIV clients was implemented. This was done through routine mentorship and sensitization of health care workers. The program also monitored IPT initiation monthly using EMR, and all eligible clients not initiated on IPT were flagged and followed up for initiation. To support completion of IPT, TB and HIV services were integrated, health care workers were sensitized on importance of IPT among PLHIV, documentation on follow up visit done, and the program leveraged existing structures for

conducting tracing for LTFU. Clients who developed TB while on IPT had surveillance done and management administered as per the drug resistance results.

A detailed listing of the interventions in each thematic area was as shown in table 1 below:

**Table 1 List of interventions in each thematic area**

Thematic area	Interventions	
ACF/ICF	Tools for screening and documentation	<b>TB ACF Stamp innovated by CHS Shinda</b>
		Incorporation of TB screening in the OPD/IPD HTS register
		<b>Incorporation of TB screening questions in the patient cards</b>
		Integration of TB screening question in the ART distribution forms -CHS Shinda innovation for TB screening among DSD clients
	Diagnosis	<b>Stamping of the ART distribution forms using ACF stamp</b>
		Use of TB LAM to support TB case identification for PLHIV
	Capacity Building	<b>Scale up GeneXpert utilization to improve TB case identification through intensified sample networking</b>
		Sensitization and mentorship to HTS providers on TB screening
		<b>Having focal ACF persons at health facility level to spearhead ACF activities</b>
		Sensitization and mentorship to Clinical teams on ICF and TB diagnostic work up
	Supervision	<b>Sensitization and mentorship to community ART treatment supporters</b>
		Involvement of the health management teams both at the health facilities and the at the county to support ACF
	Monitoring	<b>TB diagnosis and management as an agenda for facility MDTs</b>
		Regular biweekly reviews of ACF implementation at program level
<b>Monthly facility and program level performance reviews</b>		
CQI Activities	Rewarding the best ACF implementing health facility and best health facility in TB identification	
	<b>Initiation of CQI for TB case identification and treatment outcome</b>	
IPT	<b>EMR</b>	Use of EMR to monitor patient level data on IPT uptake amongst the PLHIV
	<b>Capacity Building</b>	<b>Sensitization of the HCW on importance of IPT to PLHIV</b>
	<b>Monitoring</b>	Having the facility MDT discuss their IPT data and identify any gaps
		<b>Data reviews on IPT implementation; ensure all eligible clients are initiated and followed through to successful completion</b>
TB Treatment	<b>Tools and documentation</b>	Modification of TB diary to monitor appointment and sputum follow ups
	<b>Treatment Monitoring</b>	<b>Active follow up of all TB clients to ensure treatment completion</b>
		Promptly and actively follow up all transfer out clients with the support of the CTLC and SCTLC and technical officers to ensure continuity of treatment at the receiving health facility
		<b>Monthly review of Treatment Information Basic Unit (TIBU) (Patient Management System) data and verification with the source document (TB4 register) at facility level to follow up on outcomes and sputum follow ups</b>

	<b>Contact Tracing</b>	Active contact tracing for all bacteriologically confirmed cases, screening the contacts and diagnostic work up, IPT for under 5 year contacts
	<b>Mortality Audits</b>	<b>Utilization of mortality audit forms to do TB mortalities</b>
<b>Overall Monitoring</b>	Initiation of TB dashboard to monitor TB/HIV performance	
	<b>Weekly monitoring of TB performance at regional level, monthly at program level and quarterly at County level through TB/HIV TWG</b>	

**2. DESIGN**

We used a pre-/post-intervention design to evaluate processes and outcomes of efforts to improve TB ACF, ICF, and the diagnosis and management of TB both among PLHIV accessing HIV clinic settings, and among clients attending outpatient clinics in Siaya County. The evaluation type, design, and key indicators for each evaluation question is summarized in the evaluation matrix, Appendix 1A. The key outcomes were TB screening and IPT uptake. The evaluation periods were defined as the baseline period (October 2016-September 2018) and endline period (October 2018 – September 2020). Retrospective data from these two periods was used for the evaluation. Whereas, assessment of ICF was restricted to PLHIV clients accessing the HIV clinic, assessment of ACF included all outpatient clinic settings: Family planning, Maternity, PNC, IPD, MNCH and OPD.

Data for these evaluations included individual patient-level data from health information systems implemented by the project and the County, routine patient level data - service delivery information collected by the NTLTD-Program through the TIBU system (a national data management system for TB data) and data from periodic and systematic assessment of health management units at County and health facility level.

**3. POPULATION**

The study population for this evaluation included:

- 1) Clients in Siaya County accessing HIV/TB services from 119 CHS Shinda Project supported health facilities in the seven Sub-counties of Alego Usonga, Bondo, Gem Wagai, Gem Yala, Rarieda, Ugenya, and Ugunja.

- 2) PLHIV and accessing HIV/TB services from 119 CHS Shinda Project supported health facilities (List of facilities is provided in Appendix 1D & 1E), in the seven Sub-counties.

### **Eligibility**

Routinely collected data from all clients seeking outpatient services and all PLHIV enrolled and accessing HIV/TB treatment and prevention services from the 119 CHS Shinda supported health facilities were included in the evaluation. All age groups with available data were included in the quantitative evaluation.

## **4. SAMPLING METHODOLOGY**

The evaluation used routinely collected data only, no clients or patients were recruited for quantitative data collection. The data used were; (1) ACF sample in general client population and (2) ICF census for PLHIV population and (3) TIBU census for PLHIV population were used for the evaluation. The analysis used sample data for the AFC analysis given the large number of clients seen at the facilities and also paper-based record system for ACF activities.

### **1. ACF and ICF Sample size**

The evaluation sample was estimated from baseline quarterly workload of the CHS Shinda Project for the period April to June, 2017 which was 66,045 at HIV clinics (for population of individuals living with HIV and accessing HIV/TB services from 119 CHS Shinda Project supported health facilities) and 124,521 clients at OPDs (general population in Siaya County accessing HIV/TB services from 119 CHS Shinda Project supported health facilities). The number of clients on HIV care and treatment was 66,045 while the number of clients diagnosed with TB in the same period was 389 at baseline. We therefore anticipated a large increase in these numbers by the end of the project to an estimated total of 7,000 clients diagnosed with TB by the end of the project based on exponential increase in the number of clients served over the project period due to intensified activities.

For the general population, the number of selected health facilities were 28 out of a total 119 supported health facilities listed in appendix 1D. The total sample size was 12,750 clients. The sample selected for the baseline period and endline period was 6,447 and 6,303 respectively. The estimated minimum sample required based on a Chi-square test [80% power and a significance level (alpha) set 5%] for a

5% difference in the proportion of TB cases identified at baseline and end line was 2,502 clients (1,251 in each intervention period). The final estimated evaluation sample required was 3,753 clients (1,877 in each intervention period) adjusted for an estimated design effect of 1.5 to account for health facility level clustering.

### Facility Sample Size for ACF Sample selection

CHS Shinda supports TB/HIV services in 119 of the 141 TB/HIV treatment sites in Siaya County. To ensure fair representation across the county, the population was divided into groups called strata, representing the seven (7) Sub-counties in Siaya County. Out of 119 health facilities, 28 sites (four facilities from each of the Sub-counties in Siaya County [two large facilities and two small facilities]) were purposively selected to be included in the evaluation. The sampled facilities and sample distribution was as listed in Table 2 below:

**Table 2 Sampling of facilities and patient records**

<i>Region</i>	Population Screened for TB	No. of health facilities	Population to be sampled
<i>Alego Usonga</i>	368,946	23	677
<i>Bondo</i>	294,964	24	542
<i>Gem</i>	555,364	29	1,020
<i>Rarieda</i>	329,253	22	605
<i>Ugenya</i>	217,506	11	399
<i>Ugunja</i>	277,951	10	510
<i>Grand Total</i>	2,043,984	119	3,753

### Systematic random sampling strategy to select ACF clients

A random sample was obtained from each region based on the percentage that each subgroup represented in the population. To select a client sample (n=3,753) of clients from this population of

approximately N= 2,043,984 clients screened and tested for TB at CHS Shinda supported health facilities, we used a stratified random sample proportional to size.

We obtained the facility registers to ascertain the estimated number of clients screened and tested for TB within the period of interest (baseline and end line).

The sampling fraction was estimated as,  $n$  (sample of clients screened required for facility) /  $N$  (Total number of clients screened). The first client selected was randomly selected using the random number generator in MS Excel to ensure the entire sampling was random.

## **2. ICF Sample size**

For the HIV care and treatment population, the number of selected health facilities (with EMR) were 103 out of a total 119 CHS Shinda supported health facilities [87% of all facilities] listed in appendix 1E. These were the health facilities with client information updated in the EMR system for all the clinical encounters since enrollment into HIV care and treatment or those with all the clinical encounters available in the system as from October 2016. A script was developed to query and extract the data on clients who had at least one clinical encounter during the baseline period that formed the workload and those clients with at least one clinical encounter during the implementation period formed the workload. A census of all 67,817 and 88,379 eligible clients at baseline and end line period were extracted respectively. Therefore, based on these criteria, a client might be counted as part of the workload at baseline and end line if the same client visited the facility for HIV services at any given time during the baseline period and remained active until the implementation period.

## **3. TIBU System Sample size**

The TB treatment outcome population data for PLHIV clients was extracted from the TIBU system for all the 119 CHS Shinda supported health facilities as listed in appendix 1E. A census of all (4,848) TB patients that were started on TB treatment within the baseline period (2,870) or the end line period (1,978) were included in the analysis.

## 5. DATA COLLECTION, MANAGEMENT, AND ANALYSIS

### Data Collection

The evaluation utilized quantitative data captured through the national MOH system as well as other supplementary systems for both PLHIV and general population. The data collection was done retrospectively for both populations from various data sources using similar procedures for abstraction from files, registers, and EMR systems. The primary source of individual- and facility-level data included TB patient level tools and TB related registers, TB laboratory related tools & registers, TB ACF tools, Web-based/online data systems. The above source documents for quantitative data which are MOH tools capture patient information and are filled in by healthcare service providers either in real time or after the patient had left into the TIBU system and Kenya EMR Systems. Data from all these sources were triangulated to update the evaluation databases [Data dictionary for ACF and ICF provided in appendix 1B and 1C].

### Data Management and Storage

Data from each of the databases was shared with the CHS Shinda Project data manager on a weekly basis for updating the central database. However, for sites with EMR systems evaluation data were mainly extracted from the national TIBU system and Kenya EMR into the ACF evaluation database. Trained data clerks checked and verified records for completeness and accuracy before importation into the evaluation database by the evaluation data management team. The patients' unique database identifiers were hashed into complex alphanumeric codes (and the identifier deleted) during any download or export from the databases to only assist in correct data merging and protect the confidentiality of the clients. All the evaluation records and material such as compact discs are stored under lock and key in a cabinet at the CHS Head Office, for a period of five years after which the paper records and compact discs will be shredded. All the other data in the evaluation database will be destroyed by running permanent deletion software such as 'Active Eraser' on the computers, flash and hard drives to prevent any recovery of the same. All the final electronic analysis datasets and files were stored in a password-protected computer of the Monitoring & Evaluations (M&E) advisor at CHS Shinda project main office in Siaya County. All data used were coded using unique database identifiers to safeguard individual patient details. Routine data quality checks were done by the M&E officers in charge of the various health facilities to enforce data quality. Data is owned jointly by MOH and CHS, with use and release determined by applicable MOH, CDC, and CHS policy.

## **Statistical Analysis**

Statistical analysis for quantitative data was done using Stata software version 15 (Stata Corp, College Station, TX) and R version 3.5.1 (R Core Team, Vienna, Austria). Baseline characteristics of patients and health facilities were determined. The median (interquartile range) and proportions (counts) were used as appropriate. Data from the baseline period and endline period evaluations were compared to assess whether there were changes in client and facility characteristics, screening uptake and outcome, IPT access and completion, TB testing, diagnosis, and treatment outcomes. The baseline period was used as the reference point.

In bivariate analysis, Chi-Square tests of association were used to compare the baseline and endline proportions. Key indicators data were presented by the period or appropriate test or treatment outcome disaggregation variables. Univariable and multivariable logistic regression analyses for key outcomes such as IPT initiation, TB diagnosis, TB outcomes, were used to assess for demographic and clinical factors associated with various TB treatment outcomes. The odds ratio (OR) and respective 95% confidence intervals (CIs) were presented. The individual level correlation and health facility level clustering were accounted for and robust variance estimates used to generate the CI. We had low levels of missing data for the main outcomes. Missing data for key outcomes and predictors was also assessed for using Little's Chi-squared test for the missing completely at random (MCAR) assumption by doing a sensitivity analysis among the variables comparing those with and without missing data. There were no significant patterns in the missing data based on the Little's Chi-squared test, we therefore assumed the data were missing completely at random. Complete case analysis was therefore used for all logistic regression analyses. All statistical tests were evaluated at the 5% level of significance.

## **Evaluation Limitations**

The evaluation relied on routinely collected health facility data which had some missing data or may have had incorrect values written in source documents. Also, some patients that were recorded as having incomplete or missing TB outcomes were probably enrolled in or provided treatment at other health facilities. We were unable to obtain some variables in the ICF data such as type of TB and type of TB patient (new or repeat) among others due to challenges with linkage of variables and final treatment outcomes to the TIBU system, in the absence of a common unique identifier in both TIBU

and Kenya EMR. We therefore relied on the records from the EMR for the HIV client population and used TIBU system data for analyzing TB treatment outcomes. Active utilization of EMR to capture TB indicators was initiated in FY20 and thus baseline TB indicators were not fully captured.

## **ETHICAL CONSIDERATIONS**

All the quantitative data proposed to be used in this evaluation were obtained from routinely collected data sources. Each client was assigned a unique identifier in the database and confidentiality was ensured by stripping personal identifiers to safeguard patient details. In addition, the results were reported in aggregate without referencing patient details. All key staff involved in the evaluation were trained on human subjects' protections and evaluation leads trained (or had a refresher course) on good clinical practice (GCP). 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. Approval for the evaluation was obtained from CDC Associate Director of Science (CGH-KEN-5/20/20-500d4) and local ethical approval provided by AMREF ethics and scientific review committee (P760-2020).

## FINDINGS

### TB Active case finding

#### TB screening coverage among clients attending outpatient clinic settings by period

As shown in Table 3 below, majority of clients, 99.7% (12,718/12,750) accessing the OPD were screened for TB. A significantly greater proportion of clients screened at endline had presumptive TB as compared to those screened at baseline period, 18.1% (1,134/6,303) vs. 16.3% (1,053/6,447) respectively, p-value <0.001.

**Table 3 TB screening outcomes among clients attending the OPD clinic settings in the baseline and endline periods**

Characteristics	Baseline	Endline	Total	P-value
	(Oct 2016-Sep 2018)	(Oct 2018–Sept 2020)		
n (%)	6,447 (50.6)	6,303 (49.4)	12,750 (100.0)	
<b>Screening Outcomes</b>				
No signs	5,349 (83.0)	5,145 (81.6)	10,494 (82.3)	
Not Screened	32 (0.5)	5 (0.1)	37 (0.3)	
On TB treatment	13 (0.2)	19 (0.3)	32 (0.3)	
Presumptive	1,053 (16.3)	1,134 (18.1)	2,187 (17.2)	<0.001

#### Characteristics of TB screening among clients attending the OPD clinic settings

A total of 12,750 records were sampled from the workloads in various departments within 28 health facilities across the seven Sub Counties in Siaya County between October 2016 and September 2020. The median age was 24 years (IQR: 11.0 - 35.0).. The majority of the records sampled were of females clients, 66.5% (8,475/12,750), with approximately half, 52% (6,634/12,750), aged below 25 years. Out of the sampled records, the proportion of clients who received HIV testing was 12.7% (1,621/12,750) with an overall yield of 2.1% (34/1,621). Likewise, 81.9% (10,435 /12,750) of the sampled records were drawn from outpatient clinics with a fairly equal distribution in all the seven Sub Counties. The majority of the records 41.6% (5,301 /12,750) were drawn from KEPH level 4 facilities as shown in Table 4.

**Table 4 Characteristics of clients screened for TB in outpatient clinic settings**

<b>Characteristics</b>	<b>Total</b>
n (%)	12,750 (100.0)
<b>Sex</b>	
Female	8,475 (66.5)
Male	4,275 (33.5)
<b>Age (Years), median (iqi)</b>	24.0 (11.0; 35.0)
<b>Age (years)</b>	
Child (< 15 yrs)	3,723 (29.2)
Adult (> 15 yrs)	9,027 (70.8)
<b>NTLD Age (years) Category</b>	
0-9	2,886 (22.6)
10-14	837 (6.6)
15-19	1,306 (10.2)
20-24	1,605 (12.6)
25-34	2,768 (21.7)
35-44	1,299 (10.2)
45-54	688 (5.4)
55-64	629 (4.9)
65+	732 (5.7)
<b>HIV status</b>	
Negative	1,587 (97.9)
Positive	34 (2.1)
<b>Department</b>	
Family planning	54 (0.4)
Maternity	12 (0.1)
PNC	6 (0.0)
IPD	313 (2.5)
MNCH	1,925 (15.1)
OPD	10,435 (81.9)
<b>Sub County</b>	
Alego Usonga	2,038 (16.0)
Bondo	2,040 (16.0)
Gem Wagai	2,425 (19.0)
Gem Yala	1,617 (12.7)
Rarieda	1,877 (14.7)

Ugenya	1,505 (11.8)
Ugunja	1,248 (9.8)
<b>KEPH Facility levels</b>	
Level 2	3,569 (28.0)
Level 3	3,880 (30.4)
Level 4	5,301 (41.6)

### Characteristics of clients screened for TB in outpatient clinic settings by Evaluation Period

The number of sampled records was 6,447 at baseline and 6,303 at endline. A comparison of sampled client characteristics by intervention period showed statistically significant differences (all p-values <0.05) between the baseline and endline period in the sampled client characteristics by gender, age, department, sub county and KEPH facility levels as shown in Table 3. There were more males in the endline sample than in the baseline sample, 34.6% (2,178/6,303) vs. 32.5% (2,097/6,447) respectively. The median (IQR) age for the clients screened for TB was 24 (IQR: 11-34) and 23 (IQR: 12-37) years at endline and baseline respectively. We had more adults screened in the endline sample than in baseline sample, 71.9% (4,534/6,303) vs. 69.7% (4,493/6,447). The HIV testing yield was 2.4% (20/817) in the endline and 1.8% (14/784) in the baseline sample. Majority of the sampled clients were seen at the OPD (81.9%) with a fairly even distribution in all the seven Sub Counties. Level 4 facilities accounted for most of the clients screened in the end line compared to baseline, 46.2% (2,911/6,303) vs. 37.1% (2,390/6,447) as shown in Table 5.

**Table 5 Characteristics of TB screening clients attending outpatient clinic settings by period**

Characteristics	Baseline	Endline	P-value
	(Oct 2016-Sep 2018)	(Oct 2018 – Sept 2020)	
<b>n (%)</b>	<b>6,447 (50.6)</b>	<b>6,303 (49.4)</b>	
<b>Sex</b>			
Female	4,350 (67.5)	4,125 (65.4)	
Male	2,097 (32.5)	2,178 (34.6)	<0.001
<b>Age (Years), median (IQR)</b>	23.0 (11.0; 34.0)	24.0 (12.0; 37.0)	<0.001
<b>Age (Years)</b>			

Child	1,954 (30.3)	1,769 (28.1)	
Adult	4,493 (69.7)	4,534 (71.9)	<0.001
<b>NTLD Age (Years)</b>			
<b>Category</b>			
0-9yrs	1,489 (23.1)	1,397 (22.2)	
10-14	465 (7.2)	372 (5.9)	
15-19	643 (10.0)	663 (10.5)	
20-24	874 (13.6)	731 (11.6)	
25-34	1,457 (22.6)	1,311 (20.8)	
35-44	641 (9.9)	658 (10.4)	
45-54	315 (4.9)	373 (5.9)	
55-64	257 (4.0)	372 (5.9)	
65+	306 (4.7)	426 (6.8)	0.00
<b>HIV status</b>			
Negative	770 (98.2)	823 (97.6)	
Positive	14 (1.8)	20 (2.4)	0.41
<b>Department</b>			
Family planning	0 (0.0)	1 (0.0)	
Maternity	51 (0.8)	3 (0.0)	
PNC	12 (0.2)	0 (0.0)	
IPD	6 (0.1)	0 (0.0)	
MNCH	23 (0.4)	290 (4.6)	
OPD	879 (13.6)	1046 (16.6)	<0.001
<b>Sub County</b>			
Alego Usonga	1,137 (17.6)	901 (14.3)	
Bondo	522 (8.1)	1,518 (24.1)	
Gem Wagai	1,326 (20.6)	1,099 (17.4)	
Gem Yala	709 (11.0)	908 (14.4)	
Rarieda	1,257 (19.5)	620 (9.8)	
Ugenya	690 (10.7)	815 (12.9)	
Ugunja	806 (12.5)	442 (7.0)	<0.001
<b>KEPH Facility levels</b>			
Level 2	1,616 (25.1)	1,953 (31.0)	
Level 3	2,441 (37.9)	1,439 (22.8)	
Level 4	2,390 (37.1)	2,911 (46.2)	<0.001

*iqi – interquartile interval*

## Outcomes of TB screening and treatment among clients attending outpatient clinic settings

As shown in Table 6, nearly all, 99% (2,157/2,187), of the presumptive clients were investigated for TB. A higher proportion of presumptive TB cases were identified at endline compared to baseline period, 18% (1,134/6,303) vs. 16.3% (1,053/6,447). Among the clients with presumptive TB who received a diagnostic workup for TB, a higher proportion were diagnosed with TB at endline compared to baseline period, 12.6% (140/1,134) vs. 9.3% (97/1,053) respectively. The proportion of tests done using GeneXpert as mode of TB investigation were similar at the endline and baseline period, 55.0% (77/1,134) vs. 54.8% (51/1,053), respectively.

**Table 6 Outcomes of TB screening and treatment among clients attending outpatient clinic settings**

Characteristics	Baseline (Oct 2016–Sept 2018)	Endline (Oct 2018–Sept 2020)	P-value
n (%)	6,447 (50.6)	6,303 (49.4)	
<b>Screening Outcomes</b>			
No signs	5,349 (83.0)	5,145 (81.6)	
Not Screened	32 (0.5)	5 (0.1)	
On TB treatment	13 (0.2)	19 (0.3)	
Presumptive TB	1,053 (16.3)	1,134 (18.0)	<0.001
<b>TB diagnosis</b>			
No	946 (90.7)	974 (87.4)	
Yes	97 (9.3)	140 (12.6)	<0.001
<b>Mode of TB investigation</b>			
GeneXpert	51 (54.8)	77 (55.0)	
Other	1 (1.1)	3 (2.1)	
Sputum Microscopy	8 (8.6)	17 (12.1)	
X Ray	33 (35.5)	43 (30.7)	0.45
<b>TB treatment outcomes</b>			
Cured/Treatment complete	71 (73.2)	114 (70.4)	
Died	7 (7.2)	6 (4.3)	
LTFU	8 (8.2)	3 (2.1)	
Still on treatment	0 (0.0)	3 (2.1)	

Transferred out	11 (11.3)	14 (10.0)	<0.001
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The baseline and endline percentage TB diagnosis yielded in the general client population accessing outpatient clinic settings in each sub county is shown in Figure 4 below.

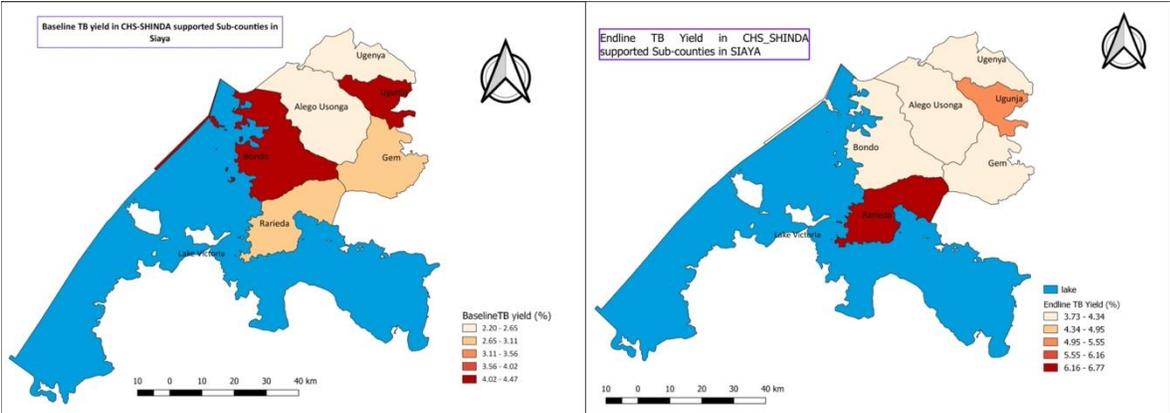


Figure 4 Baseline and Endline percentage TB yield

**TB ICF Results**

**TB screening coverage among clients attending HIV clinic settings by evaluation period**

The CCC workload at CHS Shinda supported health facilities was 67,817 and 88,379 at baseline and endline respectively as shown in Table 7. The workload included any client who was active at any given time during the review period. The average TB screening uptake at baseline and endline periods was 96% (64,866/67,817) and 98% (87,050/88,379) respectively.

Table 7 TB screening coverage among clients attending HIV clinic settings by period

	Baseline (Oct 2016-Sep 2018)	Endline (Oct 2018-Sep 2020)
<b>TB Screening Coverage</b>		
No. of clients visiting the department (workload) (No.)	67,817	88,379
Number of clients screened (No.)	64,866	87,050
Proportion of clients screened (%)	96%	98%

## Characteristics of clients attending HIV clinic settings screened for TB by evaluation period

More than half of the patients screened were females, 65.2% (42,323/64,866) and 65.3% (56,815/87,050) at baseline and end line with clients aged between 35-44 years having higher proportions, 28.1% (18,212/64,866) and 28.4% (24,753/87,050) of the patients visiting HIV clinics at baseline and end as shown in Table 8.

There were significant differences in characteristics of screened HIV clients between the baseline and endline periods such as age categories, sub-county and KEPH facility levels as shown in Table 8.

**Table 8 Characteristics of clients screened for TB in HIV clinic settings by period**

<b>Characteristics</b> n (%)	Baseline (Oct 2016-Sep 2018) N=64,866	Endline (Oct 2018– Sep 2020) N=87,050	P-value
<b>Sex</b>			
Female	42,323 (65.2)	56,815 (65.3)	0.939
Male	22,543 (34.8)	30,235 (34.7)	
<b>Age (years)</b>			
Child (<15 years)	4,550 (7.0)	5,956 (6.8)	0.194
Adult (>15 years)	60,316 (93.0)	81,094 (93.2)	
<b>Age (years) Category</b>			
0-9	2,257 (3.5)	2,950 (3.4)	<0.001
10-14	2,293 (3.5)	3,006 (3.5)	
15-19	2,065 (3.2)	2,631 (3.0)	
20-24	3,368 (5.2)	4,808 (5.5)	
25-34	15,521 (23.9)	21,926 (25.2)	
35-44	18,212 (28.1)	24,753 (28.4)	
45-54	11,386 (17.6)	14,795 (17.0)	
55-64	6,667 (10.3)	8,443 (9.7)	
>65	3,097 (4.8)	3,738 (4.3)	
<b>Time on ART before IPT initiation</b>			
0-6 months	19,597 (38.3)	37,125 (47.6)	<0.001
7-12 months	2,717 (5.3)	3,780 (4.8)	
>12 months	28,838 (56.4)	37,143 (47.6)	
<b>WHO stage IPT enrollment</b>			
WHO Stage1	25,998 (40.1)	38,489 (44.2)	
WHO Stage2	22,784 (35.1)	30,814 (35.4)	

WHO Stage3	15,094 (23.3)	16,644 (19.1)	
WHO Stage4	990 (1.5)	1,103 (1.3)	<0.001
<b>Viral suppression at IPT initiation</b>			
<1000 copies/ml	14,535 (22.4)	17,745 (20.4)	
>=1000 copies/ml	2,391 (3.7)	2,938 (3.4)	
Missing	47,940 (73.9)	66,367 (76.2)	<0.001
<b>Sub County</b>			
Alego Usonga	14,358 (22.1)	16,895 (19.4)	
Bondo	13,512 (20.8)	20,030 (23.0)	
Gem Wagai	6,609 (10.2)	8,726 (10.0)	
Gem Yala	8,056 (12.4)	9,110 (10.5)	
Rarieda	10,231 (15.8)	15,474 (17.8)	
Ugenya	5,238 (8.1)	7,859 (9.0)	
Ugunja	6,862 (10.6)	8,956 (10.3)	<0.001
<b>KEPH Facility Level</b>			
Level 2	15,995 (24.7)	31,478 (36.2)	
Level 3	23,596 (36.4)	29,540 (33.9)	
Level 4	25,275 (39.0)	26,032 (29.9)	<0.001

### Outcomes of TB screening among patients attending HIV clinics

TB screening outcomes among patients attending HIV clinics from baseline and endline are shown in Table 9. There was an increase in the proportion of presumptive TB cases at end line 16.6% (14,466/87,050) as compared to baseline 5.7% (3,687/64,866). The proportion of presumptive TB cases not investigated was lower at endline 0.5% (78/14,466) compared to baseline, 21.9% (808/3,687). The use of GeneXpert as a mode of investigation for TB diagnosis increased from 70.0% (2,581/3,681) at baseline to 97.1% (14,046/14,466) at endline. The absolute number of TB cases diagnosed in the endline period (3,495) was substantially higher than in the baseline period (1,995),  $p < 0.001$ .

**Table 9 Outcomes of TB screening among patients attending HIV clinics**

Characteristics	Baseline	Endline	P-value
	(Oct 2016-Sep 2018)	(Oct 2018– Sep 2020)	
	N=64,866	N=87,050	
	n (%)	n (%)	
<b>TB Screening Outcomes</b>			
No signs	61,179 (94.3)	72,584 (83.4)	<0.001
Presumptive TB	3,687 (5.7)	14,466 (16.6)	
<b>Mode of TB investigation</b>			
GeneXpert	2,581 (70.0)	14,046 (97.1)	
Sputum Microscopy	100 (2.7)	73 (0.5)	
X Ray	198 (5.4)	269 (1.9)	<0.001
Not done	808 (21.9)	78 (0.5)	
<b>Diagnosed with TB</b>			
No	1,692 (45.9)	10,971 (75.8)	
Yes	1,995 (54.1)	3,495 (24.2)	<0.001
<b>TB Diagnosis by Mode of TB investigation</b>			
GeneXpert	1797 (90.1)	3,153 (90.2)	<0.001
Sputum Microscopy	0 (0.0)	73 (2.1)	
X Ray	198 (9.9)	269 (7.7)	

**Table 10 TB case identification ratios**

Evaluation Period	Number of clients screened (y)	Diagnosed with TB (x)	TB cases identified per 1,000 $\left(\frac{x}{y} \times 1000\right)$
Baseline	1,995	64,866	31 TB cases identified per 1,000
Endline	3,495	87,050	40 TB cases identified per 1,000

Table 10 shows the rates of TB case identification at baseline and endline, showing a 29% increase in the rate of TB case identification per 1,000 clients screened.

### **IPT outcomes among clients with known HIV-positive status by intervention period**

IPT initiation increased in the endline period to 89.7% (78, 048/87,050) from 78.9% at baseline (51,152/64,866) as shown in Table 11. Completion of the six-month IPT among patients decreased slightly from baseline, 98.6% (50,443/51,152), to endline, 96.2% (75,070/78,048). The proportion of

clients who developed TB disease while on IPT was higher at endline 0.1% (58/78,048) compared to baseline 0.0% (7/51,152). Clients who were discontinued, and those who stopped, IPT also increased over the two periods reaching 0.4% (274/78,048) and 1.6% (1,255/78,048) at endline, respectively.

**Table 11 IPT outcomes among clients with known HIV-positive status by intervention period**

Characteristics n (%)	Baseline (Oct 2016-Sep 2018) N=64,866	Endline (Oct 2018– Sep 2020) N=87,050	P-value
<b>Initiated IPT</b>			
No	13,714 (21.1)	9,002 (10.3)	
Yes	51,152 (78.9)	78,048 (89.7)	<0.001
<b>IPT Outcomes</b>			
Completed	50,443 (98.6)	75,070 (96.2)	
Developed TB	7 (0.0)	58 (0.1)	
Died	10 (0.0)	40 (0.1)	
Discontinued	33 (0.1)	274 (0.4)	
Incomplete	543 (1.1)	1,097 (1.4)	
Lost to follow up	54 (0.1)	104 (0.1)	
Stopped	27 (0.1)	1,255 (1.6)	
Transferred Out	33 (0.1)	138 (0.2)	
Drug Toxicity	2 (0.0)	12 (0.0)	<0.001

### Client and facility-level characteristics associated with non-completion of IPT

On univariable analysis, results shown in Table 12, clients had higher odds of IPT non-completion if they received IPT at KEPH level two compared to KEPH level four facility [OR= 1.20 (95% CI 1.11-1.30)]. The odds of IPT Non-completion significantly reduces for clients who had been longer on ART, [OR= 2.15 (95% CI 1.74-2.65)] for 7-12 months against [OR= 7.36 (95%CI 6.71-8.10)] for those on ART for six months or less. Clients who were virally suppressed at IPT initiation, OR= 0.77 (95% CI 0.59-1.00) had lower odds of completing IPT than those who are virally suppressed. The odds of IPT Non-completion was significantly higher for age-groups 20-24 years [OR= 2.54 (95% CI 2.11-3.08)] and 25-34 years [OR= 1.34 (95% CI 1.13-1.59)] with age-group 0-9 years as the reference as shown in Table 12.

On multivariable analysis, clients had significantly higher odds of IPT Non-completion if they received IPT in Alego Usonga [aOR = 1.40 (95% CI 1.02-1.94)], Bondo [aOR= 2.57(95% CI (1.93-3.45)], and

Ugenya [aOR= 3.25 (95% CI (2.31-4.61))] sub-counties compared to Rarieda Sub-county and among those on ART for six months or less [aOR= 2.09 (95% CI 1.72-2.54)]. The odds of IPT Non-completion was still significantly higher for age-group 20-24 years [aOR= 1.66 (95% CI 1.06-2.65) in comparison to age-group 0-9 years. Clients who were not virally suppressed at IPT initiation also had significantly lower odds of IPT Non-completion [aOR= 0.70(95% CI 0.53-0.92)] compared to those who had viral suppression as shown in Table 12.

**Table 12 Client and facility-level characteristics associated with Non-completion of TB Preventive Therapy (IPT) in HIV clinic**

Outcome: IPT complete vs. Incomplete n (%)	IPT Incomplete	IPT Complete	Univariable		Multivariable	
			OR (95% CI)	P value	aOR (95% CI)	P value
<b>KEPH level</b>						
Level 4	1,157 (31.4)	39,944 (31.8)	Reference		Reference	
Level 2	1,420 (38.5)	40,850 (32.5)	1.20 (1.11-1.30)	<0.001	1.33 (1.06-1.66)	0.013
Level 3	1,110 (30.1)	44,719 (35.6)	0.86 (0.79-0.93)	<0.001	1.65 (1.28-2.13)	<0.001
<b>Sub County</b>						
Rarieda	353 (9.6)	22,635 (18.0)	Reference		Reference	
Alego usonga	693 (18.8)	26,938 (21.5)	1.65 (1.45-1.88)	<0.001	1.40 (1.02-1.94)	0.041
Bondo	1,144 (31.0)	25,008 (19.9)	2.93 (2.60-3.31)	<0.001	2.57 (1.93-3.45)	<0.001
Gem Wagai	416 (11.3)	12,538 (10.0)	2.13 (1.84-2.46)	<0.001	0.95 (0.6-1.46)	0.814
Gem Yala	288 (7.8)	14,769 (11.8)	1.25 (1.07-1.46)	0.005	0.86 (0.58-1.27)	0.457
Ugenya	421 (11.4)	11,139 (8.9)	2.42 (2.10-2.80)	<0.001	3.25 (2.31-4.61)	<0.001
Ugunja	372 (10.1)	12,486 (9.9)	1.91 (1.65-2.21)	0.024	0.53 (0.31-0.88)	0.019
<b>Sex</b>						
Female	2,437 (66.1)	81470 (64.9)	Reference			
Male	1,250 (33.9)	44,043 (35.1)	0.95 (0.89-1.02)	0.136		
<b>Age Category (Years)</b>						
0-9	147 (4.0)	3,841 (3.1)	Reference		Reference	
10-14	61 (1.7)	4,638 (3.7)	0.34 (0.25-0.46)	<0.001	0.17 (0.07-0.37)	<0.001
15-19	173 (4.7)	3,561 (2.8)	1.27 (1.01-1.59)	0.037	1.09 (0.65-1.81)	0.748
20-24	510 (13.8)	5,244 (4.2)	2.54 (2.11-3.08)	<0.001	1.66 (1.06-2.65)	0.030
25-34	1454 (39.4)	28,443 (22.7)	1.34 (1.13-1.59)	0.001	0.90 (0.62-1.34)	0.593
35-44	844 (22.9)	36,726 (29.3)	0.60 (0.50-0.72)	<0.001	0.43 (0.29-0.65)	<0.001
45-54	289 (7.8)	23,380 (18.6)	0.32 (0.26-0.40)	<0.001	0.32 (0.21-0.50)	<0.001
55-64	141 (3.8)	1,3625 (10.9)	0.27 (0.21-0.34)	<0.001	0.27 (0.16-0.45)	<0.001
65+	68 (1.8)	6,055 (4.8)	0.29 (0.22-0.39)	<0.001	0.40 (0.22-0.70)	0.002

<b>Time on ART before IPT</b>						
<b>initiation</b>						
>12 months	509 (13.8)	65472 (52.2)	Reference		Reference	<0.001
0-6 months	3,071 (83.3)	53,651 (42.7)	7.36 (6.71-8.10)	<0.001	2.09 (1.72-2.54)	<0.001
7-12 months	107 (2.9)	6,390 (5.1)	2.15 (1.74-2.65)	<0.001	1.72 (1.27-2.28)	<0.001
<b>WHO stage IPT enrollment</b>						
WHO Stage4	38 (1.0)	1639 (1.3)	Reference		Reference	
WHO Stage1	2,173 (58.9)	52,331 (41.7)	1.79 (1.32-2.52)	<0.001	1.44 (0.65-4.07)	0.426
WHO Stage2	1,041 (28.2)	45,516 (36.3)	0.98 (0.72-1.39)	0.935	1.05 (0.48-2.98)	0.913
WHO Stage3	435 (11.8)	26,027 (20.7)	0.72 (0.52-1.02)	0.056	1.04 (0.46-2.96)	0.937
<b>Viral suppression at IPT</b>						
<b>initiation</b>						
<1000 copies/ml	477 (88.7)	31,803 (85.8)	Reference		Reference	
>=1000 copies/ml	61 (11.3)	5,268 (14.2)	0.77 (0.59-1.00)	0.059	0.70 (0.53-0.92)	0.013
<b>Period</b>						
Baseline(Oct 2016-Sep 2018)	709 (19.2)	50,443 (40.2)	Reference		Reference	
Endline(Oct 2018-Sep 2020)	2,978 (80.8)	75,070 (59.8)	2.82 (2.60-3.07)	<0.001	1.30 (1.09-1.56)	0.004

### Client and facility-level characteristics associated with TB diagnosis

On univariable analysis, female clients compared to male [OR = 1.31 (95% CI 1.24-1.40)], and those aged between 25-34 years had higher odds of TB diagnosis using age group 0-9 years as reference, [OR = 1.46 (95% CI 1.24-1.72)]. There were significantly higher odds of positive TB diagnosis at end line period compared to baseline period [OR = 1.32 (95% CI 1.25-1.39)], denoting a 32% increase in TB cases in the endline period as shown in Table 13.

On multivariable analysis, there were higher odds of TB diagnosis among female clients compared to male clients [aOR = 1.40 (95% CI 1.31-1.50)], as well as, among clients aged between 25-34 years [aOR = 1.28 (95% CI 1.07-1.55)] compared to those aged 0-9 years. Clients classified as WHO stage III and IV [aOR = 1.59 (95% CI 1.47-1.73) and aOR = 1.72 (95% CI 1.35-2.17)] had significantly higher odds of being diagnosed with TB compared to WHO stage 1. The odds of TB diagnosis at endline were significantly higher compared to baseline period [aOR = 1.25 (95% CI 1.17-1.33)], denoting a 25% increase in TB cases in the endline period. The odds of TB diagnosis were still significantly lower for clients seen at KEPH level 4 facility compared to KEPH level 2 [aOR = 1.23

(95% CI 1.14-1.33)] and KEPH level 3 [aOR = 1.25 (95% CI 1.15-1.35)]. The odds of being diagnosed with TB was significantly higher among clients who had not completed IPT therapy compared to those who had completed [aOR = 1.42 (95% CI 1.22-1.65)]. Clients aged 55-64 years and 65+ years in comparison to age-group 0-9 years [aOR=0.72 (95% CI 0.59-0.89) and aOR= 0.50 (95% CI 0.38-0.65)] were less likely to be diagnosed with TB as shown in Table 13.

**Table 13 Client and facility-level characteristics associated with TB diagnosis among HIV positive clients**

<b>Outcome: TB Diagnosis</b>		<b>Univariable</b>			<b>Multivariable</b>	
<b>Positive vs. Negative</b>	<b>TB Negative</b>	<b>TB Positive</b>	<b>OR (95% CI)</b>	<b>P value</b>	<b>aOR (95% CI)</b>	<b>P value</b>
n (%)	146426 (96.4)	5490 (3.6)				
<b>MOH facility level</b>						
Level 4	49,694 (33.9)	1,613 (29.4)	Reference		Reference	
Level 2	45,604 (31.1)	1,869 (34.0)	1.26 (1.18-1.35)	<0.001	1.23 (1.14-1.33)	<0.001
Level 3	51,128 (34.9)	2,008 (36.6)	1.21 (1.13-1.29)	<0.001	1.25 (1.15-1.35)	<0.001
<b>Sub County</b>						
Alego usonga	30,307 (20.7)	946 (17.2)	Reference		Reference	
Bondo	32,178 (22.0)	1,364 (24.8)	0.03 (0.03-0.03)	<0.001	1.36 (1.24-1.49)	<0.001
Gem Wagai	14,772 (10.1)	563 (10.3)	1.36 (1.25-1.48)	<0.001	1.22 (1.08-1.37)	0.002
Gem Yala	16,596 (11.3)	570 (10.4)	1.22 (1.10-1.36)	<0.001	1.13 (1.01-1.27)	0.036
Rarieda	24,844 (17.0)	861 (15.7)	1.10 (0.99-1.22)	<0.001	1.12 (1.00-1.24)	0.040
Ugenya	12,662 (8.6)	435 (7.9)	1.11 (1.01-1.22)	<0.001	1.06 (0.93-1.21)	0.379
Ugunja	15,067 (10.3)	751 (13.7)	1.10 (0.98-1.23)	0.024	1.56 (1.39-1.74)	<0.001
<b>Sex</b>						
Male	51,185 (35.0)	1,593 (29.0)	Reference		Reference	
Female	95,241 (65.0)	3,897 (71.0)	1.31 (1.24-1.40)	<0.001	1.40 (1.31-1.50)	<0.001
<b>Age Category (Years)</b>						
0-9	5,043 (3.4)	164 (3.0)	Reference		Reference	
10-14	5,123 (3.5)	176 (3.2)	1.06 (0.85-1.31)	0.619	1.00 (0.78-1.27)	0.981
15-19	4,545 (3.1)	151 (2.8)	1.02 (0.82-1.28)	0.852	0.98 (0.76-1.26)	0.865
20-24	7,882 (5.4)	294 (5.4)	1.15 (0.95-1.4)	0.167	0.94 (0.75-1.18)	0.579
25-34	35,751 (24.4)	1,696 (30.9)	1.46 (1.24-1.72)	<0.001	1.28 (1.07-1.55)	0.009
35-44	41,311 (28.2)	1,654 (30.1)	1.23 (1.05-1.45)	0.0125	1.11 (0.93-1.34)	0.273
45-54	25,316 (17.3)	865 (15.8)	1.05 (0.89-1.25)	0.568	0.96 (0.79-1.16)	0.644
55-64	14,734 (10.1)	376 (6.8)	0.78 (0.65-0.95)	0.011	0.72 (0.59-0.89)	0.002
65+	6,721 (4.6)	114 (2.1)	0.52 (0.41-0.66)	<0.001	0.50 (0.38-0.65)	<0.001
<b>Time on ART before IPT initiation</b>						
>12 months	63,895 (51.2)	2,086 (46.3)	Reference		Reference	

0-6 months	54,579 (43.8)	2,143 (47.6)	1.20 (1.13-1.28))	<0.001	1.15 (1.07-1.23)	<0.001
7-12 months	6,225 (5.0)	272 (6.0)	1.34 (1.17-1.52)	<0.001	1.33 (1.16-1.51)	<0.001
<b>WHO stage IPT enrollment</b>						
WHO Stage1	62,326 (42.6)	2,161 (39.4)	Reference		Reference	
WHO Stage2	51,791 (35.4)	1,807 (32.9)	1.01 (0.94-1.07)	0.847	1.13 (1.05-1.21)	0.001
WHO Stage3	30,319 (20.7)	1,419 (25.8)	1.34 (1.26-1.45)	<0.001	1.59 (1.47-1.73)	<0.001
WHO Stage4	1,990 (1.4)	103 (1.9)	1.49 (1.21-1.82)	<0.001	1.72 (1.35-2.17)	<0.001
<b>Viral suppression at IPT</b>						
<b>initiation</b>						
<1000 copies/ml	31,223 (85.9)	1,057 (84.4)	Reference		Reference	
>=1000 copies/ml	5,134 (14.1)	195 (15.6)	1.12 (0.96-1.31)	0.147		
<b>IPT Completion</b>						
Yes	124,699 (97.2))	4,300 (95.5)	Reference		Reference	
No	3,486 (2.8)	201 (4.5)	1.63 (1.40-1.88)	<0.001	1.42 (1.22-1.65)	<0.001
<b>Period</b>						
Baseline(Oct 2016-Sep 2018)	62,871 (42.9)	1,995 (36.3)	Reference		Reference	
Endline(Oct 2018-Sep 2020)	83,555 (57.1)	3,495 (63.7)	1.32 (1.25-1.39)	<0.001	1.25 (1.17-1.33)	<0.001

### **Client and facility-level characteristics associated with Non-completion of TB treatment among TB/HIV positive clients**

On univariable analysis, results shown in Table 14, clients had higher odds of not completing TB treatment if they received TB treatment at KEPH levels 4 compared to KEPH level 2 [OR= 1.29 (95% CI 1.10-1.52)]. Clients diagnosed with EPTB and clients categorized as underweight had higher odds of not completing TB treatment [OR= 1.57 (95% CI 1.31-1.88)] and [OR= 1.60 (95% CI 1.38-1.86)] respectively as shown in Table 14.

On multivariable analysis, there were higher odds of not completing TB treatment if TB treatment was received at KEPH level 4 compared to KEPH level 2 facilities [aOR= 1.35 (95% CI 1.14-1.61)] and among male clients compared to female clients [aOR= 1.25 (95% CI 1.08-1.45)]. Clients diagnosed with EPTB and clients categorized as underweight had higher odds of not completing TB treatment [aOR= 1.61 (95% CI 1.33-1.94)] and [OR= 1.62 (95% CI 1.39-1.89)] respectively. The odds of clients not completing their TB treatment therapy at endline was significantly lower compared to baseline period [aOR = 0.69 (95% CI 0.59-0.80)] as shown in Table 14 below.

**Table 14 Client and facility-level characteristics associated with non-completion of TB treatment among TB/HIV positive clients**

Outcome: TB treatment; Complete vs. Incomplete n (%)	Complete TB treatment 3839 (79.2)	Incomplete TB treatment 1009 (20.8)	Univariable		Multivariable	
			OR (95% CI)	P value	aOR (95% CI)	P value
<b>KEPH Level</b>						
Level 2	1,384 (36.1)	342 (33.9)	Reference		Reference	
Level 3	1,178 (30.7)	259 (25.7)	0.88 (0.74-1.06)	0.201	0.95 (0.78-1.16)	0.643
Level 4	1,277 (33.3)	408 (40.4)	1.29 (1.10-1.52)	<0.001	1.35 (1.14-1.61)	0.001
<b>Sub County</b>						
Rarieda	563 (14.7)	102 (10.1)	Reference			
Alego usonga	852 (22.2)	338 (33.5)	2.19 (1.72-2.81)	<0.001	1.86 (1.44-2.41)	<0.001
Bondo	740 (19.3)	187 (18.5)	1.39 (1.07-1.82)	0.014	1.17 (0.89-1.54)	0.265
Gem Wagai	340 (8.9)	80 (7.9)	1.30 (0.94-1.79)	0.112	1.25 (0.90-1.73)	0.186
Gem Yala	469 (12.2)	100 (9.9)	1.18 (0.87-1.59)	0.290	1.02 (0.75-1.38)	0.918
Ugenya	418 (10.9)	108 (10.7)	1.43 (1.06-1.92)	0.020	1.27 (0.92-1.74)	0.141
Ugunja	457 (11.9)	94 (9.3)	1.14 (0.84-1.54)	0.417	0.99 (0.72-1.36)	0.950
<b>Sex</b>						
Female	1,818 (47.4)	410 (40.6)	Reference			
Male	2,021 (52.6)	599 (59.4)	1.31 (1.14-1.51)	<0.001	1.25 (1.08-1.45)	0.003
<b>Age Category (Years)</b>						
55-64*	340 (8.9)	62 (6.1)	Reference			
0-9	141 (3.7)	27 (2.7)	1.05 (0.63-1.7)	0.846	0.71 (0.43-1.17)	0.192
10-14	90 (2.3)	19 (1.9)	1.16 (0.64-2)	0.610	0.74 (0.41-1.30)	0.312
15-19	53 (1.4)	15 (1.5)	1.55 (0.8-2.87)	0.174	1.24 (0.63-2.32)	0.518
20-24	191 (5.0)	45 (4.5)	1.29 (0.84-1.97)	0.235	1.20 (0.78-1.85)	0.402
25-34	1,135 (29.6)	325 (32.2)	1.57 (1.17-2.13)	0.003	1.43 (1.06-1.96)	0.021
35-44	1,172 (30.5)	312 (30.9)	1.46 (1.09-1.98)	0.013	1.27 (0.94-1.74)	0.121
45-54	571 (14.9)	170 (16.8)	1.63 (1.19-2.26)	0.003	1.48 (1.07-2.07)	0.019
65+	146 (3.8)	34 (3.4)	1.28 (0.8-2.01)	0.299	1.30 (0.81-2.07)	0.275
<b>BMI category</b>						
normal	1,571 (40.9)	321 (31.8)	Reference			
underweight	1,984 (51.7)	649 (64.3)	1.60 (1.38-1.86)	<0.001	1.62 (1.39-1.89)	<0.001
overweight	284 (7.4)	39 (3.9)	0.67 (0.47-0.95)	0.029	0.71 (0.49-1.01)	0.068
<b>Type of TB</b>						
Pulmonary	500 (13.0)	192 (19.0)	Reference			
Extra Pulmonary	3,339 (87.0)	817 (81.0)	1.57 (1.31-1.88)	<0.001	1.61 (1.33-1.94)	<0.001
<b>Period</b>						
Baseline(Oct 2016-Sep 2018)	2,194 (57.2)	676 (67.0)	Reference			
Endline(Oct 2018-Sep 2020)	1,645 (42.8)	333 (33.0)	0.66 (0.57-0.76)	<0.001	0.69 (0.59-0.80)	<0.001

## Outcomes among TB/HIV co-infected clients treated for TB among

Results in Table 15 show that a higher proportion 35.1% (557/1,585) of TB client cured were those registered KEPH level 3 health facilities while the majority of the TB clients completing treatment and those who failed treatment were registered for TB treatment in KEPH level 2 health facilities at 38.4% (866/2,254) and 42.4% (28/66) respectively. On the other hand, almost half of TB deaths, LTFU and transfer out outcomes were reported at KEPH level 4 health facilities at 40.9% (313/766), 43.6% (61/140), and 48.6% (18/37) respectively. Geographically, Alego Usonga Sub-county contributed the highest proportion of TB clients reported to have not completed treatment due to death 30.4% (233/766), failed treatment 50% (33/66), LTFU 42.1% (59/140) and transfer out 35.1% (13/37). Significantly higher proportion of the clients that reported to have died 59% (452/766), failed treatment 60.6% (40/66), LTFU 60.7% (85/140) and transferred out 59.5% (22/37) were males.

**Table 15 Outcomes among TB/HIV co-infected clients treated for TB**

Columns by: TB Diagnosis	Cured	Treatment Complete	Died	Failed treatment	LTFU	Transfer Out	Total	P-value
n (%)	1585 (32.7)	2254 (46.5)	766 (15.8)	66 (1.4)	140 (2.9)	37 (0.8)	4848 (100.0)	
<b>Facility levels</b>								
Level 2	518 (32.7)	866 (38.4)	250 (32.6)	28 (42.4)	50 (35.7)	14 (37.8)	1726 (35.6)	
Level 3	557 (35.1)	621 (27.6)	203 (26.5)	22 (33.3)	29 (20.7)	5 (13.5)	1437 (29.6)	
Level 4	510 (32.2)	767 (34.0)	313 (40.9)	16 (24.2)	61 (43.6)	18 (48.6)	1685 (34.8)	<0.001
<b>Sub County</b>								
Alego_usonga	353 (22.3)	499 (22.1)	233 (30.4)	33 (50.0)	59 (42.1)	13 (35.1)	1190 (24.5)	
Bondo	336 (21.2)	404 (17.9)	141 (18.4)	8 (12.1)	30 (21.4)	8 (21.6)	927 (19.1)	
Gem_wagai	167 (10.5)	173 (7.7)	67 (8.7)	1 (1.5)	12 (8.6)	0 (0.0)	420 (8.7)	
Gem_yala	202 (12.7)	267 (11.8)	80 (10.4)	5 (7.6)	15 (10.7)	0 (0.0)	569 (11.7)	
Rarieda	248 (15.6)	315 (14.0)	80 (10.4)	10 (15.2)	8 (5.7)	4 (10.8)	665 (13.7)	
Ugenya	116 (7.3)	302 (13.4)	89 (11.6)	1 (1.5)	9 (6.4)	9 (24.3)	526 (10.8)	
Ugunja	163 (10.3)	294 (13.0)	76 (9.9)	8 (12.1)	7 (5.0)	3 (8.1)	551 (11.4)	<0.001
<b>Sex</b>								
Female	655 (41.3)	1163 (51.6)	314 (41.0)	26 (39.4)	55 (39.3)	15 (40.5)	2228 (46.0)	
Male	930 (58.7)	1091 (48.4)	452 (59.0)	40 (60.6)	85 (60.7)	22 (59.5)	2620 (54.0)	<0.001
<b>Age Category, n (%)</b>								
0-9yrs	10 (0.6)	131 (5.8)	19 (2.5)	0 (0.0)	5 (3.6)	3 (8.1)	168 (3.5)	

10-14	11 (0.7)	79 (3.5)	16 (2.1)	2 (3.0)	1 (0.7)	0 (0.0)	109 (2.2)	
15-19	13 (0.8)	40 (1.8)	11 (1.4)	2 (3.0)	2 (1.4)	0 (0.0)	68 (1.4)	
20-24	90 (5.7)	101 (4.5)	32 (4.2)	3 (4.5)	8 (5.7)	2 (5.4)	236 (4.9)	
25-34	560 (35.3)	575 (25.5)	242 (31.6)	20 (30.3)	49 (35.0)	14 (37.8)	1460 (30.1)	
35-44	554 (35.0)	618 (27.4)	226 (29.5)	28 (42.4)	44 (31.4)	14 (37.8)	1484 (30.6)	
45-54	191 (12.1)	380 (16.9)	137 (17.9)	8 (12.1)	23 (16.4)	2 (5.4)	741 (15.3)	
55-64	114 (7.2)	226 (10.0)	52 (6.8)	3 (4.5)	7 (5.0)	0 (0.0)	402 (8.3)	
>65	42 (2.6)	104 (4.6)	31 (4.0)	0 (0.0)	1 (0.7)	2 (5.4)	180 (3.7)	<0.001
<b>BMI category</b>								
Underweight	797 (50.3)	1187 (52.7)	512 (66.8)	38 (57.6)	76 (54.3)	23 (62.2)	2633 (54.3)	
Normal	691 (43.6)	880 (39.0)	222 (29.0)	27 (40.9)	58 (41.4)	14 (37.8)	1892 (39.0)	
Overweight	97 (6.1)	187 (8.3)	32 (4.2)	1 (1.5)	6 (4.3)	0 (0.0)	323 (6.7)	<0.001
<b>Type of TB</b>								
Extra Pulmonary	1 (0.1)	499 (22.1)	175 (22.8)	0 (0.0)	17 (12.1)	0 (0.0)	692 (14.3)	
Pulmonary	1584 (99.9)	1755 (77.9)	591 (77.2)	66 (100.0)	123 (87.9)	37 (100.0)	4156 (85.7)	<0.001
<b>Mode of TB investigation</b>								
GeneXpert	1303 (82.2)	1205 (53.5)	404 (52.7)	57 (86.4)	78 (55.7)	31 (83.8)	3078 (63.5)	
Sputum Microscopy	282 (17.8)	828 (36.7)	291 (38.0)	8 (12.1)	54 (38.6)	6 (16.2)	1469 (30.3)	<0.001
X Ray	0 (0.0)	221 (9.8)	71 (9.3)	1 (1.5)	8 (5.7)	0 (0.0)	301 (6.2)	
<b>Period</b>								
Baseline (Oct 2016-Sep 2018)	1029 (64.9)	1165 (51.7)	508 (66.3)	51 (77.3)	88 (62.9)	29 (78.4)	2870 (59.2)	
Endline (Oct 2018-Sep 2020)	556 (35.1)	1089 (48.3)	258 (33.7)	15 (22.7)	52 (37.1)	8 (21.6)	1978 (40.8)	<0.001

## **SUMMARY OF FINDINGS**

### **Active Case Finding**

We had the following key findings from ACF analysis results:

1. The vast majority (99.7%) of clients accessing the OPD during the study period were screened for TB
2. Most of patients screened through ACF were in Kenya Essential Package of Health (KEPH) level 3 facilities.
3. The availability of diagnostic methods such as Chest X-ray and GeneXpert enabled TB diagnosis in both evaluation periods.
4. A significantly greater proportion of clients screened at endline had presumptive TB as compared to those screened at baseline period (18.0% vs. 16.3%; p-value<0.001).
5. ACF increased the number of presumptive TB cases identified by 7.7%, which translated to a concomitant 44.3% increase in TB cases diagnosed.
6. The TB identification rate increased from 15 to 22 per 1,000 clients screened

### **TB Preventive Therapy**

1. IPT initiation significantly increased in the end line period (89.7%) compared to the baseline (78.9%).
2. IPT completion rate was better in clients who have been on ART longer than 6 months.
3. In the multivariable analysis factors associated with non-completion of IPT included being from Alego Usonga [aOR = 1.40 (95% CI 1.02-1.94)], Bondo [aOR= 2.57(95% CI (1.93-3.45)], and Ugenya [aOR= 3.25 (95% CI (2.31-4.61)] sub-counties compared to Rarieda Sub-county, on ART for six months or less [aOR= 2.09 (95% CI 1.72-2.54)], age-group 20-24 years [aOR= 1.66 (95% CI 1.06-2.65) compared to age-group 0-9 years, and those virally suppressed at IPT initiation compared to those who had not virally suppressed [aOR= 0.70(95% CI 0.53-0.92)].

## **Intensified Case Finding**

We had the following key findings from ICF analysis results:

1. TB screening coverage among PLHIV accessing care was high (97%) across the study period
2. There was a significant increase in the number of presumptive TB cases identified among PLHIV at the endline compared to baseline (16.6% vs. 5.7%; p-value<0.001).
3. TB identification rate increased from 31 to 40 per 1,000 clients screened (29% increase in the rate of TB case identification per 1,000 clients screened)
4. More adult females were screened in ICF, consistent with the demographic distribution of PLHIV.

## **TB Treatment Outcomes**

1. Treatment success (Treatment completion and cure rates) was slightly better at endline compared to baseline that is 2194 (1029 cured and 1165 completed) out of 2870 cases (76%) at baseline compared to 1645 (556 cured and 1089 completed) out of 1978 cases (83%) at end line.
2. The proportion of those with successful treatment outcomes (cured and completing TB treatment) was higher (83%) at the end line compared to the baseline period for PLHIV (76%). This is also in keeping with routine program data that indicated steady improvement in treatment cure rates (treatment complete and cure rates) from 72.6% in 2018 to a high of 89.9% in the first quarter of 2021 (TIBU).
3. Better treatment outcomes were also recorded in patients whose treatment was started in level 3 (sub county) and level 2 dispensaries. Level three facilities recorded significantly higher cure rates and treatment completions. Level two facilities recorded better completion rates but did not have better cure rates. The majority of TB deaths, LTFU and transfer out were in level 4 health facilities.
4. However, clients in level 2 facilities were also more likely to fail treatment compared to other levels

5. Female clients had better treatment completion outcomes as opposed to the male clients. Male clients had significantly higher odds of having poor outcomes (Died, failed treatment and LTFU) compared to female clients.
6. Clients with pulmonary TB also had better odds of completing treatment compared to those with extrapulmonary TB.
7. Within the County, there were variations in treatment completion rates amongst the Sub-counties; Alego Usonga had a significantly lower treatment completion rate compared to other sub counties.
8. Clients initiating treatment while underweight had higher odds of treatment completion compared to clients with a normal weight.

## DISCUSSION

### Active and Intensified Case Finding

The main findings in this evaluation shows that ACF improved TB screening among patients attending OPD in the sampled CHS Shinda supported health facilities being screened. The number screened at endline was higher compared to baseline although not statistically significant. In both evaluation periods' majority of the OPD patients screened had no symptoms suggestive of TB. Furthermore, the missed TB screening opportunities were less at endline compared to baseline. Similarly, the number of presumptive TB cases was significantly higher at endline compared to baseline. In both evaluation periods the proportion of females was more than males and adults were more than children, mirroring the gender and age distribution of those currently on ART in the Siaya County population of PLHIV.

Despite improved outcomes for PLHIV on ART, some clients still developed TB while on ART hence the need for intensified screening in the CCC through ICF. This is in line with both WHO and Kenya national TB/HIV guidelines that require that every PLHIV is screened for TB at every clinical visit/encounter (17). A study done at AMPATH Kenya on ICF found that despite intensified screening in the CCC there were missed opportunities for screening and testing for TB due to health system related factors (18). These findings are similar to our evaluation findings where 0.1% and 0.5% were missed opportunities for ACF at endline and baseline periods respectively. The gap in ICF screening could be attributable to clients already diagnosed with TB and on treatment, attritions from care such as LTFU and missed opportunities. Therefore, there is need to strengthen the existing systems to improve the quality of screening by service providers in the CCC.

On characteristics of the patients screened under both ACF and ICF, the proportion of female clients was more than male clients and majority of them were adults. These ICF findings are similar to the gender and age distribution of those currently on ART within Siaya County. During the evaluation period, ACF interventions reached more male clients at the endline compared to baseline. Embedding ACF alongside male friendly services such as flexi hours and multi-disease screening at stand-alone testing booths may have contributed to the higher numbers of men seen at endline period.

During the project implementation, there was a deliberate effort from the program to improve the quality of TB screening among clients attending all service delivery points, OPD, IPD and CCC. This entailed engagement of HTS providers in OPD to screen for TB, continuous sensitization, mentorship, and provision of revised screening registers that provides for reporting on TB screening. In the CCC, regular focused data driven mentorship and CMEs were done to ensure quality ICF implementation. These contributed to an increase in numbers presumed to have TB with subsequent increase in numbers of TB cases identified.

CHS Shinda supported all KEPH levels of health facilities within Siaya county and TB ACF and ICF was implemented across the seven Sub-counties during the evaluation period. The majority of the OPD clients screened were in Gem Wagai and the least was in Ugunja with most patients screened in KEPH level 4 facilities followed by KEPH level 2 and 3 health facilities respectively. Both Ugunja Sub-county and KEPH level 4 health facilities screened significantly higher number of clients at endline compared to baseline period of review. From the 29 health facilities sampled for this evaluation, majority were KEPH level 4 facilities. According to the Kenya health structure, KEPH Level 4 health facilities have capacity to offer holistic services including OPD services, TB clinics, chest x-ray (CXR), in patient services and the comprehensive HIV Clinics. This would explain the tendency of many patients seeking services in KEPH level 4 facilities, thus the noted higher numbers screened for TB . However, for ICF most of the patients screened received services in KEPH level 3 facilities.

During the evaluation period the PTB clients had a diagnostic work up for TB through either Gene Xpert, sputum microscopy or CXR. This was made possible by the availability of the equipment within the County which has three GeneXpert machines and 59 health facilities were able to conduct tests using sputum microscopy. Furthermore, the program has strengthened the sample networking system where specimens from all the 119 CHS supported health facilities are delivered effectively to the testing points and results back to the facilities within a short period of time (24 hours). In both evaluation periods, most of the PTB clients had GeneXpert done as a diagnostic work up for TB.

An evaluation of ACF in Western Kenya conducted in 2019 concluded that efficient TB ACF strategies are important in settings with high TB burden and limited resources (19). Similar findings were reported in a systematic review of population-based infectious disease surveillance (PBIDS)

platforms with links to health facilities in Kenya in 2018 that found that facility-based TB ICF detected more TB cases per the number of specimens tested and the number of persons screened, including those with HIV than home-based TB screening (20). We could attribute this to the fact that majority of patients coming to the hospital were more likely to have any of the TB symptoms compared to the general populations who were well and at home. According to the Kenya TB prevalence survey conducted between 2015 and 2016, Kenya is estimated to be missing 40% of the incident TB cases and to find the missing people with TB and close the detection gap, one of the key strategies is implementation and scaling up of TB case finding (8). The Kenya national TB/HIV guidelines require that every PLHIV is screened for TB at every clinical visit/ encounter (17).

From the evaluation findings, TB diagnosis among the PLHIV was more likely among adult females, above the age of 65 years, at WHO stage III or IV and residing in either Bondo or Ugunja Sub-counties. This is consistent with the WHO classification of opportunistic infections where TB (specifically PTB) is in stage III whereas EPTB in in stage IV (21). HIV is the most potent risk factor for TB infection (22). HIV-infection increases the risk of TB 20-fold compared with HIV-seronegative individuals in high HIV-prevalence countries (1), and TB in HIV-infected individuals has resulted in escalating public health emergencies in high HIV-prevalence settings. These findings are consistent with the National TB and leprosy program annual report of 2019 that reported an increase in TB case notification between 2016 and 2018 (7).

### **Tuberculosis Preventive Therapy**

Overall, IPT uptake among the PLHIV was below 90% both at baseline and endline with a significant increase in the end line period to 89.7%, following the adoption of IPT policy in the National HIV guideline which supports screening and initiation of IPT for all eligible PLHIV clients. Completion of the six-month IPT therapy both at baseline and endline was above 95%, this was attributed by intensified health care worker sensitization on the importance of IPT among PLHIV, integration of HIV/TB services, utilization of EMR in the sites and leveraging on existing structures for conducting tracing of clients who are LTFU. The IPT completion rate is higher than other studies done in Africa with findings ranging from 80% to 94% (23–26). Among the patients who did not complete IPT we had higher non completion rate at endline compared to baseline with mortality at 0.1%, LTFU 0.1%, and transfer outs at 0.2%. About 1.6% stopped IPT, this could be largely attributed to the national drug stock out of IPT. Those who developed TB were 0.1%, which is attributed to intensified quality

TB screening and timely follow ups of clients on IPT. In the evaluation we were not able to get documented reasons for stopping IPT. However, based on unpublished programmatic data, other reasons for stopping IPT were drug stock outs and non-adherence.

Clients had higher odds of IPT non-completion if they received IPT at KEPH levels 2 and 3 health facilities compared to KEPH level 4 health facilities. This could be attributed to factors such as infrastructure and staffing within the higher KEPH level facilities. However, this finding differs from another study done in Kenya that showed lower IPT completion rates at KEPH levels 4, 5, and private health facilities (26). A study in Swaziland found high IPT completion rates despite the level of facility delivering it (27).

Clients who have been on ART for more than 6 months had better IPT completion rates which could be attributed to the clients having received literacy classes resulting to improved adherence on medications. The evaluation showed that clients aged 15-19 and 20-24 years had lower IPT completion rates compared to those aged 0-9 years, this could be attributed to the cohorts being in the adolescent stage and having issues with adherence to medication due to stigma. However, this finding contrasts with a study that showed that all age groups below 25 years had lower IPT completion rates (28).

### **TB treatment outcomes**

The evaluation results suggest an improvement in TB treatment outcomes. The proportion of those with successful treatment outcomes (cured and completing TB treatment) was higher at the end line (83%) compared to the baseline period (76%) for PLHIV. This is also in keeping with routine program data that indicated steady improvement in treatment cure rates (treatment complete and cure rates) from 72.6% in 2018 to a high of 89.9% in the first quarter of 2021 (TIBU).

Better treatment outcomes were also recorded in patients whose treatment was started in KEPH levels 2 and 3 health facilities. KEPH Level 3 facilities recorded significantly higher cure rates and treatment completions. KEPH Level 2 facilities recorded better completion rates but did not have better cure rates. Further studies are required to explain the factors associated with these outcomes to improve the success of TB control. Death rates, treatment failure and LTFU rates were significantly higher in Alego Usonga and KEPH level four facilities. Alego Usonga hosts the Siaya County Teaching and Referral Hospital, the largest referral facility in Siaya county. It receives referrals for TB patients who have advanced and complicated disease for specialized management which may account for majority of the proportion of patients with poor treatment outcomes. KEPH Level four facilities also tend to

be farther from patients compared to the lower KEPH level facilities. This might have had a negative impact on the treatment completion rates. Male clients were also more likely to have poor treatment outcomes compared to female clients. A retrospective study done in Cameroon in 2017 also found that being female was one of the significant factors associated with treatment success (29). Efforts to improve early diagnosis and to improve adherence to medication have been employed to reduce these adverse outcomes. Counselling, sustained supervision, home visits, and health education have been used successfully as interventions to reduce defaulter rate/loss to follow-up of TB patients including facility-based DOTS. Clients with PTB had better treatment outcomes compared to those with EPTB. A study conducted in University of Gondar Teaching Hospital TB clinic in Ethiopia also found lower treatment success rates amongst clients with EPTB compared to those with PTB (30). Clients starting treatment while underweight were also likely to complete treatment compared to clients starting while overweight. The significance of this finding needs further evaluation.

## **CONCLUSION:**

The findings showed that quality TB screening through ACF/ICF by health care workers improved the number of presumptive TB cases identified which resulted in an increased number of clients diagnosed with TB.

The findings also showed that high completion rates for IPT can be achieved through intensified health care worker sensitization on the importance of IPT among PLHIV, integration of HIV/TB services and leveraging on existing structures for conducting tracing for LTFU.

Interventions by the project improved TB treatment success rates for the clients in the project supported health facilities. Significant improvement over time have also been noted. Female clients, those with PTB and those started in KEPH level 3 facilities were more likely to have favorable treatment outcomes.

## Lessons Learnt

1. TB diagnosis support through the use of GeneXpert and Chest X-ray improves the diagnosis of TB among the presumptive TB cases.
2. Early detection of TB among the general out-patient patients improves TB treatment outcomes.
3. Involvement of sensitized and mentored HTS providers in TB screening as first level screeners minimizes missed opportunities for TB presumptive case identification.
4. Utilization of ACF stamps for non-comprehensive care centre (CCC) departments that have not integrated TB screening questions in electronic medical records (EMR) or patient cards helps to reduce any missed opportunities.
5. Involvement of the mentored community antiretroviral therapy (ART) treatment supporters in screening for TB for DSD clients helps in improving case finding.
6. Utilization of the modified TB diary to monitor appointment and sputum follow-up helps to track defaulters and improving appointment keeping resulting in better treatment success rate (TSR) and cure rate.
7. Active engagement of the County Tuberculosis and Leprosy coordinator (CTLC) and Sub county Tuberculosis and Leprosy coordinator (SCTLC) to support in follow up of clients transferred out helps to improve documentation of treatment outcomes resulting in improvement of TSR.
8. The introduction and regular utilization of a TB dashboard to monitor TB/HIV performance during site mentorship and review of performance has improved the quality of care for TB patients.
9. Utilization of EMR to monitor patient level data has helped improve IPT uptake and completion rates.
10. Integration of TB/HIV services helps improve IPT completion among the PLHIV through synchronizing appointment dates and prompt tracing of missed appointments.
11. Leveraging on existing structures (using peer educators, appointment management systems, treatment literacy groups, psychosocial support groups (PSSG) and CHS retention action plan) to support in follow-up of LTFU clients on TB and IPT medications which has led to better outcomes.

12. Integration of TB screening questions in the ART distribution forms and TB screening in the HTS OPD of inpatient department (IPD) screening registers helps to minimize missed opportunities for TB screening.

### **Key Considerations:**

1. We propose scaling up the incorporation of standardized TB screening processes into routine HIV testing services (HTS) in public health facilities in order to improve TB case identification.
2. We propose the revision of other service delivery registers to incorporate TB screening and outcomes as institutionalized in the HTS register.
3. Conduct continuous sensitization and re-sensitization of health care workers on importance of IPT among PLHIV, and to improve the quality of TB screening.
4. Consider broader adoption of the following strategies to avoid missed opportunities for TB screening: Conduct routine TB screening among differentiated service delivery (DSD) clients in community antiretroviral groups (CAGs) and facility antiretroviral groups (FAGs), and incorporate standardized TB screening tool into the ART distribution forms either through placement of a stamp (as done in this evaluation) or adoption of revised tools.
5. Monitor the process and provide a forum for sharing the best practices to be scaled up through regular focused ACF/ICF, IPT and TB treatment performance review meetings at facility multidisciplinary team (MDT), program level and County technical working group (TWG)
6. Support ongoing integration of TB and HIV services to enable prompt follow up and better IPT completion rates.
7. Inclusion of reasons for not completing/stopping IPT in the electronic medical records;— this information helps to identify gaps and design strategies to improve IPT completion.
8. Develop interventions to support completion of IPT among ages 15–24 years. The interventions may be guided by qualitative assessments of facilitators and barriers to IPT completion.
9. Cross learning opportunities among regions should be promoted as a means to facilitate adoption of best practices to improve TB treatment outcomes

10. Quality of care at KEPH level 3 health facilities should be replicated in lower KEPH level health facilities to improve treatment cure outcomes.
11. Factors leading to poor outcomes at KEPH level 4 health facilities need to be further studied to inform and improve programing at this level.
12. Special interventions targeting men to improve adherence to treatment and ultimately favorable TB treatment outcomes needs to be explored and developed.
13. Special care, which can include more frequent follow ups for clients with extra pulmonary TB (EPTB), should be considered as a means to improve patient outcomes

## **DISSEMINATION OF FINDINGS**

Evaluation findings will be disseminated to all key stakeholders including the health workers, CHMTs, SCHMTs, 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 posted (in English) on a publicly accessible website within 90 days of report CDC clearance. Only de-identified individual patient-level meta data was released according to the CDC data policy on a limited release approved by CDC, MOH, CHS program, and data team. All the other aggregate data used was under general release to the public.

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## APPENDIX

### 1A Matrix with the evaluation design details

Evaluation Questions	Evaluation Type	Design	Data collection methods	Primary source document	Target population	Indicators	Periods
1. What is the coverage of TB screening among clients attending the OPD and HIV clinic settings?	Outcome	Pre and Post , Descriptive	Quantitative methods	TB patient level tools TB active case finding tools	General Client Population PLHIV	<b>Indicators (by sex, age, HIV status, health facility and department):</b> No. of clients visiting the department (workload) Number of clients screened Proportion of clients screened	Midline period (April 2016- March 2019) and Endline period (April 2019 – March 2021 )
2. What were the outcomes of TB screening in the general client population?	Outcome	Pre and Post, Descriptive	Quantitative methods	TB patient level tools TB related registers TIBU System	General Client Population	<b>Indicators (by sex, age, HIV status, and department):</b> Proportion of screened clients with presumptive TB, evaluated for TB diagnosis using GeneXpert, microscopy, chest radiograph (and results of any test(s) completed), diagnosed with TB by method of diagnosis, linked to care for TB treatment, completed TB treatment; among clients with unknown or previous HIV-negative status: tested for HIV, HIV-positive, HIV-positive	Midline period (April 2016- March 2019) and Endline period (April 2019 – March 2021 )

						and linked to care/ART	
3. What were the outcomes of IPT among clients with known HIV-positive status?	Outcome	Pre and Post , Descriptive	Quantitative methods	TB patient level tools TB-related registers Data collection templates, TIBU System, IQCare Electronic Medical Records System	PLHIV	<b>Indicators (by sex, age, clinical status, facility, etc.):</b> Proportion eligible for IPT; among those eligible for IPT: initiated IPT, completed IPT, reasons for discontinuing among those failing to complete IPT, developed TB during or after completing IPT, died, lost to follow-up	Midline period (April 2016- March 2019) and Endline period (April 2019 – March 2021 )
4. What client and facility-level factors were associated with outcomes of interest including failure to complete IPT, TB diagnosis, failure to complete TB treatment, death, loss to follow-up, etc.?	Outcome	Analytical	Quantitative methods	TB patient level tools, TB related registers, TB lab-related tools & registers, TB active case finding tools, Data collection templates, TIBU System, DHIS2, IQCare Electronic Medical Records Systems	General Client Population P LHIV	<b>Outcomes:</b> Completion/failure to complete IPT, TB diagnosis, linkage to care for TB treatment / ART, completion/failure to complete TB treatment, death, loss-to-follow-up. <b>Covariates:</b> Age, sex, facility, department, HIV status, TB History (New TB case, Previously Treated (Includes: smear-	Midline period (April 2016- March 2019) and Endline period (April 2019 – March 2021 )

					positive relapse, smear negative relapse, extra pulmonary relapse, return after default, failure), Other (Includes: transferred in), Type of TB (Pulmonary/Extra Pulmonary); <b>Extra          Variables Among          clients with HIV:</b> time since HIV diagnosis, on ART, ART regimen, viral load/suppression, co- morbidities, WHO stage at diagnosis, initiated IPT, completed IPT
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## 1B ACF Data Dictionary

Variable Name	Variable Label	Answer Label	Answer Code	Variable Type
deviceid	deviceid	Open ended		String
starttime	starttime	Open ended		String
endtime	endtime	Open ended		String
generated_note_name_5	generated_note_name_5	Open ended		String
sub_county	Sub county	Open ended		String
region	CHS regions	Open ended		String
facility_name	The name of facility data collected	Open ended		String
department	Department patient data abstracted from	Open ended		String
dateofbirth	Date of birth of the patient	Open ended		String
calculated_age	Age calculated at time of data collection	Open ended		Integer
sex	sex of the patient abstracted	Open ended		String
weight	Weight of the patient in Kgs	Open ended		String
height	Height of the patient in cm	Open ended		String

calculated_bmi	Calculated BMI	Open ended		Integer
screening_outcomes	TB screening outcomes	Open ended		String
screening_date	Date screened for TB	Open ended		String
mode_investigation	The mode of TB investigation	Open ended		String
mode_investigation_01	If presumptive what is the mode of investigation	Open ended		String
mode_investigation_02	If presumptive what is the mode of investigation	Open ended		String
mode_investigation_03	If presumptive what is the mode of investigation	Open ended		String
diagnosed_tb	Patient diagnosed with TB	Open ended		String
ident_investigation	Method used to diagnose the TB patient	Open ended		String
date_diagnosed_tb	Date diagnosed with TB	Open ended		String
type_tb	The type of TB	Open ended		String
specific_eptb	specific_EPTB	Open ended		String
type_tb_patient	The type of TB patient	Open ended		String
date_started_tbtreat	Date started TB treatment	Open ended		String
tb_treatment_outcomes	TB treatment outcomes	Open ended		String
date_tb_treatment_outcome	Date of TB treatment outcomes	Open ended		String
tested_for_hiv	Patient tested for HIV	Open ended		String
hiv_test_result	HIV test results	Open ended		String
why_hivtest_not_done	Why was the HIV test not done	Open ended		String
linked_care	Client linked to care	Open ended		String
date_confirmed_positive	Date client confirmed HIV positive	Open ended		String
date_enrolled_hivcare	Date enrolled in HIV	Open ended		String
date_started_art	Date started ART treatment	Open ended		String
current_regimen	Current regimen client was on during abstraction	Open ended		String
date_initiated_current_regimen	Date initiated into current regimen	Open ended		String
vl_time_of_tb_diagnosis	viral load at TB diagnosis	Open ended		Numeric
date_vl_result	Date of viral load results	Open ended		String
vl_after_6months_treatment	Viral load after 6 months of treatment	Open ended		long
date_vlafter_6months_treatment	Date of viral load done after 6months of treatment	Open ended		String
who_stage_tb_diagnosis	WHO stage at TB diagnosis	Open ended		String
initiated_ipt	Client initiated into IPT	Open ended		String
ipt_start_date	Date started IPT	Open ended		String
ipt_outcomes	Outcomes of IPT	Open ended		String
ipt_outcome_date	Date of IPT outcome	Open ended		String
co_icd10	comorbidities	Open ended		String
metainstanceid	meta:instanceID	Open ended		String
facility_level	Facility levels as defined in KMFL	Open ended		String

dateofbirth_1	dateofbirth formatted	Open ended		Numeric
screening_date_1	screening_date formatted	Open ended		Numeric
date_diagnosed_tb_1	date_diagnosed_tb formatted	Open ended		Numeric
date_tb_treatment_outcome_1	date_tb_treatment_outcome formatted	Open ended		Numeric
date_confirmed_positive_1	date_confirmed_positive formatted	Open ended		Numeric
date_enrolled_hivcare_1	date_enrolled_hivcare formatted	Open ended		Numeric
date_started_art_1	date_started_art formatted	Open ended		Numeric
date_initiated_current_regimen_1	date_initiated_current_regimen formatted	Open ended		Numeric
date_vl_result_1	date_vl_result formatted	Open ended		Numeric
date_vlafter_6months_treatment_1	date_vlafter_6months_treatment formatted	Open ended		Numeric
ipt_start_date_1	ipt_start_date formatted	Open ended		Numeric
ipt_outcome_date_1	ipt_outcome_date formatted	Open ended		Numeric
date_started_tbtreat_1	date_started_tbtreat formatted	Open ended		Numeric
evaluation_period	Period: Baseline(Oct 2016-Sep 2018)/ Endline(Oct 2018–Mar 2021)			Numeric
		Baseline(Oct 2016-Sep 2018)	0	
		Endline(Oct 2018–Mar 2021)	1	
age_cat_other	RECODE of calculated_age (Age calculated at time of data collection)			Integer
		0-9yrs	1	
		10-14	2	
		15-19	3	
		20-24	4	
		25-34	5	
		35-44	6	
		45-54	7	
		55-64	8	
		65+	9	
age_adult	RECODE of calculated_age (Age calculated at time of data collection)			Integer
		Child	1	
		Adult	2	
hiv_status				Numeric
		Negative	1	
		Positive	2	

bmi_cat	RECODE of calculated_bmi (Calculated BMI)			Integer
		underweight	1	
		normal	2	
		overweight	3	
		obesity	5	
who_cat	WHO stage at TB diagnosis			Numeric
		Stage I	1	
		Stage II	2	
		Stage III	3	
		Stage IV	4	
comorbidities	Co-morbidities [TB treatment]	Open ended		String
timeon_ARTb4IPT	Time on ART before IPT	Open ended		Numeric
timeon_ARTb4IPT_cat	RECODE of timeon_ARTb4IPT (Time on ART before IPT)			Numeric
		0-6 months	1	
		7-12 months	2	
		>12 months	3	
timeon_ARTb4TBtreat	Time on ART before TB treatment	Open ended		Numeric
timeon_ARTb4TBtreat_cat	RECODE of timeon_ARTb4TBtreat (Time on ART before TB treatment)			Numeric
		0-6 months	1	
		7-12 months	2	
		>12 months	3	
kp_vl_cat	Known Positives viral load at time of TB diagnosis			Numeric
		<1000 copies/ml	1	
		>=1000 copies/ml	2	
month_6_vl_cat	Viral load after 6 months of HIV treatment			long
		<1000 copies/ml	1	
		>=1000 copies/ml	2	
ipt_out_cat		Open ended		Numeric
IPT_complete	IPT completion Status			Numeric
		IPT Incomplete	0	
		IPT Complete	1	
diag_cat		Open ended		Numeric
TB_diagnosis	TB Diagnosis			Numeric
		TB Negative	0	
		TB Positive	1	
treatment_outcomes_cat		Open ended		Numeric
TB_treatment_completion	Completion of TB treatment			Numeric

		Incomplete TB treatment	0	
		Cured	1	
		Complete TB treatment	2	
time_since_HIV_diagnosis	Time since HIV diagnosis (months)	Open ended		Numeric
mode_investigation_category	The mode of TB investigation			long
		g_xpert	1	
		g_xpert other	2	
		g_xpert s_micro	3	
		g_xpert s_micro x_ray	4	
		g_xpert x_ray	5	
		other	6	
		other x_ray	7	
		s_micro	8	
		s_micro g_xpert	9	
		s_micro other	10	
		s_micro x_ray	11	
		x_ray	12	
		x_ray g_xpert	13	
		x_ray s_micro	14	
screened	Was the patient screened for TB?	Open ended		String

## 1C ACF Data Dictionary

Variable Name	Variable Label	Answer Label	Answer Code	Variable Type
mfl	mfl	Open ended		Integer
subcounty	Sub County	Open ended		String
facility_name	facility name	Open ended		String
facility_level	MOH facility level	Open ended		String
date_of_birth	D.O.B	Open ended		Integer
age	Age of the patient in years at start of ART	Open ended		Numeric
gender	Gender	Open ended		String
art_start_date	ART start date	Open ended		Integer
current_regimen	Current ART Regimen	Open ended		String
regimen_line	ART Regimen Line	Open ended		String
current_regimen_date	current_regimen_date	Open ended		String

initial_regimen	Initial ART Regimen	Open ended		String
who_stage_enrollment	WHO Stage	Open ended		String
ipt_start_date	IPT start date	Open ended		Integer
ipt_outcome_date	IPT outcome date	Open ended		Integer
ipt_outcome	IPT outcome	Open ended		String
weight	Patient weight	Open ended		String
height	Patient height	Open ended		String
ipt_viral_load	Viral load at IPT initiation	Open ended		String
ipt_regimen	ART regimen at IPT initiation	Open ended		String
tb_screened	Screened for TB	Open ended		String
presumptive	Screened clients with presumptive TB	Open ended		String
screening_date	Date Screened for presumptive TB	Open ended		Integer
presumptive_test	TB diagnosis test done	Open ended		String
diagnosed_tb	TB diagnosis results	Open ended		String
date_diagnosed_tb	Date diagnosed with TB	Open ended		String
viral_load_date	Date of current Viral Load	Open ended		String
ab	viral_load_date	Open ended		String
viral_load_results	Current Viral Load results	Open ended		Integer
type_of_tb	Type of TB	Open ended		String
date_treatment_started	Date TB treatment started	Open ended		Integer
treatment_outcome	TB treatment outcomes	Open ended		String
treatment_outcome_date	TB treatment outcomes date	Open ended		Integer
sub_county		Open ended		Numeric
evaluation_period	Period: Baseline(Oct 2016-Sep 2018)/ Endline(Oct 2018–Mar 2021)			Numeric
		Baseline(Oct 2016- Sep 2018)	0	
		Endline(Oct 2018– Mar 2021)	1	
agecat	RECODE of age (Age of the patient in years at start of ART)			Numeric
		0-9	1	
		10-14	2	
		15-19	3	
		20-24	4	
		>25	5	
age_cat_other	NTLD Age Category			Numeric
		0-9yrs	1	
		10-14	2	
		15-19	3	

		20-24	4	
		25-34	5	
		35-44	6	
		45-54	7	
		55-64	8	
		65+	9	
age_adult	Age (Child/Adult)			Numeric
		Child	1	
		Adult	2	
sex	gender			Numeric
		Male I	1	
		Female	2	
weight	weight			Numeric
height	height			Numeric
BMI		Open ended		Numeric
BMI_ad	BMI status			Numeric
		underweight	1	
		normal	2	
		overweight	3	
		obesity	5	
who_cat	WHO stage at TB diagnosis			Numeric
		Stage I	1	
		Stage II	2	
		Stage III	3	
		Stage IV	4	
ipt_out_categ		Open ended		Numeric
IPT_complete	IPT completion Status			Numeric
		IPT Incomplete	0	
		IPT Complete	1	
diag_categ		Open ended		Numeric
TB_diagnosis	TB Diagnosis			Numeric
		TB Positive	0	
		TB Negative	1	
tb_out		Open ended		Numeric
TB_treatment_completion	Completion of TB treatment			Numeric
		Incomplete TB treatment	0	
		Cured	1	
		Complete TB treatment	2	

timeon_ARTb4IPT	Time on ART before IPT	Open ended		Numeric
timeon_ARTb4IPT_cat	Time on ART before IPT initiation			Numeric
		0-6 months	1	
		7-12 months	2	
		>12 months	3	
timeon_ARTb4TBtreat	Time on ART before TB treatment	Open ended		Numeric
facility_name_cat	facility name	List		long
TB_treatment_completion_status	TB treatment completion status			Numeric
		Incomplete TB treatment	0	
		Complete TB treatment	1	
facility_level_cat	MOH facility level			long
		Level 2	1	
		Level 3	2	
		Level 4	3	
sub_county_cat	Sub County			long
		Alego usonga	1	
		Bondo	2	
		Gem Wagai	3	
		Gem Yala	4	
		Rarieda	5	
		Ugenya	6	
		Ugunja	7	
type_of_tb_cat	Type of TB			long
		Extra Pulmonary	1	
		Pulmonary	2	
timeon_ARTb4TBtreat_cat	Time on ART before TB treatment			Numeric
		0-6 months	1	
		7-12 months	2	
		>12 months	3	
Regimen_Line_Cat	ART Regimen			Numeric
		First line	1	
		Second/Third line/Other	2	
who_cat_tb	WHO stage at TB diagnosis			Numeric
		Stage I	1	
		Stage II	2	

		Stage III	3	
		Stage IV	4	
		Missing	5	
ipt_viral_load_clean		Open ended		double
viral_load_tpt_categ_1000	Viral suppression at IPT initiation [<1000 copies/ml]			double
		>=1000 copies/ml	0	
		<1000 copies/ml	1	
		Missing	2	
viral_load_tpt_categ_400	Viral suppression at IPT initiation [<400 copies/ml]			double
		>=400 copies/ml	0	
		<400 copies/ml	1	
		Missing	2	
sex_categ	Sex			Numeric
		Female	0	
		Male	1	
BMI_categ	BMI category			Numeric
		underweight	1	
		normal	2	
		overweight	3	
		obesity	5	
		Missing	6	
who_stage_enrollment_IPT	WHO stage IPT enrollment			long
		WHO Stage1	1	
		WHO Stage2	2	
		WHO Stage3	3	
		WHO Stage4	4	
		Missing	5	
TB_diagnosis_new	TB Diagnosis			Numeric
		TB Negative	0	
		TB Positive	1	
IPT_complete_new	IPT Completion status			Numeric
		IPT Incomplete	0	
		IPT Complete	1	
		Missing	2	

## 1D List of facilities (n=29) included in ACF sampled dataset

akala health centre
ambira sub district hospital
benga bi dispensary
bondo district hospital
future life dispensary
got agulu sub district hospital
got osimbo dispensary
got regea dispensary
jera dispensary
kabura dispensary
kapiyo dispensary
mabinju dispensary
malanga health centre
maliera mission dispensary
manyuanda health centre rarieda
matangwe community health centre
matibabu ukwala clinic
mulaha dispensary
nyagoko dispensary
ogero dispensary
ong ielo health centre
siaya district hospital
sifuyo dispensary
sikalame dispensary
simenya dispensary
uluthe dispensary
umer dispensary
wagoro dispensary rarieda
yala sub district hospital

### 1E List of facilities (n=103) included in ICF census dataset

Abidha Health Centre
Akala Health Centre
Ambira Sub-District Hospital
Asayi Dispensary
Bar Achuth Dispensary
Bar Agulu Dispensary
Bar Aluru Dispensary (Rarieda)

Bar Ndege Dispensary
Bar Olengo Dispensary
Bar-Sauri Dispensary
Barding Dispensary
Bondo District Hospital
Dienya Health Centre
Dolphil Nursing & Maternity Home
Future Life Dispensary
Gobei Health Centre
Gongo Health Centre
Got Agulu Sub-District Hospital
Got Matar Dispensary
Got Regea Dispensary
Hawinga Health Centre
Inuka Hospital & Maternity Home
Jera Dispensary
Kabura Dispensary
Kagwa Health Centre
Kambajo Dispensary
Kambare Dispensary
Kapiyo Dispensary
Kogelo Dispensary
Lidha Dispensary
Lieta Health Centre (Rarieda)
Ligala Dispensary
Ligega Health Centre
Lihanda Health Centre
Mageta Dispensary
Mahaya Health Centre (Rarieda)
Malanga Health Centre
Maliera Mission Dispensary
Marenyo Health Centre
Masala Dispensary
Masogo Dispensary (Gem)
Masumbi Dispensary
Matangwe Community Health Centre
Matibabu Ukwala Clinic
Mawere Dispensary
Midhine Dispensary
Misori Dispensary
Mulaha Dispensary

Mwer Dispensary
Ndeda Dispensary
Ndere Health Centre
Ndori Health Centre
Nyagoko Dispensary
Nyaguda Dispensary
Nyangu Dispensary
Nyawara Health Centre
Nyenye Misoro Dispensary
Odede Community Health Center
Oding Dispensary
Ogam Dispensary
Ogero Dispensary
Ong'ielo Health Centre
Ouya Dispensary
Oyamo Dispensary
Pap Kodero Health Centre
Rabar Dispensary
Rageng'ni Dispensary
Rambugu Dispensary (Rarieda)
Rambula Dispensary
Ramula Health Centre
Rera Dispensary
Rwambwa Health Centre
Sagam Community Hospital
Saradidi Dispensary
Sega Dispensary
Serawongo Dispensary
Siala Kaduol
Siaya District Hospital
Sifuyo Dispensary
Sigomere Health Centre
Sikalame Dispensary
Simenya Dispensary
Sirembe Dispensary
St Joseph's Obaga Dispensary
St Mary's Yala Dispensary
Sumba Community Dispensary
Ting'wangi Health Centre
Tingare Dispensary
Uhembo Dispensary

Uhuyi Dispensary
Ukwala Health Centre
Ulungo Dispensary
Uluthe Dispensary
Umer Dispensary
Urenga Dispensary
Uriri Dispensary
Usenge Dispensary
Usigu Dispensary
Uyawi Dispensary
Wagai Dispensary
Wagoro Dispensary (Rarieda)
Yala Sub-District Hospital
ya Health Centre