Improving TB and HIV care in South Africa

Evaluation of a combined TB/HIV training and mentoring approach for nurses in Francis Baard District, Inxuba Yethemba Sub-District, and O.R. Tambo Sub-District

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ABBREVIATIONS

ABC	Abacavir
AFB	Acid-fast bacilli
AIDS	Acquired immunodeficiency syndrome
ALT	Alanine aminotransferase
ANC	Antenatal Care
ART	Antiretroviral treatment/therapy
AZT	Zidovudine (also known as ZDV)
CDC	Centres for Disease Control and Prevention
CHC	Community Health Centre
CPT	Cotrimoxazole preventive therapy
CTX	Cotrimoxazole
DNA	Deoxyribonucleic acid
DOH	Department of Health
DOTS	Directly observed treatment, short-course
DST	Drug sensitive testing
EFV	Efavirenz
FBC	Full blood count
HAART	Highly active antiretroviral therapy
HBC	Home-based care
HCW	Health care worker
HIV	Human immunodeficiency virus
INH	Isoniazid
IPC	Infection prevention and control
INH	Isoniazid
IPT	Isoniazid preventive treatment
M&E	Monitoring and Evaluation
MDR-TB	Multidrug-resistant tuberculosis
NDOH	National Department of Health
NGO	Non-governmental organisation(s)
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NSP	National Strategic Plan
NVP	Nevirapine
OIs	Opportunistic infections
OPD	Outpatient department
PCR	Polymerase chain reaction
PHCs	Primary health care centres
PICT	Provider-initiated testing and counselling
PLHIV	Person/people living with HIV and AIDS
PMTCT	Prevention of mother-to-child transmission of HIV
SANAC	South African National AIDS Council
TB	Tuberculosis
UW	University of Washington
VL	Viral Load
WHO	World Health Organisation
XDR	Extremely drug resistant

EXECUTIVE SUMMARY

Introduction
The Republic of South Africa has dual epidemics of HIV and Tuberculosis (TB). In 2012, South Africa had an estimated 6.43 million people living with HIV. In 2013, it had an estimated 530,000 incident cases of TB and an estimated 62% were among persons living with HIV. It also had 26,023 cases of rifampicin- or multidrug-resistant TB, and 612 cases of extremely drug-resistant TB.

South Africa adopted a public health approach to TB and HIV care with access at primary health care facilities, nurse-initiated and managed antiretroviral therapy (NIMART), and integration of TB and HIV care. A five-day "TB and HIV Care and Management Course for Health Care Workers" was combined with on-site mentoring for nurses who had previously been trained to initiate and manage antiretroviral therapy (ART). An evaluation with a pre/post design was conducted in three districts in South Africa to assess the effects of the course on clinical patient monitoring and integration of TB and HIV care.

Methods
Two cross-sectional, unmatched samples of patient charts at 76 primary health care facilities were collected retrospectively in 2014 for patients initiating ART in 2011-12 (pre-training) and 2013 (post-training) on two HIV measures: viral load monitoring at six months following ART initiation; and creatinine clearance (CrCl) monitoring to assess for risk of renal toxicity three months following ART initiation on regimens with tenofovir. Similarly, two samples from patient registers were collected for patients initiating TB treatment to measure sputum monitoring at the end of the intensive phase of TB treatment, and initiation of ART among TB patients co-infected with HIV. Data was also collected on additional elements related to quality HIV care, TB screening and management, and integration of HIV and TB care. We conducted a chi-square test of the difference in the proportion of patients with appropriate care pre- and post-training, adjusting for clustering at the facility level.

Results
HIV File Results Data were analyzed from 1,074 pre-training and 1,048 post-training records of patients who initiated ART. Pre-training, 2.8% (N=30) of patients were on once-daily efavirenz, emtricitabine, and tenofovir, compared to 63.7% (N=666) post-training. Viral load documentation rates were 37.0% pre-training and 35.6% post-training (p=0.678). The median viral load decreased, however, from 75 copies/ml pre-training to less than 50 copies/ml post-training (p=0.003).

The documentation rate of CrCl monitoring prior to ART initiation was 69% pre-training and 73.3% post-training (p=0.130). At three months following initiation, (CrCl) test documentation was 10.6% pre-training and 10% post-training (p<0.758), and at six months following initiation, it was 17.6% pre-training and 22.6% post-training (=0.089).

Documentation of TB symptom screening increased from 71.8% pre-training to 81.3% post-training (p=0.003). Documentation of screening for IPT eligibility increased from 41.2% pre-training to 63.1% post-training (p<0.001), and documentation of IPT initiation increased from 32.8% pre-training to 41.0% post-training (p=0.004). Documentation of TB treatment initiation among people with a positive TB test was 75.5% pre-training compared to 78.3% post-training (p=0.719).

TB File Results Data were also analyzed from 1,063 pre-training and 1,008 post-training records of patients who initiated TB treatment. At the end of the intensive phase of TB treatment, documentation of TB test was 70.4% pre-training and 71.1% post-training (p=0.811). At initiation of TB treatment, the percentage of tests performed with GeneXpert increased from 27.3% pre-training to 67.7% post-training (p<0.001) and documentation of TB test increased from 85.7% pre-training to 90.0% post-training (p=0.011).

Documentation of an HIV test among those with TB not known to be HIV positive was 77.7% pre-training and 80.2% post-training (p = 0.396). Documentation of ART initiation among TB patients co-infected with HIV was 65.9% pre-training and 66.5% post-training (p=0.878).

Conclusion
Although none of the four primary measures increased post-training, the evaluation documented many other improvements in TB and HIV

care. These areas may have been supported by the course, which occurred at the same time as other efforts to improve care. Among patients with HIV who had an available viral load test result within four to eight months of initiating ART, the median viral load was statistically significantly lower post-training. Documentation of creatinine clearance increased at initiation of ART and within five to eight months of initiation. The increase in documentation of TB tests at initiation of TB treatment was statistically signicant. Increases in screening for TB and IPT and initiation of IPT among patients who initiated ART were also statistically significant.

INTRODUCTION

The Republic of South Africa has dual epidemics of HIV and Tuberculosis (TB). In 2012, South Africa had an estimated 6.43 million people living with HIV, which was more than any other country, and a prevalence of 29.5% among pregnant women aged 15-49 attending antenatal clinics.[i ii iii] Birnbaum, et al. estimated that HIV accounted for 48% of deaths in South Africa in 2006.[iv] In 2013, South Africa also had an estimated 530,000 (430,000-630,000) incident cases of TB, representing 1,003 (827-1,194) cases per 100,000 persons. An estimated 330,000 (270,000-390,000; 62%) of these cases were among persons living with HIV, indicating a significant link between HIV and TB.[iii] It also had 26,023 cases of rifampicin- or multi-drug resistant TB, and 612 cases of extremely drug-resistant TB, and was ranked second among all countries in both categories.[v]

However, these sobering statistics are accompanied by recent progress in policies and access to treatment.[vi vii] For example, the government is guided by the HIV/AIDS, Sexually Transmitted Infection (STI) and TB National Strategic Plan for South Africa 2012-2016.[viii] In mid-2013, fixed-dose combination (FDC) pills, composed of efavirenz, tenofovir, and emtricitabine were rolled out as first-line therapy across South Africa. By mid-2014, an estimated 2.6 million persons were on antiretroviral therapy (ART).[ix] As of January 2015, all pregnant women and persons with a CD4 count of ≤ 500 cells/mm^3 are eligible for lifelong ART. And, the 2012-2016 National Strategic Plan called for integration of HIV and TB treatment.[viii]

South Africa has adopted a public health approach to TB and HIV care, with access at primary care facilities, task shifting of HIV management from doctors to nurses, and additional services provided by community health workers and district outreach teams. Capacity building is key to support nurses and other health professionals as they take on new responsibilities. As a response, training programs were developed for Nurse Initiated Management of ART (NIMART).[x xi] One of these trainings, developed by researchers at the University of Cape Town, was an algorithmic and educational outreach intervention called the Practical Approach to Lung Health in South Africa (PALSA),[xii] and PALSA PLUS, which sought to integrate lung health, TB, HIV, and ART care.[xiii] The Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) trial combined PALSA PLUS with organizational support to address the organizational and health system issues associated with task shifting.[xiv xv xvi] PALSA PLUS has been updated to include multiple other non-communicable diseases, such as diabetes and cardiovascular diseases, as primary care (PC) 101.

To further support nurses in the roll-out of NIMART, a mentoring guideline was developed by the National Department of Health specific to HIV, TB, and HIV/TB Co-Infection competencies.[xvii] Following training, nurses were expected to be mentored through a specified number of patient cases in order to achieve competency in the newly-learned skill and receive authorization from the Nursing and Pharmacy Councils to prescribe ART.

In this context, the National Department of Health (DOH) worked with implementing partners to develop an advanced TB and HIV training model for nurses that would support integrated management of HIV and TB through the development of clinical reasoning skills, and putting knowledge into practice. A five-day "TB and HIV Care and Management Course for Health Care Workers" training was combined with on-site mentoring to support primarily nurses who had been previously trained to initiate and manage patients on ART. The partners conducted an evaluation with a pre/post design to tests the effects of the course on monitoring patients and integration of TB and HIV care.

METHODS

Evaluation Design

The evaluation had a pre/post design with patients clustered within primary health care facilities as the unit of analysis. The four primary questions addressed in the evaluation were:

- Did the percentage of newly-initiated patients on ART who had a viral load test within six months of initiation increase after training?
- Did the percentage of newly-initiated patients on an ART regimen with tenofovir (TDF) who had a creatinine clearance test (CrCl) within three months of initiation increase after training?
- Did the percentage of newly-identified TB patients with a TB test at the end of the intensive phase of TB treatment increase after training, where TB test is defined as a sputum sample for acid-fast bacilli or GeneXpert® MTB/RIF (GXP) test based on a sputum specimen?
- Did the percentage of newly-identified TB patients co-infected with HIV who started ART increase after training, where ART treatment was documented in the ART register?

Facilities

The partners were asked to conduct the training and on-site mentoring program in Frances Baard district of the Northern Cape Province and two districts in the Eastern Cape: OR Tambo and Chris Hani. Table 1 reports population data from the 2011 census[xviii] and selected HIV and TB indicators from the District Health Barometer[xix] on each of the provinces and districts. Each district differs from the national statistics but all data are consistent with high prevalence of HIV, TB, and drug-resistant TB.

In each district, the health management team selected two health sub-districts that would be the primary and secondary intervention sites. The evaluation was conducted only at the primary intervention sites where the training was conducted first because they completed the training within the time frame of the evaluation. The management team in Frances Baard (FB) decided to include all 34 facilities in the district. The management team in OR Tambo selected Qaukeni and in Chris Hani, the management team selected Inxuba Yethemba (IY) as their primary sites. For facilities, an additional inclusion criterion for the analysis of HIV measures was that three or more patients initiated ART in each time period (pre/post) of the evaluation. An additional inclusion criterion for the analysis of TB measures was that three or more patients initiated TB treatment in each time period.

Table 1. Comparison of the provinces and districts where the evaluation was conducted to national statistics on population,[xviii] HIV and TB[xix]

	South Africa	Northern Cape	Frances Baard	Eastern Cape	Chris Hani	OR Tambo
Population 2011 Census	51,770,560	1,145,861	382,086	6,562,052	795,461	1,364,943
% 2011 SA Population (%)			0.74		1.54	2.64
HIV prevalence among women at ANC clinics 2012 (%)	29.5	17.8	23	29.1	29	30.1
Incidence of TB cases per 100,000 population in 2013	621	728	692	782	789	828
Smear conversion rate at 2 months (new pulmonary smear-positive cases) 2013 (%)	60.9	71.1	85.4	51.7	54.9	52.8
TB Rifampicin resistance confirmed client rate 2013/14 (%)	6.6	5.5	5.0	6.2	4.8	5.6
% of TB cases with known HIV status (ETR.Net) 2013 (%)	90.0	77.5	76.1	88.5	93.2	88.7
TB/HIV co-infected client on ART (ETR.Net) 2013 (%)	66.2	68.9	68.3	84.0	85.9	88.0

Participants

Trainees

The participants in the advanced TB and HIV course were professional nurses or doctors who were currently managing patients with HIV, TB, and/or drug-resistant TB in clinical practice. Many of the participants had previous training in NIMART, the World Health Organization's Integrated Management of Childhood Illness training program, and/or foundational training in HIV or TB.

Patients

Anonymous patient data were collected for all people diagnosed with HIV who started ART during the evaluation time periods (see below), and whose recorded age was 15 or more years. Patients were excluded if their ART start data was not recorded. Anonymous patient data were also collected on all people diagnosed with TB who started TB treatment during the evaluation time periods and whose recorded age was eight or more years and whose weight qualified for the adult TB treatment guidelines. Patients were excluded if their TB treatment start data was not recorded.

Intervention

Training and mentoring interventions were designed and implemented in a collaborative process with five phases described below.

Phase 1: Consultation with key stakeholders

Prior to field work, stakeholder meetings were held in each district or subdistrict, which included DOH leadership, non-governmental organizations, and others invited by DOH. The stakeholders identified priority areas for programming and government officials to accompany the data collection teams, and contacted facilities in advance the baseline assessment.

Phase 2: Baseline assessments

Baseline assessments with multiple components were conducted in a staggered manner in January through April of 2013. Facility assessments designed to characterize the service delivery context and identify systemic issues were conducted. Data management systems and quality of care issues at the facilities related to HIV/AIDS and TB prevention, care, and treatment were assessed using data from four sources: patient charts, registers, facility manager interviews, and a clinical skills audit. The patient charts, and HIV Counseling and Testing, pre-ART, ART, Antenatal Care, TB admissions, and TB-suspect registers were reviewed to follow patients accessing services in each area at clinics. The skills audit was a self-assessment of TB and HIV competencies completed by nurses using a national tool. The assessment results were shared with each district/sub-district, and quality improvement plans were developed to target the areas in which gaps were detected.

Phase 3: Design of training materials

A task team was assembled with key national stakeholders to develop a standardized training program in 2011. The five-day "TB and HIV Care and Management Course for Health Care Workers" was designed to strengthen diagnosis, care, treatment, and monitoring of patients infected with HIV/AIDS and TB, including drug-resistant TB care in primary health care facilities. The training materials included numerous clinical resources to support the health care worker in the clinic setting, such as the Clinical Resource Guide with the most recent guidelines for care of HIV, TB, and sexually transmitted infections, as well as opportunistic infections and medication side effects. The training program was piloted in three provinces in 2012. Subsequently, the task team reconvened to revise and update the training materials in 2013-2014. They were most recently updated to reflect the 2015 ART guidelines in January 2015.

The curriculum is case-based and has 11 sessions, as listed in Table 2. Ten teaching and learning methods were used: lecture, case studies, role plays, large- and small-group work and discussions, individual work, demonstration and practice, and simulated patients. For group work, we carefully combined participants who had TB or HIV experience with participants who had less experience so they could learn from each other. The simulated patient sessions, also referred to as Observed Structured Clinical Examinations, followed Integrated Management of Adult and Adolescent Illness examples, providing an opportunity for complex patient management learning.

Table 2: Topics of the "TB and HIV Care and Management Course for Health Care Workers"

Session	Topic
1	Introduction and TB and HIV Review
2	Diagnosis of HIV in Adults and Children
3	Diagnosis and Management of Other Opportunistic Infections
4	Antiretroviral Therapy for the Treatment of HIV Infection
5	Diagnosis of TB and Drug Resistant TB in Adults and Children
6	Management and Treatment of Pulmonary and Extra-Pulmonary TB
7	Drug Resistance and Multidrug-Resistant TB
8	Management of TB in an HIV-Infected Person and Adherence
9	Infection Control and Prevention
10	Community-Based Care and Patient Education
11	Putting it all together

The training sessions were adapted to each district/sub-district to address specific gaps that were identified during the baseline assessment. For example, because challenges with physical examination skills were identified in the OR Tambo district, male and female physical examination videos were added to their training.

Phase 4: Training and on-site mentoring.
The course was taught two to eight times in consecutive weeks in each district/sub-district, and we worked with the district/sub-district management team and Regional Training Centres to schedule training for health professionals during those weeks. Training was provided in a staggered manner to each district/sub-district between February and September 2013. The facility managers and mentors from the District Support Partners were encouraged to attend the first week of training so they were also capacitated and familiar with the content in order to mentor accordingly.

Mentoring is an integral activity to the objectives of South Africa's National Strategic Plan.[xx] One method of on-site mentoring is side-by-side coaching of nurses during patient encounters to build both clinical competence and confidence in a supportive manner. Other mentoring methods are case consultations, distance mentoring (such as calling a mentor with a specific question), and thorough chart reviews and discussion.

In collaboration with the District Support Partner in each of the districts, mentoring was provided after the training sessions, continuously between March 2013 and May 2014. The three goals were to:

1. Ensure transfer of knowledge from training into clinical practice

2. Assist facilities in developing continuous quality improvement plans
3. Support development and implementation of facility infection control plans

Mentoring was also aligned to National, Provincial, and (sub) District health goals, such as the roll out of FDC or the elimination of Streptomycin for TB treatment.

Phase 5: Follow-Up Assessments.
A pre/post evaluation was conducted following training and mentoring to assess for areas of improvement following the intervention. Data for both pre- and post-training time periods was collected simultaneously using a revised tool. The assessments were conducted February and May 2014.

Phase 6: Report back and follow-up consultation with key stakeholders.
Following field work and result analysis, stakeholder meetings were once again held in each district or sub-district between September and December 2014 to provide results and discuss continued areas for intervention and the opportunity for strategizing on quality improvement measures moving forward.

Evaluation Measures

The selection of measures was based on key clinical areas covered in the TB/HIV course curriculum and availability of data. The training and on-site mentoring focused on new guidelines, advances in HIV and TB practice, and integration of TB and HIV care. The measures focused on monitoring of patients and integration of TB and HIV care. We also collected data on implementation of new guidelines and advances in practice, which are reported as descriptive statistics and results.

For three of the measures, we used the South African Guideline-defined time periods for clinical monitoring. For these testing time periods, we defined a date range (i.e., two to four months) to account for patients who may not have accessed care at the exact interval. Creating the measures relied on an accurate date of initiation of treatment, as noted in the exclusion criteria. Each measure (range of dates) is listed below.

- Percentage of newly-initiated patients on ART who had a viral load test within six (four to eight) months of initiation.
- Percentage of newly-initiated patients on an ART regimen with tenofovir (TDF) who had a creatinine clearance test within three (two to four) months of initiation.
- Percentage of newly identified TB patients with a TB test two (one to four) months after initiating TB treatment with Rifampicin, Isoniazid, Pyrazinamide, Ethambutol (regimen 1), or three (one to four) months after initiating TB treatment with the four drugs listed above plus Streptomycin (regimen 2).
- Percentage of newly-identified TB patients co-infected with HIV who started on ART where ART treatment is documented in the ART register.

The three testing measures refer to documentation of test rather than result. Test results were missing for 2.1% of viral load tests and 1.9% of TB tests. We did not collect CrCl test results. These data were collected from the lab slips, and a test result would only be missing if the specimen was bad, which should be comparable to the percentage missing for viral load tests.

Although initiation of children and pregnant women on ART according to new national DOH guidelines were an important part of the courses, measures for them were not included in the evaluation. The number of children initiated on ART in each facility was too small to analyze. The change in guidelines for pregnant women during the course of the TB/HIV training program made it difficult to evaluate the effect of the training with a pre/post design because the national DOH supported several efforts to implement the new guidelines.

Time periods

The time periods were selected pre- and post-training and varied across districts/subdistricts as their training schedules varied. Mentoring was ongoing at some facilities during the post-training time period. For the pre-training data, we selected patients on ART whose six-month viral load test should have occurred before the TB/HIV course, which meant that they initiated ART at least six to eight months before the TB/HIV course. Similarly, we selected patients on TB treatment who initiated

treatment at least three to four months before the TB/HIV course. Table 3 shows the intervention dates, time period when patient monitoring should have occurred, and a five-month time period identified for selecting each sample of patients in each district/subdistrict. For some facilities, it was necessary to select the pre-training sample over a period longer than five months. The actual time periods (percentage pre-training who were from the five identified months) are summarized below:

ART Initiation Date Ranges for HIV Files

Pre-Training	
Frances Baard	April 2011 to May 2012 +/- 3 days (87%)
IY	September 2011 to August 2012 +/- 3 days (78%)
Qaukeni	July 2011 to September 2012 +/- 3 days (85%)
Post-Training	
Frances Baard	January 2013 to May 2013 +/- 3 days
IY	January 2013 to May 2013 +/- 3 days
Qaukeni	February 2013 to June 2013 +/- 3 days

TB Initiation Date Ranges for TB Files

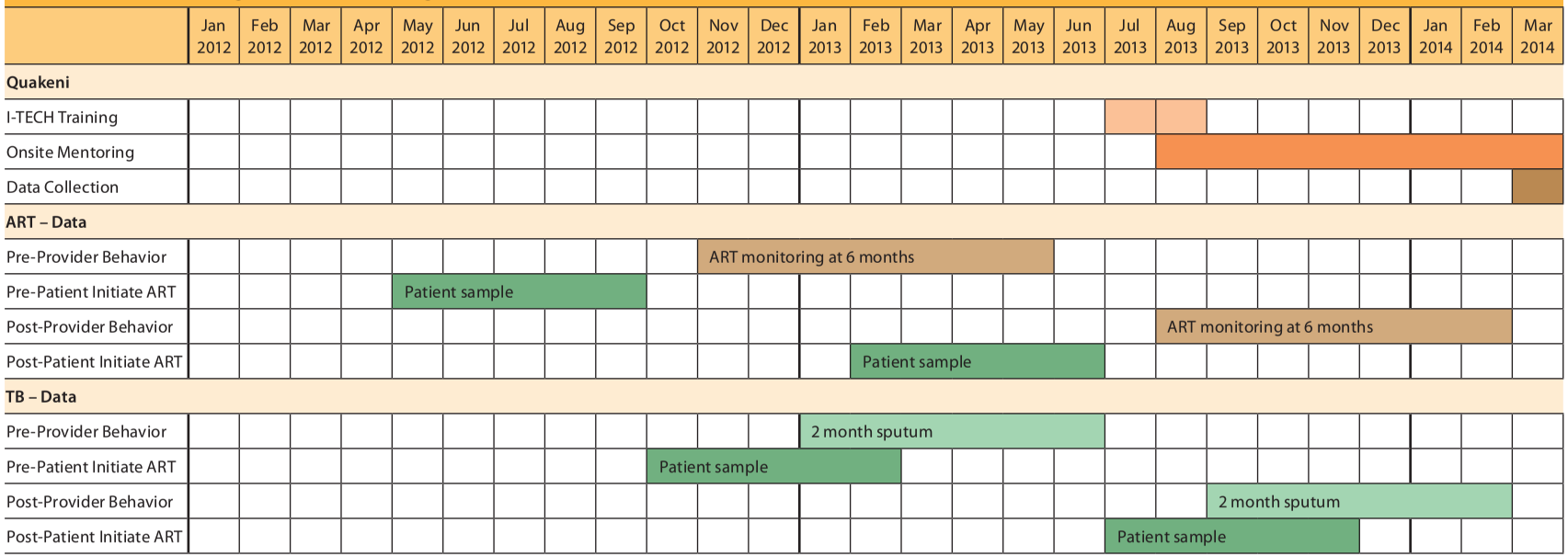
Pre-Training	
Frances Baard	August 2011 to October 2012 +/- 3 days (76%)
IY	December 2011 to January 2013 +/- 3 days (69%)
Qaukeni	January 2012 to February 2013 +/- 3 days (82%)
Post-Training	
Frances Baard	June 2013 to October 2013 +/- 3 days
IY	June 2013 to October 2013 +/- 3 days
Qaukeni	July 2013 to November 2013 +/- 3 day

Table 3. Time periods for selecting patient's files

Data Collection: Sampling Patients and Tracking Provider Behavior

	Jan 2012	Feb 2012	Mar 2012	Apr 2012	May 2012	Jun 2012	Jul 2012	Aug 2012	Sep 2012	Oct 2012	Nov 2012	Dec 2012	Jan 2013	Feb 2013	Mar 2013	Apr 2013	May 2013	Jun 2013	Jul 2013	Aug 2013	Sep 2013	Oct 2013	Nov 2013	Dec 2013	Jan 2014	Feb 2014	Mar 2014
Francis Baard																											
I-TECH Training																											
Onsite Mentoring																											
Data Collection																											
ART – Data																											
Pre-Provider Behavior							ART monitoring at 6 months																				
Pre-Patient Initiate ART	Patient sample																										
Post-Provider Behavior																		ART monitoring at 6 months									
Post-Patient Initiate ART													Patient sample														
TB – Data																											
Pre-Provider Behavior								2 month sputum																			
Pre-Patient Initiate ART						Patient sample																					
Post-Provider Behavior																			2 month sputum								
Post-Patient Initiate ART																	Patient sample										
IY																											
I-TECH Training																											
Onsite Mentoring																											
Data Collection																											
ART – Data																											
Pre-Provider Behavior										ART monitoring at 6 months																	
Pre-Patient Initiate ART				Patient sample																							
Post-Provider Behavior																			ART monitoring at 6 months								
Post-Patient Initiate ART														Patient sample													
TB – Data																											
Pre-Provider Behavior											2 month sputum																
Pre-Patient Initiate ART									Patient sample																		
Post-Provider Behavior																			2 month sputum								
Post-Patient Initiate ART																	Patient sample										

Data Collection: Sampling Patients and Tracking Provider Behavior (continued)



Sample Size Calculations

Patients clustered within facilities were the unit of analysis. The sample size calculations focused on the number of patients per facility, because the number of facilities within each district/subdistrict was fixed. For ART patient records, we used as a baseline value the percentage of patients with a documented viral load test six or 12 month after initiating ART from the baseline assessment, which was 57.2%. The coefficient of variation—which was 0.7—was calcuated with data from the baseline assessment conducted in Emalahleni subdistrict in Chris Hani district. We assumed a 10% loss of clusters across time periods, unequal cluster sizes,[xxi] and an intraclass correlation coefficient equal to 0.2. As shown in Table 4, 1136 patients from 71 facilities and an average of 16 patients per facility had an 80% power to detect a 15% absolute increase in the number of patients with a six-month viral load test.

Table 4. Sample size calculations for viral load monitoring six months after ART initiation

Parameters		
p1	0.57	Baseline percentage of patients on ART with six or 12 month viral load
Zα	1.96	Two-tailed 5% type I error
Zβ	0.84	80% power
Zβ	1.28	90% power
K	71	Number of clusters
M	16	Mean number of individuals per cluster
Cv	0.7	Coefficient of variation (from IY data)
Lfu	0.1	10% loss to follow up (entire clusters)

Pilot Data				
Province	**K**	**N**	**Received Viral Load**	**P**
IY	21	84	33	39.3%
FB	31	55	47	85.5%
Qaukeni	19	27	15	55.6%
Total	71	166	95	57.2%

Cluster randomization under unequal cluster sizes - number of clusters needed						
	Percent increase					
ICC	0.05	0.1	0.125	0.15	0.175	0.2
0.05	202	**50**	32	22	16	12
0.1	310	76	48	33	24	18
0.15	418	102	**65**	45	32	24
0.2	526	129	81	56	40	31
0.25	633	155	98	**67**	49	37
0.3	741	181	115	79	**57**	43
0.4	956	**234**	148	101	73	**55**

KEY

Too many clusters required

Sufficient number of clusters required

What we can detect assuming an interclass correlation coefficient (ICC) of 0.2

For TB chart reviews, we used the percentage of patients with a documented TB test two to three months after initiating TB treatment from the baseline assessment, which was 65.6%, as the baseline value. The coefficient of variation from the same source was 0.86, and the assumptions were the same as above. As shown in Table 5, 1168 patients from 73 facilities and an average of 16 patients per facility had an 80% power to detect a 15% absolute increase in the number of patients with a TB test at the end of the intensive phase of treatment.

The baseline assessment also provided information on the volume of patients at each facility. For patients who initiated ART, it seemed possible to collect data on 16 or more patients at each facility over a two-month period. For patients who initiated TB treatment, it did not seem possible to collect data on 16 patients at every facility over a six-month period, hence the potential for uneven cluster size.

Table 5. Sample size calculations for TB test at end of intensive phase of TB treatment

Parameters		
p1	0.656	Baseline percent new TB cases receiving two- to three-month TB test
Zα	1.96	Two-tailed 5% type I error
Zβ	0.84	80% power
Zβ	1.28	90% power
K	73	Number of clusters
M	16	Mean number of individuals per cluster
Cv	0.86	Coefficient of variation (from IY data)
Lfu	0.1	10% loss to follow up (entire clusters)

Pilot Data				
Province	**K**	**N**	**Received TB Test**	**P**
IY	25	62	43	69.4%
FB	31	65	47	72.3%
Qaukeni	17	181	100	55.2%
Total	73	308	190	65.6%

Cluster randomization under unequal cluster sizes - number of clusters needed						
	Percent increase					
ICC	0.05	0.1	0.125	0.15	0.175	0.2
0.05	223	**54**	34	24	17	13
0.1	349	84	**53**	36	26	19
0.15	476	115	72	49	35	26
0.2	603	145	90	**62**	44	33
0.25	730	175	109	74	53	39
0.3	857	205	128	87	**63**	46
0.4	1110	**266**	166	113	80	**59**

KEY

Too many clusters required

Sufficient number of clusters required

What we can detect assuming an interclass correlation coefficient (ICC) of 0.2

Data Collection

Data were simultaneously collected and entered electronically using tablets. The data collection forms were designed by utilising the Open Data Kit (Open Data Kit, 2013 Seattle, WA). Three separate forms were created to audit ART patient files, TB patient files, and facility assessments (results in Appendix B). The forms were designed with limits for the ranges of variables, required fields, and several consistency checks to improve the data accuracy. The simultaneous process gave the data collection teams an opportunity to identify errors when they had access to the data source and correct them. The forms also had appropriate skip patterns to minimize the chance of entering data in the wrong field and to reduce the data collection burden. A one-week pilot test of the data collection methods was conducted at 12 facilities in Emalahleni subdistrict in the Eastern Cape from 27-31 January 2014, and appropriate corrections and revisions were made.

Although data were initially collected at baseline in order to best tailor the training, forms were later revised, and thus, data were collected retrospectively for both data points. Data were collected by three data collection teams, each composed of at least three people, including two I-TECH study staff and one representative from the local department of health district/sub-district or the District Support Partner, who was responsible for mentoring. All team members attended a one-day training session on the data collection forms. Data collection dates in each district/sub-district are reported in Figures 1 and 2 (Appendix A). Each team planned to collect data from one facility per day on average but they collected data from some facilities in one-half day and others in two days. Documentation sometimes differed across facilities; for example, the viral load test may have been documented in the laboratory book instead of patient files. The data collection teams collected data from the most reliable source at the facility and entered the source of the data on the forms. Data were uploaded onto FormHub© (Modi Research Group, 2012/13, New York, NY) each evening.

Data Analysis

Descriptive statistics on the sample of patients who initiated ART (Tables 6 and 7) and the sample who initated TB treatment (Table 6 and 8) were analyzed to report frequencies and averages, as appropriate. We conducted a chi-square test of the difference in the proportion of patients with appropriate treatment pre- and post-training for each measure, adjusting for clustering at the facility level.

We performed logistic regression analyses to test the main effect of the time period with co-variates for district/subdistrict, patient age, and patient gender. Regression analyses were clustered on the facility with robust standard errors using the binomial family and a logit link to estimate the odds ratio (OR). When patient age and gender did not alter the main effects across time periods or were not statistically significant in the mulitvariate analysis, the variable was not included in the multivariate analyses reported below. Although district/sub-district variables were often statistically significant in the multivariate analyses, they did not alter the main effects across time periods. The results reported below include the district/subdistrict variables but not their interaction with time period. Results were presented with 95% confidence intervals (95% CI). All analyses will be performed with Stata® version 11 (Stata Corp, 2009 College Station, Texas).

Table 6. Description of the evaluation samples

	Total	Frances Baard	IY	Qaukeni
Demographic Factor	**N (%)**	**N (%)**	**N (%)**	**N (%)**
ART CHART REVIEWS				
Gender				
Female	1,455 (68.6)	474 (62.2)	494 (69.7)	487 (74.8)
Male	661 (31.2)	287 (37.7)	213 (30.0)	161 (24.7)
Not documented	6 (0.3)	1 (0.1)	2 (0.3)	3 (0.5)
Age (years)				
15 – 24	312 (14.7)	90 (11.8)	124 (17.5)	98 (15.1)
25 – 34	822 (38.7)	309 (40.6)	252 (34.5)	261 (40.1)
35 – 44	553 (26.1)	219 (28.7)	179 (25.3)	155 (23.8)
≥ 45	421 (19.8)	143 (18.8)	151 (21.3)	127 (19.5)
Unknown	14 (0.7)	1 (0.1)	3 (0.4)	10 (1.5)
Year of HIV diagnosis				
< 2011[A]	599 (28.2)	188 (24.7)	239 (33.7)	172 (26.4)
2011	246 (11.6)	94 (12.3)	95 (13.4)	57 (8.8)
2012	525 (24.7)	137 (18.0)	199 (28.1)	189 (29.0)
2013	449 (21.2)	142 (18.6)	133 (18.8)	174 (26.7)
Not documented	303 (14.3)	201 (26.4)	43 (6.1)	59 (9.1)
Total	2,122 (100.0)	762 (100.0)	709 (100.0)	651 (100.0)
TB CHART REVIEWS				
Year of HIV diagnosis				
Female	897 (43.3)	361 (42.7)	228 (40.6)	308 (46.4)
Male	1,166 (56.3)	481 (56.9)	330 (58.8)	355 (53.5)
Unknown	8 (0.4)	4 (0.5)	3 (0.5)	1 (0.2)
Age (years)				
8 – 14	34 (1.6)	8 (1.0)	11 (2.0)	15 (2.3)
15 – 24	304 (14.7)	109 (12.9)	82 (14.6)	113 (17.0)
25 – 34	598 (28.9)	282 (33.3)	143 (25.5)	173 (26.1)
35 – 44	502 (24.2)	221 (26.1)	161 (28.7)	120 (18.1)
≥ 45	552 (26.7)	215 (25.4)	161 (28.7)	176 (26.5)
Unknown	81 (3.9)	11 (1.3)	3 (0.5)	67 (10.1)
Total	2,071 (100.0)	846 (100.0)	561 (100.0)	664 (100.0)

[A] Patients were diagnosed with HIV as early as 1993.

Ethical Considerations

The evaluation protocol was approved by the Walter Sisulu University Faculty of Health Sciences, Human Research Committee, Protocol Number 050/2012. An informed consent process was not necessary for nurses because they were invited to participate in training and mentoring by the DOH as part of their normal responsibities. An informed consent process was not necessay for patients because no identifying information was collected about them. The Human Subjects Division of the University of Washington determined that the evaluation did not meet the regulatory definition of research under 45 CFR 46.102 (d).

RESULTS

Sample Description

Data on the ART monitoring measures and integration of TB/HIV care were collected from a total of 76 facilities, including 1,200 patients who initiated ART pre-training and 1,210 post-training. Observations were excluded because the patient's ART start date was outside the time period (N=130), or the ART start date was missing (N=25), or the patient was less than 15 years of age (N=5). Additionally, data were only analyzed from facilities that had at least three pre-training and three post-training records for a total of 67 (88%) facilities. In total, 1,074 (90%) pre-training observations and 1,048 (87%) post-training were analyzed. Flow diagrams for the three districts/subdistricts are presented in Figure 1 (Appendix A).

Characteristics of the sample of patients who initiated ART are reported at the top of Table 6. Sixty-eight percent were female, 15% were 15-24 years of age, 29% 25-34 years, 26% 35-44 years, and 20% 45 or more years. They were younger than the population of all people on ART in South Africa,[xxii] because they were just initiating ART. Twenty-one percent of the sample were diagnosed with HIV in 2013, 25% in 2012, 12% in 2011, and 28% in 2010 or earlier. As shown in Table 7, 3% of the patients were on a FDC regimen pre-training and 64% post-training. Eighty percent were on a regimen of tenofovir/lamivudine/efavirenz pre-training and 94% post-training.

Table 7. ART initiation and regimens before and after training

	Total	Pre-Training	Post-Training
	N (%)	N (%)	N (%)
ART regimen documented at initiation (N = 2,122)			
Yes	2,116 (99.7)	1,071 (99.7)	1,045 (99.7)
No	6 (0.3)	3 (0.3)	3 (0.3)
ART regimen at initiation (N = 2,116)			
FDC (TDF/3TC/EFV)	696 (32.9)	30 (2.8)	666 (63.7)
TDF/3TC/EFV	1,142 (54.0)	825 (77.1)	317 (30.3)
Other regimens[A]	278 (13.1)	218 (20.1)	62 (6.0)
Among those who switched ARV regimens, switched to FDC (N = 483)[B]			
Yes	420 (88.6)	299 (87.2)	121 (92.4)
No	54 (11.4)	44 (12.8)	10 (7.7)

[A] Includes TDF/3TC/NVP (N=97), D4T/3TC/EFV (N=60), AZT/3TC/EFV (N=45) & other regimens (N=76)

[B] N=9 were initiated on FDC and switched to another regimen (pre-training: n=1, post-intervention: n=8).

3TC: Lamivudine, AZT: Zidovudine, D4T: Stavudine, EFV: Efavirenz, FDC: Fixed-dose combination, NVP: Nevirapine, TDF: Tenofovir

Data on the TB treatment monitoring and integration of TB/HIV care were collected from a total of 76 facilities, including 1,132 patients who initiated TB treatment pre-training and 1,098 post-training. Observations were excluded because the patient's TB treatment start date was outside the time period (N=69) or the ART start date was missing (N=20). Additionally, data were only analyzed from facilities that had at least three pre-training and three post-training records for a total of 65 (86%) facilities. In total, 1,063 (94%) pre-training observations and 1,008 (92%) post-training were analyzed. Flow diagrams for the three districts/sub-districts are presented in Figure 1 (Appendix A).

Characteristics of the sample of patients who initiated TB treatment are reported at the bottom of Table 6. They were more likely to be male and older than the sample who initated ART. Forty-three percent were female, 2% were 8-14 years of age, 15% were 15-24 years, 29% 25-34 years, 24% 35-44 years, and 27% 45 or more years. As shown in Table 8, 76% were new patients pre-training and 86% post-training. Among new patients or patients with a GeneXpert test, 91% pre-training initiated treatment on Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, and 93% post-training. Among retreatment patients without GeneXpert test, 70% pre-training initiated treatment with Streptomycin, and 16% post-training.

Table 8. TB regimen information, before and after training

	Total	Pre-Training	Post-Training
	N (%)	N (%)	N (%)
Patient category at TB diagnosis (N = 2,071)			
New patient	1,675 (80.9)	808 (76.0)	867 (86.0)
Retreatment after cure	202 (9.8)	130 (12.2)	72 (7.1)
Retreatment after default	78 (3.8)	49 (4.6)	29 (2.9)
Retreatment after failure	48 (2.3)	41 (3.9)	7 (0.7)
Transfer-In/other	39 (1.9)	22 (2.1)	17 (1.7)
Not documented	29 (1.4)	13 (1.2)	16 (1.6)
Initiated on Regimen 1[A] during the intensive phase if a new patient or received GeneXpert (N = 1,815)			
Yes	1,672 (92.1)	783 (90.9)	889 (93.2)
No	143 (7.9)	78 (9.1)	65 (6.8)
Initiated on Regimen 2[B] during the intensive phase if a retreatment case and did not receive GeneXpert (N = 211)			
Yes	127 (60.2)	121 (69.5)	6 (16.2)
No	84 (39.8)	53 (30.5)	31 (83.8)

[A] Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol

[B] Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, and Streptomycin

Patients who initated ART

The results for monitoring viral load and kidney function among patients who initiated ART are reported in Table 9.

Table 9. Receipt of HIV monitoring services after ART initiation among eligible participants

	Total	Pre-Training	Post-Training	
	N (%)	N (%)	N (%)	p=[A]
Receipt of an HIV viral load test 4-8 months after ART initiation (N = 1,819)				
Yes	661 (36.3)	356 (37.0)	305 (35.6)	0.678
No	1,158 (64.7)	607 (63.0)	551 (64.4)	
Receipt of a baseline creatinine clearance test 3 months prior to 1 month after ART initiation (N = 2,122)				
Yes	1,509 (71.1)	741 (69.0)	768 (73.3)	0.130
No	613 (28.9)	333 (31.0)	280 (26.7)	
Among those on a Tenofavir-based regimen, receipt of a creatinine clearance test 2-4 months after ART initiation (N = 1,915)				
Yes	197 (10.3)	91 (10.0)	106 (10.6)	0.758
No	1,718 (89.7)	821 (90.0)	897 (89.4)	
Among those on a Tenofavir-based regimen, receipt of a creatinine clearance test 5-7 months after ART initiation (N =1,765)				
Yes	352 (19.9)	166 (17.6)	186 (22.6)	0.089
No	1,413 (80.1)	735 (82.4)	636 (77.4)	

[A] Chi^2 test adjusting for clustering at the facility level.

The percentage of patients with a documented viral load test four to eight months after initiation of ART was 37% pre-training, and 36% post-training (p=0.678). After adjusting for district/sub-district, adjusted odds of having a documented viral load test were the same in both time periods periods (OR=1.0, 95% CI=0.7,1.3, p=0.716), as shown in Table 10.

Table 10. HIV viral load test results before and after training among eligible participants

	Total	Pre-Training	Post-Training	
	N (%)	N (%)	N (%)	p=[A]
HIV viral load among those with a documented 4-8 months after ART initiation				
LDL (<50 copies/ml)	355 (54.9)	163 (46.8)	192 (64.2)	< 0.001
51-399 copies/ml	137 (21.2)	80 (23.0)	57 (19.1)	
400 – 1000 copies/ml	46 (7.1)	37 (10.6)	9 (3.0)	
> 1000 copies/ml	109 (16.9)	68 (19.5)	41 (13.7)	
HIV viral load is <1000 copies/ml, among thos with a result documented 4-8 months after ART initiation				
Yes	538 (83.2)	280 (80.5)	258 (86.3)	0.116
No	109 (16.9)	68 (19.5)	41 (13.7)	
Total[B]	647 (100.0)	348 (100.0)	299 (100.0)	

[A] Chi^2 test adjusting for clustering at the facility level.
[B] 14 individuals had a documented 6-month viral load test with a missing test result.
LDL: Lower than detectable limit

Among patients with a test, viral load decreased post-training (p=0.001), as shown in Table 11. For example, 45.7% of patients had a viral load less than 50 copies/ml pre-training compared to 61.9% post-training. The median viral load was 75 copies/ml (interquartile range (IQR): <50 – 604) pre-training and <50 copies/ml (IQR: <50 – 118) post-training (p=0.003), as shown in Figure 3 (Appendix A).

Table 11. Odds of receiving a six month viral load test after ART initiation, adjusted for clustering at the facility level

Covariate	Unadjusted		Adjusted (N = 1,819)	
Study area (N=1,819)	**OR (CL)**	**p =**	**OR (CL)**	**p =**
Receipt of an HIV viral load test 4-8 months after ART initiation (N = 1,819)				
Frances Baard	Reference		Reference	
Inxuba Yethemba	0.8 (0.6, 1.2)	0.325	0.8 (0.6, 1.2)	0.320
Qaukeni	0.3 (0.2, 0.4)	**< 0.001**	0.3 (0.2, 0.4)	**< 0.001**
Study arm (N=1,819)				
Pre-training	Reference		Reference	
Post-training	0.9 (0.7, 1.2)	0.676	1.0 (0.7, 1.3)	0.716
Patient gender (N=1,814)				
Female	Reference		Not selected	
Male	1.2 (1.0, 1.6)	0.071		
Patient age (years) (N=1,807)				
15 – 24	0.9 (0.7, 1.2)	0.526	Not selected	0.089
25 – 34	0.9 (0.7, 1.1)	0.337		
35 – 44	1.0 (0.8, 1.2)	0.708		
≥ 45	Reference			
Goodness of fit testing			**Chi^2 (df)**	**p =**
Pearson's Chi^2 test			8.2 (2)	**0.017**
Hosmer-Lemeshow test			8.2 (4)	0.086

Documentation of creatinine clearance test among patients who initiated ART at three time points are reported in Table 9: before initiating ART, two to four months after initiation, and five to seven months after initiation. Documentation of test before or within one month of ART initiation increased from 69% pre-training to 73.3% post-training (p=0.130) among all patients who initiated ART. Documentation was low after initiation among patients on ART regimens with tenofovir. At two to four months after initiation, it was 10.6% pre-training and 10% post-training (p=0.758). After adjusting for district/sub-district, adjusted odds of having a documented test were the same in both time periods (OR=0.9, 95% CI=0.6, 1.4, p=0.629), as shown in Table 12. At five to eight months after initiation, it was 17.6% pre-training and 22.6% post-training (p=0.089).

Table 12. Odds of receiving a creatinine clearance test one to four months after ART initiation if initiated on a TDF-based regimen, adjusted for clustering at the facility level

Six Month Viral Load				
Covariate	**Unadjusted**		**Adjusted (N = 1,924)**	
Study area (N=1,915)	**OR (CL)**	**p =**	**OR (CL)**	**p =**
Frances Baard	Reference		Reference	
Inxuba Yethemba	0.3 (0.1, 0.6)	**< 0.001**	0.3 (0.1, 0.6)	**< 0.001**
Qaukeni	0.2 (0.1, 0.4)	**< 0.001**	0.2 (0.1, 0.4)	**< 0.001**
Study arm (N=1,915)				
Pre-intervention	Reference		Reference	
Post-intervention	0.9 (0.6, 1.4)	0.757	0.9 (0.6, 1.4)	0.629
Patient gender (N=1,910)				
Female	Reference		Not selected	
Male	1.3 (0.9, 1.7)	0.118		
Patient age (years) (N=1,931)				
15 – 24	1.0 (0.5, 1.8)	0.956	Not selected	
25 – 34	1.0 (0.6, 1.5)	0.847		
35 – 44	1.1 (0.7, 1.8)	0.651		
≥ 45	Reference			
Goodness of fit testing			**Chi^2 (df)**	**p =**
Pearson's Chi^2 test			9.5 (2)	**0.009**
Hosmer-Lemeshow test			9.5 (4)	**0.049**

Patients who Initiated TB Treatment

Documentation of TB sputum test for initiating and monitoring TB treatment are reported in Table 13. At initiation of TB treatment, documentation of a sputum test increased from 85.7% pre-training to 90.0% post-training (p=0.011). The percentage of tests performed with GeneXpert increased from 27.3% pre-training to 67.7% post-training (p<0.001). Among patients with a documented sputum test result, 69.1% pre-training and 84.3% post-training (p<0.001) had a positive test result. Others may have initiated treatment based on hospital diagnosis without record of sputum results.

Table 13. Receipt of TB monitoring services after TB treatment initiation among eligible participants

	Total	Pre-Training	Post-Training	
	N (%)	N (%)	N (%)	p=[A]
Initial TB test documented at diagnosis (N =2,071)				
Yes	1,818 (87.8)	911 (85.7)	907 (90.0)	0.003
No	253 (12.2)	152 (14.3)	101 (10.0)	
GeneXpert documented at diagnosis (N =2,071)				
Yes	972 (46.9)	290 (27.3)	682 (67.7)	<0.001
No	1,099 (53.1)	773 (72.7)	326 (32.3)	
Initial TB test documented positive at diagnosis (N = 1,818)				
Yes	1,394 (76.7)	629 (69.1)	765 (84.3)	<0.001
No	424 (23.3)	282 (31.0)	142 (15.7)	
End of intensive phase TB test documented 1-4 months after TB treatment initiation (N = 2,006)				
Yes	1,419 (70.7)	727 (70.4)	692 (71.1)	0.811
No	587 (29.3)	306 (29.6)	281 (28.9)	
Among those on Regimen 1[B], end of intensive phase TB test documented 1 – 4 months after TB treatment initiation (N = 1,715)				
Yes	1,223 (71.3)	578 (70.9)	645 (71.7)	0.815
No	492 (28.7)	237 (29.1)	255 (28.3)	
Among those on Regimen 2[C], end of intensive phase TB test documented 1 – 4 months after TB treatment initiation (N = 200)				
Yes	143 (71.5)	123 (72.8)	20 (64.5)	0.389
No	57 (28.5)	46 (27.2)	11 (35.5)	
If end of intensive phase TB was positive, additional end of intensive phase TB test documented 0.5 – 1.5 months later (N = 167)				
Yes	65 (38.9)	25 (32.9)	40 (44.0)	0.185
No	102 (61.1)	51 (67.1)	51 (56.0)	

[A] Chi^2 test adjusting for clustering at the facility level.

[B] Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol

[C] Rifampicin, Isoniazid, Pyrazinamide, Ethambutol, and Streptomycin

At the end of the intensive phase of TB treatment, documentation of sputum test one to four months after initiation of TB treatment was 70.4% pre-training and 71.1% post-training (p=0.811). After adjusting for district/sub-district, adjusted odds of having a documented TB test were the same in both time periods periods (OR=1.0, 95% CI=0.8,1.4, p=0.793), as shown in Table 14. Results were similar among the subsample of patients who initiated treatment with of Rifampicin, Isoniazid, Pyrazinamide, and Ethambutol (regimen 1), and the subsample who initated treatment with Streptomycin (regimen 2).

Table 14. Odds of receiving a correct end of intensive phase TB test after intiating TB treatment, adjusted for clustering at the facility level

Six Month Viral Load				
Covariate	**Unadjusted**		**Adjusted (N = 1,924)**	
Study area (N=2,006)	**OR (CL)**	**p =**	**OR (CL)**	**p =**
Frances Baard	Reference		Reference	
Inxuba Yethemba	0.9 (0.6, 1.3)	0.553	0.9 (0.6, 1.3)	0.540
Qaukeni	0.5 (0.3, 0.8)	**0.006**	0.5 (0.3, 0.8)	**0.006**
Study arm (N=2,006)				
Pre-training	Reference		Reference	
Post-training	1.0 (0.8, 1.4)	0.810	1.0 (0.8, 1.4)	0.793
Patient gender (N=2,006)				
Female	Reference		Not selected	
Male	1.2 (0.9, 1.5)	0.139		
Patient age (years) (N=1,931)				
8 – 14	0.5 (0.2, 0.9)	**0.031**	Not selected	
15 – 24	1.1 (0.8, 1.6)	0.661		
25 – 34	1.1 (0.8, 1.4)	0.569		
35 – 44	1.0 (0.7, 1.3)	0.834		
≥ 45	Reference			
Goodness of fit testing			**Chi^2 (df)**	**p =**
Pearson's Chi^2 test			25.7 (22)	0.781
Hosmer-Lemeshow test			8.5 (8)	0.974

Integration of TB/HIV care

The percentage of patients who initiated ART with documentation of TB symptom screen, Isoniazid Prophylactic Therapy (IPT) screen, IPT initiation, and TB treatment initiation were compared between time periods. There were two steps for IPT screening: 1) patients without TB symptoms were eligible for IPT initiation; and 2) patients with TB symptoms were given a TB sputum test and those with negative test results were eligible for IPT initiation. As shown in Table 15, documentation of TB symptom screening increased from 71.8% pre-training to 81.3% post-training (p=0.003). Documentation of IPT screening increased from 41.2% pre-training to 63.1% post-training (p<0.001), and IPT initiation increased from 32.8% pre-training to 41.0% post-training (p=0.004). Documentation of TB treatment initiation in HIV charts was 75.5% pre-training compared to 78.3% post-training (p=0.719).

Similarly, the percentage of TB patients with documentation of an HIV test, ART initiation, ART start date, and CD4 test were compared between time periods. Documentation of an HIV test among those not known to be HIV positive was 77.7% pre-training and 80.2% post-training (p=0.396). On average, 54% of those test results were positive for HIV. Among patients who tested positive for HIV, documentation of ART initiation was 65.9% pre-training and 66.5% post-training (p=0.878). After adjusting for district/sub-district and gender, adjusted odds of having a documented test were the same in both time periods periods (OR=1.0, 95% CI=0.7, 1.4, p=0.852), as shown in Table 15. Among patients who initiated ART, results were similar across time periods for documentation of ART start date and CD4 tests.

Table 15. Integration of care between TB/HIV services, before and after training

	Total	Pre-Training	Post-Training	
	N (%)	N (%)	N (%)	p=[A]
ART CHART REVIEWS				
Documented TB symptom screen				
Yes	1,623 (76.5)	771 (71.8)	852 (81.3)	<0.003
No	499 (23.5)	303 (28.2)	196 (18.7)	
Screened for IPT				
Yes	1,103 (52.0)	442 (41.2)	661 (63.1)	<0.001
No	1,019 (48.0)	632 (58.9)	387 (36.9)	
Documented initating IPT				
Yes	782 (36.9)	352 (32.8)	430 (41.0)	<0.005
No	1,340 (63.2)	722 (67.2)	618 (59.0)	
Documented initiating TB treatment, among those with a positive TB test result (N = 122)				
Yes	94 (77.1)	40 (75.5)	54 (78.3)	0.719
No	28 (23.0)	13 (24.5)	15 (21.7)	
Total	2,122 (100.0)	1,074 (100.0)	1,048 (100.0)	
TB CHART REVIEWS				
Has a documented HIV test, among those not known positive at diagnosis (N = 1,629)[B]				
Yes	1,286 (78.9)	630 (77.7)	656 (80.2)	0.396
No	343 (21.1)	181 (22.3)	162 (19.8)	
Documented initiating ART, among those who are HIV positive (N = 1,139)				
Yes	754 (66.2)	391 (65.9)	363 (66.5)	0.878
No	385 (33.8)	202 (34.1)	183 (33.5)	
Documented initiating ART before or within 8 weeks of TB diagnosis, among those who tested HIV positive (N = 989)[C]				
Yes	516 (52.2)	250 (49.5)	266 (55.0)	0.379
No	473 (47.8)	255 (50.5)	218 (45.0)	
ART start date documented if documented initiating ART (N = 754)				
Yes	657 (87.1)	335 (85.7)	322 (88.7)	0.303
No	97 (12.9)	56 (14.3)	41 (11.3)	
CD4 test documented, if documented initiating ART (N = 754)				
Yes	657 (87.1)	348 (89.0)	309 (85.1)	0.246
No	97 (12.9)	43 (11.0)	54 (14.9)	

[A] Chi2 test adjusting for clustering at the facility level.
[B] 445 (21.5%) of individuals were known to be HIV positive at TB diagnosis.
[C] Excluding 149 individuals who were documented initiating ART but have no ART start date documented (N=97) or an incomplete ART start date (N=52).

Table 16. Odds of being on ART documented in the ART register among patients co-infected with HIV, adjusted for clustering at the facility level.

Six Month Viral Load				
Covariate	**Unadjusted**		**Adjusted (N=1,134)**	
Study area (N=1,138)	**OR (CL)**	**p =**	**OR (CL)**	**p =**
Frances Baard	Reference		Reference	
Inxuba Yethemba	1.4 (0.8, 2.2)	0.212	1.4 (0.8, 2.3)	0.205
Qaukeni	0.6 (0.4, 1.0)	**0.033**	0.6 (0.3, 1,0)	**0.031**
Study arm (N=1,138)				
Pre-intervention	Reference		Reference	
Post-intervention	1.0 (0.7, 1.4)	0.903	1.0 (0.7, 1.4)	0.852
Patient gender (N=1,134)				
Female	Reference		Reference	
Male	0.8 (0.6, 1.1)	0.125	0.8 (0.6, 1.0)	0.067
Patient age (years) (N=1,092)				
8 – 14	-[A]		Not selected	
15 – 24	0.9 (0.6, 1.4)	0.748		
25 – 34	1.0 (0.8, 1.4)	0.766		
35 – 44	1.4 (1.0, 2.0)	**0.041**		
≥ 45	1.0			
Goodness of fit testing			**Chi^2 (df)**	**p =**
Pearson's Chi^2 test			4.0 (7)	0.784
Hosmer-Lemeshow test			3.6 (8)	0.890

[A] No children ages 8 – 14 were documented as HIV positive.

DISCUSSION

None of the four primary measures increased post-training. Documentation of viral load test within four to eight months of initiation of ART averaged 36%, documentation of kidney function test within two to four months of initiation of an ART regimen with tenofovir averaged 10%, and neither increased after training. Documentation of TB test at the end of the intensive phase of TB treatment averaged 71%, and documentation of ART initiation among TB patients co-infected with HIV averaged 34%, and neither increased after training. Continued interventions to support monitoring of patients in treatment for HIV or TB and integration of TB and HIV care are needed.

The evaluation, however, documented many improvements in treatment for HIV and TB. Among patients on ART with a viral load test result within four to eight months of initiating ART, the median viral load was statistically significantly lower after training. Documentation of kidney function test increased at initiation of ART and within five to eight months of initiation. The increase in documentation of TB test at initiation of TB treatment was statistically signicant. Increases in screening for TB and IPT and initiation of IPT among patients who initiated ART were also statistically significant.

The measures were carefully chosen to reflect changes that could be potentially attributed to the course. Many of the changes in treatment may have been facilitated by the training, which occurred at the same time as other efforts to improve treatment. For example, the decrease in viral load occurred as the recommended and available ART regimens transitioned to fixed-dosed combinations, which may have improved adherence. The improvements in documentation of TB test at initiation to TB treatment occurred at the same time that GeneXpert was introduced to facilities and made TB tests easier to perform. The improvements in IPT screening and initiation occurred at the same that new IPT registers were introduced to facilities. The training emphasized each of these guideline changes and may have facilitated their uptake among clinicians.

Current best practice is to combine training with other interventions to strengthen the health system. For example, training nurses on drug-resistant TB would only improve the quality of care when a TB test for drug susceptibility is available at the facility. Similary, introducing GeneXpert at a facility would only improve the quality of care when nurses understand how to interpret the results and prescribe or refer patients accordingly. The challenge is attributing effects between the combination of interventions.

Other changes occurred at the facilities that reduced the effectiveness of the training. For example, facility managers in all areas reported staff turnover after the TB/HIV training, so while the files were not linked to training and mentoring participants, the post-training time period may not always reflect care provided by people who attended the course.

Summarizing the strengths of the evaluation, the TB/HIV course was adapted to the context of national training programs in South Africa, and focused on training new guidelines, advances in HIV and TB practice, and integration of TB and HIV care. Within each district/sub-district, the TB/HIV training program was adapted to specific concerns that were identified during the baseline assessment. The evaluation measured the effects of training on a large sample of facilities and patients. The electronic data collection method was innovative and accommodated the heterogeneity of record-keeping methods across districts/sub-districts and facilities. Documentation of ART start date, key information for measuring appropriate monitoring, was better than anticipated, and would be a resource for monitoring treatment in the future.

The pre/post design was a limitation of the evaluation because it did not control for other ongoing improvements at the facilities or for staff turnover, as noted above. In addition, on-site mentoring at the facilities was ongoing during the post-training time period. The data collection had to be completed by March 2014 due to funding constraints. Consequently, the pre/post design measured the effects of the course and, potentially, the partial effects of on-site mentoring, rather than the pure effects of the course or the full-effects of the training and mentoring activities.

CONCLUSION

Although none of the four primary measures increased post-training, the evaluation documented many other improvements in TB and HIV care. These areas may have been supported by the course, which occurred at the same time as other efforts to improve care. Among patients with HIV who had an available viral load test result within four to eight months of initiating ART, the median viral load was statistically significantly lower post-training. Documentation of creatinine clearance increased at initiation of ART and within five to eight months of initiation. The increase in documentation of TB tests at initiation of TB treatment was statistically signicant. Increases in screening for TB and IPT and initiation of IPT among patients who initiated ART were also statistically significant.

APPENDIX A: FIGURES

Figure 1: Flow chart for HIV data collection in each district/sub-district

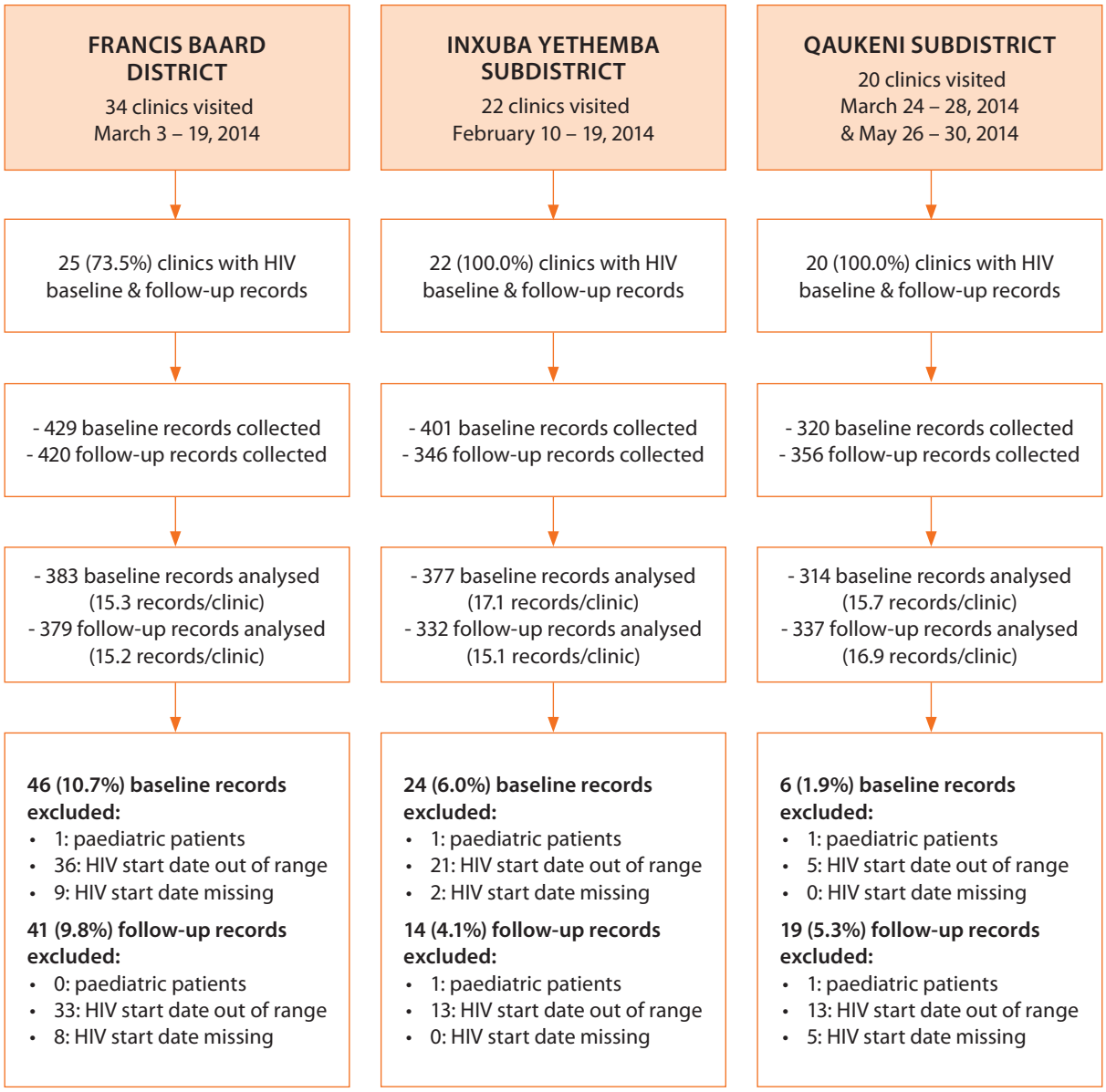


Figure 2: Flow shart for TB data collection in each district/subdistrict

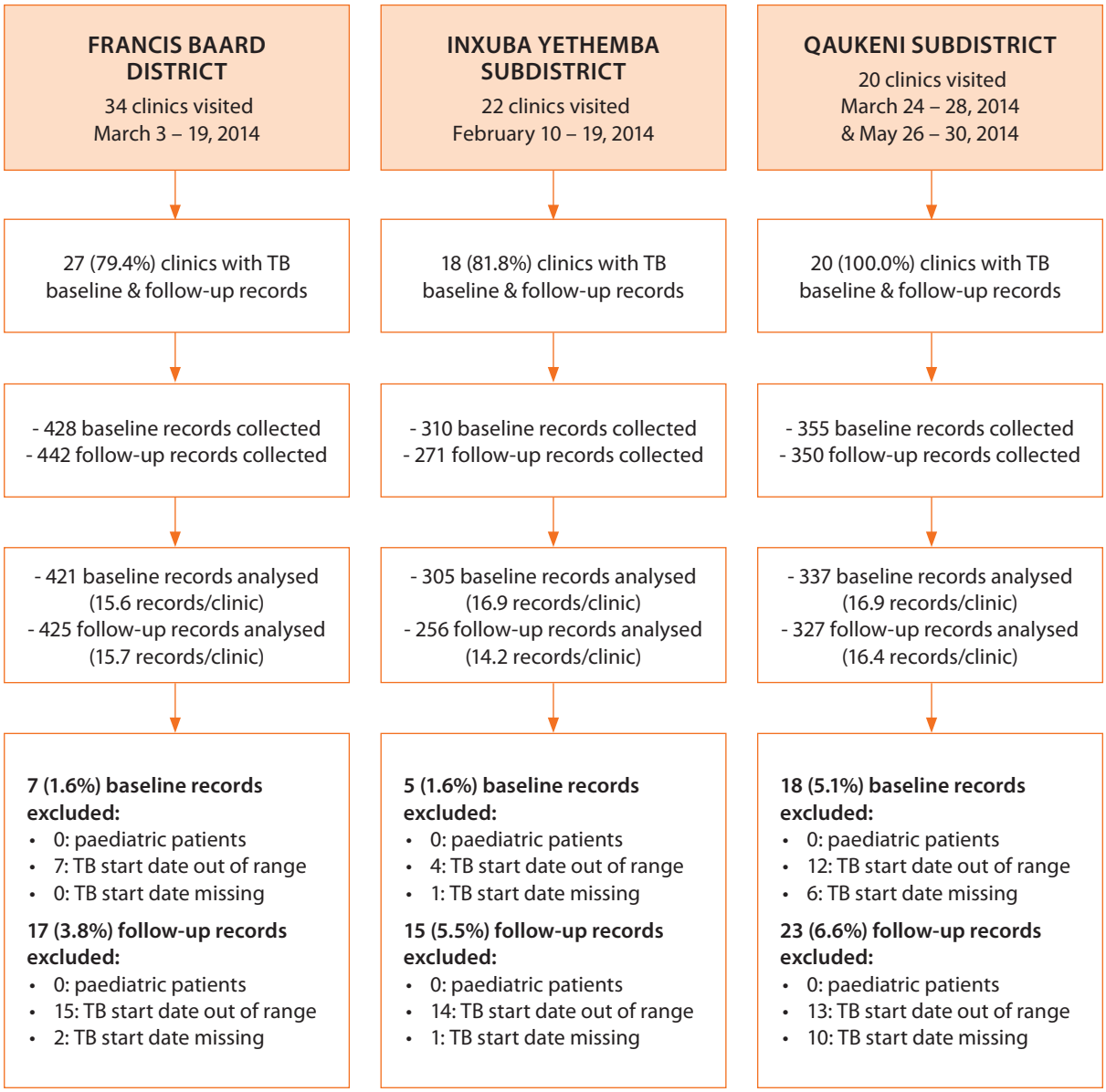
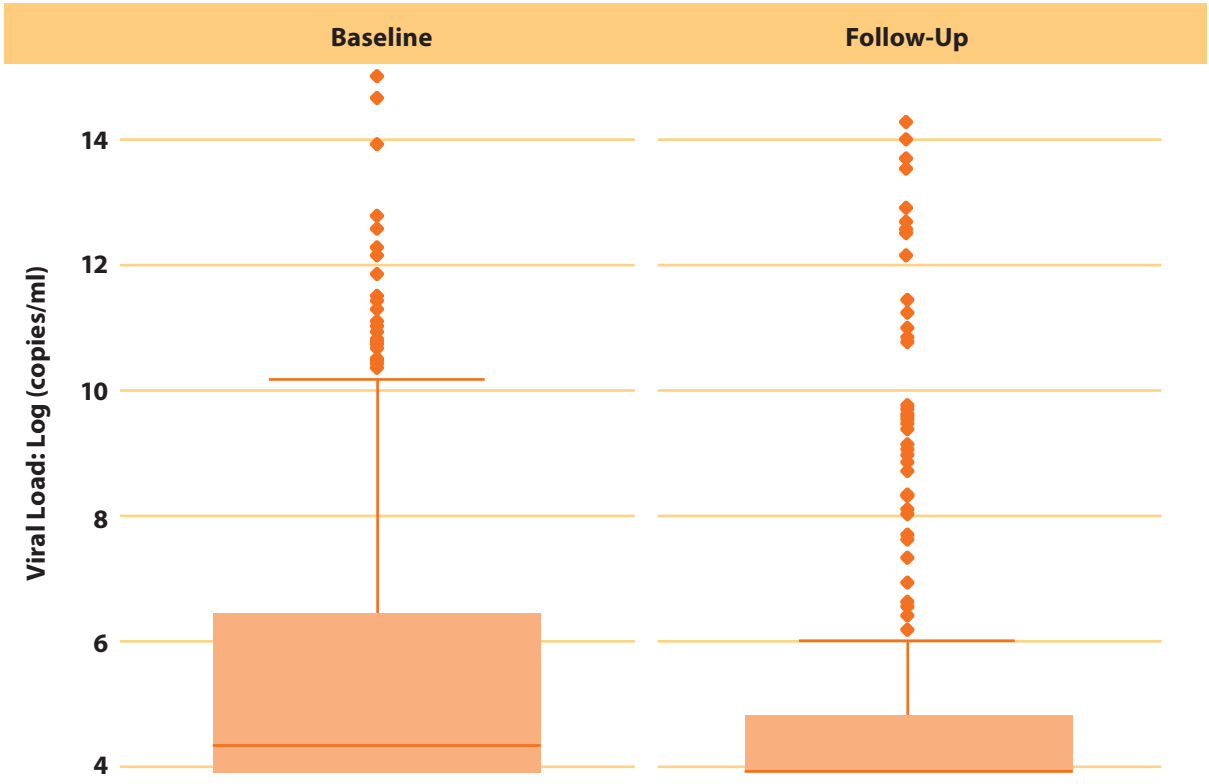


Figure 3: HIV viral load among those with a viral load test result 5-7 months after ART intitiation before and after training.

Box plots represent the log-transformed median and inter-quartile range of viral load test results before training (N=348) and after training (N=299). The lower detectable limit (LDL) of viral load tests was 20, 40, or 50 copies/ml, and all tests that were <50 copies/ml were coded as LDL and labeled as "<50 copies/ml", represented by a log-transformed value of 3.9 on the plot. The lines through boxes indicate the median log-transformation of the six month viral load test result, and the upper and lower limits of the boxes indicate the inter-quartile range. (Kruskall-Wallis Equality-of-Populations test accounting for clustering at the facility level; p=0.003).



APPENDIX B: FACILITY ASSESSMENT RESULTS

Table 1. Facility Characteristics

	Total	Inxuba Yethemba	Frances Baard	Qaukeni
Facility characteristics	**Median (Range)**	**Median (Range)**	**Median (Range)**	**Median (Range)**
Catchment population[A]	9,000 (900 – 248,000)	4,861 (900 – 11,200)	9,834 (1,000 – 248,000)	11,260 (3,499 – 71,275)
Client population (monthly)[B]	2,000 (0 - 9,500)	900 (250 – 2,800)	2,450 (0 – 9,000)	2,000 (900 – 9,500)
Total paediatric clients[C]	11 (0 – 530)	9 (0 – 38)	6.5 (0 – 530)	23.5 (0 – 100)
Facility type	**N (%)**	**N (%)**	**N (%)**	**N (%)**
Clinic	63 (82.9)	19 (86.4)	25 (73.5)	19 (95.0)
CHC	9 (11.8)	2 (9.1)	6 (17.7)	1 (5.0)
Satellite / Mobile clinic	3 (2.6)	1 (4.6)	2 (5.9)	0 (0.0)
District Hospital	1 (1.3)	0 (0.0)	1 (2.9)	0 (0.0)
Reporting using the following documentation in the facility				
HCT register	75 (98.7)	22 (100.0)	33 (97.1)	20 (100.0)
Pre-ART (Wellness) register	72 (94.7)	21 (95.5)	33 (97.1)	18 (90.0)
ART register	66 (86.8)	22 (100.0)	26 (76.5)	18 (90.0)
ART stationary	75 (98.7)	22 (100.0)	33 (97.1)	20 (100.0)
TB suspect register	76 (100.0)	22 (100.0)	34 (100.0)	20 (100.0)
TB admission register	73 (96.1)	22 (100.0)	31 (91.2)	20 (100.0)
TB stationary	74 (97.4)	22 (100.0)	33 (97.1)	19 (95.0)
IPT register	57 (75.0)	21 (95.5)	18 (52.9)	18 (90.0)
PCR register	62 (81.6)	18 (81.8)	24 (70.6)	20 (100.0)
Tier.net phase[D]				
None	2 (2.6)	0 (0.0)	2 (5.9)	0 (0.0)
Phase I – Paper-based	26 (34.2)	15 (68.2)	9 (26.5)	2 (10.0)
Phase 2 – Tier.net (Not live)	13 (17.1)	0 (0.0)	6 (17.7)	7 (35.0)
Phase 2 – Tier.Net (live)	31 (40.8)	7 (31.8)	13 (38.2)	11 (55.0)
Phase 3 – EMR	1 (1.3)	0 (0.0)	1 (2.9)	0 (0.0)
Integrate TB and HIV files[E]				
Yes	43 (68.3)	4 (44.4)	23 (67.7)	16 (80.0)
No	20 (31.8)	5 (55.6)	11 (32.4)	4 (20.0)
Total	76 (100.0)	22 (100.0)	34 (100.0)	20 (100.0)

[A] Missing data from 2 clinics in Inxuba Yethemba, 4 clinics in Frances Baard, and 1 clinic in Qaukeni. [B] One clinic in Qaukeni was missing data. [C] Missing data from 1 clinic in Inxuba Yethemba, 2 clinics in Frances Baard, and 2 clinics in Qaukeni. [D] Three clinics in Frances Baard were missing data. [E] This indicator was added during the data collection process: no data available for 13 clinics in Inxuba Yethemba.

Table 2. Staffing

	Total	Inxuba Yethemba	Frances Baard	Qaukeni
Fulltime HCWs on staff[A]	**Median (Range)**	**Median (Range)**	**Median (Range)**	**Median (Range)**
Doctors (N=67)	0 (0 – 4)	0 (0 – 1)	0 (0 – 4)	0 (0 – 0)
Professional nurses (N=76)	3 (0 – 26)	2.5 (1 – 20)	4 (0 – 26)	3 (0 – 6)
Enrolled nurses (N=72)	0 (0 – 3)	0 (0 – 1)	0 (0 – 3)	0 (0 – 3)
Auxilliary nurses (N=72)	1 (0 – 9)	0 (0 – 6)	1 (0 – 9)	2 (1 – 5)
Total (N=66)	5 (0 – 33)	3.5 (1 – 28)	6 (0 – 33)	5 (2 – 10)
Part-time HCWs on staff				
Doctors (N=72)	1 (0 – 7)	1 (0 – 2)	1 (0 – 7)	0 (0 – 1)
Professional nurses (N=66)	0 (0 – 5)	0 (0 – 1)	0 (0 – 5)	0 (0 – 3)
Enrolled nurses (N=66)	0 (0 – 5)	0 (0 – 0)	0 (0 – 5)	0 (0 – 0)
Auxilliary nurses (N=66)	0 (0 – 1)	0 (0 – 0)	0 (0 – 1)	0 (0 – 0)
Total (N=66)	1 (0 – 12)	1 (0 – 2)	1 (0 – 12)	0 (0 – 3)
Aurum nurse working in the clinic?[B]	N (%)	N (%)	N (%)	N (%)
Yes	21 (38.9)	-	19 (55.8)	2 (10.0)
No	33 (61.1)	-	15 (44.1)	18 (90.0)

[A] Missing data due to the respondent not knowing total staffing numbers.

[B] Data not collected in Inxuba Yethemba subdistrict. No clinic reported more than one aurum nurse.

Table 3. Training and Mentoring

	Total	Inxuba Yethemba	Frances Baard	Qaukeni
Nurses offering services after June 2013	**N (%)**	**N (%)**	**N (%)**	**N (%)**
NIMART trained	182 (49.2)	61 (76.3)	74 (33.8)	47 (71.2)
Initiating ART in adults	216 (59.2)	53 (66.3)	113 (51.6)	50 (75.8)
Initiating ART in Paediatrics	161 (44.1)	51 (63.8)	64 (29.2)	46 (69.7)
Currently receiving mentoring on ART Initiation	109 (29.9)	50 (62.5)	40 (18.3)	19 (28.8)
Completed mentoring on POEs and certified to initiate ART	62 (17.0)	15 (18.8)	32 (14.6)	15 (22.7)
Managing adult TB patients	240 (65.8)	89 (112.5)	105 (47.9)	46 (69.7)
Managing paediatric TB patients	236 (64.7)	89 (112.5)	105 (47.9)	42 (63.6)
Total nurses reported in clinics	365 (100.0)	80 (100.0)	219 (100.0)	66 (100.0)
How often do HST/DOH mentors visit for mentoring activities each month?[A]				
More than once per week	1 (1.9)	-	1 (2.9)	0 (0.0)
Once per week	5 (9.3)	-	4 (11.8)	1 (5.0)
2-3x per month	12 (22.2)	-	7 (20.6)	5 (25.0)
Once per month	22 (40.7)	-	14 (41.2)	8 (40.0)
Less than once per month	9 (16.7)	-	5 (14.7)	4 (20.0)
Facility manager was not sure	5 (9.3)	-	3 (8.8)	2 (10.0)
Total	54 (100.0)	-	34 (100.0)	20 (100.0)

ART: Antiretroviral therapy, DOH: Department of Health, HST: Health Systems Trust, POEs: Portfolio of Evidence , TB: tuberculosis.

[A] Data was not collected in clinics from Inxuba Yethemba.

Table 4. Lab services

	Total	Inxuba Yethemba	Frances Baard	Qaukeni
Reported stockouts by clinics	**N (%)**	**N (%)**	**N (%)**	**N (%)**
HIV tests	16 (21.1)	6 (27.3)	4 (11.8)	6 (30.0)
Specimen tubes for blood	14 (18.4)	5 (22.7)	4 (11.8)	5 (25.0)
Sputum containers	13 (17.1)	5 (22.7)	3 (8.8)	5 (25.0)
PCR DBS forms	14 (18.4)	6 (27.3)	3 (8.8)	5 (25.0)
Turnaround time for GeneXpert results				
Less than 24 hours	8 (10.5)	0 (0.0)	7 (20.6)	1 (5.0)
24 to 48 hours	40 (52.6)	11 (50.0)	18 (52.9)	11 (55.0)
48 to 72 hours	21 (27.6)	10 (45.6)	8 (23.5)	3 (15.0)
More than 72 hours	6 (7.9)	1 (4.6)	0 (0.0)	5 (25.0)
GeneXpert not available	1 (1.3)	0 (0.0)	1 (2.9)	0 (0.0)
Total	76 (100.0)	22 (100.0)	34 (100.0)	20 (100.0)

Table 5. Medication

	Total	Inxuba Yethemba	Frances Baard	Qaukeni
Reported stockouts of HIV medication	**N (%)**	**N (%)**	**N (%)**	**N (%)**
Fixed dose combination (FDC)	3 (9.1)	0 (0.0)	1 (7.7)	2 (14.3)
TDF (Tenofovir)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
3TC (Lamivudine)	2 (6.1)	1 (16.7)	1 (7.7)	0 (0.0)
3TC (paediatric formulation)	7 (21.2)	1 (16.7)	6 (46.2)	0 (0.0)
d4T (Stavudine)	4 (12.1)	1 (16.7)	1 (7.7)	2 (14.3)
AZT (Zidovudine)	1 (3.0)	0 (0.0)	1 (7.7)	0 (0.0)
ABC (Abacavir)	2 (6.1)	0 (0.0)	2 (15.4)	0 (0.0)
ABC (paediatric formulation)	7 (21.2)	1 (16.7)	5 (38.4)	1 (7.1)
EFV (Efavirenz)	1 (3.0)	0 (0.0)	1 (7.7)	0 (0.0)
EFV (paediatric formulation)	8 (24.2)	2 (33.3)	5 (38.5)	1 (7.1)
NVP (Nevirapine)	3 (9.1)	1 (16.7)	2 (15.4)	0 (0.0)
NVP syrup (paediatric formulation)	2 (6.1)	0 (0.0)	2 (15.4)	0 (0.0)
LPV-r (Lopinavir/ritonavir)	3 (9.1)	1 (16.7)	2 (15.4)	0 (0.0)

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