TITLE:

EXTENT OF IMPLEMENTATION OF HIV AND TB PROGRAMME SERVICES AND THE EFFECT OF QUALITY IMPROVEMENT INTERVENTIONS IN SELECTED DISTRICTS SUPPORTED BY BEYOND ZERO

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DISCLAIMER:

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1 EVALUATION TEAM BIOS AND ROLES

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2 EXECUTIVE SUMMARY

Background

Continuous quality improvement (CQI) is a management approach used to enhance an organisation's processes based on their measured performance [1][2][3]. CQI processes use performance data to inform an iterative and incremental transition towards an optimally performing system by building on successes and improving sub-optimum activities and outputs [4]. CQI is essential for HIV and TB services. Similarly, a thorough understanding of the requirements and impact of CQI is critical to its successful institutionalization.

Objectives

The objective of this study is to describe CQI implementation process and examine its effect on HIV and TB service delivery at selected primary healthcare facilities in two South African districts.

Method

We used a separate sample pre-, and post-test quasi-experimental study design based on data collected from clinical audit of patient cohorts seen in 2014 and 2015, respectively. Quality was measured based on the extent to which prescribed services were provided. Tailored CQI interventions were implemented based on service delivery gaps identified by the 2014 CQI audit. Data were summarized and analysed using a combination of univariate and multivariate analyses.

Results

The services identified as low quality were related to opportunistic infections management and laboratory practices. Compliance to prescribed service items in antiretroviral treatment initiation and monitoring, pharmacy, and laboratory management, exceeded 70% across study sites. Over 80% of low-quality service delivery items were improved in less than six months with targeted quality improvement support.

Conclusion

The observed improvements signal the effectiveness of the CQI approach, its capacity to rapidly improve under-performance, and the need to provide quality maintenance support to sustain or improve healthcare facilities performing well. The study strongly underscores the importance of improving the management of opportunistic infections.

Contents

Abbreviations and Acronyms

ART	Antiretroviral Therapy
AFB	Acid fast bacillus
BZ	Beyond Zero
CDC	U.S Centers for Disease Control and Prevention
CHCs	Community Health Centres
CPT	Cotrimoxazole Preventive Therapy
CQI	Continuous Quality Improvement
CrAg	Cryptococcal Antigen
DHIS	District Health Information System
HCT	HIV counselling and testing
HIV	Human Immunodeficiency Virus
HSS	Health Systems Strengthening
IPT	Isoniazid Prevention Therapy
LPA	Line Probe Assay
NIDS	National Indicator Data Set
PHC	Primary Health Care
PEPFAR	President's Emergency Plan for AIDS Relief
TAT	Turnaround time
TB	Tuberculosis
WHO	World Health Organization

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3 BACKGROUND

Continuous quality improvement (CQI) is a management approach used to enhance an organisation's processes based on their measured performance [1][2][3]. CQI processes use performance data to inform an iterative and incremental transition towards an optimally performing system by building on successes and improving sub-optimum activities and outputs [4].

CQI processes are proactive. They are able to identify and remediate latent or future programme challenges and requirements [5]. The World Health Organization's (WHO) Health Systems Strengthening (HSS) framework [6] reemphasizes the critical value of CQI models. The framework depicts quality as a bridge between the building blocks of the health system and their desired outcomes. Thus, an effective HSS model relies on functional CQI processes. This reasoning is in line with the established linkages between CQI implementation and improved health system efficiency, access and outcomes [7][8][9]. The characteristic value of CQI approaches is their ability to measure process and outcome indicators, with the aim of targeting the implementation of change at the smallest replicable units of the health system [10].

There are growing numbers of people living with HIV necessitating increasing demands for quality care. This means that sub-quality HIV and TB programmes will fail to meet their targets. This scenario, the "chronicity" of the HIV epidemic, and its manifestations could result in the following challenges: insufficient screening of high-risk individuals; failure to adequately link people to care; inability to retain people on treatment; deficiency in reengaging lost patients; and an increase in patient morbidity and mortality. These factors are key drivers of HIV transmission; they increase the costs of care and diminish programme sustainability and outcomes [11][12]. To address these concerns, the systemic approach of CQI models can be applied to yield and optimise the epidemiologic impacts and cost effectiveness of interventions [11].

Globally, CQI initiatives have reported varied and remarkable successes in the fight against the HIV epidemic [13]. Efforts to standardize HIV/AIDS programme CQI processes have for the most part been in developed countries where the epidemic and context are different from the situations in African countries [11][10][8]. The usefulness of CQI processes in low- and middle-income countries remains to be seen, in particular, it's potential to accelerate progress towards achieving epidemic control [1]. CQI was introduced in two districts of South Africa in

2014 by a U.S Centers for Disease Prevention and Control (CDC) HIV program implementing partner. In this report, we describe the CQI implementation process and examine its effect on HIV and TB service delivery at selected primary healthcare facilities in two South African districts.

4 METHODS

4.1 Study design

This was a separate sample pre- and post-test quasi-experimental study using routine programme data from two districts supported by the President's Emergency Plan for AIDS Relief (PEPFAR) South Africa funded HIV and TB programme in South Africa. The data were collected from the medical records of patients through a retrospective clinical data audit. The patient clinical data were captured during routine service delivery at two time points ─ July to December 2014 and July to December 2015.

The CQI intervention was implemented for six months between the two time points (January to June 2015). The audits focused on: adult antiretroviral therapy (ART); HIV counselling and testing (HCT); TB case finding and management; pharmacy; and laboratory delivery service areas. These five service delivery areas assessed during the audits were aligned with various inter-related targets. Such targets are contained in the UNAIDS 90-90-90 strategy [14], the district implementation plan (DIP) and in the routine PEPFAR/South African National Department of Health (NDoH) monitoring and evaluation plan. Several questions or items in each service delivery area were designed to identify gaps in the quality of services. The list of questions or items assessed are appended to this document as Supplementary Information 1.

4.2 Study population and sampling

The audits were conducted in 90 supported health facilities in the two districts described in this report as District A and District B. The 90 facilities were purposively selected using criteria described below. Ninety-three percent of the facilities were Primary Health Care facilities (PHCs) and the rest were Community Health Centres (CHCs). Seventy one percent of the facilities were from District B. About 60% of the facilities were in rural areas and 40% were in urban areas.

Prior to the implementation of the CQI project in 2014, most of the health system performance indicators in both districts required improvement, as most programme targets remained unmet. At the start of the project, District A ranked among the 10 worst-performing districts in South Africa on indicators such as management of inpatients [15]. Performance indicators for District B were the worst on management of PHCs, management of inpatients, human resources, TB case finding and TB treatment outcomes [15].

The health facilities included in this evaluation were high-volume sites or having at least 800 people regularly collecting their ART at the health facility. This is otherwise referred to as total remaining on ART (TROA). High volume sites are designated by the Department of Health based on monthly facility headcount, catchment population size, health facility utilization rate and disease burden. The 90 study sites were purposively selected using the criteria of high HIV/TB burden. All the health facilities whose patients' folders were available, in all the five service delivery areas, were eligible for the study. All records of patients initiated on ART from July to December 2014 constituted the first cohort. The second cohort consisted of all records of patients initiated on ART from July to December 2015.

A maximum of 20 patient service records and folders per facility were selected and audited. The 20 folders consisted of records of TB and/or HIV clients, from which the five service areas were assessed. Please see Supplementary Information 1 for the list of items assessed in each service area. The scoring method used is further described in the data collection tool section below. A systematic sampling method was used to select the files to be audited. The interval between audited files was calculated based on the total number of eligible files at the site. For facilities with fewer than 20 folders, all available folders were audited.

With 20 patient folders selected per health facility, a minimum sample size of 1800 patient folders was needed for the audit. The proposed sample size was intended to detect a 95% power and a 5% margin of error per each technical area (e.g., TB case management; laboratory services and pharmacy). The sample calculation assumed there were approximately 72,000 patients' folders in the 90 health facilities based on TROA of about 800. Using systematic random sampling procedure, the sampling interval (k) of 40 was calculated by dividing TROA (800) by the required sample per facility (20). Using a random starting point (x), we were able to establish every k^{th} folder to be selected until the number of 20 folders was reached. Incomplete files were replaced with the next k^{th} folder.

4.3 Study intervention

The study intervention included the CQI audits and tailored support provided by a roving team of multi-disciplinary healthcare providers. The roving CQI audit teams consisted of Nurse Mentors, Information Officers, Monitoring and Evaluation Advisors, Pharmacy Assistants, and at least one Technical Specialist. The multi-disciplinary audit teams provided comprehensive and integrated support to the audited health facilities. The audit teams were trained on CQI processes, reporting protocol and problem remediation mechanisms using a standard operating

procedure that was developed for the audits. Clinical practitioners with research and extensive health system strengthening experience provided the Roving Team training. This was done to ensure quality and implementation consistency among all teams.

Each audit involved patient files review and scoring by the team. The scoring methods are described in detail in the data collection. Then, the facility overall performance report was provided to respective healthcare facility managers. Red flags (bottlenecks) as well as improvement plans were discussed with the health facility manager. The focus of the intervention was on how to improve the activities and indicator element that was not performing well (i.e., below 50% compliance to prescribed service items). Based on identified needs, the CQI plans with specific interventions varied between health facilities. The interventions ranged from activities to improve drug procurement and dispensary procedures to clinical skills development, mentorship and supportive supervision. They also included improvements in monitoring and evaluation and information utilization for decision making, targeted service improvement, service delivery campaigns and community engagement activities, support with patient flow management and human resource management support. The use of tailored interventions to respond to prevailing service delivery gaps during quality improvement have been noted to be efficient and effective [16][17].

4.4 Data collection tool

A service audit tool was used to assess the quality of HIV and TB services provided (see Supplementary 1). The data audit tool was adapted from the standardized data audit tool developed by the NDoH for routine monitoring of health programmes. The adaptation of the audit tool was developed through an extensive consultative process with inclusive multidisciplinary healthcare teams selected from participating health facilities before the first audit in July 2014. The finalized tool was pre-tested in two randomly selected healthcare facilities. These pilot sites were excluded from the main study.

Responses on the tool were coded 1 = Yes and 0 = No. The number of "Yes" responses, divided by total number of audit items or questions per service area, determined the total facility score per service area. The formula was adjusted to exclude "not applicable" in the final facility score. Three cut-off points were used to categorize healthcare facilities' performance in each of the service areas. Green represented facilities that scored 85% and above; amber for facilities that scored between 50 and 84%; and red signified poor-performing facilities scoring below 50% in an item measured or service area.

Additionally, health facility capacity and performance indicators were obtained from the District Health Information System (DHIS) database. The collected information consisted of facility aggregates reported as percentages and ratios. The indicators collected from the National Indicator Data Set (NIDS) included health facility utilization rate, nurse and doctor workloads, number of individuals initiated on treatment prior and during the audit period, number of patients remaining in care during the period, and patient headcount. The list of health facility capacity and performance indicators are available in the appended Supplementary Information 2. With these additional data, we were able to compare the average facility performance based on routine district health information system indicator in the three months before (April - July 2014) and three months after (August - October 2015). These time points are before and after the implementation of the tailored CQI interventions developed by the CQI Team and the respective health facility managers. The additional analysis of NIDS data was to triangulate the findings of record review, and to explore possible confounders and explanatory variables of the study outcomes.

4.5 Data analysis

HIV-TB services audit data were analyzed to describe the overall performance of the health facilities programme implementation and service quality in the 2014 and 2015 cohorts. All data were analysed using STATA (Version 13.0, Stata Corp).

4.6 Reliability and validity

The inter-item correlations and Cronbach's Alpha of the respective scales service areas were also calculated to assess the tool's reliability. Apart from the original laboratory services audit tool, the rest of the audit tools were reliable, with Cronbach's Alpha at or exceeding the recommended 0.7 mark (Table 1). The reliability of the laboratory services audit tool was improved by deleting items with low inter-item and squared multiple correlations. This analysis was conducted before basic descriptive analysis to determine whether we could create reliable measurement scales using service area quality items.

Table 1: Reliability of audit tools used to assess the quality of HIV and TB services

SERVICE AREA AUDIT TOOLS	NUMBER OF ITEMS	CRONBACH'S ALPHA
Adult HIV treatment	15	0.8
HIV counselling and testing	5	0.8
TB case finding and management	10	0.9
Pharmacy	15	0.7
Laboratory (original)	8	0.5
Laboratory (revised)	5	0.7

Inter-item and squared multiple correlations analyses were used to explain the extent to which the performance of one item on a scale is affected by the scores of other items in the respective scales. Therefore, we used this analysis to identify items whose presence or absence was affected by the combined presence or absence of the rest of the items in the respective tools. Meaning, if a quality requirement (item) is met, it is highly likely that the rest of the quality requirements (items) in the audit tool are met. The items also had the highest loading in the principal component analysis and communality. This was done to identify relationships between items used to measure service area. It was also used as an objective data reduction technique to focus on the most relevant variables needed to measure each service area. We further carried out stepwise regression to identify the strongest predictors of the item. We used this analysis approach to identify possible precursors and covariates to target during routine quality maintenance audits with fewer items. Factor analysis was done to assess the validity of the tools and to explore the possibility of reducing each service area's tool to fewer clinically and statistically significant questions/items that can be used routinely.

After establishing the validity of the items and scales, we used descriptive analyses in the form of counts and percentages to present variables collected from the clinical audit and NIDS indicators. Differences in cohorts were determined using Chi-square or Fisher's Exact tests, as appropriate. Correlations were done between the extent of programme implementation and quality of services provided at the two time points. Using linear regression, the quality improvement measures and categories were adjusted against standard health systems performance indicators from NIDS of their respective service areas. The facility performance in 2014 and 2015 cohorts was compared using chi-square tests for categorical outcomes.

Continuous variables were compared with either Mann Whitney or ANOVA tests. We also calculated comparisons between districts, PHC facilities, and CHCs.

4.7 Ethics approval and consent to participate

Ethics approval to conduct the study was obtained from the University of the Witwatersrand Human Research Ethics Committee (number: M161025) and from the Associate Director for Science in the Center of Global Health, U.S. CDC. This project was reviewed in accordance with CDC human research protection procedures and was determined to be non-research. We conducted a secondary analysis of anonymised data and did not require individual patient consent. Consequently, our ethics approval was a waiver to use secondary data sources.

4.8 Conflict of interest disclosure

The authors whose names are listed immediately below certify that they have no financial or non-financial interests that may have inappropriately influenced them in the design and development of the subject matter or materials discussed in this report.

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- Dr Sisanda Gaga, MD
- Dr Jude Igumbor, PhD
- Nokuzola Mqoqi, MPH
- Dr Singilizwe Moko, PhD
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4.9 Funding information

This CQI project was supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S Centers for Disease Control and Prevention (CDC), under the terms of Cooperative Agreement Number NU2GGH001143. The evaluation was part of the CQI project by Beyond Zero. The final cost was US$47,350.91.

4.10 Dissemination plans

This CQI report will be disseminated via the publicly available Beyond Zero website (available here: https://beyondzero.org.za/news/).

A copy of the findings has been published in the Southern African Journal of HIV Medicine (available here: https://sajhivmed.org.za/index.php/hivmed/article/view/1202), and is attached as an appendix to this report.

5 RESULTS

5.1 Service area audit scores

Pharmacy and HCT service areas had the highest scores in the 2014 and 2015 audits. TB case finding and management recorded the lowest quality scores in both years showing a marginal improvement in 2015 (Table 2). The highest percentage differences in the two audits was recorded for the HCT (9%) and laboratory services (9%). Table 2 further shows that in 2015, District A had the highest HCT and adult HIV quality scores. In the same year, the highest pharmacy score manifested in District B and TB case finding and management quality audit score were relatively low in District A (73.8%) and District B (69.2%). Concurrently, District B retained the highest pharmacy score (89.8%), and District A retained highest adult ART score (84.3%). The highest improvement was reported in laboratory indices in District B (12.2%). The differences in cohorts were all statistically significant ($p<0.001$) except for District A where marginal improvement was observed because of its good performance in the previous audit.

Table 2: Percentage performance in the service areas by districts and cohorts,

Service Area	**District A**		**District B**		**Both Districts**	
	2014	**2015**	**2014**	**2015**	**2014**	**2015**
Adult ART services	84.3	87.5	79.6	84.1	80.0	83.9
HIV counselling and testing	89.8	92.2	82.6	86.9	80.8	89.8
TB case finding	66.7	73.8	65.2	69.2	68.9	72.4
Laboratory services	80.4	86.8	72.4	84.6	77.0	85.6
Pharmacy services	87.1	85.7	89.8	92.6	86.8	89.9

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). ART – antiretroviral therapy, HIV – Human immunodeficiency virus, TB - tuberculosis

In 2015, fewer (n = 18) health facilities were red flagged for intensive quality improvement in all the service areas compared to the number red-flagged in 2014 (n = 41) (Figure 1). The red flagged facilities scored below the 50% quality audit scores in the respective service areas.

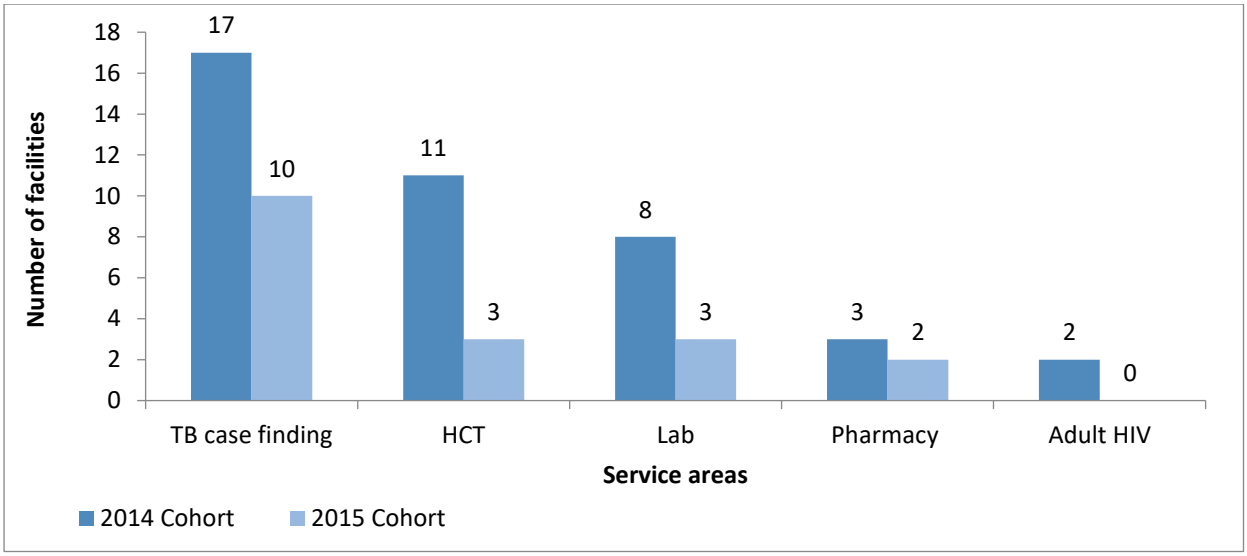

Figure 1: Number of health facilities with red-flagged service areas following the 2014 and 2015 audits

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). HCT – HIV counselling and testing; HIV – Human immunodeficiency virus; Lab – laboratory; TB – tuberculosis.

5.2 Best and worst performing items

Table 3 shows the worst and best performing items in the TB case finding and management service area based on the 2014 audit. TB case finding had the highest number of quality items that attained low audit scores. The performance of the respective service areas represents general improvement in 2015. This observation is against the backdrop that the TB service area has recorded relatively lower overall quality scores.

Items measuring TB laboratory test turnaround time recorded the lowest scores, particularly in District B. Consistently low in both districts was the provision of line probe assay (LPA) to non-converters and Isoniazid Prevention Therapy (IPT) to eligible contacts. Investigation of conversion just before three (3) months (at 11 weeks) in line with TB guidelines was relatively poor in both districts.

Equally poor in both districts was the cryptococcal antigen (CrAg) testing item of the adult ART service areas. The low proportion of patients positive for TB symptoms with appropriate further investigation was of concern under the adult ART service area. However, the adult ART service area had relatively higher overall quality audit scores compared to all other service areas. District A's relatively lower documentation of lost or rejected specimens was notable in the laboratory service area performance.

Table 3: Percentage scores of best and worst performing items in the TB case finding and management and adult ART service areas

Items	**Districts**	
	A	**B**
Line probe assay done for non-converters	27.6 %	30.4%
Baseline acid fast bacillus (AFB) tests result turnaround time (TAT) under 48 hours	28.7%	13.9%
Client investigated at 11 weeks	37.3%	59.5%
GeneXpert® result received under 48 hours	37.6%	15.1
IPT offered to eligible contacts	38.8%	32.9%
CrAg performed among eligible before ART initiated	44.5%	57.9%
Patient positive for TB symptoms had appropriate investigations ordered	52.6%	34.2%
Client diagnosed with GeneXpert®	97.0%	95.1%
Screened patient recorded at the last visit	97.1%	89.5%
Patient on Tenofovir Disoproxil Fumarate (TDF), Azidothymidine (AZT), Alluvia or Nevirapine (NVP) based regimen	99.6%	99.4%

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). ART – antiretroviral therapy; CrAG – Cryptococcal antigen; IPT – isoniazid preventive therapy; TB – tuberculosis.

5.3 Urban – rural differences in service area audit scores

When compared to the urban health facilities, the rural health facilities consistently performed better in raw audit scores for the TB case finding and management and laboratory service areas in both the 2014 and 2015 audits (Figure 2). Notwithstanding the apparent similarity in the performance in urban and rural facilities at both audits in the adult ART service area, rural facilities performed slightly better. The respective locations, however, recorded significant improvements in the 2015 cohort ($p<0.001$). The urban facilities performed better in the pharmacy service area. The highest improvement (12%) was recorded by rural facilities in the HCT area. Another area of notable improvement in both urban and rural areas was in laboratory services, with a statistical difference in 2015 in both locations compared to their performance in the 2014 audit ($p<0.001$).

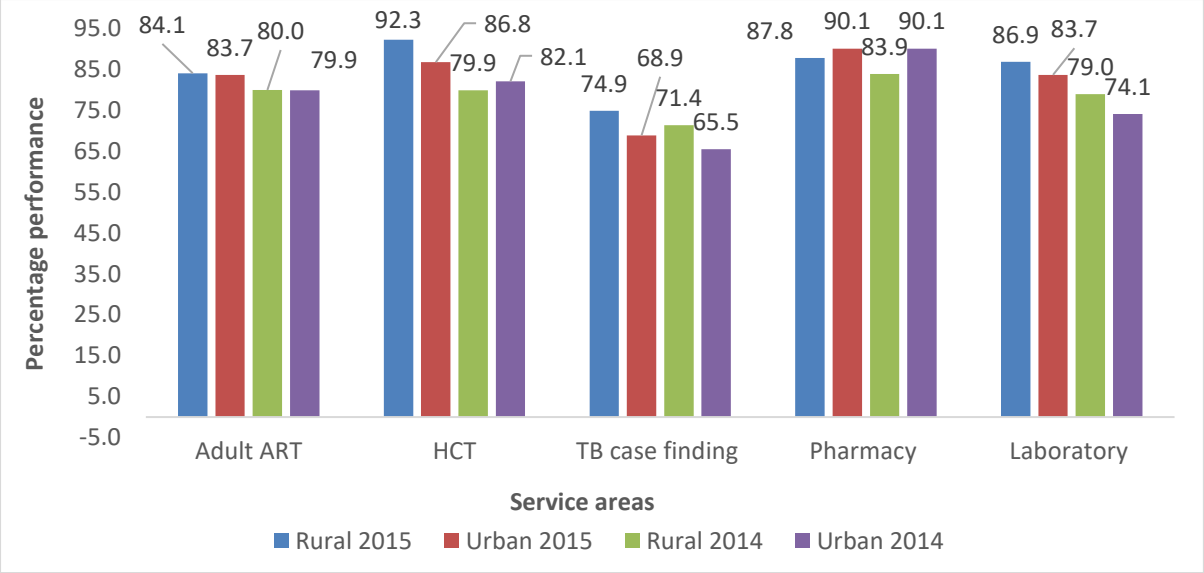

Figure 2: Urban and rural quality audit scores in 2014 and 2015 (pre and post CQI interventions)

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). ART – antiretroviral therapy; HCT – HIV counselling and testing; TB – tuberculosis.

5.4 Predictors of items with the highest loading in principal component analysis

The strength of the loading in principal component analysis is an indication of the relationship between a variable and items in the scale or in this case the service areas [18]. The adult ART service area audit item – "patient screened negative for any TB symptom and initiated for INH" – was a predictor of patients remaining on ART six months after treatment initiation ($R^2 = 0.5$). The predictors of received lab result recorded in shipping list / specimen book were the items: "rejected or lost results documented"; and "facility documenting samples on daily basis in shipping list / specimen book" ($R^2 = 0.5$). More predictions can be found in Table 4.

Table 4: Quality assessment items with the highest squared multiple correlation in each service area using the July 2014 baseline audit data

Audit tools	**Highest loading items and their predictors**		**Multiple correlation***	**Communalities%**
Adult HIV	Patient who screened positive for TB symptoms had appropriate investigations ordered?		0.8	0.9
	Main predictor:	Patient screened and recorded at last visit (R^2 = 0.7)		
HCT	HIV+ TB patient started on ART treatment?		0.6	0.8
	Main predictors: (R^2 = 0.5)	HIV + TB patient enrolled into HIV care		
		HIV + TB patient taking Cotrimoxazole prophylaxis		
TB case finding and management	Was client investigated at 11 weeks?		0.8	0.8
	Main predictor:	Was client investigated at seven weeks (R^2 = 0.5)?		
Pharmacy	Is the information on the bin card maintained and updated for HIV and TB?		-	0.9
	Main predictors: (R^2 = 0.4)	Bin card for each item in storeroom		
		ARV in stock		
		Is stock kept on shelves or pallets?		
Laboratory	Are rejected and lost samples documented in shipping list / specimen book?		0.6	0.8
	Main predictor:	Result received recorded in shipping list / specimen book? (R^2 = 0.5)		

* Multiple correlation - this is how well a variable can be predicted by other variables [29]
% Communalities – "proportion of each variable variance that can be explained by the factors"[30]

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). ART – antiretroviral therapy; ARV – antiretroviral; HCT – HIV counselling and testing; HIV – Human immunodeficiency virus; Lab – laboratory; TB – tuberculosis.

5.5 Performance of selected national indicator data sets (NIDS)

Based on the DHIS data, the 90 audited facilities varied in capacity and performance. Table 5 shows that District A had a high healthcare facility utilization rate, nurse workload and performed well in terms of HIV testing coverage. The table also depicts the relatively high HIV prevalence in District B despite the relatively low HIV testing coverage.

Table 5: Average district capacity and performance as at July 2014 based on NIDS data

CAPACITY AND PERFORMANCE INDICATORS*	DISTRICT A Mean (SD)	DISTRICT B Mean (SD)
PHC utilization rate (annualized)	3.4 (0.4)	2.6 (0.2)
PHC professional nurse clinical workload	53.2 (13.2)	26.5 (12.9)
PHC Doctor clinical workload	24.5 (9.2)	51.3 (31.3)
HIV testing coverage (annualized)	58.2 (19.2)	34.0 (32.3)
HIV prevalence among clients tested	2.4 (2.5)	8.6 (6.6)

* Indicator definitions and national averages are available in the District Health Barometer 2014/15 [15]

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). HIV – Human immunodeficiency virus; PHC – Primary Healthcare Clinic.

Figure 3 compares average facility performance based on routine DHIS indicators in the three months before (April – July 2014) and three months after (August - October 2015) CQI implementation. These time points are before and after the implementation of the tailored CQI interventions. The highest improvements were noted in HIV testing coverage (11%) and TB AFB sputum results turn-around time of under 48 hours (6%). The observed differences were also statistically significant ($p<0.001$). In addition to information in Figure 3, the data showed that TB case finding significantly increased by approximately 50% from 1.9 to 2.8 ($p<0.001$).

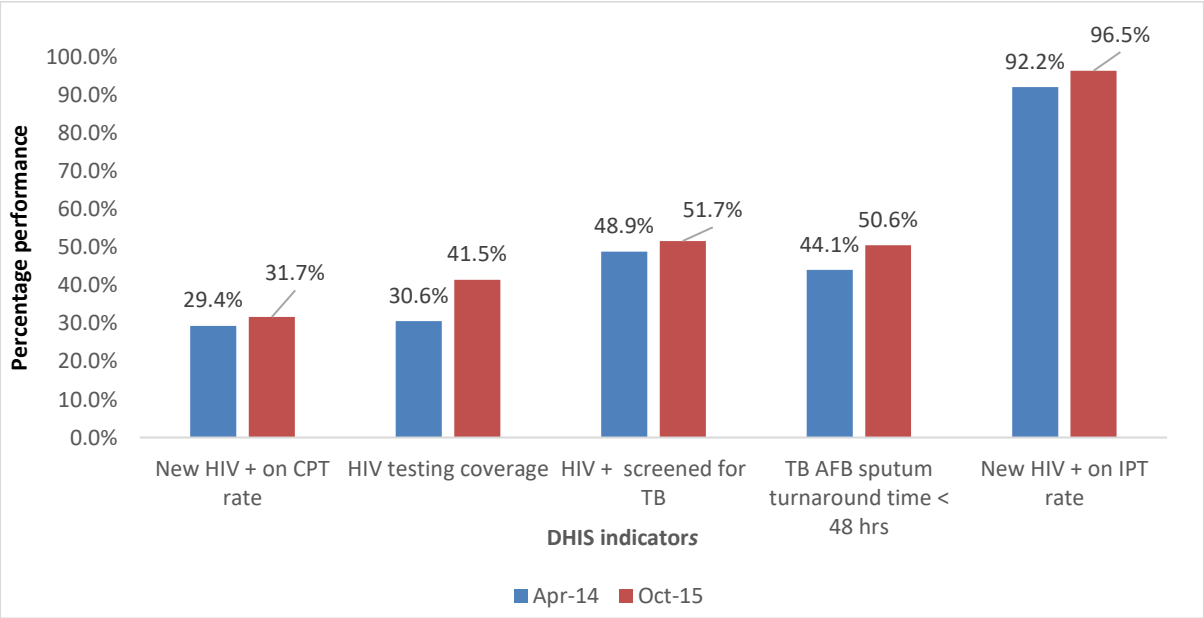

Figure 3: performance of facilities by DHIS indicator pre and post CQI intervention (April 2014 and October 2015)

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). AFB – acid fast bacilli;CPT – cotrimoxazole preventive therapy; HIV – Human immunodeficiency virus; IPT – isoniazid preventive therapy.

5.6 Relationship between service area quality scores and national indicator data set (NIDS)

Table 6 shows weak to moderate associations. These association albeit weak to moderate helps to validate our CQI instrument and establish associations between theoretically interdependent items. The strongest correlation was between the TB case finding and management audit score and the NIDS measuring the proportion of HIV positive patients screened for TB rate. Similarly, there were positive associations between HCT service area score with the NIDS indicator measuring the proportion of HIV positive patients screened for TB and HIV test coverage. HIV prevalence rate reported in the NIDS consistently demonstrated a negative relationship with the service areas quality scores to the extent that the higher the HIV prevalence the lower the quality scores. The laboratory service areas quality score showed associations with more NIDS indicators. Health facilities with higher utilization rate and workload performed better in the laboratory service area while facilities with higher HIV prevalence and higher TB screening rate performed poorly in the laboratory service area.

Table 6 also suggests that facilities that did better in the TB case management (in terms of service area score) might not have done so well with screening new HIV positive patients for TB (and vice versa). The facilities with better TB case management also had lower doctor workload.

Figure 4 shows the correlation coefficients of the average HIV positive TB patient screened rates and the TB case finding and management categories in both years and districts. Health facilities that were performing relatively better than other health facilities in the TB case finding and management service area had significantly less HIV positive screened for TB rate compared to facilities in the poor and good categories.

Table 6: Correlations between service area scores and routinely collected NIDS

National Indicator Data Set	Service area correlation coefficients				
	Adult ART	HCT	TB case finding and management	Pharmacy	Laboratory
Median HIV test coverage (Apr - Jul 2014)	0.27	0.24	0.14	0.05	0.27

Median HIV prevalence rate (Apr - Jul 2014)	-0.27	-0.26	-0.09	0.01	-0.24
Median HIV + patient screen for TB rate (Apr - Jul 2014)	0.10	0.28	-0.45	0.24	-0.19
Median HIV + initiated on IPT rate (Apr - Jul 2014)	0.13	0.16	0.15	0.10	-0.14
Median utilization rate (Apr - Jul 2014)	0.03	0.19	0.16	-0.02	0.27
Median nurse workload (Apr - Jul 2014)	0.04	0.08	0.03	-0.02	0.25
Median PHC doctor workload (Apr - Jul 2014)	-0.15	-0.11	-0.43	0.02	-0.07

Correlations significant at 0.01 level (2 tailed) highlighted in blue

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). Art – antiretroviral therapy; HCT – HIV counselling and testing; HIV – Human immunodeficiency virus; PHC – primary healthcare clinic; TB – tuberculosis.

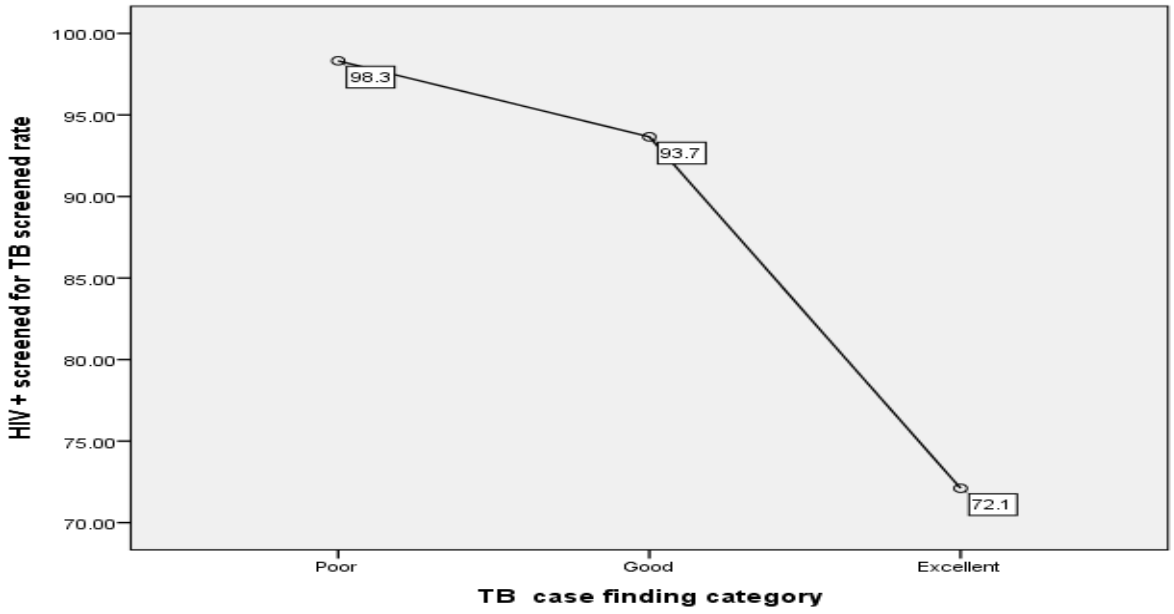

Figure 4: Average HIV + patient screen for TB rate by TB case finding and management service area quality category

Extent of implementation of HIV and TB programme services and the effect of quality improvement interventions in selected districts supported by Beyond Zero (2014 – 2015). HIV – Human immunodeficiency virus; Lab – laboratory; TB – tuberculosis.

6 DISCUSSION

This report provides evidence of improvements in processes and outcomes in all service areas following the CQI process. This observation is informed by the significant decline in the number of health facilities with red-flagged audit scores (below 50% compliance with prescribed services) as well as the observed improvements in most service areas across districts among the 2015 cohort in comparison to the 2014 cohort. While marginal improvements may be observed in scores aggregated in both districts, the magnitude of effect varies across service areas and districts. This may be attributed to the varying demand/supply ratio (e.g., patient load versus human resources) across facilities and service areas as well as other factors unique to service areas, districts and/or facilities.

Furthermore, the inverse relationship observed between the quality and volume of services provided suggests that the poor quality observed in some facilities may be a result of high volume of work. Consequently, increasing the supply and/or efficiency of human resources may improve the quality scores in such facilities. Further research would help to clarify this relationship.

Marked improvement was noted in HCT and laboratory samples and tests results management. This may be due to the implementing partner's generic interventions to improve both components at all its supported sites. Implementing partner's focus on these service areas is over and above the site-specific interventions that were developed and implemented during the CQI project.

This assessment found that the HCT had the most marked reduction in the number of facilities red-flagged between the 2014 and 2015 audits. A positive association between quality scores for HCT service area and NIDS indicators related to HIV and/or TB supports other research studies and policy documents, which suggest that a synergistic approach to HIV/TB case management will result in better service outcomes [19]. A large and compelling clinical evidence base has shown that integrated TB and HIV services leads to reduction in human immunodeficiency virus (HIV)- and tuberculosis (TB)-associated mortality and morbidity. A number of studies provide evidence of the relationships in the integration framework that applies to TB and HIV healthcare delivery [31–34].

However, integration of these services is not without systemic challenges. Insufficient stakeholder consultations, poor leadership, and lack of political-will are common bottlenecks

to the implementation of integrated HIV and TB policy in parts of South Africa [20]. A similar study in Uganda reported integration constraints in addition to other factors such as poor planning and coordination as well as inadequate provider knowledge of interpreting TB laboratory results [21]. The health system governance bottlenecks may account for the differential improvement rates observed, particularly in District A, which had the most marked quality improvement audit scores in this service area. Several studies point out that HIV and TB integration remains suboptimal and can be improved by addressing the systemic challenges affecting health service delivery, including strengthening supervision, training and the implementation of a change management programme [35–36].

Interestingly, while both districts scored high with respect to ensuring patients are diagnosed with TB utilizing the GeneXpert® [22] system, ensuring a 48-hour turn-around time for the results was suboptimal. The implication is that whereas clients may be getting the needed services, there is a need to further improve implementation fidelity of service processes. Even though the GeneXpert® test for TB is reputed to deliver results in two hours under ideal conditions, operational barriers commonly affect this turn-around time in real-world settings. Piatek et al. [22] identified the following barriers; inadequate human resources, practices of batching specimens, as well as inefficient specimen referral and transport networks. Thus, addressing these issues as part of this CQI initiative may improve the quality of GeneXpert® services, including turn-around time for all laboratory tests.

We also found that facilities with high TB case finding service area quality scores also had lower smear positive rates. This may imply that available health workers were unable to meet the demand for screening services, thus trade-offs between quality of services and meeting quantity of demand for services were occurring at the health facilities. This trade-off is not unique to the South African context. A recent study in neighbouring Lesotho also identified inadequate workforce as a major reason for poor adherence to TB control guidelines [23]. The observed pattern could be a result of the discretionary power of frontline health workers in determining how to implement the guidelines and policy [24]. In this scenario, the decision to trade quality of services for volume is likely to result from reactionary discretion of the health workers, when faced with work overload, irrespective of policies and guidelines. Walker and Gilson [25] studied the attitudes of frontline nurses in South Africa and found that personal views and values influence health workers' discretion to adhere to policy or guidelines. Thus, to minimize the impact of frontline discretionary power on quality-of-service delivery, efforts

should be made to ensure adequate distribution of health workers. Furthermore, health workers require continuous and/or ongoing training on guidelines, with emphasis on the importance of adherence to quality. Enhanced supportive supervision may also limit discretionary space of frontline workers. Specific activities that warrant further attention include ensuring that Line Probe Assays are done for none-converters, IPT is initiated for eligible contacts and turn-around time for AFB and GeneXpert® results are improved.

6.1 Limitations of the study

While this study provides useful insight into the effect of a CQI process in enhancing HIV and TB service delivery efforts in parts of South Africa, notable study limitations should be highlighted. The quality of care reported in the study did not include patient valuation of services provided despite its importance in quality measurement. However, we focused on the process of care delivery, which is one of the intermediaries of the six elements of care improvement proposed by the Institute of Medicine [26]. The six elements are patient centred care and satisfaction, timeliness, safety, equity, efficiency, and effectiveness. We did not compare our study sites with non-intervention sites to fully substantiate the impact and ascertain the efficacy of the intervention or if it translated to patient health outcome. Nonetheless, the short duration of the intervention, the high number of health facilities covered, the significant improvement in districts with long history of poor performance [15] may give credence to our CQI intervention. The study's heavy reliance on routine health services data that is prone to incompleteness should also be noted. Furthermore, the study did not measure the long-term durability and sustainability of the CQI process. However, this investigation strongly demonstrates the extent to which intended services are provided. Such information is essential to gauge and promote adherence to evidence based clinical guidelines while relying on appropriate measures to address other limitations.

6.2 Conclusion and recommendations

This assessment revealed overall improvement in the quality of adult ART services between 2014 and 2015 in both districts. The adult ART service area had relatively higher overall quality scores compared to all the other service areas. However, whereas quality scores were very high with respect to screening and treatment services, improving the screening for opportunistic infections such as CrAg as well as strengthening clinical integration of TB/HIV services is important. For example, a significant proportion of eligible clients did not have CrAg performed before commencement of ART. While the cause of this observation may be beyond

the scope of this study, a study in the Western Cape singled out forgetfulness to order the test by providers as the major cause of this implementation gap [27]. Other authors have recommended reflex laboratory testing approach as a more effective alternative to provider-induced testing. Reflexed tests automatically result in the order of one or more secondary tests based on predetermined criteria applied to the primary test [28]. Ultimately, targeting and improving poor performing items could improve any service area's overall quality score.

This study contributes to empirical evidence of the effectiveness of the CQI intervention on service delivery processes and outcomes in South Africa. Our claim stands on the significant improvement in service area outcomes following our CQI intervention. Various types of CQI methods have been widely adopted in healthcare with numerous reports of success [8]. This assessment corroborates existing studies which found the use of CQI both feasible and acceptable with respect to HIV/TB case finding and management. [20] Therefore, implementing a suitable CQI model in each district at intervals aligned to the disease burden and available resources including human resources for service delivery and technical support is critical.

Elsewhere, it has also been reported that the success of CQI initiatives depends on frontline health workers' involvement as well as strong organizational support. [29] Therefore, we encourage adequate capacitation and distribution of health workers to match demand for services. Strategies such as improving supportive supervision of health workers at service delivery points and strengthening clinical governance will ensure compliance with service delivery guidelines and enhance positive organizational behaviour. The adoption of available technological solutions to help minimize errors may also improve quality and human resource efficiency. Lastly, strengthening integrated service delivery, particularly the TB and HIV interface, is important to promote human and material resource efficiency.

1. The observed pattern could be because of the discretionary power of frontline health workers in determining how to implement the guidelines and policies. In this scenario, the decision to trade quality of services for volume is likely to result from reactionary discretion of the healthcare workers, when faced with work overload, irrespective of policies and guidelines. Walker and Gilson studied the attitudes of frontline nurses in SA, and found that personal views and values influence healthcare workers' discretion to adhere to policies and guidelines. Thus, in order to minimise the impact of frontline discretionary power on quality-of-service delivery, efforts should be made to ensure adequate distribution of healthcare workers.
2. Furthermore, healthcare workers require continuous and/or ongoing training on guidelines, with emphasis on the importance of adherence to quality.
3. Enhanced supportive supervision may also limit the discretionary space of frontline healthcare workers.
4. Specific activities that require further attention include ensuring that line probe assays are performed for non-converters, IPT is initiated for eligible contacts, and the turnaround time for AFB and GeneXpert® results is improved by strengthening the clinic-laboratory interface (CLI).

Table 7: Specific recommendations

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APPENDICES

Appendix 1: Supplementary Information 1: List of items used for quality-of-care audit

S/N	ITEMS
	Facility Adult HIV treatment
1	Is baseline CD4 count recorded?
2	Is baseline WHO clinical stage recorded?
3	Is patient's WHO clinical stage recorded at last visit?
4	Is patient's weight recorded at the last visit?
5	Is the patient eligible for Cryptococcal Antigen (CrAg) test at ART initiation (CD4 < 100)?
5.1	If patient eligible, was CrAg performed before ART initiated?
6	Is the patient on TDF, AZT, LPV-r (Alluvia) or NVP containing regimen?
6.1	If yes is Creatinine, or HB or ALT or Cholesterol or triglyceride done at baseline and at follow-up visits as per national guidelines?
7	Was the patient's TB screening documented at the last visit?
8	Did the patient screen positive for any TB symptom?
8.1	If patient screened positive for TB symptoms, were appropriate investigations ordered for PTB or EPTB?
9	If patient screened negative for any TB symptom and eligible for Isoniazid Preventive Therapy (IPT) was the patient-initiated Isoniazid (INH)?
10	Is the patient eligible for Cotrimoxazole Preventative Therapy (CPT), i.e. WHO 2, 3 or 4; and/or CD4 <200?

11	If patient eligible, was Cotrimoxazole (or with contra-indications, Dapsone) initiated?
12	Is this patient still on ART after 6 months of ART initiation?
HCT TB – HIV integration service	
13	TB patients (new & relapsed) with an HIV status recorded (*on both TB register and blue card)*
14	HIV positive TB patient enrolled into HIV care (SCR opened, CD4 recorded)
15	Is HIV positive TB patient taking cotrimoxazole (CPT)?
16	HIV+ TB patient started on ART treatment?
17	HIV+ TB patient started on ART during the first 2 to 8 weeks of TB treatment
	Age – At first diagnosis
	DOB – At first diagnosis
	Sex – At first diagnosis
TB Services and case finding	
18	Was client diagnosed on GeneXpert (GXP)?
19	Is GXP result received in less 48 hours?
20	Is baseline smear AFB done for eligible client
21	Is baseline smear AFB result turn-around time (TAT) within or < 48 hours?
22	Is the TAT correctly documented in the case identification register?
23	Was the correct coding done according to type of TB?

24	Is the patient appearing on TB Diary?
25	Was the patient investigated at 7 weeks (smears for AFB taken)?
26	Did the patient smear convert at 7 weeks?
27	Was Line Probe Assay (LPA) done for non-converters?
28	Was the patient investigated at 11 weeks (smears for AFB taken)?
29	Was 2nd and/or 3rd smear taken?
29.1	If yes, are results recorded in register
30	Is the patient's outcome recorded in register?
30.1	Is the outcome correct?
31	Was TB contact identification and tracing done?
31.1	Were the contacts screened?
31.2	Was IPT offered to eligible contacts?
Facility pharmacy services	
32	Is there a bin card for each item in the storeroom or electronic system (either)?
33	Is the information on the bin card maintained and updated for HIV and TB?
	ARVS
	Co-trimoxazole
	Isoniazid
	TB medication

34	Is the stockroom temperature monitored (information on the chart)?
35	Is the air conditioner working?
36	Is the temperature less than 25°C?
37	Is the fridge temperature monitored?

Appendix 2: Supplementary information 2: List of indicators and data requested from NDOH

All data requested are health facility level aggregate data and has no patient unique data and they include:

1. HIV prevalence
2. Health facility utilization rate
3. Nurse and doctor workloads
4. Number of people initiated on treatment during the audit period
5. Number of patients remaining in care during the period
6. Patient headcount during the audit period
7. Number of HIV/TB deaths reported during the audit period

Appendix 3: Published manuscript

Gaga, S., Mqoqi, N., Chimatira, R., Moko, S. and Igumbor, J.O., 2021. Continuous quality improvement in HIV and TB services at selected healthcare facilities in South Africa. Southern African Journal of HIV Medicine, 22(1).

A version of the CQI report has been disseminated in the Southern African Journal of HIV Medicine. A pdf copy of the published manuscript accompanies this report, a copy of which can be downloaded here: https://sajhivmed.org.za/index.php/hivmed/article/view/1202