Evaluation Report

Project Title	South Africa: Technical Assistance Program Area #2:(1) Support Quality Improvement activities Evaluation of HIV Testing and Linkage to ART Services among Patients with Presumptive TB
Cooperative Agreement Funding Opportunity Announcement (FOA)	5 NU2GGH001194-05-00
Grantee	The Trustees of Columbia University in the City of New York ICAP, Mailman School of Public Health
Grantee Address	630 West 168 Street, Box 49 New York, NY 10032
Project Period	April 1, 2014 – September 29, 2019
Annual Progress Report Budget Period	April 1, 2018 – September 29, 2019
Reporting Period Funding	$200,000
Sub-Recipients	not applicable
Project Lead	Dr. Andrea Howard
Principal Investigator	Dr. Susan Michaels-Strasser
Email Contact	icap-awards@cumc.columbia.edu

This research has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC) under the terms of U2GGH001194.

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1. Executive Summary

The overall aim of this project was to provide technical assistance (TA) to the South African National Department of Health (NDOH) to operationalize and evaluate systematic HIV testing among patients with presumptive tuberculosis (TB), and index testing, TB preventive treatment (TPT) and enrolment on antiretroviral therapy (ART) of those found to be HIV-positive. The project was conducted in Ekurhuleni District and City of Tshwane Municipality in the Gauteng Province of the Republic of South Africa from August to December 2019. PEPFAR-supported health facilities that provide HIV and TB services were purposively selected from among all PEPFAR-supported facilities in districts with high TB and HIV burden. All facilities had high patient volume and were selected in coordination with the South Africa Department of Health (DOH) and United States Centers for Disease Control and Prevention (CDC). Several meetings were held with the DOH at National, Provincial, District, and facility levels as well as with district support partners, The Wits Reproductive Health and HIV Institute (WITS RHI) and Aurum Institute. The purpose of these meetings was to introduce the project and for stakeholders to endorse outinizing HIV testing among presumptive TB patients in the selected facilities.

A rapid pre-assessment was conducted at the ten selected health facilities between August-September 2019 to document current practices and tools for: (1) HIV testing among patients with presumptive TB; (2) facilitation of index testing; and (3) linkage to ART services and TPT for individuals diagnosed as HIV-positive. Pre-assessment findings were shared with the National DOH (NDOH) and Provincial DOH. A one-day training for health care workers (HCW) from the participating facilities including nursing staff working with TB and HIV patients, lay counselors and facility managers was conducted October 24-30, 2019. Training topics included HIV testing for patients with presumptive TB, index testing, linkage to ART services and TPT. The training focused on identifying areas requiring strengthening, updating staff on revisions and updates of National Guidelines and Standards of Practice, and creating specific objectives tailored to the gaps and resources available in each clinic. HCW were mentored and provided with technical assistance and in-service trainings to support implementation of the suggested interventions for strengthening service provision for the duration of November 2019.

Routinely collected data for the month of November 2019 were abstracted from clinic records including the TB Screening Tool, TB Identification Register, Index Testing Register, Primary Health Care Tick Register (at each point of care), HIV Testing Services Register, Tier.net and patient files, by trained data capturers. Findings were shared with the NDOH, CDC and district support partners including areas requiring continued support from the district support partners

Overall, 910 patients with presumptive TB were identified in November 2019 and documented in facility data sources. Of the 910 patients with presumptive TB, 662 (73%) had a known and documented HIV status. By patient type, 72% of patients with presumptive TB without TB disease had a known HIV status, compared to 67% among patients with presumptive TB without evaluation for TB disease, and 84% among patients with TB disease. At time of identification with presumptive TB, 39% of patients had a known positive HIV status, while 8% were newly tested HIV-positive, and 26% were newly tested HIV-negative. Those patients that were diagnosed with TB disease had the highest positivity (46% known positive, and 22% newly diagnosed HIV-positive, for overall positivity of 81% among TB patients with known HIV status). Among patients with presumptive TB with TB disease ruled out, overall HIV positivity was 62% among those with a known HIV status, while among patients with presumptive TB who did not receive evaluation for TB disease, HIV positivity was 64%. Of the 426 HIV-positive patients with presumptive TB, 66% (n=279) were already on ART at the time they were identified with presumptive TB. Of the remaining 147 patients, 68 (46%) were newly initiated on ART, while 79 (54%) had no

documentation of linkage to ART. In total, 81% of HIV-positive TB patients were on ART, while 19% had no documentation of linkage. By patient type, 83% of HIV-positive patients with presumptive TB without TB disease were on ART, compared to 89% of patients with presumptive TB who were not evaluated for TB disease, and 70% among patients with TB disease. Among the 426 HIV-positive patients with presumptive TB, only 4 (1%) were offered index case testing services, and all accepted index case testing. Among the 4 patients who received index case testing services, 3 contacts were identified and 1 was tested and found to be HIV-positive. Among the 342 HIV-positive patients with presumptive TB eligible for TPT (i.e., TB disease ruled out), 85 (25%) were already on TPT at the time of identification with presumptive TB and 6 (2%) were initiated on TPT, while 251 (73%) were not started on TPT.

Although of limited duration, this project demonstrated that provision of HIV testing among patients with presumptive TB in high volume health facilities is feasible and detects a substantial number of patients with HIV. Few HIV-positive patients with presumptive TB were offered index testing services. Less than half of HIV-positive patients with presumptive TB who were not already on ART were linked to HIV treatment, and most patients in whom TB was ruled out were not initiated on TPT. Interventions aimed at improving index case testing and ensuring prompt initiation of ART and TPT for patients with presumptive TB found to be HIV-positive are recommended to be prioritized.

2. Acronyms

ADS	Associate Director for Science
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CDC	United States Centers for Disease Control and Prevention
CHC	Community Health Centre
CUIMC	Columbia University Irving Medical Center
DOH	Department of Health
HCW	Healthcare Worker
HIV	Human Immunodeficiency Virus
HSRC REC	Human Sciences Research Council Research Ethics Committee
HTS	HIV Testing Services
IRB	Institutional Review Board
M&E	Monitoring and Evaluation
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counseling
PLHIV	People Living With HIV
SOP	Standard Operating Procedure
TA	Technical Assistance
TB	Tuberculosis
WHO	World Health Organization

3. Project Background

TB is a leading cause of morbidity and mortality among people living with HIV (PLHIV), accounting for 32% of acquired immunodeficiency virus (AIDS)-related deaths.[1] South Africa is a country with a high burden of HIV and TB, with an estimated HIV prevalence of 20.4% among adults 15–49 years in 2018, and a TB incidence rate of 615 per 100,000 in 2019; 58% of TB cases are HIV positive.[2,3] Countries, including South Africa, have made significant progress in the implementation of a package of WHO-recommended TB/HIV collaborative activities aimed at mitigating the dual burden of TB/HIV.[4] Within the TB/HIV collaborative framework, it is recommended that routine HIV testing be offered to all TB patients, to all those with signs and symptoms of TB (presumptive TB, defined as current cough, fever, weight loss, and/or night sweats), and to partners of known HIV-positive TB patients.[5] South Africa has scaled-up provider-initiated testing and counseling (PITC) of TB patients and in 2017, 94% of notified TB patients had a documented HIV test result.[6] The coverage of ART for notified TB patients known to be HIV-positive has also increased in South Africa, reaching 89% in 2017.[7]

However, implementation of HIV testing among patients with presumptive TB has been less robust. Several studies have found high uptake of HIV testing and a high proportion of HIV positivity among those with presumptive TB, even as high as that among patients with active TB.[8,9,10,11] One study found that implementation of PITC among patients with presumptive TB was feasible and effective, and detected a large number of patients with HIV with minimal additional workload on staff.[12] Therefore, persons presumed to have TB are high-yield populations for identifying PLHIV who do not yet know their HIV status. This is also a high-yield intervention to reach undiagnosed HIV-positive men, as over half of TB cases are among males. In addition, programmatic data demonstrate that these PLHIV tend to have advanced HIV disease and benefit the most from early initiation of ART. Particularly in the context of Test and Start, HIV testing among this group of patients will increase HIV case finding, reduce the testing gap among men, improve early ART initiation, and reduce morbidity and mortality from HIV/AIDS and HIV-associated TB.

3.1 Rationale and Justification

Despite the WHO recommendation to offer routine HIV testing to all those with signs and symptoms of TB,[13] few countries have systematically and successfully integrated these activities into routine clinical practice. HIV testing in patients with active TB disease is well integrated into country TB and HIV programs and is widely reported on; however, there is a dearth of available data on the proportion of patients with presumptive TB with a known HIV status, who are HIV-positive, and, among those who are positive, linked to ART. Operational guidance is needed to routinize HIV testing among presumptive TB patients, and determine what processes work best in country-specific settings.

3.2 How Findings Will be Used and by Whom

Findings from the evaluation will inform routine provision of HIV testing services for patients with presumptive TB as well as index testing services and linkage to ART and TPT for those who test HIV-positive, at participating health facilities as well as health facilities in South Africa more broadly. ICAP has shared findings from the evaluation with the DOH, CDC and district support partners, including what processes worked well and what challenges arose during efforts to strengthen implementation of activities, as well as recommendations for continued implementation support beyond the period of this project.

3.3 Objectives of Evaluation

The purpose of the project was to aid the South African DOH to improve HIV testing services among patients with presumptive TB and strengthen index testing, and linkage to ART and TPT. ICAP provided technical assistance to 10 high-volume health facilities in Ekurhuleni District and City of Tshwane Municipality in the Gauteng Region of the Republic of South Africa. The evaluation assessed the achievements of the strengthened services in South Africa using data collected as part of routine service delivery and monitoring. The main objectives of this evaluation were:

1. Conduct rapid pre-assessment of current practices and tools for HIV testing among patients with presumptive TB and index testing, linkage to ART services, and linkage to TPT among patients with presumptive TB who are HIV-positive at the selected facilities in South Africa
2. Support the implementation of systematic and universal HIV testing among patients with presumptive TB at selected facilities in South Africa through development/revision of SOPs and monitoring and evaluation(M&E) tools and training and mentorship of HCW
3. Support index testing among patients with presumptive TB who test HIV-positive through development/revision of SOPs and training and mentorship of HCW
4. Support linkage to ART services among patients with presumptive TB who test HIV-positive, including those who are diagnosed with TB and those who are Xpert negative (and are not otherwise diagnosed with TB disease through clinical or radiological criteria) through development/revision of SOPs and training and mentorship of HCW
5. Support linkage of TPT among patients with presumptive TB who test HIV-positive, and are Xpert negative (and are not otherwise diagnosed with TB disease through clinical or radiological criteria) through development/revision of SOPs and training and mentorship of HCW
6. Revise/develop M&E tools to capture HIV testing, index testing, and linkage to treatment or TPT and ART initiation among patients with presumptive TB
7. Develop electronic database, and retrospectively collect routinely-collected client-level data from selected facilities on HIV testing among patients with presumptive TB, and index testing, and linkage to ART services and TPT among those who test HIV-positive; analyze results and draft report
8. Provide feedback to the South African DOH, CDC and other stakeholders on the evaluation findings to inform implementation of HIV testing of patients with presumptive TB, and index testing and linkage to ART and TPT among those who test HIV-positive

3.4 Evaluation Questions

The evaluation questions included the following:

1. How many HCW were trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing?
2. What proportion of all HCW at the participating facilities were trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing?
3. What proportion of all HCW at the participating facilities were trained on revised M&E tools?
4. What proportion of patients with presumptive TB had a known HIV-positive status?
5. What proportion of patients with presumptive TB had an unknown HIV status (not tested for HIV in the past, tested HIV-negative > 1 year ago, or tested HIV-negative < 1 year ago

6. What proportion of patients with presumptive TB with an unknown HIV status were tested for HIV and how many were found to be HIV positive?
7. What proportion of patients with presumptive TB had a known HIV status (known HIV positive, newly identified HIV positive, newly identified HIV negative?
    a. What proportion of patients with presumptive TB were HIV positive (known HIV positive and newly identified HIV-positive)?
8. What proportion of HIV-positive patients with presumptive TB were offered index testing services?
    a. What proportion of index clients accepted index testing services?
    b. What proportion of identified contracts were Known Positive?
    c. What proportion of identified contacts received HIV testing?
    d. What proportion of contacts tested HIV positive, and what proportion tested HIV negative?
    e. The HIV status of contacts elicited (number/proportion Not Tested, Known Positive, New Positive, New Negative)?
9. What proportion of HIV-positive patients with presumptive TB were linked to ART services? (include newly identified HIV-positive, pre-ART, and lost to follow-up)
10. What proportion of HIV-positive patients with presumptive TB were linked to ART services and initiated ART within 1 week of enrollment in care (disaggregated by those who were Xpert-positive and Xpert-negative [and were not otherwise diagnosed with TB disease])?
11. What proportion of HIV-positive patients with presumptive TB who were Xpert negative were initiated on TPT?

4. Evaluation Design, Methods, and Limitations

4.1 Overall Evaluation Design

This was a quantitative outcome evaluation of a strengthened approach to HIV testing among patients with presumptive TB and index testing, linkage to ART services and linkage to TPT among patients with presumptive TB who are HIV-positive at selected facilities.

Current practices at health facilities do not allow for complete documentation and tracking of patients with presumptive TB from identification to HIV testing through ART initiation for those that are HIV-positive. Existing M&E tools only collect data on TB screening, and HIV status (positive, negative, unknown) for patients who screen positive for TB. Data are not systematically collected and reported on number and proportion of patients with presumptive TB with known HIV status, tested for HIV, identified as HIV positive, offered index testing services, linked to ART services, timing of ART initiation, and linked to TPT. The project quantified the impact of implementing HIV testing among patients with presumptive TB and strengthening index testing and timely linkage to ART and TPT services among patients with presumptive TB who are HIV-positive in selected facilities in Gauteng Province in South Africa through the indicators collected. The health facilities participating in this evaluation supported the updated service delivery processes as part of efforts to improve HIV testing, index testing and linkage to ART and TPT for patients with presumptive TB. As such, all patients with presumptive TB identified at the selected health facilities were to receive the updated services. The evaluation analyzed retrospectively collected data from presumptive TB patients attending participating facilities during the implementation period.

4.2 Sampling and Sites

4.2.1 Estimated Sample Sizes

This program evaluation was intended to describe the enhanced efforts to improve implementation of HIV testing of presumptive TB patients as recommended by the South African DOH. The evaluation was designed to be descriptive with regard to testing and linkage outcomes (i.e. it was not specifically powered to answer the questions). Based on existing data from the participating health facilities, it was anticipated that approximately 1,600 patients with presumptive TB, including 880 HIV-positive patients with presumptive TB, would be identified over the anticipated 2-month evaluation period.

4.2.2 Obtained Sample Sizes

During November 2019, a total of 910 patients with presumptive TB were identified and documented in facility data sources. Of the 910 patients with presumptive TB, 353 (39%) had a known HIV-positive status, and 73 newly tested HIV-positive.

4.2.3 Evaluation Sites

The project was conducted in Ekurhuleni District and City of Tshwane Municipality in the Gauteng Region of the Republic of South Africa. Ten health facilities that provide HIV and TB services were purposively selected from among all PEPFAR-supported facilities in high TB and HIV burden districts (part of Operation 10-10). All facilities had a high patient volume and were selected in coordination with the South Africa DOH and CDC. Selected facilities include:

<u>City of Tshwane Metropolitan Municipality</u>

1. Soshanguve Block JJ Clinic
2. KT Motubase Clinic
3. Laudium Community Health Centre (CHC)
4. Pedisong 1 Clinic
5. Stanza Bopape CHC

<u>Ekurhuleni</u>

6. Ethafeni Clinic
7. Vosloorus Poly Clinic
8. Esangweni CHC
9. Tsakane Clinic
10. Goba Clinic

4.3 Data Collection Methods and Rationale

Data on individuals with presumptive TB attending services at participating facilities during November 2019 were abstracted by project Data Collectors, who de-identified patient-level data as they were abstracted. The variables listed in the table below were abstracted from facility registers and tools, including the TB Screening Tool, TB Identification Register, Index Testing Register, Primary Health Care Tick Register (at each point of care), HIV Testing Services Register, Tier.net and patient files.

Variable Name
Demographics
Facility Name
Point of Service
Sex

Age (in years)
TB Screening and HIV Testing
Date identified as presumptive TB
GeneXpert done
GeneXpert test date
GeneXpert Result (Xpert-negative, Xpert-positive RIF-S, Xpert-positive RIF-R, indeterminate)
Smear microscopy done
Date of smear microscopy
Smear microscopy result (negative, positive)
TB culture done
Date of TB culture
Culture result (negative, positive, contaminated)
Diagnosed with TB (Yes, No)
Date of TB diagnosis
HIV status at entry (known positive, tested HIV negative in the past year, unknown status [not tested for HIV in the past, or tested HIV negative > 1 year ago]
Tested for HIV (Yes, Refused HIV testing, No, Unknown, N/A)
Date of HIV test
HIV test result (Positive, Negative, Indeterminate)
Started on TB treatment
Date started TB treatment
Index Testing
Offered index testing services
Date offered index testing services
Accepted index testing services
Number of contacts elicited
Number of contacts tested for HIV
HIV status of contacts elicited (number known positive, new positive, new negative, not tested)
Linkage to ART (among HIV-positive patients without TB disease)
Already on ART (Yes, No)
Linked to ART services (Yes, No)
Date of linkage to ART services
Initiated on ART (Yes, No)
Date of ART initiation
Linkage to TPT (among HIV-positive patients without TB disease)
Already on TPT (Yes, No)
Linked to TPT (Yes, No)
Date of linkage to TPT
Initiated on TPT (Yes, No)
TPT start date

No identifying information (names, identification numbers, medical record numbers, addresses) was collected; as a result, all data for the study were completely de-identified.

4.4 Data Handling Procedures

Data abstracted from patient records and facility registers were entered into a password-protected electronic database developed by ICAP for the evaluation (during routine care, clinical data are entered into facility registers and charts by health care facility staff). The database was built in SurveyCTO. The database was backed up daily, and backups were archived on a secure and reliable Amazon storage service. No names, national identification numbers, clinic identification numbers, addresses, phone number or other personally-identifiable locator information were entered into the study database.

Patient clinical data were entered into existing registers and charts by health care facility staff during clinical care visits as part of routine service delivery. For the evaluation, data abstracted from patient records and registers were entered on the Survey CTO application using password-protected electronic tablets. Data entry occurred in a private or semi-private area of the health facility where patients and non-authorized health facility staff were not be able to see the data as they were entered. The tablets remained in the possession of ICAP Data Collectors while at the facilities and were stored in a secure location when not in use. Data were electronically uploaded to a secure, password-protected cloud-based SurveyCTO server daily when the tablet was connected to the internet. A copy of the de-identified electronic database was saved on a CUIMC-certified multi-user server; only study investigators had access to the files.

4.5 Data Quality Assurance

As part of technical support for service implementation at the implementing health facilities, ICAP supported efforts to improve the quality of routinely collected data. Abstraction of retrospective data for the evaluation was conducted by trained project Data Collectors under the supervision of the Project Coordinator. During data collection, the Project Coordinator visited each site once a week to review and monitor the work and progress of the Data Collectors. On a daily basis during data collection, daily counts and review of completed tools was carried out to ensure completeness and consistency of responses. The Project Coordinator was also available via cell and WhatsApp to address any questions or challenges from the Data Collectors.

4.6 Data Analysis Plan

Data analysis examined the impact of technical assistance for HIV testing among patients with presumptive TB, index testing, linkage to TPT, and linkage and initiation of ART services among those who are HIV-positive, following implementation. Patient-level data were collected on clients attending services at participating facilities who were identified as having presumptive TB. Descriptive univariate analyses were used to measure the following indicators, disaggregated by age group, sex, patient type (Presumptive TB – TB disease ruled out, Presumptive TB – not evaluated for TB, Presumptive TB – Diagnosed with TB), point of care, and facility:

Training

- The number of HCW trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing

HIV Testing

- The number/proportion of patients with presumptive TB identified

- The number/proportion of patients with presumptive TB with a known HIV-positive status
- The number/proportion of patients with presumptive TB with an unknown HIV status (not tested for HIV in the past, tested HIV-negative > 1 year ago, or tested HIV-negative < 1 year ago)
    - The number/proportion of patients with presumptive TB with an unknown HIV status tested for HIV
- The number/proportion of patients with presumptive TB with an unknown HIV status tested for HIV and tested HIV positive
- The number/proportion of patients with presumptive TB with a known HIV status (known HIV positive, newly identified HIV positive, newly identified HIV negative)
    - The number/proportion of patients with presumptive TB who are HIV positive (known HIV-positive and newly identified HIV positive)

Index Testing

- The number/proportion of HIV-positive presumptive TB patients offered index testing services
- The number/proportion of HIV-positive presumptive TB patients offered index testing who accepted index testing services
- The HIV status of contacts elicited (number/proportion Not Tested, Known Positive, New Positive, New Negative)
- The number/proportion of contacts of presumptive TB index cases identified that were tested for HIV
- The number/proportion of contacts tested HIV positive, and number/proportion tested HIV negative

Linkage to ART

- The number/proportion of HIV-positive patients with presumptive TB linked to ART services

Linkage to TPT

- The number/proportion of HIV-positive patients with presumptive TB who are Xpert negative (not diagnosed with TB disease) linked to TPT

The analysis also described differences in key indicators (HIV testing, documented HIV status, linkage to ART services, linkage to TPT, index testing) across health facilities. However, comparing indicators across facilities was not a primary objective of the evaluation because facility characteristics (size, location, etc.) varied greatly.

4.7 Limitations

One limitation of using routinely-collected data is the reliance on data that were originally collected as part of routine clinical care and were not collected as part of a study. Routinely-collected clinical data are often subject to increased levels of missing and incorrect information compared to data collected as part of a study. As part of ICAP's support for service implementation at these health facilities, efforts were made to ensure the highest data quality possible. Another limitation is that we did not have a pre-implementation comparison group. Data on HIV testing among patients with presumptive TB were not systematically collected at health facilities with the existing M&E tools, thus we were not be able to measure this practice prior to project implementation. Finally, due to the lengthy approval process and funding availability, the duration of project

implementation and evaluation was brief, although the activities measured should have taken place in a short period of time once a diagnosis of presumptive TB was made.

4.8 Stakeholder Engagement

A summary of stakeholder engagement is in the following table:

Stakeholder	Location	Roles and Engagement
ICAP at Columbia University	South Africa	• Participated in protocol development and site selection • Provided technical assistance on implementation of HIV testing among patients with presumptive TB, and strengthening linkage to ART services among patients with presumptive TB who test HIV positive; performed data collection; assisted with data analysis and report writing • Obtained South African Human Sciences Research Council Research Ethics Committee approval • Facilitated communication between DOH and CDC South Africa • Engaged district support partners (Aurum and Wits RHI) providing technical support to participating health facilities to collaborate on the facility assessment and training activities.
	New York	• Provided overall technical oversight and direction to all aspects of the project from protocol development to implementation, developed and monitored use of appropriate tools for data collection, performed data analysis, report writing, and disseminated results • Obtained Columbia University institutional review board (IRB) approval • Managed communication with CDC Atlanta and ICAP in South Africa
Centers for Disease Control and Prevention (CDC)	Atlanta	• Reviewed protocol • Provided technical and other support to ICAP and CDC South Africa as needed during protocol development and implementation • CDC was not engaged with the project in terms of interaction with human subjects or identifiable data. They provided technical oversight to ICAP project staff throughout.
	South Africa	• Participated in site selection

		• Provided technical and other support to ICAP and DOH as needed during protocol development and implementation • Facilitated communication and collaboration with stakeholders • CDC was not engaged with the project in terms of interaction with human subjects or identifiable data. They provided technical oversight to ICAP project staff throughout.
South Africa DOH	South Africa	• Participated in selection of facilities • Authorized participation of healthcare workers and supported project implementation • Reviewed analysis results prior to release of information • Participated in dissemination of results

4.9 Ethical Considerations and Assurances

The protocol received an exempt human subjects research determination from the Columbia University Institutional Review Board (IRB) on July 16, 2019 and received non-research determination from the CDC Associate Director for Science on August 6, 2019. The protocol was approved by the Human Sciences Research Council Research Ethics Committee in South Africa on June 14, 2019. In addition, the project received a Clearance Certificate from Tshwane Research Committee on July 25, 2019, research permission from the Ekurhuleni Health District on August 22, 2019, and an approval letter from the National Department of Health on June 12, 2019. Site approvals for all five health facilities in Tshwane district were received by August 14, 2019, while site approvals for all five health facilities in Ekurhuleni district were received by September 9, 2019.

4.9.1 Consent Process

The evaluation was conducted through a retrospective records review and secondary analysis of existing routinely collected patient data, and thus there was no consent for this aspect of the project. A waiver of consent was requested and granted for the abstraction of routine program data. The request for waiver of consent for the records review was based on several considerations: (1) the study involved no more than minimal risk to subjects and the research activities did not alter in any way the routine services that all patients receive; (2) the study did not involve any interaction or interference with routine care and as such, the waiver of consent did not adversely affect the rights and welfare of the subjects; (3) due to the high volume of patients and patients who may no longer be in care at these health facilities, the activity could not practically be carried out without the waiver of consent; (4) whenever appropriate, the subjects were provided with additional pertinent information after participation; and (5) no identifiable data were collected, and there was minimal risk of personally identifiable information being exposed.

4.10 Deviations and Adjustments from Approved SOW/Protocol

There were no deviations from the approved protocol.

4.11 Conflicts of Interest

There were no conflicts of interest among evaluators that were identified.

5. Findings, Recommendations and Conclusions

5.1 Findings

A total of 22 health care workers from the participating health facilities were trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing, including 4 facility managers, 8 professional nurses, 2 enrolled nurses, 1 assistant nurse and 7 data capturers.

Data collectors collated routinely collected data from health facility data sources, including registers, Tier.net, and patient files for November 2019, when project mentorship and technical assistance was being provided.

5.1.1 Characteristics of Patients Identified with Presumptive TB

Overall, 910 patients with presumptive TB were identified in November 2019 and documented in facility data sources. The majority (59%) were aged 25-49 years, female (59%), and identified at the Chronic point of care (65%) (Table 1). Patients were disaggregated by 'Type' – Presumptive TB with TB disease ruled out via GeneXpert or another diagnostic test; Presumptive TB without documented evaluation for TB disease; or Diagnosed with TB via GeneXpert or another diagnostic test. Most (85%) had presumptive TB with TB disease ruled out, while 11% were diagnosed with TB, and 5% had presumptive TB but did not have documentation of evaluation for TB disease.

Of the 910 patients with presumptive TB, 662 (73%) had a known and documented HIV status. By patient type, 72% of patients with presumptive TB with TB disease ruled out had a known HIV status, compared to 67% among patients with presumptive without evaluation for TB disease, and 84% among patients with TB disease. By health facility, the proportion of patients with presumptive TB who had a known HIV status varied, ranging from 47% at Vosloorus Poly Clinic to 88% at Tsakane Clinic.

Table 1. Characteristics of Patients Identified with Presumptive TB, South Africa, November 2019

	Total Patients Identified with Presumptive TB*	**Presumptive TB Patients with Known HIV Status****
	n=910 (100%)	n=662 (73%)
Age, years	n (%)	n (%)
<15	50 (6)	31 (62)
15-24	125 (14)	80 (64)
25-49	534 (59)	426 (80)
50+	195 (21)	124 (64)
Missing	6 (1)	1 (17)
Sex		
Male	373 (41)	272 (73)
Female	533 (59)	387 (73)
Not Documented	4 (<1)	3 (75)
Patient Type		

Presumptive TB (TB disease ruled out)	771 (85)	553 (72)
Presumptive TB (not evaluated for TB disease)	42 (5)	28 (67)
Diagnosed with TB	97 (11)	81 (84)
Point of Care		
Acute	170 (19)	122 (72)
Chronic	591 (65)	447 (76)
Antenatal Care	25 (3)	14 (56)
Labor and Delivery	0	0
Under 5 Clinic	14 (2)	10 (71)
Family Planning	0	-
Nutrition	0	-
Mental Health	10 (1)	8 (80)
HTS Site	24 (3)	21 (88)
Other	43 (5)	25 (58)
Not Documented	33 (4)	15 (45)
Facility		
Soshanguve Block JJ Clinic	56 (6)	36 (64)
KT Motubase Clinic	41 (5)	23 (56)
Laudium Community Health Centre (CHC)	87 (10)	71 (82)
Pedisong 1 Clinic	38 (4)	30 (79)
Stanza Bopape CHC	148 (16)	91 (61)
Ethafeni Clinic	170 (19)	131 (77)
Vosloorus Poly Clinic	45 (5)	21 (47)
Esangweni CHC	75 (8)	50 (67)
Tsakane Clinic	80 (9)	70 (88)
Goba Clinic	170 (19)	139 (82)

*Column percentages shown
**Known HIV status is defined as being known HIV-positive at entry or tested for HIV after identification with presumptive TB with a result of HIV-positive or HIV-negative; Row percentages shown

5.1.2 HIV Status of Patients with Presumptive TB

At time of identification with presumptive TB, 39% of patients had a known positive HIV status, while 8% were newly tested HIV-positive, and 26% were newly tested HIV-negative (Table 2). In total, 426 patients – 47% of all patients with presumptive TB – were HIV-positive. Only one patient had a discrepant test result. The patients that were diagnosed with TB disease had the highest HIV positivity (46% known positive, and 22% newly diagnosed HIV-positive, for overall HIV positivity of 81% among TB patients with known HIV status). Among patients with presumptive TB with TB disease ruled out, overall HIV positivity was 62% among those with a known HIV status, while among patients with presumptive TB who did not receive evaluation for TB disease, HIV positivity was 64%.

Table 2. HIV Status of Patients with Presumptive TB, South Africa, November 2019

	Known Positive at Entry	Newly Tested HIV-Positive	Newly Tested HIV-Negative	Newly Tested Discrepant	Not Tested for HIV	Total Patients Identified with Presumptive TB
	n=353 (39%)	n=73 (8%)	n=236 (26%)	n=1 (<1%)	n=247 (27%)	n=910 (100%)
Age, years	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
<15	4 (8)	2 (4)	25 (50)	0	19 (38)	50 (6)
15-24	16 (13)	10 (8)	54 (43)	-	45 (36)	125 (14)
25-49	261 (49)	54 (10)	111 (21)	-	108 (20)	534 (59)
50+	71 (36)	7 (4)	46 (24)	1 (1)	70 (36)	195 (21)
Missing	1 (17)	-	-	-	5 (83)	6 (1)
Sex						
Male	146 (39)	33 (9)	93 (25)	1 (<1)	100 (27)	373 (59)
Female	206 (39)	39 (7)	142 (27)	-	146 (27)	533 (59)
Not Documented	1 (25)	1 (25)	1 (25)	-	1 (25)	4 (<1)
Patient Type						
Presumptive TB (TB disease ruled out)	293 (38)	49 (6)	211 (27)	1 (<1)	217 (28)	771 (85)
Presumptive TB (not evaluated for TB disease)	15 (36)	3 (7)	10 (24)	-	14 (33)	42 (5)
Diagnosed with TB	45 (46)	21 (22)	15 (16)	-	16 (17)	97 (11)
Point of Care						
Acute	28 (17)	18 (11)	76 (45)	-	48 (28)	170 (19)
Chronic	282 (48)	49 (8)	116 (20)	1 (<1)	143 (24)	591 (65)
Antenatal Care	5 (20)	1 (4)	8 (32)	-	11 (44)	25 (3)
Under 5 Clinic	0	0	10 (71)	-	4 (29)	14 (2)
Mental Health	2 (20)	0	6 (60)	-	2 (20)	10 (1)

HTS Sites	6 (25)	5 (21)	10 (42)	-	3 (13)	24 (3)
Other	18 (42)	0	7 (16)	-	18 (42)	43 (5)
Not Documented	12 (36)	0	3 (9)	-	18 (55)	33 (4)
Facility						
Soshanguve Block JJ Clinic	27 (48)	-	9 (16)	-	20 (36)	56 (6)
KT Motubase Clinic	13 (32)	2 (5)	8 (20)	-	18 (44)	41 (5)
Laudium CHC	50 (58)	14 (16)	7 (8)	-	16 (18)	87 (10)
Pedisong 1 Clinic	19 (50)	3 (8)	8 (21)	-	8 (21)	38 (4)
Stanza Bopape CHC	54 (37)	14 (10)	23 (16)	-	57 (39)	148 (16)
Ethafeni Clinic	41 (24)	9 (5)	81 (48)	-	39 (23)	170 (19)
Vosloorus Poly Clinic	16 (36)	-	5 (11)	-	24 (53)	45 (5)
Esangweni CHC	44 (59)	-	6 (8)	1 (1)	24 (32)	75 (8)
Tsakane Clinic	31 (39)	15 (19)	24 (30)	-	10 (13)	80 (9)
Goba Clinic	58 (34)	16 (9)	65 (38)	-	31 (18)	170 (19)

5.1.3 Linkage to ART among HIV-positive Patients with Presumptive TB

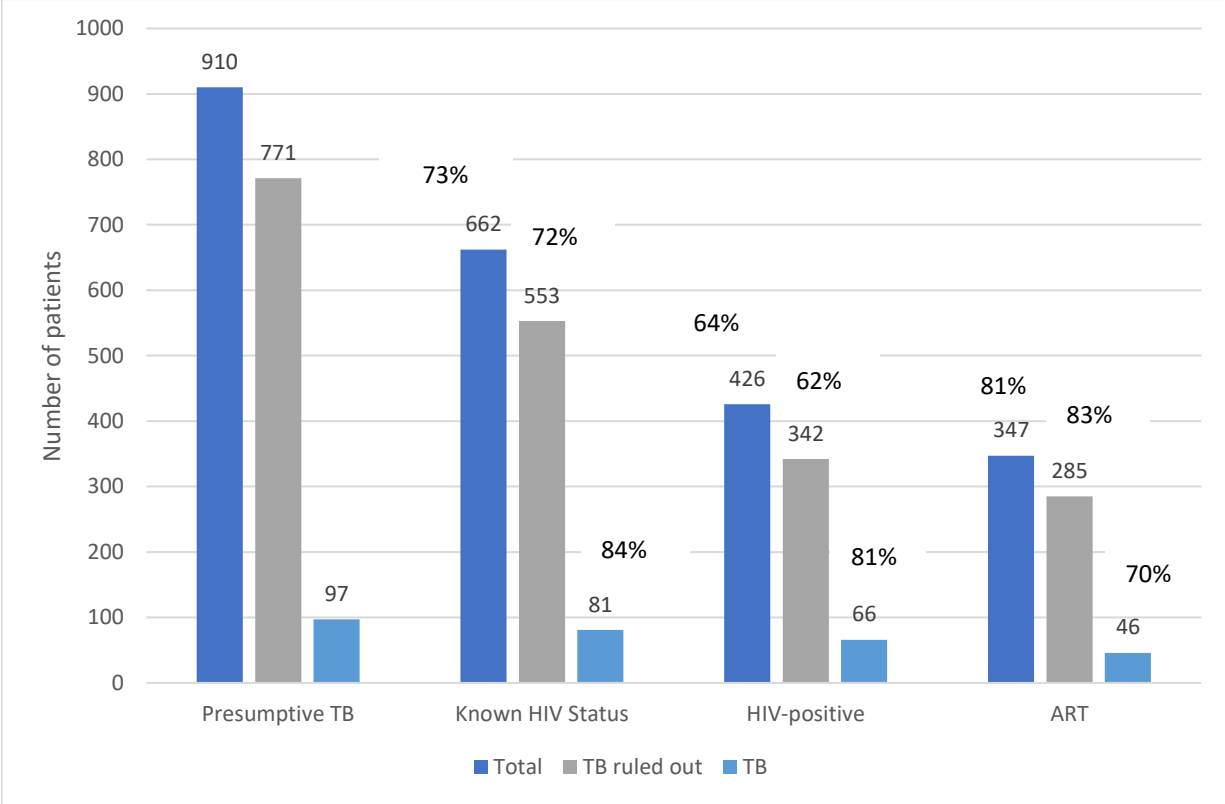
Of the 426 HIV-positive patients with presumptive TB, 66% (n=279) were already on ART at the time they were identified with presumptive TB (Table 3). Of the remaining 147 patients, 68 (46%) were newly initiated on ART, while 79 (54%) had no documentation of linkage to ART. In total, 81% of HIV-positive TB patients were on ART, while 19% had no documentation of linkage. By patient type, 83% of HIV-positive patients with presumptive TB who had TB disease ruled out were on ART, compared to 89% of patients with presumptive TB who were not evaluated for TB disease, and 70% among patients with TB disease. The cascade of HIV testing and linkage to ART among patients with presumptive TB is shown in Fgure 1.

Table 3. Linkage to ART among HIV-positive Patients with Presumptive TB, South Africa, November 2019

	Already on ART at time identified with Presumptive TB n=279 (66%)	**Newly Initiated on ART** n=68 (16%)	**Not on ART** n=79 (19%)	**Total HIV-positive patients with Presumptive TB** n=426 (100%)
Age, years	n (%)	n (%)	n (%)	n (%)
<15	2 (33)	3 (50)	1 (17)	6 (1)
15-24	12 (46)	9 (35)	5 (19)	26 (6)
25-49	205 (65)	48 (15)	62 (20)	315 (74)
50+	60 (77)	8 (10)	10 (13)	78 (18)
Missing	0	0	`1 (100)	1 (<1)
Sex				
Male	109 (61)	28 (16)	42 (24)	179 (42)
Female	169 (69)	39 (16)	37 (15)	245 (58)
Not Documented	1 (50)	1 (50)	0	2(<1)
Patient Type				
Presumptive TB (TB disease ruled out, GeneXpert MTB/RIF negative)	236 (69)	49 (14)	57 (17)	342 (80)
Presumptive TB (not evaluated for TB disease)	13 (72)	3 (17)	2 (11)	18 (4)
Diagnosed with TB (GeneXpert MTB/RIF positive)	30 (45)	16 (24)	20 (30)	66 (16)
Point of Care				
Acute	23 (50)	13 (28)	10 (22)	46 (11)
Chronic	220 (66)	48 (15)	63 (19)	331 (78)
Antenatal Care	4 (67)	1 (17)	1 (17)	6 (1)
Labor and Delivery	0	0	0	0
Under 5 Clinic	0	0	0	0
Family Planning	0			
Nutrition	0	0	0	0
Mental Health	2 (100)			2 (0<1)
HTS Sites	4 (36)	6 (55)	1 (9)	11 (3)
Other	17 (94)		1 (6)	18 (4)
Not Documented	9 (75)		3 (25)	12 (3)
Facility				

Soshanguve Block JJ Clinic	25 (93)	0	2 (7)	27 (6)
KT Motubase Clinic	13 (87)	1 (7.0)	1 (7.0)	15 (4)
Laudium Community Health Centre (CHC)	41 (64)	7 (11)	16 (25)	64 (15)
Pedisong 1 Clinic	18 (82)	3 (14)	1 (5)	22 (5)
Stanza Bopape CHC	46 (68)	7 (10)	15 (22)	68 (16)
Ethafeni Clinic	24 (48)	12 (24)	14 (28)	50 (12)
Vosloorus Poly Clinic	11 (69)	2 (13)	3 (19)	16 (4)
Esangweni CHC	26 (59)	10 (23)	8 (18)	44 (10)
Tsakane Clinic	27 (59)	12 (26)	7 (15)	46 (11)
Goba Clinic	48 (65)	14 (19)	12 (16)	74 (17)

Figure 1. HIV testing and linkage to ART among patients with presumptive TB



5.1.4 Index Case Testing among HIV-Positive Patients with Presumptive TB

Three facilities had documentation of index case testing services in the Index Testing Register and patient files: Laudium CHC, Ethafeni Clinic, and Vosloorus Poly Clinic. Among the 426 HIV-positive patients with presumptive TB, only 4 (1%) were offered index case testing services, and all accepted index case testing. Among the 4 patients who received index case testing services, 3 contacts were identified and 1 was tested and found to be HIV positive.

5.1.5 TB Preventive Treatment among HIV-Positive Patients with Presumptive TB

Among the 342 HIV-positive patients with presumptive TB eligible for TPT (i.e., TB disease ruled out), 85 (25%) were already on TPT at time of identification with presumptive TB, 6 (2%) were initiated on TPT, while 251 (73%) were not started on TPT (Table 4). Data on whether patients had previously received TPT were not captured.

Table 4. TB Preventive Treatment among Eligible HIV-positive Patients with Presumptive TB, South Africa, November 2019

	Already on TPT/IPT	**Initiated on TPT/IPT**	**Not started TPT/IPT**	**Total number of eligible HIV-positive patients with Presumptive TB**
	n=85 (25%)	n=6 (2%)	251 (73%)	n=342 (100%)*
Age, years	n (%)	n (%)		n (%)
<15	1 (25)	0	3 (75)	4 (1)
15-24	3 (14)	1 (5)	17 (81)	21 (6)
25-49	69 (28)	4 (2)	177 (71)	250 (73)
50+	12 (18)	1 (2)	53 (80)	66 (19)
Missing	0	0	1 (100)	1 (<1)
Sex				
Male	30 (23)	2 (2)	100 (76)	132 (39)
Female	55 (26)	4 (2)	150 (72)	209 (61)
Not Documented	-	-	1 (100)	1 (<1)
Point of Care				
Acute	6 (18)	1 (3)	27 (79)	34 (10)
Chronic	74 (27)	5 (2)	198 (71)	277 (81)
Antenatal Care	0	0	2 (100)	2 (1)
Mental Health	1 (50)	0	1 (50)	2 (1)
HTS Sites	1 (14)	0	6 (86)	7 (2)
Other	1 (11)	0	8 (89)	9 (3)
Not Documented	2 (18)	0	9 (82)	11 (3)
Facility				

Soshanguve Block JJ Clinic	4 (33)	0	8 (67)	12 (4)
KT Motubase Clinic	1 (8)	0	11 (92)	12 (4)
Laudium CHC	19 (35)	1 (2)	34 (63)	54 (16)
Pedisong 1 Clinic	4 (22)	0	14 (78)	18 (5)
Stanza Bopape CHC	5 (10)	1 (2)	44 (88)	50 (15)
Ethafeni Clinic	8 (19)	0	34 (81)	42 (12)
Vosloorus Poly Clinic	1 (8)	0	11 (92)	12 (4)
Esangweni CHC	9 (24)	0	28 (76)	37 (11)
Tsakane Clinic	18 (44)	2 (5)	21 (51)	41 (12)
Goba Clinic	16 (25)	2 (3)	46 (72)	64 (19)

*Eligible patients include HIV-positive presumptive TB patients with TB disease ruled out

5.2 Recommendations

Based on the evaluation findings, the following recommendations were shared with the DOH, CDC, and district support partners.

1. Complete updated version of TB National Guidelines.
2. Emphasize link between HIV testing for presumptive TB patients and Operation Phuthuma (NDOH Acceleration Plan for 90-90-90 targets).
3. Routinize HIV testing of presumptive TB patients at all service delivery points.
4. Link presumptive TB patients to care and support.
5. Ensure that all patients with presumptive TB are evaluated for TB disease.
6. If a patient is confirmed TB negative, strengthen linkage to TPT.
7. Formalize a process at each health facility to ensure all individuals with presumptive and active TB disease who are diagnosed HIV-positive are offered index testing services to strengthen HIV case finding.
8. The index testing process can be strengthened by ensuring all DOH lay counselors are prioritized to attend index testing training by the RTC
9. Strengthen HCWs' access and utilization of Guidelines and SOPs.
10. Specify training requirements for various cadres of HCW and enable ongoing in-service training with mentorship and support.
11. Routinize Quality Assurance checks.
12. Strengthen tools for Monitoring & Evaluation.
13. Follow-up on use of TB screening summary forms.
14. Record ART initiation in Primary Health Care (PHC) Comprehensive Tick Registers for individuals diagnosed HIV-positive.

6. Dissemination

A summary report of the findings was developed by the study team. The Project Manager and ICAP Country Director Ms. Blanche Pitt met with the NDOH on October 14, 2019, district support partners (virtually) on December 20, 2019, and CDC on January 8, 2020, to share the findings and discuss remaining challenges. A final draft report was shared with CDC on March 31, 2020. The

district support partners agreed to use the results of the evaluation to further strengthen the routinization of HIV testing among patients with presumptive TB and implementation of index testing and linkage to TPT and ART services among patients with presumptive TB who test HIV positive. This evaluation report will be posted on a publically accessible website within 90 days of clearance.

7. References

1. WHO TB/HIV Factsheet: www.who.int/tb/areas-of-work/tb-hiv/tbhiv_factsheet.pdf?ua=1
2. UNAIDS. www.unaids.org/en/regionscountries/countries/southafrica. Accessed November 20, 2020.
3. World Health Organization. Global TB Report 2020. https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&lan=%22EN%22&iso2=%22ZA%22. Accessed November 20, 2020.
4. Ibid.
5. WHO policy on collaborative TB/HIV activities. Guidelines for national programmes and other stakeholders. World Health Organization document WHO/HTM/TB/2012.1:1-34. Geneva: World Health Organization, 2012.
6. WHO 2018 Global TB Report.
7. Ibid.
8. Odhiambo J, Kizito W, Njoroge A, Wambua N, Njanga L, Mburu M, Mansoer J, Maum L, Phillips E, Chakaya J, De Cock KM. Provider-initiated HIV testing and counselling for TB patients and suspects in Nairobi, Kenya. In J Tuberc lung Dis. 2008 Mar;12(3 Suppl 1):63-8.
9. Macpherson P, Dimairo M, Bandason T, et al. Risk factors for mortality in smear-negative tuberculosis suspects: a cohort study in Harare, Zimbabwe. Int J Tuberc Lung Dis 2011; 15: 1390–96.
10. Srikantiah P, Lin R, Walusimbi M, et al. Elevated HIV seroprevalence and risk behaviours among Ugandan TB suspects: implications for HIV testing and prevention. Int J Tuberc Lung Dis 2007; 11: 168–74.
11. Naik B, Kumar AMV, Lal K, et al. HIV prevalence among persons suspected of tuberculosis: policy implications for India. J Acquir Immune Defic Syndr 2012; 59: e72–76.
12. Achanta S, Kumar AM, Nagaraja SB, et al. Feasibility and effectiveness of provider-initiated HIV testing and counseling of TB suspects in Vizianagaram district, south India. PLoS One 2012; 7: e41378.
13. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, 2nd ed. World Health Organization; 2016.

8. Appendices

A. Project Protocol
B. Data Collection Tool
C. Investigators and Roles

Appendix A. Project Protocol

Revision Cooperative Agreement No. U2GGH001194

HIV testing and linkage to ART services among patients with presumptive TB

An Evaluation Protocol Prepared by

Contacts:
Dr. Andrea Howard
Principal Investigator
Director, Clinical and Training Unit, ICAP
Mailman School of Public Health
Columbia University
722 W 168th Street, MPSH Box 18
New York, NY 10032
Telephone: +001 212 342 2803
Fax: +001 212 342 1824
Email: aah2138@columbia.edu

Country Contact:
Blanche Pitt, Co-Investigator
Country Director, ICAP in South Africa
Regional Director of the Population-based HIV Impact Assessment (PHIA)
ICAP-Columbia University
Lakefield Office Park, Building A, Ground Floor 1A
272 West Avenue, Lyttelton 381-JR,
Centurion 0157, South Africa
Telephone: +27 12 360 0640
Fax: +27 12 360 0664
Email: bp2360@cumc.columbia.edu

Funded by: US Centers for Disease Control and Prevention (CDC) through cooperative agreement number: U2GGH001194, President's Emergency Plan for AIDS Relief (PEPFAR)

Protocol version number: 1.4
Date: July 11, 2019

Table of Contents

Participating Institutions and Roles

Institution	Location	Role
ICAP at Columbia University	South Africa	• Participate in protocol development and site selection • Provide technical assistance on implementation of HIV testing among patients with presumptive tuberculosis (TB), and strengthening linkage to antiretroviral therapy (ART) services among patients with presumptive TB who test HIV positive; perform data collection; assist with data analysis and report writing • Obtain South African Human Sciences Research Council Research Ethics Committee approval • Facilitate communication between DOH and CDC South Africa
	New York	• Provide overall technical oversight and direction to all aspects of the project from protocol development to implementation, develop and monitor use of appropriate tools for data collection, perform data analysis, report writing, and disseminate results • Obtain Columbia University institutional review board (IRB) approval • Manage communication with CDC Atlanta and ICAP in South Africa
Centers for Disease Control and Prevention (CDC)	Atlanta	• Protocol review and approval • Provide technical and other support to ICAP and CDC South Africa as needed during protocol development and implementation • CDC will not be engaged with the project in terms of interaction with human subjects or identifiable data. They will provide technical oversight to ICAP project staff throughout.
	South Africa	• Participate in site selection • Provide technical and other support to ICAP and DOH as needed during protocol development and implementation • Facilitate communication and collaboration with stakeholders • CDC will not be engaged with the project in terms of interaction with human subjects or

		identifiable data. They will provide technical oversight to ICAP project staff throughout.
South Africa Department of Health (DOH)	South Africa	• Participate in selection of facilities • Authorize participation of healthcare workers and support project implementation • Review analysis results prior to release of information • Participate in dissemination of results

Investigators and Roles

Name	Title/affiliation	Role on project
Andrea Howard, MD, MS	Clinical & Training Unit Director, ICAP	Principal Investigator: • Overall direction and management of the project • Protocol development • Oversight of project implementation • Interpretation of results for dissemination • Manuscript development
Kieran Hartsough, MPH	Strategic Information Specialist, ICAP	Co-Investigator: • Protocol development • Train South African-based project team in monitoring and evaluation tools and data collection • Analyze data • Interpretation of results for dissemination • Manuscript development
Julia Frieze, MPH	Coordinator, ICAP	Project/Evaluation Coordinator: • Manage project for ICAP-NY • Development of protocol and data collection forms • Assist with local hiring, financial oversight and donor reporting • Project monitoring • Data review • Funder reporting • Manuscript development
Blanche Pitt	Country Director, ICAP in South Africa	Co-Investigator: • Protocol development • Supervise implementing team in South Africa • Liaise with CDC, South Africa Ethics Committee, South Africa DOH and other project stakeholders

TBN	Project Coordinator, ICAP in South Africa	Project Coordinator: • Review and provide technical input on project design • Monitor in-country project and data collection activities • Contribute to data management and review of data • Contribute to analyses and publications • Liaise with DOH to ensure project success
Hloniphile Mbuza CITI ethical training expiration date: 12/18/2021	CDC South Africa	Co-Investigator: • In-country technical and administrative oversight for project activities • Review and provide technical input on protocol and project design • Monitor project activities • Participate in data analysis and publications
Bill Coggin CITI ethical training expiration date: 03/07/2022	CDC Atlanta	Co-Investigator: • Review and provide technical input on protocol and project design • Monitor project activities • Participate in data analysis and publications
Heather Paulin CITI ethical training expiration date: 01/08/2022	CDC Atlanta	Co-Investigator: • Review and provide technical input on protocol and project design • Monitor project activities • Participate in data analysis and publications
Anand Date, MD CITI ethical training expiration date: 04/04/2022	Global TB Branch, CDC Atlanta	Technical Advisor: • Review and provide technical input on protocol and project design
Dr. Lindiwe Mvusi	South Africa DOH	Collaborator: • Review and provide technical input on protocol and project design • Monitor project activities • Participate in data analysis and publications
Dr. Zukiswa Pinini	South Africa DOH	Collaborator: • Review and provide technical input on protocol and project design • Monitor project activities • Participate in data analysis and publications

Acronyms

ADS	Associate Director for Science
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
CDC	United States Centers for Disease Control and Prevention
CHC	Community Health Centre
CUIMC	Columbia University Irving Medical Center

DOH	Department of Health
HCW	Healthcare Worker
HIV	Human Immunodeficiency Virus
HSRC REC	Human Sciences Research Council Research Ethics Committee
HTS	HIV Testing Services
IRB	Institutional Review Board
M&E	Monitoring and Evaluation
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PITC	Provider-Initiated Testing and Counseling
PLHIV	People Living With HIV
SOP	Standard Operating Procedure
TA	Technical Assistance
TB	Tuberculosis
WHO	World Health Organization

1. Protocol Summary

The overall aim of this project is to provide technical assistance (TA) to the South African National Department of Health (DOH) to operationalize and evaluate systematic human immunodeficiency virus (HIV) testing among patients with presumptive tuberculosis (TB) and enrolment of those found to be HIV positive on antiretroviral therapy (ART) at selected facilities in Gauteng Province in South Africa.

Currently, guidance on HIV screening for presumptive TB is only included in South African training manuals for key populations. Of note, the national TB/HIV guidelines are under revision. The 2014 TB Treatment Guidelines state that all confirmed TB patients must be offered HIV counselling and testing, and that ideally, the offer of an HIV test should take place during the diagnostic work-up for TB or soon after the initiation of TB treatment.[1] The guidelines recommend TB symptom screening for all patients presenting at the health facility. The TB Screening Tool and TB Identification and Follow-Up Register both include a place to document the patient's HIV status (Positive, Negative, Unknown); however, HIV status among presumptive TB patients is not routinely monitored as part of program data. A patient screened for TB and identified as having symptoms of pulmonary TB should have at least one sputum specimen examined for bacteriological confirmation of TB disease (through Xpert MTB/RIF or culture). Without bacteriological confirmation of *Mycobacterium tuberculosis* complex, a patient may be diagnosed with TB based on clinical presentation, x-ray findings, or other tests. A patient with symptoms of TB who is Xpert MTB/RIF negative should have their HIV status considered, as TB can be more difficult to diagnose in those with advanced HIV disease.

The 2016 South African HIV Testing Services (HTS) Policy does not specifically recommend HIV testing for patients with presumptive TB; however, the Policy states that provider-initiated HIV testing and counselling (PITC) should be offered to all persons attending clinical services in both the public and private sector.[2] The HTS Policy also supports intensified TB case finding, stating that HTS should include screening for TB to improve intensified TB case finding, and HIV testing of TB patients. As TB is the most common opportunistic infection among people living with HIV (PLHIV), early detection and prompt linkage to TB treatment, as well as ART initiation, can prevent morbidity and mortality. While South Africa's National Strategic Plan for HIV, TB and STIs 2017-2022 explicitly states that every person who is tested for HIV must also be screened for TB, it does not state that every person who is identified as having TB or presumptive TB should have a known HIV status.[3]

A draft South African HIV testing screening algorithm has been developed (Appendix A) to identify the eligibility for HIV testing services among adults and adolescents 15 years and older. Per the algorithm, in the general population, anyone who is not known HIV positive, and who has not been tested for HIV in the last year should be offered a test for HIV. Individuals with an HIV-negative test in the past year will be asked a series of screening questions, beginning with asking about TB symptoms. Anyone with symptoms of TB (current cough, fever, weight loss, and/or night sweats) will be tested for HIV and evaluated for TB disease. If this HIV testing strategy is adopted and rolled out, presumably all individuals identified with presumptive TB will be tested for HIV. However, the impact of testing this population systematically in finding new PLHIV is unknown.

[1] South African National TB Management Guidelines 2014
[2] South African HIV Testing Services Policy 2016
[3] South Africa's National Strategic Plan for HIV, TB and STIs 2017-2022

In September 2016, South Africa implemented the World Health Organization (WHO) evidence-based guidelines of Universal Test and Treat in support of the Joint United Nations Programme on HIV/AIDS 90-90-90 targets of ensuring that 90% of all PLHIV know their HIV status, 90% of people with diagnosed HIV infection receive sustained ART and 90% of all people receiving ART are virally suppressed.[4]

The United States President's Emergency Plan for AIDS Relief (PEPFAR) 2019 Country Operational Guidance states that all presumptive TB patients should be offered HIV testing, and that any person found to have HIV should be considered an index case with index testing initiated.[5] Thus, there is an opportunity to increase HIV testing among patients with presumptive TB, identify new positives and link them to treatment.

South Africa could benefit from enhanced TA to routinize HIV testing among patients with presumptive TB and strengthen index testing and linkage to TB preventive treatment (TPT) and ART services among patients with presumptive TB who test HIV positive. The purpose of this project is to operationalize and evaluate systematic HIV testing among patients with presumptive TB, and index testing, TPT and enrolment on ART for those found to be HIV positive.

To support the implementation of HIV testing among patients with presumptive TB, ICAP will provide technical support to the DOH to develop standard operating procedures (SOPs) for HIV testing for patients with presumptive TB (aligned with the updated HIV testing algorithm, as appropriate) as well as implement index testing for those who test HIV positive.

In addition, to strengthen linkage to ART services among patients with presumptive TB who test HIV positive, ICAP, in collaboration with DOH and CDC, will develop an operational definition for linkage, and define a series of processes and activities including strengthening of post-test counselling, formalizing referral mechanisms, and implementing navigator-facilitated linkage and tracking, especially for those who are Xpert negative (and are not otherwise diagnosed with TB disease through clinical or radiological criteria). ICAP will develop SOPs for each activity and will facilitate identification of a healthcare worker (HCW) to assume the role of "linkage officer" at each site and provide navigator-facilitated linkage and tracking. ICAP will refine/develop tools to support recording and monitoring of linkage and ART initiation, e.g., referral/back-referral forms and linkage register.

ICAP will revise monitoring and evaluation (M&E) tools to capture the number of patients with presumptive TB seen at the facility each month by point of service, number known to be HIV-positive, number with unknown or negative HIV status, number tested for HIV (disaggregated by sex and age group), number who test HIV positive, and number who are successfully linked to treatment and initiated on ART. M&E tools to capture index testing for presumptive TB patients who test HIV positive will also be introduced/revised as necessary.

ICAP will support training of HCW within 10 selected health facilities on the revised/new SOPs and M&E tools. ICAP will also provide regular onsite mentoring to support implementation of

[4] South Africa Department of Health Universal Test and Treat Policy Circular

[5] PEPFAR 2019 Country Operational Plan Guidance for all PEPFAR Countries. Available at https://www.pepfar.gov/documents/organization/288160.pdf

activities and ongoing monitoring of HIV testing and linkage services among patients with presumptive TB.
After enhanced service provision over a 2-month period, ICAP will conduct an evaluation of the project activities in collaboration with the DOH and CDC using routinely collected data during the enhanced activities (see details in Section 4.2 Evaluation Design). ICAP will collect data from the implementation period to look at variables such as proportion of patients with presumptive TB with unknown HIV status tested for HIV (see Section 5.3.1). As the CDC cooperative agreement is ending on September 30, 2019, there is a limited timeframe for project implementation.
The findings from this evaluation will be presented at a national meeting where implications for the national TB and HIV programs and recommendations will be discussed. Lessons learned may be shared with other programmes in South Africa as best-practice.

2. Introduction

2.1 Background

TB is a leading cause of morbidity and mortality among PLHIV, accounting for 32% of acquired immunodeficiency virus (AIDS)-related deaths.[6] South Africa is a country with a high burden of HIV and TB, with an estimated HIV prevalence of 18.8% among adults 15–49 years, and a TB incidence rate of 567 per 100,000; 60% of TB cases are HIV positive.[7,8] Countries, including South Africa, have made significant progress in the implementation of a package of WHO-recommended TB/HIV collaborative activities aimed at mitigating the dual burden of TB/HIV. Within the TB/HIV collaborative framework, it is recommended that routine HIV testing be offered to all TB patients, to all those with signs and symptoms of TB (presumptive TB), and to partners of known HIV-positive TB patients.[9] South Africa has scaled-up PITC of TB patients and in 2017, 94% of notified TB patients had a documented HIV test result.[10] The coverage of ART for notified TB patients known to be co-infected with HIV has also increased in South Africa, reaching 89% in 2017.[11]

However, implementation of HIV testing among patients with presumptive TB has been less robust. Several studies have found high uptake of HIV testing and a high proportion of HIV positivity among those with presumptive TB, even as high as that among patients with active TB.[12,13,14,15] One study found that implementation of PITC among patients with presumptive TB was feasible and

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[6] WHO TB/HIV Factsheet: www.who.int/tb/areas-of-work/tb-hiv/tbhiv_factsheet.pdf?ua=1
[7] UNAIDS 2017 www.unaids.org/en/regionscountries/countries/southafrica
[8] WHO Global TB Report 2018 https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=ZA&outtype=PDF
[9] WHO policy on collaborative TB/HIV activities. Guidelines for national programmes and other stakeholders. World Health Organization document WHO/HTM/TB/2012.1:1-34. Geneva: World Health Organization, 2012.
[10] WHO 2018 Global TB Report.
[11] Ibid.
[12] Odhiambo J, Kizito W, Njoroge A, Wambua N, Njanga L, Mburu M, Mansoer J, Maum L, Phillips E, Chakaya J, De Cock KM. Provider-initiated HIV testing and counselling for TB patients and suspects in Nairobi, Kenya. In J Tuberc lung Dis. 2008 Mar;12(3 Suppl 1):63-8.
[13] Macpherson P, Dimairo M, Bandason T, et al. Risk factors for mortality in smear-negative tuberculosis suspects: a cohort study in Harare, Zimbabwe. Int J Tuberc Lung Dis 2011; 15: 1390–96.
[14] Srikantiah P, Lin R, Walusimbi M, et al. Elevated HIV seroprevalence and risk behaviours among Ugandan TB suspects: implications for HIV testing and prevention. Int J Tuberc Lung Dis 2007; 11: 168–74.
[15] Naik B, Kumar AMV, Lal K, et al. HIV prevalence among persons suspected of tuberculosis: policy implications for India. J Acquir Immune Defic Syndr 2012; 59: e72–76.

effective, and detected a large number of patients with HIV with minimal additional workload on staff.[16] Therefore, persons presumed to have TB are high-yield populations for identifying PLHIV who do not yet know their HIV status. In many settings, HIV prevalence rates among persons presumed to have TB and reported TB cases are similar to, or even exceed, the rates among key populations. This is also a high-yield intervention to reach the undiagnosed HIV-positive men, as the majority of TB cases are among males. In addition, these PLHIV tend to have advanced HIV disease and benefit the most from early initiation of ART. Particularly in the context of Test and Start, HIV testing among this group of patients will increase HIV case-finding, reduce the testing gap among men, improve early ART initiation, and reduce morbidity and mortality from HIV/AIDS and HIV-associated TB.

2.2 Justification for Evaluation

Despite the WHO recommendation to offer routine HIV testing to all those with signs and symptoms of TB, few countries have systematically and successfully integrated these activities into routine clinical practice. HIV testing in patients with active TB disease is well integrated into country TB and HIV programs and is widely reported on; however there is a dearth of available data on the proportion of patients with presumptive TB with a known HIV status, who are HIV-positive, and, among those who are positive, linked to ART. Operational guidance is needed to routinize HIV testing among presumptive TB patients, and determine what processes work best in country-specific settings.

The purpose of this project is to operationalize and evaluate systematic HIV testing among patients with presumptive TB, and index testing, TPT and enrolment on ART for those found to be HIV positive. Aiming to improve HIV testing among patients with presumptive TB, identifying new HIV-positive cases, HIV index testing, and linkage to treatment and TPT as appropriate, ICAP will support the South African DOH to implement HIV testing among patients with presumptive TB, strengthen HIV index testing, and linkage to ART and TPT among those who test HIV positive. As current reporting mechanisms do not allow for complete measurement of HIV testing, index testing, and linkage to ART and TPT among patients with presumptive TB, ICAP will co-develop and revise current M&E tools and reporting processes with DOH and CDC.

Findings from this evaluation will provide information on the effectiveness of systematic HIV testing among patients with presumptive TB and will provide recommendations to the national TB and HIV programs on how to successfully implement HIV testing, HIV index testing, and linkage to ART and TPT for patients with presumptive TB. ICAP, with the DOH and CDC, will review what processes and tools worked well and what challenges arose during efforts to strengthen HIV testing among patients with presumptive TB and index testing and linkage to ART and TPT among those that are HIV positive.

2.3 Intended/Potential Use of Evaluation Findings

There is an urgent need to improve HIV testing among presumptive TB patients, and to identify patients who are HIV-positive, conduct index testing and link them to ART and TPT when appropriate. The purpose of this project is to aid the South African DOH to improve HIV testing services among patients with presumptive TB and strengthen index testing and linkage to ART and TPT.

[16] Achanta S, Kumar AM, Nagaraja SB, et al. Feasibility and effectiveness of provider initiated HIV testing and counseling of TB suspects in Vizianagaram district, south India. PLoS One 2012; 7: e41378.

HIV testing among patients with presumptive TB and index testing and linkage to ART and TPT among those who test HIV positive will be strengthened at 10 health facilities in Gauteng Province in South Africa, and the project will evaluate HIV testing among patients with presumptive TB, identification of new cases of HIV, index testing among HIV-positive presumptive TB patients, linkage to ART services, and timing of ART initiation, and linkage to TPT among patients not diagnosed with TB disease. Evaluation data will be obtained both from existing facility registers and tools as well as new/revised M&E tools introduced by the project which allow for measurement of HIV testing, index testing, and linkage to ART and TPT among patients with presumptive TB.

At the completion of the project, ICAP, DOH and CDC will share findings from the evaluation. The findings will be presented at a national meeting where implications for the national TB and HIV programs and recommendations will be discussed. Lessons learned may be shared with other programmes in South Africa as best-practice.

3. Objectives

The purpose of the project is to aid the South African DOH to improve HIV testing services among patients with presumptive TB and strengthen index testing, and linkage to ART and TPT. ICAP will provide TA to 10 health facilities over a 2-month period. The evaluation will assess the achievements of the strengthened services in South Africa using data collected as part of routine service delivery and monitoring. The main objectives of this evaluation are:

9. Conduct rapid pre-assessment of current practices and tools for HIV testing among patients with presumptive TB and index testing, linkage to ART services, and linkage to TPT among patients with presumptive TB who are HIV positive at the selected facilities in South Africa
10. Support the implementation of systematic and universal HIV testing among patients with presumptive TB at selected facilities in South Africa through development/revision of SOPs and M&E tools and training and mentorship of HCW
11. Support index testing among patients with presumptive TB who test HIV positive through development/revision of SOPs and training and mentorship of HCW
12. Support linkage to ART services among patients with presumptive TB who test HIV positive, including those who are diagnosed with TB and those who are Xpert negative (and are not otherwise diagnosed with TB disease through clinical or radiological criteria) through development/revision of SOPs and training and mentorship of HCW
13. Support linkage of TPT among patients with presumptive TB who test HIV positive, and are Xpert negative (and are not otherwise diagnosed with TB disease through clinical or radiological criteria) through development/revision of SOPs and training and mentorship of HCW
14. Revise/develop M&E tools to capture HIV testing, index testing, and linkage to treatment or TPT and ART initiation among patients with presumptive TB
15. Develop electronic database, and retrospectively collect routinely collected client level data from selected facilities on HIV testing among patients with presumptive TB, and index testing, and linkage to ART services and TPT among those who test HIV-positive; analyse results and draft report
16. Provide feedback to the South African DOH, CDC and other stakeholders on the evaluation findings to inform implementation of HIV testing of patients with presumptive TB, and index testing and linkage to ART and TPT among those who test HIV-positive

4. Methods

4.1 Evaluation Design

This is a quantitative outcome evaluation of a strengthened approach to HIV testing among patients with presumptive TB and index testing, linkage to ART services and linkage to TPT among patients with presumptive TB who are HIV positive at selected facilities.

Current practices at health facilities do not allow for complete documentation and tracking of patients with presumptive TB from identification to HIV testing through ART initiation for those that are HIV-positive. Existing M&E tools only collect data on TB screening, and HIV status (positive, negative, unknown) for patients who screen positive for TB. Data are not systematically collected and reported on number and proportion of patients with presumptive TB with known HIV status, tested for HIV, identified as HIV positive, offered index testing services, linked to ART services, timing of ART initiation, and linked to TPT. The project will quantify the impact of implementing HIV testing among patients with presumptive TB and strengthening index testing and timely linkage to ART and TPT services among patients with presumptive TB who are HIV positive in selected facilities in Gauteng Province in South Africa through the indicators collected. The health facilities participating in this evaluation will support the updated service delivery processes as part of efforts to improve HIV testing, index testing and linkage to ART and TPT for patients with presumptive TB. As such, all patients with presumptive TB identified at the selected health facilities will receive the updated services. In order to routinely monitor and evaluate service delivery among patients with presumptive TB, existing registers and M&E tools will be modified and introduced at the 10 selected health facilities.

Evaluation Questions

1. How many HCW were trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing?
2. What proportion of all HCW at the participating facilities were trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing?
3. How many HCW were trained on revised M&E tools?
4. What proportion of all HCW at the participating facilities were trained on revised M&E tools?
5. What proportion of patients with presumptive TB had a known HIV-positive status?
6. What proportion of patients with presumptive TB had an unknown HIV status (not tested for HIV in the past, tested HIV-negative > 1 year ago, or tested HIV-negative < 1 year ago
    a. What proportion of patients with presumptive TB with an unknown HIV status were tested for HIV?
7. What proportion of patients with presumptive TB with an unknown HIV status were tested for HIV and tested HIV positive?
8. What proportion of patients with presumptive TB had a known HIV status (known HIV positive, newly identified HIV positive, newly identified HIV negative?
    a. What proportion of patients with presumptive TB were HIV positive (known HIV positive and newly identified HIV-positive)?
9. What proportion of HIV-positive patients with presumptive TB were offered index testing services?
    a. What proportion of index clients accepted index testing services?

    b. The HIV status of contacts elicited (number/proportion Not Tested, Known Positive, New Positive, New Negative)?
    c. What proportion of identified contacts received HIV testing?
    d. What proportion of contacts tested HIV positive, and what proportion tested HIV negative?
10. What proportion of HIV-positive patients with presumptive TB were linked to ART services? (include newly identified HIV-positive, pre-ART, and lost to follow-up)
11. What proportion of HIV-positive patients with presumptive TB were linked to ART services and initiated ART within 1 week of enrollment in care (disaggregated by those who were Xpert-positive and Xpert-negative [and were not otherwise diagnosed with TB disease])?
12. What proportion of HIV-positive patients with presumptive TB who were Xpert negative were initiated on TPT?

The evaluation will analyze retrospectively collected data (see variables in Sections 4.6.1 and 5.3.1) from presumptive TB patients attending participating facilities during the implementation period.

Figure 1. Project timeline*

Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Develop and submit protocol to CDC Associate Director for Science, Human Sciences Research Council Research Ethics Committee and Columba University Institutional Review Board											
								Conduct rapid pre-assessment of current facility practices and tools			
								Revise /develop M&E tools			
								Support implementation of HTS; strengthen index testing and linkage to ART and TPT			
								Develop database and data collection SOP			
									Receive all ethics approvals		
										Train data collectors	
										Data collection from health facilities	
										Data analysis and report writing	
											Stakeholder feedback

*The timeline above will shift depending on receipt of funds and approval from ADS and IRBs

4.2 Evaluation Setting

The project will be conducted in the Gauteng Region of the Republic of South Africa. Health facilities that provide HIV and TB services were selected in coordination with the South Africa DOH and CDC. Health facilities were purposively selected from among PEPFAR-supported facilities in high TB and HIV burden districts, with high patient volume. Ten health facilities in Gauteng will be included in the evaluation:

City of Tshwane Metropolitan Municipality

11. Soshanguve Block JJ Clinic
12. KT Motubase Clinic
13. Laudium Community Health Centre (CHC)
14. Pedisong 1 Clinic
15. Stanza Bopape CHC

Ekurhuleni

16. Ethafeni Clinic
17. Vosloorus Poly Clinic
18. Esangweni CHC
19. Tsakane Clinic
20. Goba Clinic

Table 1 shows data from October-December 2018 on the number of presumptive TB cases, number of new/relapse TB cases, number of new/relapse TB cases with documented HIV status, and number of HIV-positive new/relapse TB cases at the selected health facilities.

Table 1: Site Level Attendance Data

Site Name	Number of presumptive TB cases Oct-Dec 2018	Number of new/relapse TB cases Oct-Dec 2018	Number of new/relapse TB cases with documented HIV status Oct-Dec 2018	Number of HIV-positive new/relapse TB cases Oct-Dec 2018
1. Soshanguve Block JJ Clinic	173	28	27	19
2. KT Motubase clinic	290	83	78	60
3. Laudium CHC	281	22	22	17
4. Pedisong 1 Clinic	169	20	19	12
5. Stanza Bopape CHC	461	85	80	55

6. Ethafeni Clinic	151	19	19	11
7. Vosloorus Poly Clinic	248	34	31	20
8. Esangweni CHC	287	43	31	22
9. Tsakane Clinic	175	32	27	18
10. Goba Clinic	246	32	28	19
Total	2,481	398	362	253

No funding will be given directly to health facilities; therefore, participating health facilities do not require Federal Wide Assurance.

4.3 Population

4.3.1 Review of Routinely Collected Data

Existing individual patient data on all presumptive TB patients receiving services over the 2-month implementation period at the 10 participating health facilities will be included in the retrospective review of existing individual patient data routinely collected for clinical care. A waiver of consent for the collection of existing routinely collected data is requested (see Section 7.1.1).

All presumptive TB patients identified at the 10 participating health facilities between July 2019 and August 2019 will be included in the evaluation.

We have estimated the number of patients with presumptive TB and HIV-positive patients with presumptive TB at the 10 facilities where implementation and M&E support will be provided based on existing data from these health facilities (see Section 4.2). Routinely collected data on all identified patients with presumptive TB during the evaluation period will be utilized to measure service provision as part of the project evaluation. We anticipate that approximately 1,600 patients with presumptive TB, including 880 HIV-positive patients with presumptive TB, will be identified over the anticipated 2-month evaluation period.

4.4 Project Activities

ICAP will support the implementation of HIV testing among patients with presumptive TB and strengthened index testing and linkage to ART and TPT services among patients with presumptive TB who test HIV positive at 10 health facilities in Gauteng Province in South Africa. ICAP will meet regularly with DOH to plan specific measures to improve HIV testing, index testing and linkage to ART and TPT services among patients with presumptive TB. Proposed activities for improved services for patients with presumptive TB include:

1. **Rapid pre-assessment, SOP development of HIV testing for presumptive TB, and HCW training**

ICAP, in coordination with the DOH, will develop a tool and conduct a rapid pre-assessment at the selected health facilities to collect information on available services, populations served, HIV testing and linkage protocol and practices and available M&E tools. Based on the pre-assessment findings, ICAP will work with the DOH and CDC to revise/develop SOPs for HIV testing for patients with

presumptive TB. In addition, training will be provided for HCW at the selected sites on the revised/new SOPs on HIV testing. Training will be provided as needed to HCW on the DOH approved HIV testing algorithm. ICAP staff will confirm all staff performing HIV diagnostic testing has or will receive basic Bio-Safety training.

2. Implementation of HIV testing among patients with presumptive TB

After HCW training, the Project Coordinator will provide weekly onsite and remote mentorship to health facility staff to support implementation of SOPs and project activities to improve HIV testing among patients with presumptive TB. The Project Coordinator will also support onsite monitoring of HIV testing among patients with presumptive TB, and documentation of implementation of services by site, and point of service, including checks for data quality and completeness.

3. Support index testing and linkage to ART and TPT services among patients with presumptive TB who test HIV positive

ICAP will collaborate with the DOH to improve index testing and linkage to ART and TPT services among HIV-positive patients with presumptive TB. As needed, ICAP will develop an SOP and M&E tools to streamline and document the index testing cascade: the offer of index testing services, acceptance of index testing services, contact elicitation, testing of contacts, and receipt of results. Training will be provided on contact elicitation and relevant M&E tools. An operational definition for linkage will be developed. To ensure that patients with presumptive TB who are newly diagnosed with HIV are promptly linked to ART services and TPT when appropriate, ICAP will define/refine a series of processes and activities including formalizing referral mechanisms, and implementing navigator–facilitated linkage, tracking (longitudinal monitoring of patients). ICAP will develop SOPs for each activity and will also facilitate identification of a HCW to assume the role of "linkage officer" at each site to provide navigator-facilitated linkage and tracking. ICAP will work with the DOH and CDC to develop/revise tools to support recording and monitoring of linkage, e.g. referral/back-referral forms and linkage register. Additionally, ICAP will support ongoing monitoring of ART initiation among patients with presumptive TB who test HIV positive and are linked.

3. Revision/Development of M&E Tools

ICAP will develop/revise M&E tools to capture the number of patients with presumptive TB seen at the facility each month by point of service, number known to be HIV positive, number with unknown HIV status, number tested for HIV (disaggregated by sex and age group), number who test HIV positive, the number who are offered index testing services, those who accept index testing services and the number of contacts elicited and tested, and those who are successfully linked to treatment and initiated on ART, and those who are linked to TPT. The Project Coordinator will support the training and weekly onsite and remote (via phone and WhatsApp) mentorship of HCW on new M&E tools.

4.4.1 Recruitment and Enrolment

Review of Routinely Collected Data

There will be no recruitment or contact with human subjects for this part of the project; only existing data collected as part of routine service delivery by HCW will be utilized for the evaluation. The evaluation will use a retrospective review of de-identified data routinely collected at the facility. A waiver of consent will be requested (see Section 7.1.1).

4.5 Data Collection

4.5.1 Patient Registers and Records

Data on individuals with presumptive TB at implementing facilities between July 2019 and August 2019 will be abstracted from facility registers and tools at the end of the project once ethical approvals are received. Data will be abstracted from the sources listed below (see Section 4.6) by project Data Collectors, who will de-identify patient-level data as they are abstracted. No identifying information (names, identification numbers, medical record numbers, addresses) will be collected and no codebook linking patients back to their medical records will be created; data for the project will be de-identified. Data collectors will use password-protected and encrypted electronic handheld Android tablets to collect data.

Data abstracted from patient records and facility registers will be entered into a password-protected electronic database developed by ICAP for the evaluation (during routine care, clinical data are entered into facility registers and charts by health care facility staff). The database will be built in SurveyCTO, which is an Open Data Kit -based platform certified by Columbia University Irving Medical Center (CUIMC) Information Technology as a multi-user platform for storing data. Data on the tablets will be uploaded to the secure cloud-based SurveyCTO server daily and removed from the tablet. No names, national identification numbers, clinic identification numbers, addresses, phone numbers or other personally-identifiable locator information will be entered into the study database. Access to the server will be limited to project personnel responsible for project monitoring and analysis.

4.6 Data Sources

4.6.1 Review of Routinely Collected Data

The evaluation will include a retrospective review of existing routinely-collected client level data from the TB Screening Tool (Appendix D), TB Identification and Follow-up Register (Appendix E), Index Testing Register (Appendix F), and Tier.net TB, HTS, and HIV/ART modules. De-identified data for individuals with presumptive TB at implementing facilities will be used for this evaluation (see Table 2). Data sources will include Tier.net (HTS, TB, ART modules) in addition to the TB Identification and Follow-up Register and patient clinical charts. In cases where there are discrepant data from different data sources, data collectors will consider Tier.net as the gold standard.

Table 2. List of Variables for Data Collection of Routinely Collected Data

Variable Name
Demographics
Facility Name
Point of Service
Sex
Age (in years)
TB Screening and HIV Testing

Date identified as presumptive TB
GeneXpert done
GeneXpert test date
GeneXpert Result (Xpert-negative, Xpert-positive RIF-S, Xpert-positive RIF-R, indeterminate)
Smear microscopy done
Date of smear microscopy
Smear microscopy result (negative, positive)
TB culture done
Date of TB culture
Culture result (negative, positive, contaminated)
Diagnosed with TB (Yes, No)
Date of TB diagnosis
HIV status at entry (known positive, tested HIV negative in the past year, unknown status [not tested for HIV in the past, or tested HIV negative > 1 year ago]
Tested for HIV (Yes, Refused HIV testing, No, Unknown, N/A)
Date of HIV test
HIV test result (Positive, Negative, Indeterminate)
Started on TB treatment
Date started TB treatment
Index Testing
Offered index testing services
Date offered index testing services
Accepted index testing services
Number of contacts elicited
Number of contacts tested for HIV
HIV status of contacts elicited (number known positive, new positive, new negative, not tested)
Linkage to ART (among HIV-positive patients without TB disease)
Already on ART (Yes, No)
Linked to ART services (Yes, No)
Date of linkage to ART services
Initiated on ART (Yes, No)
Date of ART initiation
Linkage to TPT (among HIV-positive patients without TB disease)
Already on TPT (Yes, No)
Linked to TPT (Yes, No)
Date of linkage to TPT
Initiated on TPT (Yes, No)
TPT start date

5. Data Management and Analysis

5.1 Data Entry

Patient clinical data are entered into existing registers and tools by health care facility staff during clinical care visits as part of routine service delivery. For the evaluation, data abstracted from patient registers and records will be entered into a data collection form developed by ICAP (Appendix G) for the evaluation on the SurveyCTO application using password-protected, encrypted electronic tablets. Data entry will occur in a private or semi-private area of the health facility where patients and non-authorized health facility staff will not be able to see the data as they are entered. During abstraction of data, names, national identification numbers, clinic identification numbers, addresses, phone numbers or other personally identifiable locator information available in patient registers and records will not be entered into the project database.

Data will be electronically uploaded to a secure, password-protected cloud-based SurveyCTO server daily when the tablet is connected to the internet, either in the field using a facility's Wi-Fi if available, or when back in the ICAP office, at which time the data will be removed from the tablets. SurveyCTO encrypts Internet communications with Secure Sockets Layer technology, so data are secure in transit. SurveyCTO was selected as the database platform because it is certified by CUIMC Information Technology as a multi-user data storage platform. Throughout data collection, copies of the data will be made weekly by accessing the server via secure internet connection on encrypted and password-protected laptop computers at the ICAP office. Backups will be transferred on the same day and stored on encrypted password-protected end user storage devices kept in a double-locked room in the ICAP office. All end user storage devices employ Microsoft Intune to protect against viruses and other malware. All users of end user storage devices must agree and follow Columbia University's Information Technology policies, which dictate the acceptable use of Columbia's network and computing resources and ensure data and equipment security (https://cuit.columbia.edu/columbia-it-policies-strategies).

Access to the electronic tablets will be restricted to approved project staff through password protection; encryption and password protection of tablets will prevent breach of data in the event of loss or theft. Tablets will remain in the custody of project data collectors and approved project staff while collecting data at facilities and during transportation between the ICAP office and health facilities. Tablets will be returned daily to the ICAP South Africa office where they will be kept in locked cabinets in a locked room.

5.2 Data Quality Assurance

As part of technical support for service implementation at the implementing health facilities, ICAP will support efforts to improve the quality of routinely collected data, and ensure complete records are collected for all patients receiving care at the facilities. During weekly mentorship visits at each facility, the Project Coordinator will check a random sample of 10% of the records to ensure the quality, validity, accuracy and completeness of patient records. Data quality issues will be noted and feedback provided to HCW, and to the extent possible rectified. Abstraction of retrospective data for the evaluation (to be completed after all routinely collected data are recorded) will be conducted by trained project Data Collectors under the supervision of the Project Coordinator. During data collection, the Project Coordinator will conduct data quality checks and provide feedback to data collectors. Missing fields will be included in abstraction.

5.3 Statistical Analysis

5.3.1 Review of Routinely Collected Data

Data analysis will examine the impact of technical assistance for HIV testing among patients with presumptive TB, index testing, linkage to TPT, and linkage and initiation of ART services among those who are HIV-positive, following implementation. Patient-level data will be collected on clients attending services at participating facilities who are identified as having presumptive TB. Data will be collected at the end of project implementation when all ethical and administrative approvals are received (this will be a retrospective evaluation of routinely collected existing data at the time of the analysis). Descriptive univariate analyses will be used to examine the evaluation questions listed in Section 4.1. The evaluation will measure the following indicators:

Training

- The number/proportion of HCW trained on processes of HIV testing of patients with presumptive TB, linkage to ART, linkage to TPT, and index testing

- The number/proportion of HCW trained on revised M&E tools

The following will be disaggregated by age, sex, and TB status (presumptive TB [TB disease ruled out, GeneXpert MTB/RIF negative], presumptive TB [not evaluated for TB], diagnosed with TB [GeneXpert MTB/RIF positive]):

HIV Testing

- The number/proportion of patients with presumptive TB identified, by point of service
- The number/proportion of patients with presumptive TB with a known HIV-positive status
- The number/proportion of patients with presumptive TB with an unknown HIV status (not tested for HIV in the past, tested HIV-negative > 1 year ago, or tested HIV-negative < 1 year ago)
    - The number/proportion of patients with presumptive TB with an unknown HIV status tested for HIV
- The number/proportion of patients with presumptive TB with an unknown HIV status tested for HIV and tested HIV positive
- The number/proportion of patients with presumptive TB with a known HIV status (known HIV positive, newly identified HIV positive, newly identified HIV negative)
    - The number/proportion of patients with presumptive TB who are HIV positive (known HIV-positive and newly identified HIV positive)

Index Testing

- The number/proportion of HIV-positive presumptive TB patients offered index testing services
- The number/proportion of HIV-positive presumptive TB patients offered index testing who accepted index testing services
- The HIV status of contacts elicited (number/proportion Not Tested, Known Positive, New Positive, New Negative)
- The number/proportion of contacts of presumptive TB index cases identified that were tested for HIV

- The number/proportion of contacts tested HIV positive, and number/proportion tested HIV negative

Linkage to ART

- The number/proportion of HIV-positive patients with presumptive TB linked to ART services (include newly identified HIV positive, pre-ART, and lost to follow-up)
- The number/proportion of HIV-positive patients with presumptive TB linked to ART services who initiated ART within 1 week of enrollment in care
- The proportion of HIV-positive patients with presumptive TB who are Xpert negative linked to ART services who initiated ART within 1 week of enrollment in care

Linkage to TPT

- The number/proportion of HIV-positive patients with presumptive TB who are Xpert negative (not diagnosed with TB disease) linked to TPT

The analysis will also assess differences in key indicators (HIV testing, documented HIV status, index testing offer and acceptance, linkage to ART services, timeliness of ART initiation, linkage to TPT, etc.) across health facilities. However, comparing indicators across facilities is not a primary objective of the evaluation because facility characteristics (size, location, etc.) vary greatly. Confidence intervals will be calculated for measures as appropriate. Further analyses such as stratification by facility or sex and statistical comparisons such as patient and facility factors associated with testing or linkage will be conducted as appropriate based on the results of the descriptive analyses. All analyses as appropriate will account for potential clustering by site. Data will be imported into SAS 9.4 or other software for cleaning and analysis.

5.4 Project Reviews and Reports

Per CDC guidelines, written progress reports will be submitted annually, and a final project report will be submitted to CDC upon completion of implementation and analysis. Interim updates will be provided through conference calls and meetings, as needed, with key stakeholders.

5.5 Record Retention and Disposal

5.5.1 Review of Routinely Collected Data

The de-identified routinely collected patient-level data will be kept indefinitely.

5.6 Data Access

CDC-funded evaluation projects are required to make the data that support the conclusions of peer-reviewed scientific research publications freely available in public repositories at publication in machine-readable formats. ICAP will make de-identified datasets from this project publicly available upon publication, per CDC requirements.

5.7 Data Ownership

All routinely collected data belong to the South African DOH. ICAP, in collaboration with CDC and the DOH, will analyze the data. CDC will not interact with study subjects for research purposes and will not receive any individually-identifiable information. CDC will only have access to data that have been de-identified. All final project databases will not include patient names, medical record numbers, or any other individually identifiable information. Project data are jointly owned by the South African DOH and ICAP.

Datasets created for public release will contain a general description of the study, including data collection procedures, as well as a codebook with variable names and descriptions. As this project involves participants who are HIV-positive and are considered a stigmatized and vulnerable group, data from the project will be made available upon request rather than made publicly available on websites for automatic download. Requests will be made to ICAP at Columbia University and data will be shared following receipt of the request. Information about the data will be made available on appropriate websites and in publications and other presentations of data.

5.8 Data and Safety Monitoring

5.8.1 Review of Routinely Collected Data

The evaluation includes a retrospective review of existing routinely collected patient level data. As such, the retrospective review will not include safety monitoring.

Tablets will be encrypted and stored in a secure location (i.e., a locked cabinet) when not in use. Routinely collected data will be electronically uploaded to a secure password-protected SurveyCTO server daily and the data will be removed from the tablets. Only project personnel will have access to the password-protected database on the server.

6. Training

All project staff will be trained in Good Clinical Practice and protection of human subjects. ICAP will use a training program that has been developed for local staff working on research projects. The training provides background and teaches competencies around protocol adherence, client confidentiality and protection of human subjects. All project staff will receive this training before the start of evaluation activities.

Project staff will receive protocol training, including detailed training on SOPs and utilization of data collection tools. They will be trained in the use of tablets for data collection, the SurveyCTO applications, and data submission.
Data Collectors will be trained in data abstraction using standard ICAP data abstraction procedures which include extensive training on patient confidentiality. Throughout data abstraction activities, the Data Collectors will receive ongoing technical supervision from the Project Coordinator.

Project Clinics that do not currently conduct HIV diagnostic testing will be trained using the DOH approved algorithm. ICAP staff will confirm all staff performing HIV diagnostic testing has or will receive basic Bio-Safety training.

7. Ethical Considerations

The evaluation protocol will be submitted for review by the South African Human Sciences Research Council Research Ethics Committee (HSRC REC), the CUIMC Institutional Review Board (IRB), and the Center for Global Health Associate Director for Science (ADS) Office. As CDC investigators are non-engaged, CDC IRB review and approval are not required.

7.1 Consent Process

7.1.1 Review of Routinely Collected Data

The evaluation will be conducted through a retrospective records review and secondary analysis of existing routinely collected patient data, and thus there will be no consent for this aspect of the project. A waiver of consent is requested for the abstraction of routine program data. The request for waiver of consent for the records review is based on several considerations: (1) the study involves no more than minimal risk to subjects and the research activities will not alter in any way the routine services that all patients receive; (2) the study does not involve any interaction or interference with routine care and as such, the waiver of consent will not adversely affect the rights and welfare of the subjects; (3) due to the high volume of patients and patients who may no longer be in care at these health facilities, the activity could not practically be carried out without the waiver of consent; (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation; and (5) no identifiable data will be collected, and there is minimal risk of personally identifiable information being exposed.

7.2 Participation of Vulnerable Populations

A proportion of data for this evaluation may be from children and pregnant and breastfeeding women. As indicated above, ICAP will ensure that data are de-identified at the facility. There will be no direct interactions with clients as part of the evaluation process (see Appendix B Confidentiality Agreement).

7.3 Risks and Benefits

7.3.1 Review of Routinely Collected Data

As the evaluation of routinely-collected data entails the use of routinely-collected patient data, one risk is that personal information may be revealed during the data collection (abstraction) process, including HIV status through a breach of data security procedures. As described below (Section 7.4.1), measures will be employed to ensure that confidentiality is protected during data abstraction processes. In addition, there will be no storing of patient identifiable information and no codebook linking patient data to their identities which reduces the risk of breaches of confidentiality following the completion of data collection.

There are no direct benefits to patients whose data are included in the evaluation.

7.4 Confidentiality

Standard non-legal confidentiality agreements will be signed by the ICAP Principal Investigator and co-investigators, Project Coordinators, and Data Collectors (Appendix B).

7.4.1 Review of Routinely Collected Data

For this component of the evaluation, patient records will be reviewed and abstracted data will be entered into the SurveyCTO form on tablets in private offices or spaces within the health facilities so that other patients or non-affiliated staff cannot see any sensitive information. Data will be electronically uploaded to a secure, password-protected cloud-based SurveyCTO server daily when the tablet is connected to the internet, either in the field using a facility's Wi-Fi if available, or when back in the ICAP office, at which time the data will be removed from the tablets. Throughout data collection, copies of the data will be made weekly by accessing the server via secure internet connection on encrypted and password-protected laptop computers at the ICAP office. Backups will be transferred on the same day and stored on encrypted password protected end user storage devices kept in a double-locked room in the ICAP office. Access to the datasets will be restricted to

approved project staff, responsible for project monitoring, data management and analysis, through password protection at the workstations, network drives and SurveyCTO server. Locked doors will enforce restricted physical access to the computers. In New York, data will be stored on a CUIMC-certified multiuser server at Columbia University.

7.4.2 Protocol Non-Adherence Event

Should a protocol non-adherence event arise, including the breach of confidentiality or anything else related to the leaking of private information, the Project Coordinator will immediately report to ICAP, CDC, and DOH. The CUIMC IRB, South African HSRC REC, and CDC ADS will be informed according to their respective guidelines. Information will be gathered to discover the root cause, and appropriate steps will be taken to prevent recurrence. If misconduct is discovered, institution-specific procedures will be followed.

7.5 Alternatives to Participation

7.5.1 Review of Routinely Collected Data

There will be no consent for the retrospective review of routinely collected data per the waiver of consent requested and there are no alternatives to participation (see Section 7.1 Consent Process).

7.6 Conflicts of Interest

Per the PEPFAR Evaluation Standards of Practice guidance, the evaluation team will manage any conflicts of interest of evaluators to ensure credibility and mitigate bias. Members of the evaluation team will certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the evaluation's subject matter through signing the Evaluation team Conflict of Interest Statement prior to the initiation of the evaluation (See Appendix C).

If conflicts of interest are discovered among members of the evaluation team, actions will be taken to resolve the conflict of interest. Specific actions will be determined by the nature of the conflict and the timing of when it is discovered. The actions taken may include but are not limited to:

- Removal of the individual with the conflict of interest from participating in the evaluation activities;
- Revising the role of the individual with the conflict of interest so the relationships is no longer relevant/no longer presents a conflict; and
- Assessment of the individuals' contribution to the evaluation activities for bias prior to delivery of final evaluation outputs.

8. Project Monitoring

As the project sponsor, the CDC may conduct monitoring or auditing of study activities to ensure the scientific integrity of the study and to ensure the rights and protection of project participants. Monitoring and auditing activities may be conducted by:

- CDC staff ("internal")
- authorized representatives of CDC (e.g., a contracted party considered to be "external")
- both internal and external parties

Monitoring or auditing may be performed by means of on-site visits to the Investigator's facilities or through other communications such as telephone calls or written correspondence. The visits will be scheduled at mutually agreeable times, and the frequency of visits will be at the discretion of CDC. During the visit, any study-related materials may be reviewed and the Investigator along with project staff should be available for discussion of findings.
The project may also be subject to inspection by regulatory authorities (national or foreign) as well as the International Ethics Committees/IRBs to review compliance and regulatory requirements. In addition, ICAP will conduct monitoring during project implementation. The objective of site monitoring is to ensure that the site is adhering to the protocol and all human subjects' protection guidelines. Monitoring will be performed by the Project Coordinator and will include a review of the site's overall performance as it relates to the evaluation protocol and the site's implementation and quality assurance plans. In addition, there will be a review of patient records, confidentiality guidelines and data entry.

9. Dissemination and Reporting of Results

The results for this project will have relevance primarily for clinical providers and policymakers who oversee program implementation and develop HIV testing care and treatment guidelines. Additionally, the results will be useful to the South African DOH, and potentially other countries, in identifying ways to improve and document HIV testing among presumptive TB patients to identify those HIV-positive and start them on ART. Dissemination of the results will target these audiences in South Africa and in other settings where the findings may be relevant. Dissemination of findings will include the publication of papers in scientific journals and presentation of findings at scientific and other public health-related meetings. The investigators involved with the project will also participate in and contribute data for guideline development processes to assist in the full effective utilization of the findings. Information on the findings relevant for wider audiences, including the general public, will also be disseminated through press releases to print and other media outlets.

9.1 Evaluation Report

A final evaluation report will be produced in alignment with PEPFAR ESoP requirements and posted on a publicly accessible website within 90 days of clearance. The report will convey that the evaluation was undertaken in a manner to ensure credibility, objectivity, transparency, and the generation of high-quality information and knowledge. Recommendations in the report will be supported by a specific or clearly defined set of findings and conclusions that are feasible, specific, responsive to the purpose, and action-oriented. The report will include the following sections:

I. Cover and title pages;
    i. Executive summary
    ii. Project background
    iii. Evaluation purpose and questions
    iv. Evaluation design, methods, and limitations
    v. Findings and conclusions
    vi. Recommendations
    vii. Dissemination
    viii. References
    ix. Relevant appendices

The total budget and annual expenditures related to the evaluation will be included in the Evaluation report. The amount will be shared with the activity manager/project office for entry into the DATIM evaluation inventory.

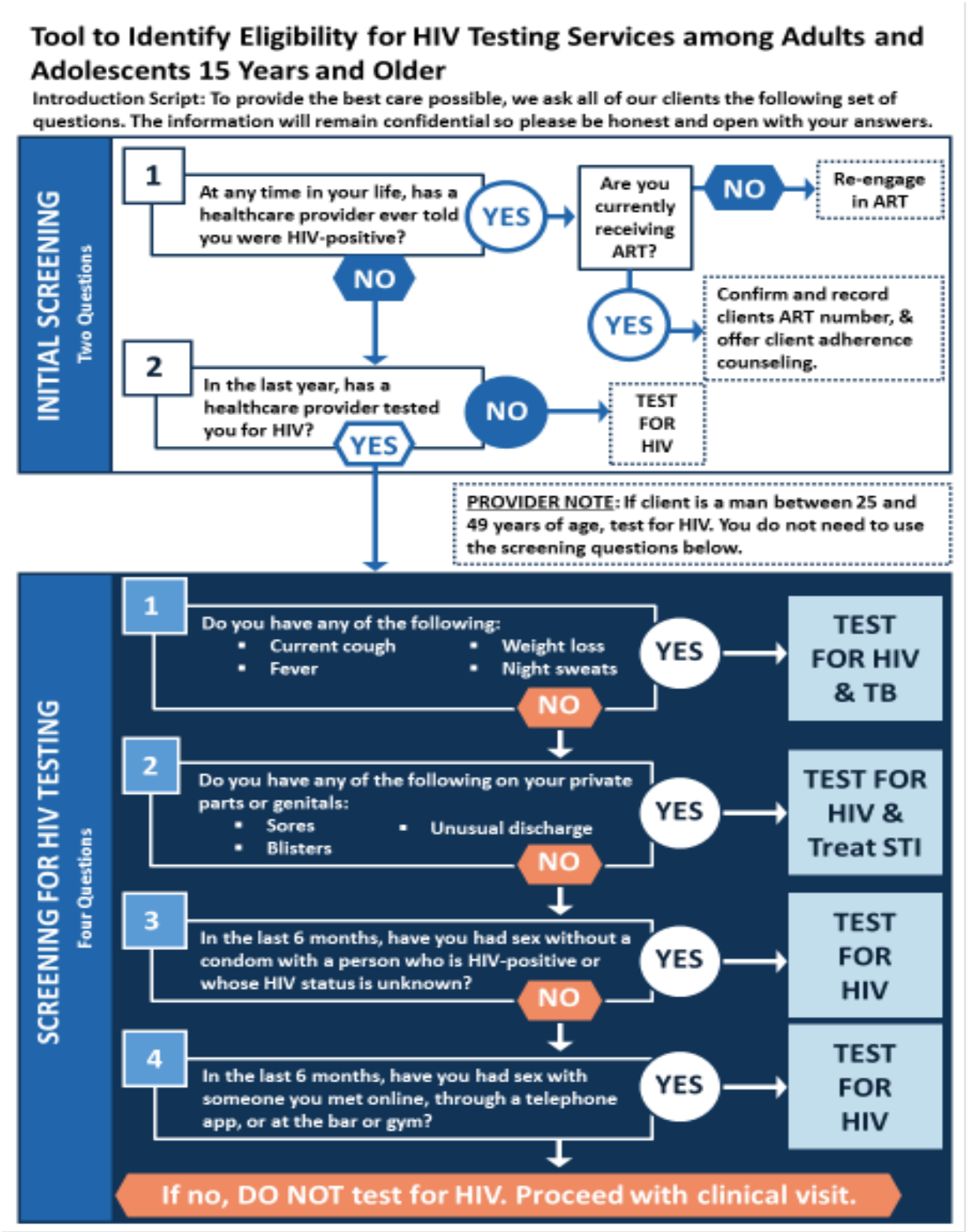
10. Challenges and Limitations

One limitation of using routinely collected data is the reliance on data that were originally collected as part of routine clinical care and were not collected as part of a research study. Routinely collected clinical data are often subject to increased levels of missing and incorrect information compared to data collected as part of a research study. As part of ICAP's support for service implementation at these health facilities, efforts will be made to ensure the highest data quality possible. Another limitation is that we do not have a pre-implementation comparison group. Data on HIV testing among patients with presumptive TB are not systematically collected at health facilities with the current M&E tools, thus we will not be able to measure this practice prior to project implementation.

11. Timeline

The conduct of the proposed activities in this protocol are anticipated to take 6 months to complete including data analysis (see Figure 1).

Appendix A: South African Tool to Identify Eligibility for HIV Testing Services among Adults and Adolescents 15 Years and Older



Appendix B: Confidentiality Agreement

CONFIDENTIALITY AGREEMENT

In consideration of my access to the records and information described below and maintained under the Strengthen HIV testing, index testing and linkage to ART services among patients with presumptive TB in South Africa project, I agree as follows:

1. "Confidential Information" means the following records, data and information:
   - Any study material with a study participant's, or potential participant's, name, unique identification number, or contact information
   - Protocols and protocol-specific forms
   - Laboratory test results for participants or potential participants
   - Any medical records of participants or potential participants
   - Any HIV-related conditions and/or status

2. I agree not to reveal anything about the evaluation details learned in this training.

3. I agree not to make use of, disseminate, disclose or in any way circulate any Confidential Information except as necessary to conduct this project, including compliance with applicable laws and regulations that may require disclosure of Confidential Information.

4. I agree not to disclose any computer password or otherwise provide access to Confidential Information to any unauthorized person.

5. I agree to maintain appropriate procedures to ensure that Confidential Information remains confidential.

6. The obligations of confidentiality imposed on me by this Confidentiality Agreement do not apply to any information that is now in or hereafter comes into the public domain through no improper action or inaction by me.

7. I agree to comply with all applicable laws and regulations regarding the confidentiality of individually identifiable health care information.

8. I agree to notify my supervisor immediately should I become aware of an actual breach of confidentiality or a situation which could potentially result in a breach, whether this is on my part or on the part of another person.

9. I agree that these agreements remain applicable after the evaluation has ended.

Date: ____/ _____/ _____

Name of Individual (Print): _____

Signature: _____

Title: _____

Appendix C: Conflict of interest statement

Evaluation team Conflict of Interest Statement

Project title: Strengthen HIV testing, index testing and linkage to ART services among patients with presumptive TB in South Africa

Background

Per the PEPFAR Evaluation Standards of Practice guidance, "it is vital to manage any conflicts of interest of the evaluator and the evaluation team to ensure credibility and mitigate bias. In advance, everyone on the evaluation team must disclose any personal, financial, or other relationships they have that might pose a conflict of interest (or the appearance of a conflict) in their role as evaluators."

Conflict of interest statement

To this end, all members of the evaluation team listed below certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the evaluation's subject matter.

We confirm, to the best of our knowledge, there is no conflict or potential conflict of interest that would preclude me from participating in the: Strengthen HIV testing and linkage to ART services among patients with presumptive TB in South Africa project. We further confirm that we are aware of no circumstances that would create the perception of a conflict of interest due to our participation in this on-site evaluation.

Evaluator team members name	Signature	Date

The evaluators whose names are listed immediately below report the following details of affiliation or involvement in an organization or entity with a financial or non-financial interest in the evaluation subject matter. Please specify the nature of the conflict on a separate sheet of paper if the space below is inadequate.

Evaluator names:

Appendix D: South Africa DOH TB Screening Tool

TB SYMPTOM SCREENING TOOL FOR ADULTS AND CHILDREN

PATIENT DETAILS

Surname:	First Name:
Physical Address:	Age:
Telephone Number:	Patient folder Number:

MEDICAL HISTORY

Close contact of a person with infectious TB:	Yes	No	Unknown	(Tick √)
Type of index patient:	DS-TB	Rif Resistant TB	MDR-TB or XDR-TB	
Diabetic:	Yes	No	Unknown	
HIV Status:	Positive	Negative	Unknown	
Other: (Specify)				

TB SYMPTOM SCREEN

1. ADULTS

Symptoms (Tick √)	Yes	No
Cough of 2 weeks or more OR of any duration if HIV positive		
Persistent fever of more than two weeks		
Unexplained weight loss >1.5kg in a month		
Drenching night sweats		

2. CHILDREN

Symptoms (Tick √)	Yes	No
Cough of 2 weeks or more which is not improving on treatment		
Persistent fever of more than two weeks		
Documented weight loss/ failure to thrive (check Road to Health Card)		
Fatigue (less playful/ always tired)		

If "Yes" to one or more of these questions, consider TB.
If the patient is coughing, collect sputum specimen and send it for Xpert testing.
If the patient is not coughing but has the other symptoms, clinically assess the patient or refer for further investigation.

Date of last TB test:			
Patient referred for assessment and investigation:		Yes	No
Date of referral:	Facility name:		
Name:	Date:		

Appendix E: South Africa DOH TB Identification Register

GW20/12, 2018

TUBERCULOSIS IDENTIFICATION REGISTER

District: _____ Sub-District: _____ Facility Name: _____

Specimen Barcode Number [1]	Patient Folder Number	Surname (Top row) First name (s) (Bottom row)	Date of birth (Top row) dd/mm/yyyy / Age (bottom row)	Gender M/F	Physical Home Address [2]	Telephone / Cellphone	Contact (Y/N) (Top row) / DS/ DR-TB (bottom row)	HIV Status (Pos./ Neg. /Unk)	Pregnant (Y/ N)	Diabetes Mellitus (Y/ N/ Unk)	BASELINE TEST RESULTS: Date Sputum collected [5] dd/mm/yyyy	BASELINE TEST RESULTS: DateSputum test Result received [6] dd/mm/yyyy	BASELINE TEST RESULTS: Xpert (top row) / Smear microscopy (bottom row)	TEST RESULT TURN AROUND TIME [7] (Tick): <48hrs	TEST RESULT TURN AROUND TIME [7] (Tick): >48hrs	TB CULTURE/ LPA/ DST RESULTS: Date sputum collected dd/mm/yyyy	TB CULTURE/ LPA/ DST RESULTS: Culture Result (Pos/ Neg)	TB CULTURE/ LPA/ DST RESULTS: Drug Resistance on LPA/ DST (Tick): R	H
TOTALS:								Total number positive	Total number preg-nant	Total number Dia-betic			Total tested Positive				Total tested Positive	Total MDR-TB	

[1] Place Barcode sticker from the laboratory form/ write Barcode number eg. AAGX8459

[2] Full detailed address of where the patient lives or can be reached during the day

[5] Write date when the patient produced sputum specimen

[6] Write date when the test results were received by the facility

[7] Tick whether sputum results were back within 48hrs or after 48hrs in the facility.

health
Department
Health
REPUBLIC OF SOUTH AFRICA

Quarter/ Year: _____

	OTHER TESTS DONE		PATIENTS DIAGNOSED WITH TB (DS/ DR-TB)			IPT Start Date for contacts <5years dd/mm/yyyy	REMARKS
	Test	Result	Date Treatment Started [1] dd/mm/ yyyy	Died before Treat-ment Started (Tick)	Lost to follow-up (Tick)		
			Total started Rx	Total died	Total not on Rx		

[1] Write date on which the patient was started on treatment.

Appendix F: South Africa DOH Index Testing Register

INDEX TESTING REGISTER - Ekurhuleni

Counsellor Name:_____ **Facility Name:** _____ **Period of Completion:**_____ **000 501** THE AURUM INSTITUTE

INDEX CASE				PARTNER / CHILD																		
				INFORMATION					PRIOR HIV TEST STATUS						HIV TESTING SERVICES PROVIDED						
Index Testing Programme Reference Number 000 001	Identity/Passport/ Asylum Number	Visit Date	Age (yrs) Gender: Male (M); Female (F); TransMale (TGM); TransFemale (TGF)	Name and Surname ID Number	Date Partner/ Child Came/ went to Facility	Partner/ Child Reference Number 000 001/P01 or 000 001/C01	Relationship to Index Case	Age (yrs) Gender: Male (M); Female (F); TransMale (TGM); TransFemale (TGF)	Tested Before? Y / N	Prior Test Result P / N / Discrepant	Date of Last Test (mm/yyyy)	Does Partner Consent to HIV Testing? Y / N / NA	Partner / Child Test Results P / N / Discrepant	If Positive, Linked to ART? Y / N / NA	Date Linked To ART (dd/mm/yyyy)	Tested As Couple? Y / N / NA	Couple Discordant? Y / N / NA	If Negative, Linked To HIV Prevention Services? Y / N / NA	Type of Prevention Service: Condoms (C), VMMC (V), PrEP (Pr), PEP (Pe)	Comments /Referral Modality
TOTAL CLIENTS OFFERED INDEX TESTING:				**TOTAL CONTACTS:**																		

v3. Sep 2018

Appendix G: Draft Data Abstraction Tool

Notes for programming of electronic tool:

- DC = Data Collector
- All questions are required
- "Data Entry" column is just for internal information / use and should indicate to Informatics when programming whether a DC can choose one answer or more than one (single vs multi select answers)
- The numbers in the "Possible Answers" column are only for backend use and should not appear in the application which the DC can see
- The default scroll wheel date should be January 1, 2019
- For all numbers and dates, please have the following errors:
    - If a number is entered or a date is selected and then the DC also selects "Not Documented"
    - If a number or date is not selected and then the DC also selects "Date / Number Entered / Selected"
- The questions should appear one question per screen

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
T01	Municipality	Select one of the answers	1 – City of Tshwane Metropolitan Municipality 2 – Ekurhuleni	
T02	Facility	Select one of the answers	1 – Soshanguve Block JJ Clinic 2 – KT Motubase Clinic 3 – Laudium Community Health Centre (CHC) 4 – Pedisong 1 Clinic 5 - Stanza Bopape CHC 6 – Ethafeni Clinic 7 – Vosloorus Poly Clinic 8 – Esangweni CHC 9 – Tsakane Clinic 10 – Goba Clinic	If select T01=1 then Facility responses 1-5 should be available If select T01=2 then Facility responses 6-10 should be available
	Section A – TB Screening, Evaluation and Diagnosis *Data Sources: TB Screening Tool, TB Identification Register, Tier.Net TB Module* *Collect all data on clients who were identified with presumptive TB during the implementation period (X-X 2019)*			
A01	Date identified as having presumptive TB (i.e., TB symptom screened positive)	Enter a date using scrolling wheel as day, month, year		Date restricted between X-X 2019
A02	Point of service where identified	Select one of the answers	1 – Outpatient 2 – Inpatient 3 – Antenatal care	

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
	with presumptive TB		4 – Labor and delivery 5 – Under 5 clinic 6 – Nutrition 88 – Not Documented (Empty)	
A03	Sex	Select one of the answers	1 – Male 2 – Female 88 – Not Documented (Empty)	
A04	Age	Enter number	1 – Number Entered 88 – Not Documented (Empty)	
A05	GeneXpert MTB/RIF Conducted	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A08
A06	Date GeneXpert MTB/RIF Conducted	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
A07	GeneXpert MTB/RIF Result	Select one of the answers	1 – Xpert-negative 2 – Xpert-positive RIF-S 3 – Xpert-positive RIF-R 4 – Xpert-positive, RIF indeterminate 5 – Invalid/no result/error 88 – Not Documented (Empty)	
A08	Smear Microscopy Done	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A11
A09	Date of Smear Microscopy	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
A10	Smear Microscopy Result	Select one of the answers	1 – Negative 2 – Positive 88 – Not Documented (Empty)	
A11	TB Culture Done	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A14
A12	Date of TB Culture	Enter a date using scrolling	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
		wheel as day, month, year		
A13	Result of TB Culture	Select one of the answers	1 – Culture negative 2 – Culture positive 88 – Not Documented (Empty)	
A14	Diagnosed with TB	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to next section
A15	Date of TB Diagnosis	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
A16	Started on TB Treatment	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	
A17	Date started on TB Treatment	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
	<u>Section B</u> – HIV Testing – DATA SOURCE *Data Sources: TB Screening Tool, TB Identification and Follow-up Register, Tier.Net HTS and HIV/ART modules* *Link the data for the same individual for the time period of X-X DATE*			
B01	HIV Status at Entry (a time when identified with presumptive TB)	Select one of the answers	1 – Known Positive (KP) 2 – Tested HIV negative in the past year 3 – Unknown status [not tested for HIV in the past] 4 – Unknown status [tested HIV-negative >1 year ago] 88 – Not Documented (Empty)	If select 1, 2 or 4, continue to next question If select 3 or 88, skip to B03
B02	Date of last HIV Test	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	
B03	Tested for HIV	Select one of the answers	1 – Yes 2 – No 3 – Refused HIV testing 88 – Not Documented (Empty)	If yes, continue to next question If no, refused HIV testing, or not documented, skip to next section

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
B04	Date of HIV Test	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
B05	HIV Test Result	Select one of the answers	1 – Positive 2 – Negative 3 – Discrepant 4 – Indeterminate 88 – Not Documented (Empty)	
	<u>Section C</u> – Linkage to ART *Data Sources: Tier.net HTS and HIV/ART modules* *Continue to link the data for the same client for the time period of X-X DATE*			
C01	On ART at time identified with presumptive TB	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, skip to next section If no or not documented, continue to the next question
C02	Linked to ART services	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to next question If no or Not Documented, skip to next section
C03	Date of linkage to ART Services	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
C04	Initiated on ART	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to next question If no or Not Documented, skip to next section
C05	Date of ART Initiation	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
	<u>Section D</u> – Index Testing *DATA SOURCE: Index Testing Register* *Continue to link the data for the same client for the time period of X-X DATE*			

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
D01	Client offered index testing services	Select one of the answers	1 – Yes 2 – No	If yes, continue to the next question If no, skip to next section
D02	Date offered index testing services	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
D03	Client accepted index testing services	Select one of the answers	1 – Yes 2 – No	If yes, continue to the next question If no, skip to next section
D04	Number of contacts elicited	Enter number	1 – Number Entered 4 – Not Documented (Empty)	
D05	Number of contacts tested for HIV	Enter number	1 – Number Entered 4 – Not Documented (Empty)	If number entered 1 or greater, continue to the next question If number entered is 0 or Not Documented, skip to next section
D06	HIV status of contacts tested for HIV		Number Known Positive_____ Number newly identified positive_____ Number newly identified negative_____ Number discrepant_____ Number with result not documented (Empty)_____	
	<u>Section E</u> – Linkage to TB Preventive Treatment (TPT) *Data Source: Tier.net HIV/ART module* *Continue to link the data for the same client for the time period of X-X DATE*			
E01	Client already on TPT	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, skip to next section If no or not documented, continue to the next question in this section
E02	Client linked to TPT	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to the next question in this section If no, skip to next section

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
E03	Date of linkage to TPT	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
E04	Initiated on TPT	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to the next question in this section If no, skip to next section
E05	Date initiated on TPT	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between X-X 2019
	<u>Section G</u> – Comments			
G01	Are there any additional comments to note for this client?	Select one of the answers	1 – Yes 2 – No	If yes, go to next question If no, end data abstraction
G02	Please provide other comments:	Free text		

Appendix B. Data Collection Tool

HIV Testing among Presumptive TB – Data Abstraction Tool

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
T03	Municipality	Select one of the answers	1 – City of Tshwane Metropolitan Municipality 2 – Ekurhuleni	
T04	Facility	Select one of the answers	1 – Soshanguve Block JJ Clinic 2 – KT Motubase Clinic 3 – Laudium Community Health Centre (CHC) 4 – Phedisong 1 Clinic 5 - Stanza Bopape CHC 6 – Ethafeni Clinic 7 – Vosloorus Poly Clinic 8 – Esangweni CHC 9 – Tsakane Clinic 10 – Goba Clinic	If select T01=1 then Facility responses 1-5 should be available If select T01=2 then Facility responses 6-10 should be available
T05	ICAP ID #	Please enter the sequential ICAP ID # (DO NOT enter patient ID numbers from patient folders or registers!)	Text Box	
	<u>Section A – TB Screening, Evaluation and Diagnosis</u> *Data Sources: TB Screening Tool, TB Identification Register, Tier.Net TB Module, patient charts* *Collect all data on clients who were identified with presumptive TB during the implementation period* ***01 November 2019 to 30 November 2019***			
A18	Date identified as having presumptive TB (i.e., TB symptom screened positive)	Enter a date using scrolling wheel as day, month, year		**Date restricted between period 01November 2019 to 30 November 2019**
A19	Point of service where identified with presumptive TB	Select one of the answers	1 – Acute 2 – Chronic 3 – Antenatal care 4 – Labor and delivery 5 – Under 5 Clinic 6 – Family Planning 7 – Nutrition 8 - Mental Health	

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
			9 – HTS Sites 10 – Other: Please Specify 88 – Not Documented (Empty)	
A20	Sex	Select one of the answers	1 – Male 2 – Female 88 – Not Documented (Empty)	
A21	Age	Enter number	1 – Number Entered 88 – Not Documented (Empty)	
A22	GeneXpert MTB/RIF Conducted	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A08
A23	Date GeneXpert MTB/RIF Conducted	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
A24	GeneXpert MTB/RIF Result	Select one of the answers	0 – Xpert-negative 1 – Xpert-positive RIF-S 2 – Xpert-positive RIF-R 3 – Xpert-positive, RIF indeterminate 4 – Invalid/no result/error 5 – Not Detected 6 - Detected 88 – Not Documented (Empty)	
A25	Smear Microscopy Done	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A11
A26	Date of Smear Microscopy	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
A27	Smear Microscopy Result	Select one of the answers	1 – Negative 2 – Positive 88 – Not Documented (Empty)	
A28	TB Culture Done	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to A14
A29	Date of TB Culture	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
A30	Result of TB Culture	Select one of the answers	1 – Culture negative 2 – Culture positive 88 – Not Documented (Empty)	
A31	Diagnosed with TB	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	If yes, continue to next question If no or not documented, skip to next section
A32	Date of TB Diagnosis	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
A33	Started on TB Treatment	Select one of the answers	1 – Yes 0 – No 88 – Not Documented (Empty)	
A34	Date started on TB Treatment	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
	<u>Section B</u> – HIV Testing – DATA SOURCE			

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
	Data Sources: TB Screening Tool, TB Identification and Follow-up Register, Tier.Net HTS and HIV/ART modules, patient charts *Link the data for the same individual for the time period* ***01 November 2019 to 30 November 2019***			
B06	HIV Status at Entry (at time when identified with presumptive TB)	Select one of the answers	1 – Known Positive 2 - Negative 3 – Unknown 88 – Not Documented (Empty)	If select 1 or 2, continue to next question If select 3 or 88, skip to B03
B07	Is the date of last HIV test available		1 - Yes 0 - No	If No, skip to B04
B08	Date of last HIV Test	Enter a date using scrolling wheel as day, month, year		Date is not restricted
B09	Tested for HIV	Select one of the answers	1 – Yes 2 – No 3 – Refused HIV testing 88 – Not Documented (Empty)	If yes, continue to next question If no, refused HIV testing, or not documented, skip to next section
B10	Date of HIV Test	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
B11	HIV Test Result	Select one of the answers	1 – Positive 2 – Negative 3 – Discrepant 4 – Indeterminate 88 – Not Documented (Empty)	
	<u>Section C</u> – Linkage to ART **ONLY asked for patients who are HIV-positive** *Data Sources: Tier.net HTS and HIV/ART modules, patient charts* *Continue to link the data for the same client for the time period* ***01 November 2019 to 30 November 2019***			

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
C06	On ART at time identified with presumptive TB	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, skip to next section If no or not documented, continue to the next question
C07	Initiated on ART	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to next question If no or Not Documented, skip to next section
C08	Date of ART Initiation	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01 November 2019 to 20 December 2019
	<u>Section D</u> – Index Testing **ONLY asked for patients who are HIV-positive, and restricted to patients who were newly identified positive, OR who were newly initiated on ART** *DATA SOURCE: Index Testing Register, patient folders* *Continue to link the data for the same client for the time period* ***01 November 2019 to 30 November 2019***			
D07	Client offered index testing services	Select one of the answers	1 – Yes 2 – No	If yes, continue to the next question If no, skip to next section
D08	Date offered index testing services	Enter a date using scrolling wheel as day, month, year	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01November 2019 to 20 December 2019
D09	Client accepted index testing services	Select one of the answers	1 – Yes 2 – No	If yes, continue to the next question If no, skip to next section

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
D10	Number of contacts elicited	Enter number	1 – Number Entered 4 – Not Documented (Empty)	
D11	Number of contacts tested for HIV or who were already known to be HIV-positive	Enter number	1 – Number Entered 4 – Not Documented (Empty)	If number entered 1 or greater, continue to the next question If number entered is 0 or Not Documented, skip to next section
D12	HIV status of contacts tested for HIV or who were already known to be HIV-positive		Number Known Positive_____ Number newly identified positive_____ Number newly identified negative_____ Number discrepant_____ Number with result not documented (Empty)_____	
	<u>Section E</u> – Linkage to TB Preventive Treatment (TPT) **ONLY asked for patients who are HIV-positive and DO NOT have active TB disease** *Data Source: Tier.net HIV/ART module, patient charts* *Continue to link the data for the same client for the time period* ***01 November 2019 to 30 November 2019***			
E06	Client already on TPT	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, skip to next section If no or not documented, continue to the next question in this section
E07	Initiated on TPT	Select one of the answers	1 – Yes (Y) 2 – No (N) 88 – Not Documented (Empty)	If yes, continue to the next question in this section If no, skip to next section
E08	Date initiated on TPT	Enter a date using scrolling	1 – Date Selected 88 – Not Documented (Empty)	Date restricted between period 01

Field	Question	Data Entry	Possible Answers	Notes / Restrictions / Skips
		wheel as day, month, year		November 2019 to 20 December 2019
	<u>Section F</u> – Comments			
F01	Are there any additional comments to note for this client?	Select one of the answers	1 – Yes 2 – No	If yes, go to next question If no, end data abstraction
F02	Please provide other comments:	Free text		

Appendix C Investigators and Roles

Name	Title/affiliation	Role on project
Andrea Howard, MD, MS	Clinical & Training Unit Director, ICAP	Principal Investigator: • Overall direction and management of the project • Protocol development • Oversight of project implementation • Interpretation of results for dissemination • Report development
Kieran Hartsough, MPH	Strategic Information Specialist, ICAP	Co-Investigator: • Protocol development • Train South African-based project team in monitoring and evaluation tools and data collection • Analyze data • Interpretation of results for dissemination • Report development
Blanche Pitt	Country Director, ICAP in South Africa	Co-Investigator: • Protocol development • Supervise implementing team in South Africa • Liaise with CDC, South Africa Ethics Committee, South Africa DOH and other project stakeholders

Curriculum Vitae

ANDREA A. HOWARD, MD, MS

Dr. Andrea A. Howard is a board-certified internal medicine and infectious disease doctor, with 26 years of experience in clinical public health. Dr. Howard has led ICAP's efforts to support HIV/tuberculosis (TB) integration and strengthen HIV/TB prevention, control, care, and treatment activities in several sub-Saharan African countries since 2007. Currently, as the Director of the Clinical and Training Unit, Dr. Howard manages ICAP's provision of clinical, laboratory, and training support and capacity building to projects focused on strengthening HIV/AIDS and HIV/TB prevention, care, and treatment programs, improving the clinical capacity of individual providers and ICAP-supported health care facilities, and improving the clinical mentorship provided to local health care providers. Dr. Howard is also an Associate Professor of Epidemiology at Columbia University and has extensive academic and research experience in Epidemiology, Population Health, and Medicine. Dr. Howard has a Medical degree and a Master's Degree in Clinical Research Methods.

EDUCATION

1998-2000	Master of Science in Clinical Research Methods, Albert Einstein College of Medicine, Bronx, USA
1990-1994	Doctor of Medicine, Weill Medical College of Cornell University, New York, USA
1986-1990	Bachelor of Arts in Chemistry, Colgate University, Hamilton, USA

PROFESSIONAL EXPERIENCE

2014-Present	**Director of the Global HIV Implementation Science Research Training Program,** Mailman School of Public Health at Columbia University, New York, USA
2012-Present	**Director of the Clinical and Training Unit,** ICAP at Columbia University, New York, USA
2010-Present	**Associate Professor of Epidemiology,** Columbia University Medical Center, New York, USA
2008-Present	**Attending Physician,** Harlem Hospital, New York, USA
2011	**Acting Director of the Clinical Unit,** ICAP at Columbia University, New York, USA
2009-2011	**Deputy Director of the Clinical Unit,** ICAP at Columbia University, New York, USA
2007-2009	**TB/HIV Clinical Officer,** ICAP at Columbia University, New York, USA
2007-2009	**Assistant Professor of Clinical Epidemiology,** Mailman School of Public Health at Columbia University, New York, USA
2002-2007	**Assistant Professor of Epidemiology & Population Health and Medicine,** Albert Einstein College of Medicine, Bronx, USA
2000-2007	**Assistant Attending Physician,** Montefiore Medical Center, the Bronx, USA
2000-2002	**Instructor of Epidemiology & Population Health and Medicine,** Albert Einstein College of Medicine, Bronx, USA
1997-2000	**Clinical and Research Fellow,** Albert Einstein College of Medicine and affiliated hospitals, Bronx, USA
1994-1997	**Intern and Resident,** the New York Hospital-Weill Medical College of Cornell University, New York, USA

BOARD QUALIFICATIONS

1999-Present Diplomate in Infectious Diseases
1997-Present Diplomate in Internal Medicine

OTHER ACTIVITIES

2014-Present Doctoral Committee, Department of Epidemiology, Mailman School of Public Health at Columbia University, New York, USA
2009-Present Lecturer, Epidemiology and Control of Tuberculosis, Mailman School of Public Health, Columbia University, New York, NY
2008-2019 Course Director, Infectious Disease Epidemiology, Mailman School of Public Health, Columbia University, New York, NY
2008-2011 Steering Committee, Infectious Diseases Epidemiology Training Program, Mailman School of Public Health at Columbia University, New York, USA
2007 General Clinical Research Center Advisory Committee, Albert Einstein College of Medicine, the Bronx, USA
2006-2007 Faculty Senate, Albert Einstein College of Medicine, the Bronx, USA
2004-2006 Admissions Committee, Montefiore Internal Medicine Residency Program, Albert Einstein College of Medicine, the Bronx, USA
2004-2006 Admissions Committee, Medical Students, Albert Einstein College of Medicine, the Bronx, USA
2001-2007 Admissions Committee, Clinical Research Training Program, Albert Einstein College of Medicine, the Bronx, USA
2000-2007 Appointments and Promotions Committee, Department of Epidemiology & Population Health, Albert Einstein College of Medicine, the Bronx, USA

PUBLICATIONS (SELECTED)

1. Kunins HV, **Howard AA**, Klein RS, Arnsten JH, Litwin AH, Schoenbaum EE, Gourevitch MN. Validity of a self-reported history of a positive tuberculin skin test: a prospective study of drug users. *J Gen Intern Med.* 2004; 19:1039-44.
2. Sivapalasingam S, Klein RS, **Howard A**, Qin A, Tseng C, Gourevitch MN. Housing insecurity and lack of public assistance are risk factors for tuberculin skin test conversion among persons who use illicit drugs in New York City. *J Addiction Med.* 2009;3:172-7.
3. **Howard AA**, El-Sadr WM. Integration of tuberculosis and HIV services in Sub-Saharan Africa: lessons learned. Clin Infect Dis 2010;50(S3):S38-44.
4. Toro PL, Schneider KL, Carter RJ, Abrams EJ, El-Sadr WM, **Howard AA**. Maternal and infant outcomes with concurrent treatment of tuberculosis and HIV infection in pregnant women. *J Acquir Immune Defic Syndr.* 2011;56:e63-6.
5. **Howard AA**, Gasana M, Getahun H, Harries A, Lawn SD, Miller B, Nelson L, Sitieni J, Coggin WL. PEPFAR support for the scaling up of collaborative TB/HIV activities. *J Acquir Immune Defic Syndr.* 2012;60:S136-44.
6. Saito S, **Howard AA**, Reid MJ, Elul B, Scardigli A, Verkuijl S, Umubyeyi Nyaruhirira A, Nash D. TB diagnostic capacity in sub-Saharan African HIV Care settings. *J Acquir Immune Def Syndr.* 2012;61:216-20.
7. Reid MJA, Saito S, Nash D, Scardigli A, Casalini C, **Howard AA**. Implementation of tuberculosis infection control measures at HIV care and treatment sites in sub-Saharan Africa. *Int J Tuberc Lung Dis.* 2012;16:1605-12.
8. Boltaev A, Deryabina A, Kusainov A, **Howard AA**. Evaluation of a pilot medication-assisted therapy program in Kazakhstan: Successes, challenges and opportunities for scale-up. *Adv Prev Med.* 2012; article ID 308793.

9. Kidder DP, Bachanas P, Medley A, Pals S, Nuwagaba-Biribonwoha H, Ackers M, **Howard A**, DeLuca N, Mbatia R, Sheriff M, Arthur G, Katuta F, Cherutich P, Somi G for the PwP Evaluation Study team. HIV prevention in care and treatment settings: Baseline risk behaviors among HIV patients in Kenya, Namibia, and Tanzania. *PLoS ONE*. 8(2): e57215. doi:10.1371/journal.pone.0057215.
10. McNairy, **Howard AA**, El-Sadr WM. Antiretroviral therapy for prevention of HIV and tuberculosis: a promising intervention, but not a panacea. *J Acquir Immune Def Syndr.* 2013; 63 (suppl 2):S200-7.
11. Ahmad Khan F, Verkuijl, S, Parrish A, Chikwava F, Ntumy R, El-Sadr W, **Howard AA**. Performance of symptom-based tuberculosis screening among people living with HIV: Not as great as hoped. *AIDS*. 2014; 28:1463-72
12. Medley A, Seth P, Pathak S, **Howard AA**, DeLuca N, Matiko E, Mwinyi A, Katuta F, Sheriff M, Makyao N, Wanjiku L, Ngare C, Bachanas P. Alcohol use and its association with HIV risk behaviors among a cohort of patients attending HIV clinical care in Tanzania, Kenya and Namibia. *AIDS Care.* 2014; 26:1288-97.
13. Middleton L, **Howard AA**, Dohrn J, Von Zinkernagel D, Parham Hopson D, Aranda-Naranjo B, Hall C, Malata A, Bvumbe T, Chabela A, Molise N, El-Sadr WM. The Nursing Education Partnership Initiative (NEPI): Innovations in nursing and midwifery education. *Academic Medicine.* 2014; 89 (8Suppl): S24-8.
14. Eduardo E, Lamb MR, Kandula S, **Howard A**, Mugisha V, Kimanga D, Kilama B, El-Sadr W, Elul B. Characteristics and outcomes among older HIV-positive adults enrolled in HIV programs in four sub-Saharan African countries. *PLOS One.* 2014; doi:10.1371/journal.pone.0103864.
15. Reed J, Grund J, Liu Y, Mwandi Z, **Howard AA**, McNairy ML, Chesang K, Cherutich P, Bock N. Evaluation of loss-to-follow-up and post-operative adverse events in a voluntary medical male circumcision program in Nyanza Province, Kenya. J Acquir Immune Defic Syndr 2015; 69(1):e13-23.
16. Saito S, **Howard AA**, Chege D, Ellman TM, Ahoua L, Elul B, Rabkin M. Monitoring quality at scale: implementing quality assurance in a diverse, multi-country HIV program. AIDS. 2015; 29 (Suppl 2):S219-36.
17. Agarwal M, Lamb MR, **Howard AA**, Abrams E, El-Sadr WM, Elul B. Sex differences in mortality and loss among 21,461 older adults on antiretroviral therapy in sub-Saharan Africa**.** *J Acquir Immune Defic Syndr.* 2016 Oct;73(2):e33-5. PMID: 27632148.
18. Bachanas P, Kidder D, Medley A, Pals SL, Carpenter D, **Howard A**, Antelman G, DeLuca N, Mohenje O, Sheriff M, Somi G, Katuta F, Cherutich P, Moore J. Delivering prevention interventions to people living with HIV in clinical care settings: results of a cluster randomized trial in Kenya, Namibia and Tanzania. AIDS Behav 2016. doi 10.1007/s10461-016-1349-2.
19. Smith, J, Odera D, Chege, D, Patnaik P, Muigai E, Michasels-Strasser S, **Howard AA**, Yu-Shears J, Dohrn J. Identifying the gaps: An assessment of nurses' training, competency, and practice in HIV care and treatment in Kenya. J Assoc Nurses AIDS Care 2016;27:322-30.
20. Daftary A, Hirsch-Moverman Y, Kassie GM, Melaku Z, Gadisa T, Saito S, **Howard AA**. A qualitative evaluation of the acceptability of an interactive voice response system to enhance adherence to isoniazid preventive therapy among people living with HIV in Ethiopia. AIDS Behav 2016. doi 10.1007/s10461-016-1432-8.
21. **Howard AA**, Hirsch-Moverman Y, Frederix K, Daftary A, Saito S, Gross T, Wu, U, Maama LB. The START Study to evaluate the effectiveness of a combination intervention package to enhance antiretroviral therapy uptake and retention during TB treatment among TB/HIV patients in Lesotho: rationale and design of a mixed methods cluster randomized trial. Global Health Action 2016; 9:31543.

22. Turinawe K, Vandebriel G, Lowrance DW, Uwinkindi F, Mutwa P, Boer KR, Mutembayire G, Tugizimana D, Nsanzimana S, Pevzner E, **Howard AA**, Gasana M. Operating characteristics of a tuberculosis screening tool for people living with HIV in out-patient HIV care and treatment services, Rwanda. PLoS One 2016;11(9):e0163462.
23. Hirsch-Moverman Y, Daftary A, Yuengling KA, Saito S, Ntoane M, Frederix K, Maama LB, **Howard AA**. Using mHealth for HIV/TB treatment support in Lesotho: Enhancing patient-provider communication in the START Study. JAIDS 2017; 74 S1:S37-43.
24. Hayes-Larson E, Hirsch-Moverman Y, Saito S, Frederix K, Pitt B, Maama LB, **Howard AA**. Prevalence, patterns and correlates of HIV disclosure among TB-HIV patients initiating antiretroviral therapy in Lesotho. AIDS Care 2017;29(8):978-984. doi: 10.1080/09540121.2017.1280124.
25. **Howard AA**, Hirsch-Moverman Y, Saito S, Gadisa T, Daftary A, Melaku Z. The ENRICH Study to evaluate the effectiveness of a combination intervention package to improve isoniazid preventive therapy initiation, adherence and completion among people living with HIV in Ethiopia: rationale and design of a mixed methods cluster randomized trial. Contemp Clin Trials Commun 2017;doi: 10.1016/j.conctc.2017.03.001.
26. O'Connor DE, Frederix K, Saito S, Maama LB, Hirsch-Moverman Y, Pitt B, Hayes-Larson E, Lebelo L, Shale M, **Howard AA**. Pulmonary tuberculosis diagnostic practices among people living with HIV in Lesotho. Int J Tuberc Lung Dis 2017;21(10):1133-1138.
27. Hayes-Larson E, Hirsch-Moverman Y, Saito S, Frederix K, Bitt B, Maama-Maime L, **Howard AA**. Depressive symptoms and hazardous/harmful alcohol use are prevalent and correlated with stigma among TB-HIV patients in Lesotho. Int J Tuberc Lung Dis 2017;21 (11):S34-41.
28. Ellman TM, Alemayehu B, Abrams EJ, Arpadi, S, **Howard AA**, El-Sadr WM. Selecting a viral load threshold for routine monitoring in resource-limited settings: optimizing individual health and population impact. J Int AIDS Soc 2017; 20(S7):16-18.
29. Hirsch-Moverman Y, **Howard AA**, Frederix K, Lebelo L, Hesseling A, Nachman S, Mantell J, Lekhela T, Maama LB, El-Sadr W. The PREVENT Study to evaluate the effectiveness and acceptability of a community-based intervention to prevent childhood TB in Lesotho: study protocol for a cluster randomized controlled trial. Trials 2017; 18:552. doi: 10.1186/s13063-017-2184-0.
30. Hirsch-Moverman Y, Burkot C, Saito S, Frederix K, Pitt B, Melaku Z, Gadisa T, **Howard AA.** Reaching the end of the line: operational issues with implementing phone-based unannounced pill counts in resource-limited settings. PLoS One 2017;12:30185549. Doi: 10.1371/journal.pone.0185549.
31. Courtenay-Quirk C, Pals S, **Howard AA**, Ujamaa D, Henjewele C, Munuo G, Urasa P, Nyamkara M. Increasing partner HIV testing and linkage to care in TB settings: Findings from an implementation study in Pwani, Tanzania. AIDS Care 2018;30:1600-4.
32. Mukherjee T, Hirsch-Moverman Y, Saito, S, Gadisa T, Melaku Z, **Howard AA**. Determinants of alcohol use among people living with HIV initiating isoniazid preventive therapy in Ethiopia. Drug Alcohol Depend 2019; 2014: 107465. doi: 10.1016/j.drugalcdep.2019.04.036.

LANGUAGES: English

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES**

NAME: Blanche Pitt

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Country Director ICAP South Africa; Regional Project Director PHIA

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Leeds Metropolitan University	MS	05/1991	Health Promotion
Leeds Metropolitan University	PGD	05/1990	Health Promotion

A. Personal Statement

I am a public health specialist with more than 25 years of senior management experience in managing health services in the formal sector including building capacity for improved service delivery. I am highly experienced in project design and management and management an expert at building strategic partnerships with key stakeholders and partners as well as national health leaders in South Africa. I have played leadership roles in various US-Government grants, including, establishing the Regional Office and serving as the Regional Director for the CDC-funded Population-based HIV Impact Assessments Project (PHIA). As Regional Director of PHIA, I provide high-level strategic guidance and oversight to the national PHIA surveys to ensure their timely and high quality implementation. To date, over 400,000 children and adults in thirteen African countries and Haiti have enrolled in these household-based, nationally representative surveys which are measuring national HIV incidence and prevalence of viral load suppression to assess the reach of HIV care and treatment programs. I also manage ICAP's regional and national team at ICAP South Africa's office, who have made major contributions to the successful implementation of the high profile PHIA project as well as important strides to achieving HIV epidemic control in the Republic of South Africa. Prior to serving as ICAP's Regional Director of PHIA and Country Director of ICAP South Africa, I served as Country Director for ICAP in Lesotho, where I led ICAP's highly successful US-government grant portfolio focused on the scale-up of HIV/TB and HIV care and treatment. I also held prior country director positions with the African Medical and Research Foundation in South Africa and served as the Director of Health Promotion within the National Ministry of Health in South Africa where I lead the planning and implantation of health promotion and disease prevention services for communicable and non-communicable diseases throughout South Africa.

B. Positions and Honors

Positions and Employment

1988 - 2001	Director, Health Promotion, National Ministry of Health, South Africa
2002 - 2007	Country Director, The African Medical Research Foundation, South Africa
2008 - 2011	Country Director, The African Medical Research Foundation, Tanzania
2011 - 2015	Country Director, ICAP at Columbia University Lesotho, Lesotho
2015 -	Regional Project Director, PHIA & Country Director ICAP South Africa, South Africa

Completed Research Support

U2GGH002173 (El-Sadr, PI) 12/31/2018 – 09/29/2025
HIV-Focused Population Surveys in Countries Supported Under PEPFAR (CDC)
The major goal of this project is to conduct national population-based HIV impact assessments over a six-year period, integrating capacity building into each stage of the assessments, to help define the status of the HIV epidemic in selected countries targeted by CDC.

Role: Regional Director

U2GGH001226 (Justman, PI) 09/30/2014– 09/29/2020
Population-based HIV Impact Assessments in Resource Constrained Countries Supported Under PEPFAR (CDC)
The major goal of this project is to conduct national population-based HIV impact assessments over a five-year period, integrating capacity building into each stage of the assessments, to help define the status of the HIV epidemic in selected countries targeted by CDC.
Role: Regional Director

U2GGH002196 (Michaels-Strasser, PI)
Strengthening the Health System Capacity to Implement HIV Prevention, Care and Treatment Services in the Republic of South Africa under PEPFAR (CDC) 09/30/2019 – 09/29/2020
The major goal of this project is to provide technical assistance (TA) to governmental, non-governmental and community partners in South Africa (SA) to build human resources for health (HRH) capacity to ensure a resilient SA health system able to achieve UNAIDS goals by 2030.

U2GGH001194 (Howard,PI) 08/1/2019-12/30/2019
The major goal of this project was to routinize HIV testing among patients with presumptive TB and strengthen index testing and linkage to TB preventive treatment (TPT) and ART services among patients with presumptive TB who test HIV positive.

U2GGH001194 (Rabkin, PI) 2018/03/01- 2019/09/30
The major goal of the process evaluation was to inform ongoing implementation of expanded WBPHCOT activities by providing insights into the successes, challenges, barriers, facilitators and potential areas for improvement of the expanded WBPHCOT activities.

Kieran Hartsough, MPH

410 Central Park West, Apt 12E, New York, NY 10025
kieran.hartsough@gmail.com | 510.325.4005

SUMMARY OF EXPERIENCE

More than ten years of experience designing, overseeing, implementing, and conducting scientific projects to identify and solve public health problems related to infectious diseases at local, state, and non-governmental agencies. Strong backgroundin managing projects, including budget development, providing technical advice and assistance to local health agencies, as well as global health partners including Ministries of Health and PEPFAR implementing partners, collecting and analyzing routine, evaluation, and public health surveillance data, overseeing epidemiologic investigations, evaluating programs, and disseminating scientific findings through reports, publications and presentations. Strong background in informatics, including development and utilization of health management information systems, data visualizations, electronic medical records, and mHealth. Skillful communicator with expertise in tuberculosis and HIV/AIDS, and experience in emergency response and surveillance.

EDUCATION

Master of Public Health — May 2011

Mailman School of Public Health, Columbia University, New York, NY
Concentration: Epidemiology | Focus: Infectious Disease

Bachelor of Arts — December 2002

University of California, Berkeley, Berkeley, CA
Major: Political Science | Concentration: International Relations
Study abroad at the Institut d'Etudes Politiques and Université Toulouse II – Le Mirail, Toulouse, France

PROFESSIONAL EXPERIENCE

ICAP at Columbia University | New York, NY — November 2015 – Present

Strategic Information Unit

Strategic Information Specialist

- Program planning, development, and implementation: Provide technical assistance to country programs to carry outprogram monitoring and evaluation, surveillance, informatics activities and implementation science for improving evidence-based responses to public health concerns

- Provide support in programmatic monitoring, reporting, and informatics for President's Emergency Plan forAIDS Relief (PEPFAR)-supported (both Centers for Disease Control and Prevention [CDC] and USAID) evidence-based programs in multiple countries related to HIV/AIDS, HIV testing, tuberculosis (TB), maternaland child health (MCH), gender-based violence, key populations, orphans and vulnerable children, health systems strengthening, health information systems, human resources for health, and quality improvement
- Provide overall leadership support of strategic information and improved data demand for HIV, HIV/TB, and health systems strengthening-related projects in Cameroon, Lesotho, Myanmar, South Sudan, and Tanzania;previously supported programs in Burundi, Cote d'Ivoire, Democratic Republic of the Congo (DRC), and Ethiopia
- Remotely provide support for monitoring and evaluation, data review and reporting, data use andvisualization, quality improvement, and program planning
- Support projects related to HIV care and treatment with direct facility and community-based support (Burundi, Cameroon, Cote d'Ivoire, DRC, Ethiopia, South Sudan, Tanzania), as well as projects focused onstrategic information, including national roll out of health management information systems (Cameroon,Ethiopia, Lesotho, Myanmar), and a public-private partnership to decrease TB among miners (Lesotho)
- Coordinate and lead monitoring and evaluation activities related to COVID-19 response projects across multiple countries in Africa, including a training and capacity building project with Resolve to Save Livesacross 13 countries, a privately funded COVID-19 fever clinic and health brigade project across three countries, and a CDC-funded sentinel surveillance project in DRC
- Travel to supported countries as needed to provide onsite technical assistance and trainings
- Contribute to the development of project protocols, standard operating procedures, data collection instruments (both paper-based and electronic), questionnaires, donor reports, evaluation reports, and IRBsubmissions
- Act as a technical resource for staff on the most current knowledge and skills on the epidemiology of TB,epidemiologic and research methods, data analysis, and informatics
- Led the development and implementation of data collection tools for a bi-annual survey among ICAP-supported facilities on services provided at the facility level
- Apply ethical principles in epidemiologic investigations: submit protocols to Institutional Review Board (IRB)at Columbia University, Ministry of Health ethical review committees, and CDC's Associate Director for Science; apply IRB processes as directed; follow ethics guidelines and principles when planning studies, conducting research, and collecting, disseminating, and using data; train staff on confidentiality policies andprocedures to prevent unethical behavior

- Data Management, Analysis, and Interpretation: Manage and analyze routinely collected aggregate and individual-level data, as well as data from program evaluations, to assess and evaluate program implementation and effectiveness, monitor progress to targets, and guide informed decision-making
  - Conduct data analyses (both quantitative and qualitative), including descriptive, and adjusted measures ofassociation via multivariable and regression techniques, for specific projects and on an ad-hoc basis
  - Lead and coordinate strategic information-related aspects of program evaluations, including an evaluationof the TB/HIV cascade and TB infection and prevention control in Lesotho, an assessment of pediatric HIV testing and prevention of mother-to-child transmission services in Lesotho, an evaluation of integration ofTB services into MCH settings in Eswatini, an assessment of improving HIV testing among patients with presumptive TB in South Africa, and a global assessment of HIV-related stigma and discrimination among PEPFAR-supported implementing

partners; support includes developing project protocols, data collection/analysis plans, data collection tools, training materials, conducting trainings, and analysis and write up of results
    - Coordinate quarterly aggregate data reporting and development of technical reviews to monitor progresstowards targets set internally and by external funding agencies
    - Conduct literature reviews to inform program development and drafting of reports and manuscripts
    - Synthesize relevant data to develop action-oriented recommendations aimed at meeting program targets,improving data quality and program outcomes, and for future program implementation
    - Support development and implementation of web-based reporting systems, including DHIS2, and electronicdata collection tools (SurveyCTO, CommCare, Qualtrics), and electronic medical records (OpenMRS)
    - Work with Strategic Information Unit, informatics team, clinical staff, and country-based teams to identifyand prioritize areas for enhanced data use and visualization (using Tableau, Power BI, DHIS2)
- Grants management: Oversaw strategic information-related aspects of grants management for numerous CDC,
  USAID, and private grants
    - Develop program workplans, including goals and objectives, and program indicators and targets forsubmission to funding agencies
    - Monitor and evaluate overall program progress toward program goals and objectives established inworkplans and targets specified by funding agencies
    - Develop and review budgets for informatics and evaluations to ensure that funds were sufficient for plannedprogram activities
    - Write routine progress reports (semi- and annual progress reports), continuation applications, technicalreview responses, and requests for no-cost extensions
    - Contribute technical input to competitive funding proposals
    - Participate in routine monitoring calls with funding agencies to share information on program progress
    - Monitor sub-awardee performance, and progress toward workplan objectives, and budgets
- Establish and maintain relationships: Build strong and longstanding relationships with internal staff, located at headquarters and country offices, and external organizations (e.g., funding agencies, Ministries of Health) to achieveorganizational goals and foster peer-to-peer learning
    - Establish and maintain relationships with country teams and program collaborators to achieveorganizational goals
    - Routinely adjust to different individuals' work styles, approaches, and perspectives across internal andexternal partners to meet organizational goals
    - Successfully collaborate and consult with various units within ICAP (clinical and training, grants management, informatics, communications) to address programmatic and budget issues and ensureconsistent communication between all partners
    - Work to achieve consensus on routine programmatic issues with my own team
- Deliver clear and effective communication: Routinely deliver clear, effective communication in an organizationalsetting with internal and external partners
    - Communicate detailed information on specific programs or functions clearly to internal and externalpartners to effectively collaborate to reach organizational goals
    - Write and disseminate results of program performance, evaluation findings, and reports for both internaland external audiences
    - Deliver oral presentations to a variety of internal (e.g., colleagues) and external audiences of varying size tocommunicate results of program performance and provide technical guidance

- Use clear and effective communication skills to explain complex information and provide strategic information and informatics guidance to internal and external partners during webinars, routine meetings,presentations, and written correspondence

California Department of Public Health| Sacramento, CA February 2013 – October 2014
Program Research and Evaluation Section, Office of AIDS

Research Scientist | Informatics Specialist and Analyst

- Program planning, development, and implementation: Led the research and evaluation of statewide HIV riskreduction activities aimed at reducing the morbidity, mortality, and transmission of HIV
  - Worked as part of a team conducting operational research to inform policy and programmatic decisions
  - Monitored behavioral and social interventions implemented to prevent HIV transmission
  - Collaborated with technical staff to analyze prevention program implementation to inform programmaticdecision-making
  - Acted as a technical resource and transferred the most current knowledge and skills to colleagues toimprove prevention services and adhere to data confidentiality guidelines
- Data Management, Analysis, and Interpretation: Analyzed RRA data to monitor progress towards achieving Stateand CDC goals and objectives, and evaluate prevention programs' impact in reducing HIV transmission
  - Managed, analyzed, and reported on client and encounter level RRA and HIV testing data in LEO (CaliforniaHIV prevention reporting system) using SAS
  - Advised on upgrades/improvements and contributed to pilot testing of the LEO system
  - Mapped new electronic AIDS Case Reporting Form to HIV/AIDS surveillance system
  - Conducted routine data quality assessments to ensure accuracy and reliability of data
  - Reported client level and aggregate data and program budget information semiannually to the CDC
  - Completed internal and external ad hoc data requests
- Establish and maintain relationships: Built relationships with internal staff and external organizations (e.g., localhealth departments) to achieve organizational goal of HIV prevention
  - Established and maintained relationships with colleagues to achieve organizational goals
  - Routinely adjusted to different individuals' work styles, approaches, and perspectives across internal andexternal partners to meet organizational goals
  - Worked to achieve consensus on routine grants management issues with my own team
- Customer service: Assessed internal and external customers' informatics needs and identified solutions responsiveto individual customer needs
  - Worked with Office of AIDS program and information technology staff and external users to enhance LEO tobetter meet users' needs
- Deliver clear and effective communication: Routinely deliver clear, effective communication in an organizationalsetting with both internal and external partners
  - Communicated detailed information on programmatic results clearly to colleagues at state and local healthagencies to effectively collaborate in implementing HIV prevention activities
  - Made oral presentations to a variety of internal (e.g., colleagues) audiences of varying size to communicateresults of operational research and technical assistance needs
  - Tailored written communications (e.g., technical reports, quarterly reports to funding agency, emails) toaddress the most critical issues in a compelling and diplomatic manner

New York City Department of Health and Mental Hygiene (NYC DOHMH)| New York, NY August 2011 – January 2013

Bureau of HIV/AIDS Prevention and Control

HIV Testing Unit

Project Officer | Technical Assistance Coordinator

- Program planning, development, implementation, and evaluation: Implemented and evaluated a public healthprogram aimed at improving tailored HIV testing services in NYC
    - Provided programmatic monitoring and technical oversight to NYC health care facilities and community- based organizations contracted to routinize HIV testing or implement targeted HIV testing strategies for highrisk or at-risk populations
    - Monitored and evaluated contractors' performance in meeting program expectations and goals, andensured the technical quality and integrity of their program
    - Maintained strong working relationships with contractors and assisted them in creating and implementingtheir programs
    - Conducted monthly calls and quarterly on-site visits with contractors to discuss program success, reviewdata, and troubleshoot program operational issues
    - Collaborated with senior staff to develop goals, objectives, and priorities for the HIV testing program
- Data Management, Analysis, and Interpretation: Analyzed HIV testing and linkage to care data to monitor andimprove timeliness, completeness, and accuracy of data reported by contractors
    - Assisted in the development and pilot testing of a new HIV services reporting system (eSHARE), and advisedon upgrades/improvements
    - Led trainings for contractors on the use and understanding of eSHARE
    - Analyzed eSHARE data for completeness and program monitoring purposes, and cleaned data using SAS
    - Provided monthly analysis of Primary Care Information Project HIV testing data from small practices andcommunity health centers using SAS
- Grants management: Managed 16 Prevention and Ryan White contracts totaling $4 million
    - Reviewed and finalized contract documents, including scopes, budgets, and quality assurance/qualitymanagement plans
    - Monitored and evaluated overall program progress toward program goals established in workplans
    - Worked with grants managers to review budgets and program spending to ensure spending was consistentwith the budget narrative and within the project period
    - Participated in routine monitoring calls with CDC partners to share information on program progress
    - Collaborated with major contractor and administrator for testing contracts in reviewing corrective actionand compliance plans, assessing testing targets and addressing data and agency issues
    - Monitored contractor performance, progress toward workplan objectives, and budgets
- Customer service: Helped serve internal and external customers more effectively by identifying opportunities forprogram improvement and implementing solutions
    - Provided technical advice and assistance to contractors (e.g., healthcare provider organizations, community-based organizations) on how to best implement tailored HIV testing services
    - Coordinated efforts and led routine internal meetings across different units to foster information sharingand strengthen collaborations across the HIV testing and prevention units
- Establish and maintain relationships: Built relationships with internal staff and external organizations (e.g., healthcare provider organizations, community-based organizations) to achieve organizational goal of improving tailoredHIV testing in NYC

- Established and maintained strong working relationships with provider organizations to implement HIVtesting services and ensure prompt linkage to care for those who test HIV-positive
- Routinely adjusted to different individuals' work styles, approaches, and perspectives across internal andexternal partners to meet the HIV testing program's goals
- Successfully led collaborations with internal and external partners to accomplish shared goal of improvingtailored HIV testing services in NYC
- Actively listened to team members' and contractors concerns and tried to understand their perspectives tominimize potential conflict and improve interpersonal relationships
- Worked to achieve consensus on routine programmatic issues within my team to achieve team goals

- Deliver clear and effective communication: Routinely delivered clear, effective communication in an organizationalsetting with both internal and external partners (e.g., colleagues, senior staff, and external partners) to share updates on program implementation, best practices, challenges, successes, and long-term public health program goals
  - Communicated detailed information on specific programs or functions clearly to colleagues, senior staff, andexternal partners, including staff from health care facilities and community-based organizations to describe program activities, best practices, and goals
  - Successfully coordinated and developed semi-annual provider meetings for funded contractors to discuss program successes and challenges, quality assurance, testing data, and to network and share best practices
  - Made oral presentations to a variety of audiences of varying size during staff and senior staff meetings, andwith external partners, including staff from health care facilities and community-based organizations (5-50 people)
  - Used clear and effective communication skills to explain complex concepts and policies around HIV testingto internal and external partners
  - Prepared technical reports and scientific presentations for conferences and meetings

New York City Department of Health and Mental Hygiene (NYC DOHMH)| New York, NY June 2007- July 2011

Bureau of Tuberculosis Control
Office of Surveillance and Epidemiology

Epidemiologist

- Oversaw tuberculosis (TB) epidemiology services for Manhattan and Staten Island, providing epidemiologic analysisof patients with TB to determine contact investigation needs to stop transmission of TB
- Reviewed characteristics (clinical, demographic, socio-behavioral) of patients with TB to identify contacts to patientswith TB and ensure their evaluation
- Led the planning and implementation of culturally appropriate health interventions (e.g., TB contact investigations and outbreak investigations) at different levels (e.g., individuals, congregate settings where a TB exposure occurred)to understand TB transmission in NYC and prevent further spread
- Wrote scientific reports of investigations, including recommendations for interventions
- Provided epidemiologic consultation and technical assistance to field staff and healthcare professionals regarding TB exposure investigations, data management and clinical evaluation of contacts
- Incorporated etiologic and epidemiologic principles into the development of disease prevention and controlstrategies such as contact and outbreak investigations
- Acted as a technical resource for staff on the most current knowledge and skills on epidemiologic investigationmethods and TB molecular epidemiology methods

- Applied ethical principles in epidemiologic investigations: submitted protocols to Institutional Review Board (IRB);applied IRB processes as directed; followed ethics guidelines and principles when planning studies, conducting research, and collecting, disseminating, and using data; trained staff on confidentiality policies and procedures to prevent unethical behavior
- Established and maintained relationships with internal partners, healthcare providers, and outside organizations tosupport epidemiologic review of patients with TB, and contact investigations to support prevention of TB transmission
- Worked as a team with Bureau staff to develop and pilot test a web-based electronic surveillance system (Maven)that replaced the previous TB register, and trained staff in its use and understanding
- Managed and analyzed TB epidemiology data to detect infectious disease outbreaks, guide epidemiologicinvestigations, and conduct scientific research
- Analyzed TB epidemiology data to assess trends and identify potential outbreaks
- Supported the data management of results of large congregate setting contact investigations
- Conducted epidemiologic analysis of molecularly clustered cases including re-interviewing patients, gatheringsurveillance data from multiple sources, and analyzing data to establish links between patients and interrupt transmission
- Synthesized relevant data to develop action-oriented recommendations aimed at meeting program targets,improving data quality and program outcomes, and conducting epidemiologic investigations of TB clusters
- Served as co-investigator of 'Stop TB in the Foreign-Born' study (initiative to decrease TB among foreign-born populations in NYC through development of culturally appropriate interventions): wrote study protocol and IRB application; collaborated on drafting the study's survey instruments; and assisted in coordinating logistics of studyimplementation
- Conducted literature reviews, chart review and data abstraction
- Conducted data cleaning, and analyses (including descriptive, and adjusted measures of association via multivariableand regression techniques) of data from epidemiologic studies using SAS
- Created maps using ArcGIS to visualize and examine data
- Used clear and effective communication skills to explain complex concepts and policies about TB transmission, riskof infection, and NYC TB Control investigation practices to individual TB patients and groups of individuals exposedto patients with TB
- Used clear and effective communication skills to liaise with CDC, healthcare providers, infection prevention andcontrol practitioners, and state TB Control programs on contact investigations, outbreak detection and inter- jurisdictional issues
- Made clear, effective oral presentations to a variety of audiences of varying size: internal meetings (5-50 people),and external partners (5-30 people)

New York City Department of Health and Mental Hygiene (NYC DOHMH)| New York, NY May 2008-April 2011

Bureau of Tuberculosis Control

Office of Surveillance and Epidemiology

Cohort Epidemiologist

- Oversaw TB cohort review process to assess success of TB control program and individually review every TB patientand associated contact tracing activities on a quarterly basis
- Monitored and evaluated key program indicators to assess success of TB control efforts
- Acted as a technical resource for staff and transferred knowledge and skills on New York City cohort review process
- Provided technical advice and assistance to local, state, and international health agencies working to

enhance theirTB control programs and learn from the success of the New York City model
- Applied ethical principles in evaluation activities: followed ethics guidelines and principles when collecting, disseminating, and using data; trained staff on confidentiality policies and procedures to prevent unethical behavior
- Established and maintained relationships with colleagues and external organizations (e.g., state health agencies, New Jersey Medical School National Tuberculosis Center) to ensure quality and continuity of cohort review process,and disseminate the lessons learned from New York City's experience
- Successfully developed and led trainings on program evaluation for domestic and international TB controlpractitioners. Provided trainings to TB controllers from London, United Kingdom, local and state health departments, CDC, and the New England TB Consortium
- Managed the abstraction of data reported to the health department and oversaw cohort review data managementpractices, and analyzed cohort review data to monitor and improve program performance
- Synthesized data and presented findings during quarterly cohort review meetings and in written cohort reviewsummary reports.
- Developed action-oriented recommendations aimed at meeting program targets, and improving data quality andprogram outcomes
- Routinely delivered clear, effective communication in an organizational setting with both internal and external partners (e.g., colleagues, senior staff, state, local and international health agencies) to share updates on cohortreview implementation
- Made clear, effective oral presentations to a variety of audiences of varying size: internal meetings (5-50 people),and external partners (5-30 people)

Med-IQ | Baltimore, MD (remote) **April 2011 – June 2016**

Consultant | Data Analyst

- Analyzed participant survey and chart review data to evaluate program outcomes among clinicians participating incontinuing medical education interventions
- Led the interpretation and presentation of data for evaluation reports on clinical practice and behavioralinterventions around continuing medical education
- Restructured and cleaned datasets and implemented data analysis plans in preparation for data analyses
- Analyzed data using SPSS, SAS, and Excel to evaluate knowledge improvement, retention, and behavior changeoutcomes
- Analyzed survey data at three timepoints by implementing statistical techniques such as non-parametric and pairedt-test methods
- Analyzed participant chart review data collected pre- and post-interventions by implementing statistical techniquessuch as Pearson's chi-square, correlation, analysis of variance, linear and logistic regression models
- Synthesized all relevant intervention data to develop action-oriented recommendations intended to inform thedesign and implementation of future interventions
- Demonstrated integrity by following ethics guidelines and principles when planning studies, conducting research,and collecting, disseminating, and using data
- Wrote clear, effective summary reports for evaluation projects that measured performance improvement amongparticipants taking continuing medical education interventions

Millennium Villages Project, Earth Institute, Columbia University | New York **August – December 2006Health Analyst**

- Helped evaluate The Millennium Villages project, which was a 5-year tailored capacity-building initiative, whichreached nearly 400,000 people in 79 villages across 10 African countries
- Evaluated results of health-related household surveys conducted in Kenya to assess program progress towardsobjectives and desired outcomes and improve program implementation, data collection
- Collaborated with a specialized team to interpret results from household surveys and develop reports on findingsand recommendations
- Finalized data analysis plan with input from others prior to analyzing data
- Conducted descriptive data analysis as well as measures of association of data from the household surveys using SASand Excel
- Routinely synthesized results of the household surveys and shared with colleagues and jointly developed action-oriented recommendations
- Served as technical resources to internal partners regarding how to conduct analyses and present results
- Applied ethical principles in evaluation activities: followed ethics guidelines and principles when conductingresearch, and analyzing, disseminating, and using data

Interfaith Center on Corporate Responsibility| New York, NY September – December 2005Public Health Research Associate

- Under the Access to Healthcare Working Group, conducted detailed research and analysis into corporate responsesto HIV/AIDS, pharmaceutical business practices and incentives for lower drug prices
- Analyzed costs, benefits, risks, and chances of success of potential incentives for lower drug prices
- Communicated detailed information on complex information with supervisor and senior staff to describe researchfindings
- With colleagues, wrote a report that described pharmaceutical firms' responses to AIDS - *Benchmarking AIDS:Evaluating Pharmaceutical Responses to the Public Health Crisis in Emerging Markets*
- Wrote clear and detailed shareholder and company recommendations

Berkeley Free Clinic| Berkeley, CA **April 2003 – July 2005**

Counselor

- Contributed to the design, implementation, and management of clinic services, specifically hepatitis testing,education and vaccination, and health services referrals and resources
- Counseled clients on hepatitis prevention, and hepatitis resources, and provided hepatitis testing and vaccination
- Facilitated training of counselors in counseling, phlebotomy, vaccination, and lab work
- Acted as a technical resource and transferred the most current knowledge and skills to help clients receive the bestservices for their needs either through the clinic or through referrals to outside services
- Maintained confidentiality of client information through secure data systems and following ethical principles
- Assisted satellite harm reduction services through a syringe exchange services van, providing sterile syringes andother clean injection drug use materials, collecting used syringes, and providing information on harm reduction strategies
- Worked with team members to innovate and expand clinic services
- Served as Shift Coordinator, coordinating activities of the hepatitis testing and vaccination services at the clinic,which involved managing clinic staff and interfacing with clients

AIDS Legal Referral Panel | San Francisco, CA **March – May 2004Development Intern**

- Worked under direction of the Development Director to research and identify grant opportunities
- Wrote and applied for foundation grants to support the organization's mission – to provide free and low-cost legalassistance and education to persons living with HIV/AIDS
- Raised $25,000 through grant writing

PUBLICATIONS AND PRESENTATIONS

Msukwa M, Stelmach R, Rabkin M, Abo K, Ahoba I, Gildas Anago M, Boccanera R, Brou H, Flueckiger R, **Hartsough K**, Zech J, Nugent R. Out-of-pocket health spending was not associated with missed appointments for adults on antiretroviral therapy in Côte d'Ivoire. Presented at AIDS 2020 (virtual).

Ayalneh H, Aragaw S, Bayoa F, **Hartsough K,** Michaels-Strasser S. I-Surge Strategy in South Sudan: Improving HIV Case Identification and ART Enrollment Across Health Facilities in South Sudan. Presented at AIDS 2020 (virtual).

Wells C, Aidala A, Harris T, **Hartsough K**, Frieze J, Nightingale V, Klindera K, Gardi H, Htoo Razak M, Gantt T, Rodriguez E. Training in Healthcare Settings to Reduce Stigma and Discrimination towards Key Populations: Coverage and Opportunities for Improvement. Presented at AIDS 2020 (virtual).

Soares Linn J, Jha A, Tchissambou T, Ilunga Y, Dane S, Zidana-Ndovi S, **Hartsough K**, Malele Bazola F. Social and sexual network strategies for targeted identification of HIV-positive clients among the key population (KP) in Democratic Republic of the Congo (DRC). Presented at AIDS 2020 (virtual).

Stelmach RD, Rabkin M, Abo K, Ahoba I, Anago MG, Boccanera R, Brou H, Flueckiger R, **Hartsough K**, Msukwa M, Zech J, Young F, Nugent R. Out-of-Pocket Spending on Health for People Living with HIV in Côte d'Ivoire. Presented at CROI 2020 (virtual).

Reidy W, Nuwagaba-Biribonwoha H, Shongwe S, Sahabo R, **Hartsough K**, Wu Y, et al. (2019) Engagement in care among women and their infants lost to follow-up under Option B+ in eSwatini. PLoS ONE 14(10): e0222959.

Howard A, **Hartsough K**, Curran K, Frederix K, Pevzner E, Asiimwe F, Maama-Maime L, Date A. Gaps in the intensified case finding and isoniazid preventive therapy cascade among people living with HIV (PLHIV) in Lesotho. Presented at the Union World Conference on Lung Health, October 2018, The Hague, the Netherlands.

Assefa T, Melaku Z, Amdino W, Abebe A, Rabkin M, **Hartsough K**, Fayorsey R. Implementation of appointment spacing model of differentiated care in Ethiopia-successes and challenges. Presented at AIDS 2018, Amsterdam, the Netherlands.

Howard A, **Hartsough K**, Curran K, Frederix K, Asiimwe F, Maama-Maime L, Marealle S, Pevzner E. High Mortality among PLHIV with TB in Lesotho Despite High ART Uptake. Presented at CROI 2018, March 2018, Boston, MA.

Gadisa T, **Hartsough K**, Schaaf A, Tau P, Harris TG. HIV-Positivity among HIV-Exposed Infants in Lesotho in the Era of Option B+. Presented at CROI 2018, March 2018, Boston, MA.

Reidy W, Harriet Nuwagaba-Biribonwoha H, Shongwe S, Sahabo R, **Hartsough K**, Mthethwa S, Abrams EJ. Engagement in Care and Infant HIV Testing among Lost to Follow-Up Option B+ Patients. Presented at CROI 2018, March 2018, Boston, MA.

Gutema Y, Fayorsey R, Tulu N, **Hartsough K**, D'Aquila E, Melaku Z. Improving HIV Treatment Outcomes in Ethiopia by Integrating HIV Services and Mental Health Care. Presented at ICASA 2017, December 2017, Abidjan, Côte d'Ivoire.

Hailu M, Gutema Y, Melaku Z, Lulseged S, Tulu N, Alemayehu B, D'Aquila E, **Hartsough K**, Fayorsey R. Implementing Routine HIV Viral Load Monitoring to Achieve UNAIDS 'Third 90' in Ethiopia. Presented at ICASA 2017, December 2017, Abidjan, Côte d'Ivoire.

Aragaw S, Bayoa F, Ayalneh H, Ndagije F, **Hartsough K,** D'Aquila E, Fayorsey R, Michaels-Strasser S. High Retention Rates of Patients on Antiretroviral Therapy in a Complex Emergency Setting in Yambio State Hospital, Republic of South Sudan. Presented at ICASA 2017, December 2017, Abidjan, Côte d'Ivoire.

Hartsough K, Schaaf, A, Gadisa T, Tau P, Harris TG. Health Provider Perspective on the Pediatric HIV Referral System in Lesotho. Presented at IAS 2017, July 2017, Paris, France.

Harris TG, Schaaf A, **Hartsough K**, Tau P, Gadisa T. Assessment of Pediatric HIV Testing and Linkage to HIV Care and Treatment in Lesotho, 2014. Presented at IAS 2017, July 2017, Paris, France.

Howard A, Saito S, Frederix K, Hirsch-Moverman Y, Maama LB, Tau P, **Hartsough K**, Mugizi C, El-Sadr WM. Integrated TB/HIV Services for Migrant Miners and Their Families in Lesotho. Presented at CROI 2016, February 2016, Boston, MA.

King A, Stadelmann L, **Hartsough K**, Cutler B, Sweeney MM, Tsoi B. Newly diagnosed positives identified by HIV testing programs in New York City. Presented at AIDS 2012, July 2012, Washington, DC.

Santana Camacho A, Sullivan Meissner J, Lancki N, **Hartsough K**, Alexander M.
Conducting a Health Needs Assessment to Inform Interventions to Reduce Tuberculosis in Foreign-Born Populations in New York City, 2011-2012. Presented at the National TB Controllers Association Conference, June 2012, Atlanta, GA.

Hartsough K, Ahuja SD, Anger H, Dworkin F. Characteristics and Treatment Outcomes of Isoniazid-Monoresistant Tuberculosis Cases, New York City, 1995-2005. Presented at the joint meeting of Interscience Conference on Antimicrobial Agents and Chemotherapy and the Infectious Diseases Society of America, October 2008, Washington, DC.

Hartsough K, Rosan DE, Sachs L. Benchmarking AIDS: Evaluating Pharmaceutical Responses to the Public Health Crisis in Emerging Markets. Interfaith Center on Corporate Responsibility, Corporate Examiner, 2006, Vol.34 No.6-7

Rosan D, Aires B, Rowan C, Compere L, Byron J, **Hartsough K**, Finn S. Benchmarking research-based pharmaceutical company responses to AIDS, TB, & malaria. Presented at AIDS 2006, Toronto, Canada.

SKILLS

Software Applications

Expert: Microsoft Office Suite (Excel, Word, Visio, PowerPoint, OneNote, Outlook), EndNote
Intermediate: Microsoft Access

Analysis, Data Visualization, and Mapping Software Applications

Expert: SAS, Epi Info, Stat/Transfer
Intermediate: SPSS, Tableau, Power BI
Beginner: Stata, R, ArcGIS

Health Management Information Systems and Data Collection Tools

Expert: DHIS2, SurveyCTO

Intermediate: CommCare, OpenMRS, Kobo
ToolboxBeginner: REDCap

Languages

French (Intermediate- spoken, written, read)Nepali (Basic – spoken)

PROFESSIONAL DEVELOPMENT

EPIC Summer Institute, Mailman School of Public Health, Columbia University, New York, NY: Multi-Level Modeling;Program Evaluation for Public Health
New Jersey Medical School Global Tuberculosis Institute, Newark, NJ: Cultural Awareness in TB Control
NYC DOHMH GIS Center, New York, NY: Introduction to ArcGIS; Beginner GIS; Intermediate GIS; Introduction to SpatialStatistics
The SAS Institute, New York, NY: SAS Programming I – Essentials; SAS Programming II – Data Manipulation Techniques;Statistics I – Introduction to ANOVA, Regression, and Logistic Regression; Statistics II – ANOVA and Regression; Data Cleaning Techniques
University of California, Davis Extension, Davis, CA: Public Health Informatics