Evaluation of access to tuberculosis (TB) and HIV testing and treatment services among patients with presumptive TB

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Introduction

Mozambique has high tuberculosis (TB) incidence rates (>350 per 100,000 persons), very high rates of HIV/TB co-infection among individuals, as well as rising numbers of multi-drug resistant (MDR) TB cases (WHO 2019). All persons with positive TB screening should undergo diagnostic testing for TB as well as HIV testing and counseling (HTC) as part of the provider-initiated testing and counseling (PITC) strategy. In an effort to monitor whether all patients with presumptive TB undergo this recommended TB and HIV testing, the Provincial Health Directorate of Zambézia (DPS-Z), in collaboration with Friends in Global Health (FGH), a subsidiary of Vanderbilt University Medical Center (VUMC), developed a tool to register patients with positive TB screening in all sectors of the health facility (HF), and track the flow of these patients through the cascade of TB and HIV counseling and testing. We evaluated the results of the use of this tool in one health facility in Zambézia.

Methods

We conducted an internal outcomes evaluation. A descriptive, retrospective analysis was performed on programmatic data of all adults and children that were registered as having presumptive TB using the pilot tool between July 2018 to November 2019 in the Alto Molócuè Rural Hospital.

Results

Nine hundred and five patients (704 adults, 201 children) were included in this evaluation. The largest proportion of adult patients (36%) were registered in the adult outpatient clinic, while the largest proportion of children (29%) with a presumptive diagnosis of TB were registered in the community by the Directly Observed Treatment, Short-course (DOTS) volunteers. Clinicians registered the majority of cases, followed by DOTS volunteers and Cough Officers, a cadre of TB-focused health volunteers. For 797 (88%) patients (643 adults, 154 children), TB diagnostic tests were requested. Final diagnosis of tuberculosis (laboratorial or clinical) was given to 93 (10%) (73/704 adults, 19/201 children) patients. Among the patients with presumptive TB, 149 (16%) were known HIV-positive. HIV testing among those with unknown or HIV-negative status, or those without any documentation of previous testing was documented for 568 (75%). HIV positivity rate among those newly tested was 3% among children but higher among adults (12%).

Limitations

The results are not necessarily representative or generalizable for the entire province, or for the country, as this evaluation was conducted in only one health facility. We also acknowledge that interpretation of these results depends on the completeness of the data.

Conclusion

Patients with presumptive TB in Alto Molócuè have relatively high HIV positivity rates. The introduction of a separate logbook to register patients with presumptive diagnosis of TB could facilitate tracking of TB diagnostic testing and HIV testing.

Project Background

Tuberculosis (TB) remains a major public health problem in Mozambique, as the nation consistently ranks in the top 14 countries globally in terms of TB burden, specifically having high TB incidence rates (>350 per 100,000 persons), very high rates of HIV/TB co-infection among individuals, as well as rising numbers of multi-drug resistant (MDR) TB cases (WHO 2019).

Elimination of TB hinges on reductions in TB incidence and TB-associated mortality. Consistent with the Sustainable Development Goals (SDGs), targets to achieve elimination include reducing TB incidence by 80% and TB-associated mortality by 90% by the year 2030 when compared to Mozambique's TB incidence and mortality data from 2015. The challenge is that to accomplish this, Mozambique needs to consistently reduce incidence and mortality data (on an average of 4-5% per annum) to have a realistic chance of attaining these lofty goals by 2030.

Although all health facilities have the capacity to screen for TB, there are persistent challenges in terms of implementing and sustaining high quality TB screening programs and tracking all patients with TB through the recommended cascade of TB and HIV testing.

As part of the FAST (Finding TB cases Actively, Separating safely, and Treating effectively) strategy that was recently adopted by Mozambique, Cough Officers have been identified as a key cadre to substantially increase the identification of patients with presumptive TB on the Health Facility level. However, there is a paucity of data describing the impact that this type of task shifting approach has had in terms of TB case identification.

On health facility level, the identification of patients with a presumptive TB diagnosis is typically done by clinicians at all health facility service delivery points and by Cough Officers in the waiting rooms. On a community level, community-based directly observed treatment - short-course (CB-DOTS) volunteers and Traditional Healers identify cases of presumptive TB. Persons with presumptive TB identified by Cough Officers are referred to the clinical consultation rooms for further TB screening and investigation. During the clinic visit, formal testing of persons with presumptive TB is performed using microscopy (Ziehl-Neelsen or LED), and/or GeneXpert MTB/RIF (mycobacterium tuberculosis/rifampin [resistance]) devices. The national guidelines recommend the use of GeneXpert for all patients. All persons with presumptive TB should also undergo formal HIV testing and counseling (HTC) as part of the Provider-initiated Testing and Counseling (PITC) optimization strategy. When a TB and/or a HIV diagnosis is made, a clinical file for HIV care and/or for TB care is immediately opened and care is provided in accordance with existing national guidelines.

To further understand TB testing among TB presumptive cases and possible ways to improve the process, within the Quality Improvement (QI) program, a Specific Quality Improvement Project (SQuIP) was conducted focusing on the utilization of GeneXpert for TB diagnosis to identify possible bottlenecks within the TB care cascade. Results from the SQuIP showed that many cases of presumptive TB were not being properly registered using conventional/established data collection instruments such as the logbooks from the laboratory and outpatient and inpatient departments of the health facility, despite orientation and training for healthcare professionals to screen for TB within all service delivery points.

Another national and international recommendation is HIV testing and counseling for all persons with a presumptive TB diagnosis to markedly increase the timely identification of incident HIV among "at-risk" persons. The referral and presentation of patients with presumptive TB to their nearest health facility provides a unique opportunity to test for HIV and to facilitate the subsequent initiation of ART if/when indicated.

Mozambique currently does not have data on the proportion of patients with presumptive TB who are also tested for HIV. No specific monitoring (registry) tool has existed to track TB screening and related cases of TB-positive screenings performed at all the various service delivery points within the health facilities.

Challenges with the primary data source for presumptive TB cases were also identified in Malawi, where a revised register for presumptive TB case was piloted in 2014–2016. The use of presumptive TB registers with HIV-related variables has enabled Malawi to standardize the recording of HIV status for all presumptive TB cases, thereby simplifying the estimation of HIV prevalence among persons with presumptive TB. The observed increasing trend in the proportion of persons with presumptive TB having their HIV status ascertained demonstrates the feasibility of this initiative in routine health care in resource-constrained settings, once the proper tools have been provided.

The Provincial Health Directorate of Zambézia (DPS-Z), in collaboration with VUMC/FGH, has developed a tool to track and register positive TB screening, hence, presumptive TB cases, as well as to track the provision of HIV counseling and testing among all presumptive TB cases (for both adult and pediatric populations), implemented by FGH/DPS-Z as **a Specific Quality Improvement Project (SQuIP)**.

With this report, we describe the results of this Quality Improvement Project: the access to/uptake of TB and HIV testing and treatment services among patients with presumptive TB, specifically in Alto Molócuè rural hospital in Zambézia, where the pilot of this new TB screening registry instrument was implemented by DPS-Z with the support of VUMC/FGH between July 2018 and November 2019.

Based on the results of this evaluation, we plan to guide the DPS-Z and Ministry of Health (MOH) on:

- Identification of HIV-positive patients/optimized PITC;
- Identification of patients with presumptive TB diagnosis/intensified TB testing per sector.

Costs related to the implementation of this evaluation include time spent by evaluation staff to collect data in the health facility of Alto Molócuè, as well as analyzing the data and dissemination of findings (anticipated expenditures equal to <1% of the total Avante Zambézia budget).

Purpose and questions

Overall objective

The overall objective of the evaluation is to estimate coverage of TB and HIV testing among persons with presumptive TB who have presented for care in the selected VUMC/FGH-supported health facility within Zambézia province, as a result of a Quality Improvement Initiative.

Secondary objectives of this evaluation include:

- Describe the service delivery point(s)/sector(s) and cadre(s) of health care staff (i.e., physicians, counselors, cough officers, CB-DOTS volunteers, or traditional healers) that identify presumptive TB cases, per age disaggregation (0-14 years of age, 15+ years of age);
- Assess the proportion of persons with presumptive TB undergoing (per age disaggregation (0-14 years of age, 15+ years of age)):
    - TB testing (bacilloscopy and GeneXpert), in total and per service delivery point/sector;
    - HIV testing and counseling in total and per service delivery point/sector;
- Determine the absolute number and proportion of persons with presumptive TB (per age disaggregation (0-14 years of age, 15+ years of age)) that are:
    - Newly diagnosed with HIV, in total and per service delivery point/sector;
    - Newly diagnosed with HIV and engaged/enrolled in HIV services/care; in total and per service delivery point/sector;
    - Newly diagnosed with HIV, engaged/enrolled in HIV services/care and started ART; in total and per service delivery point/sector;
- Determine the proportion of persons diagnosed with TB (clinical diagnosis/acid-fast bacilli [AFB] smear/GeneXpert MTB/RIF result) that initiate anti-TB therapy, per age disaggregation (0-14 years of age, 15+ years of age);
- Compare anti-TB therapy initiation rates by HIV status (i.e., rates among persons with presumptive TB who are HIV-positive versus those who are HIV-negative), per age disaggregation (0-14 years of age, 15+ years of age).

Design/ Methods/ Limitations

Type of evaluation

We conducted an internal outcomes evaluation. Secondary analyses were performed on data from patients with presumptive TB identified in the offices of the Rural Hospital of Alto Molócuè, one of the HF supported by FGH in Zambézia.

Stakeholder engagement

Mozambique MOH and FGH/VUMC staff were involved in the pilot and the evaluation. From the MOH, the evaluation was collaborated on by the Provincial TB Focal Point (which was a position at the time of the implementation of this QI project) from the DPS in Zambézia; this collaborator participated in the design of the pilot as well as the concept note for this evaluation. From FGH/VUMC, evaluation collaborators included members of the Technical team, the QI department, the TB Technical Advisor, and the Evaluations team. All project collaborators were involved in the design and implementation of the evaluation. The concept note for secondary analysis was reviewed and approved by the CDC-MZ Associate Director of Science (ADS) team prior to implementation.

Sampling strategy

We have included all routine data available in the registry book for diagnosis of TB and HIV among TB presumptive cases – adults (pilot tool) (Appendix 2), the registry book for diagnosis of TB and HIV among TB presumptive cases – children (pilot tool) (Appendix 3), the MOH PITC registry books (for verification if needed), MOH Laboratory registry book (acid fast bacilli [AFB] smear, GeneXpert MTB/RIF) (for verification if needed) , the MOH TB registry book and OpenMRS for positive patients.

Methods

Inclusion criteria for this evaluation included:

- All patients arriving at the health facility identified as presumptive TB at all service delivery points;

- All age groups (i.e., all adults [≥15 years of age] and all children [<15 years of age]) were included in the evaluation.

Table 1. List of indicators of interest and data sources

Indicators, disaggregated by age and sex	- Number of cases with presumptive TB identified by sector and type of health care staff - Number of TB presumptive cases undergoing TB testing (AFB smear or GeneXpert MTB/RIF) - Number of TB presumptive cases undergoing TB testing (AFB smear or GeneXpert MTB/RIF) with result positive, negative or indeterminate - Number of TB presumptive cases undergoing PITC at the clinic visit - Number of TB presumptive cases undergoing PITC and with result HIV+, HIV- and indeterminate - Number of TB presumptive cases who have a TB diagnosis (smear result and/or clinical) - Number of TB presumptive cases also diagnosed with TB who initiated TB treatment - Number of TB presumptive cases also diagnosed with HIV who opened a clinical file for HIV care - Number of TB presumptive cases also diagnosed with HIV who initiated ART - Proportion of TB presumptive cases who are coinfected with HIV/TB
Source Documents	- Registry book for diagnosis of TB and HIV among TB presumptive cases – adults (pilot tool) (Appendix 2) - Registry book for diagnosis of TB and HIV among TB presumptive cases – children (pilot tool) (Appendix 3) - MOH PITC registry books (for verification if needed) - MOH Laboratory registry book (AFB smear, GeneXpert MTB/RIF) (for verification if needed) - MOH TB registry book

Evaluation Period

The evaluation covered a period of 17 months (from July 2018 to November 2019). Data collection took place in the same period, and these collected data were aggregated and included in this analysis.

Ethical considerations

The secondary data analysis is covered under the blanket protocol "*Quality Improvement for HIV Care and Treatment in Zambézia province of the Republic of Mozambique under the President´s Emergency Plan for AIDS Relief (PEPFAR); Cooperative Agreement (CoAg)# GGH001943.*" This data use and evaluation plan were approved the VUMC Institutional Review Board (IRB, #201887), the Institutional Research Ethics Committee for Health of Zambézia Province (*Comité Institucional de Bioética para Saúde – Zambézia*; CIBS-Z-20) and was reviewed in accordance with the CDC human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

Deviations from SOW/Protocol

There were no protocol deviations during the implementation of this assessment.

Quality assurance

FGH's Technical and QI staff provided in-service training for clinical and community staff on the implementation of the intervention, use of the pilot tools, and following the Standard Operating Procedures (SOP) with fidelity (including steps for TB screening, data recording, sample collection and HIV testing in patients with a presumptive TB diagnosis at the HF). This staff training took place on July 17th, 2018 and was reinforced with routine on-the-job/in-service training as well. FGH personnel ensured and verified the quality of the data recorded by the health facility personnel involved in the pilot.

The programmatic data used in these analyzes were collected by personnel from the Evaluations team, with support from the QI team.

Analysis plan

A descriptive, retrospective analysis was performed using programmatic data and we herein present results from this descriptive analysis including frequency tables.

Limitations of design

This assessment was carried out in only one health facility (rural hospital) in the Alto Molócuè district, so we acknowledge that the results are not necessarily representative or generalizable for the rest of the province, or for the country.

We also acknowledge that interpretation of these results depends on the completeness of the data, as the evaluation was conducted using routinely collected data missingness of data may have occurred, which could further difficult our ability to interpret these results.

Additionally, there was one secondary outcome that we were unable to evaluate: determining the absolute number and proportion of persons with presumptive TB that are newly diagnosed with HIV, engaged/enrolled in HIV services, and started on ART; in total and per service delivery point/sector. At the time of data collection, these data were only available by way of manual data collection from hardcopy records, and resources were not available to pursue the necessary manual data collection, as many data were missing from the tool in this pilot. As such, this analysis was not performed.

Findings

1. *Characteristics of the participants*

A total of 905 patients were included in the evaluation, 704 adults and 201 children. **Table 2** below presents the sociodemographic characteristics of the patients in this evaluation.

Table 2: Sociodemographic data

		Adults (n=704)	Children (n=201)
Sex		N (%)	N (%)
	Male	398 (57%)	98 (49%)
	Female	304 (43%)	102 (51%)
	Missing	2 (0%)	1 (1%)
Age			
	Median [IQR]	35 [25-50]	8 [3-12]

2. *TB screening by sector and personnel*

Of the 704 adult patients with presumptive TB, 255 (36%) were identified in the Adult Outpatient sector, and the sector where the lowest number of presumptive TB patients were identified was the Child-at-Risk Clinic with 9 (1%). (**Figure 1**).

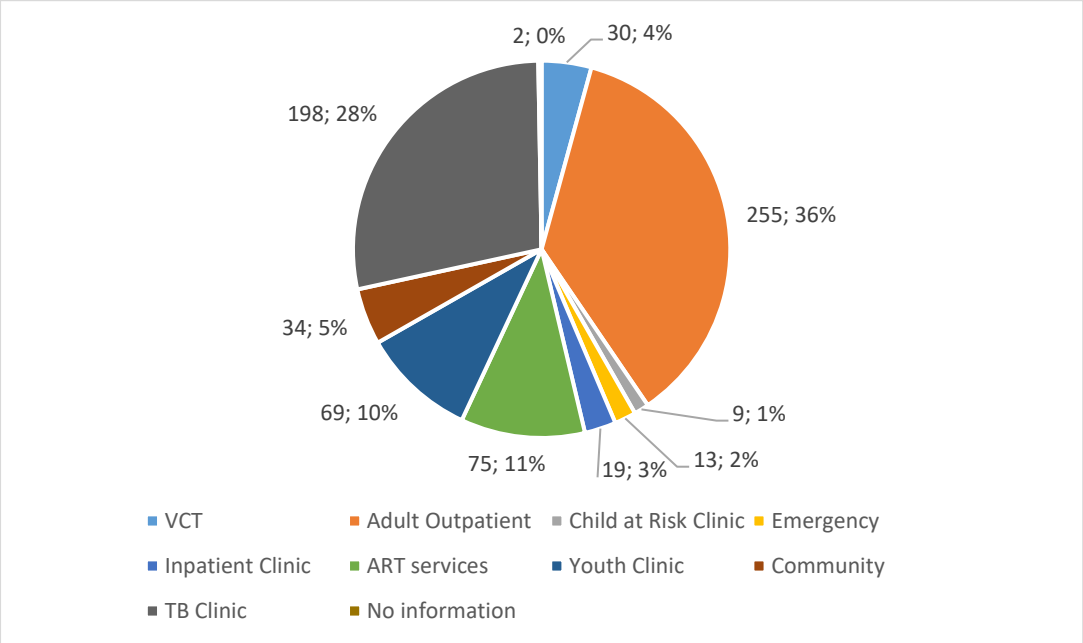

Figure 1. Sectors where adult presumptive TB cases were registered (adults).

While for children, the majority 59 (29%) and 57 (28%) were identified in the community and pediatric inpatient ward, respectively; the sectors with the lowest frequency of identified patients were the Child-at-Risk Clinic and External Consultations with 1 (1%) child identified in each (**Figure 2**).

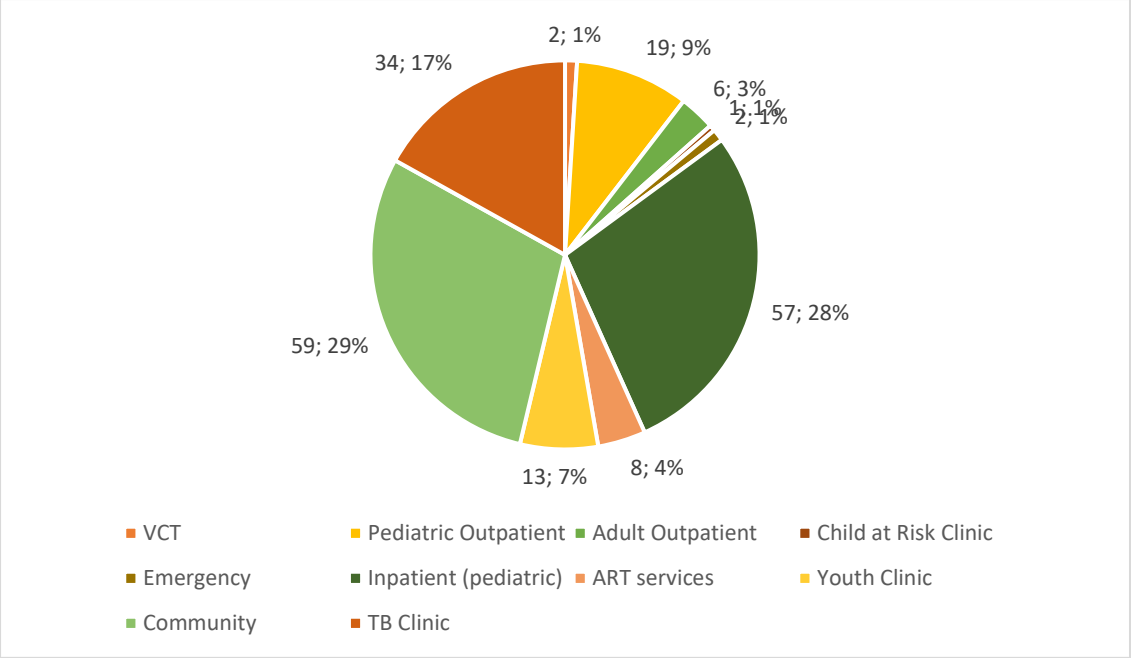

Figure 2. Sectors where pediatric presumptive TB cases were registered

As for the staff/cadre of health worker who identify patients with a presumptive diagnosis of tuberculosis, clinicians were the ones most frequently identifying patients with 398 (57%) and 96 (48%) adults and children respectively, followed by Cough Officers (160 (23%) and 19 (9%) for adults and children, respectively) and DOTS-volunteers (101 (14%) and 75 (37%) for adults and children, respectively) (**Figure 3**).

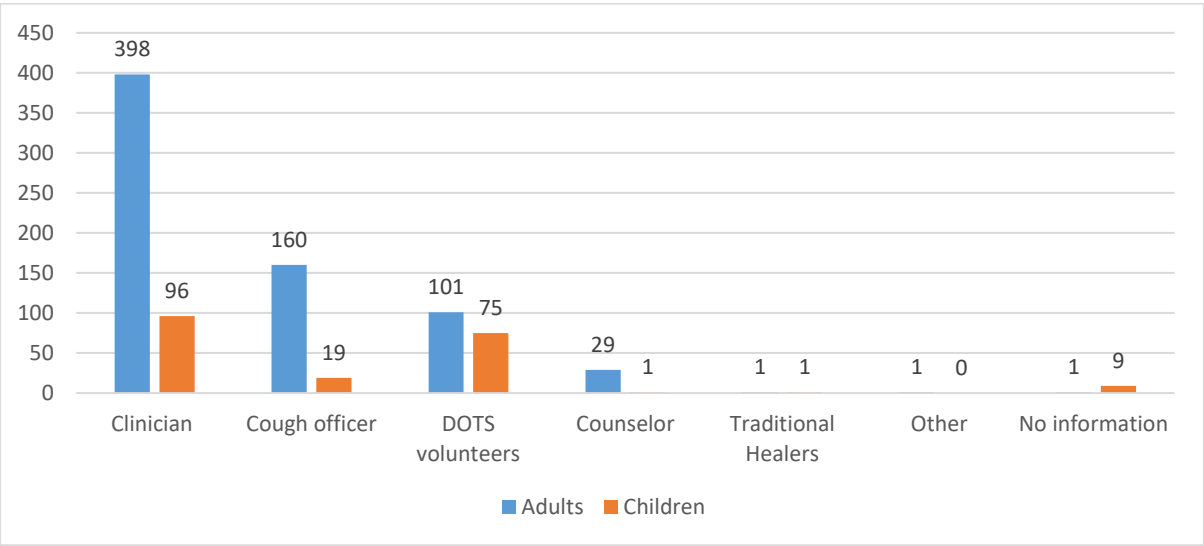

Figure 3. Number of identifications of TB suspect, by type of provider (adults and children).

3. TB testing in people with suspected TB

Of the 704 adults with suspected TB, samples were requested for 643 (91%) patients; samples were not requested for 55 (8%) patients, and no information on samples was obtained for only 6 (1%) of these adult patients. The majority (601, 93%) of samples were done using GeneXpert and 15 were sent for bacilloscopy (BK) (which is synonymous with AFB smear and the terminology is interchangeable). Of the total number of people with a requested sample, 39 (6%) had a positive laboratory diagnosis. A total of 73/698 (10%) had a positive final diagnosis of TB (laboratory and/or clinical diagnosis). **Figure 4** illustrates the flow of TB diagnosis, through laboratory or clinical confirmation.

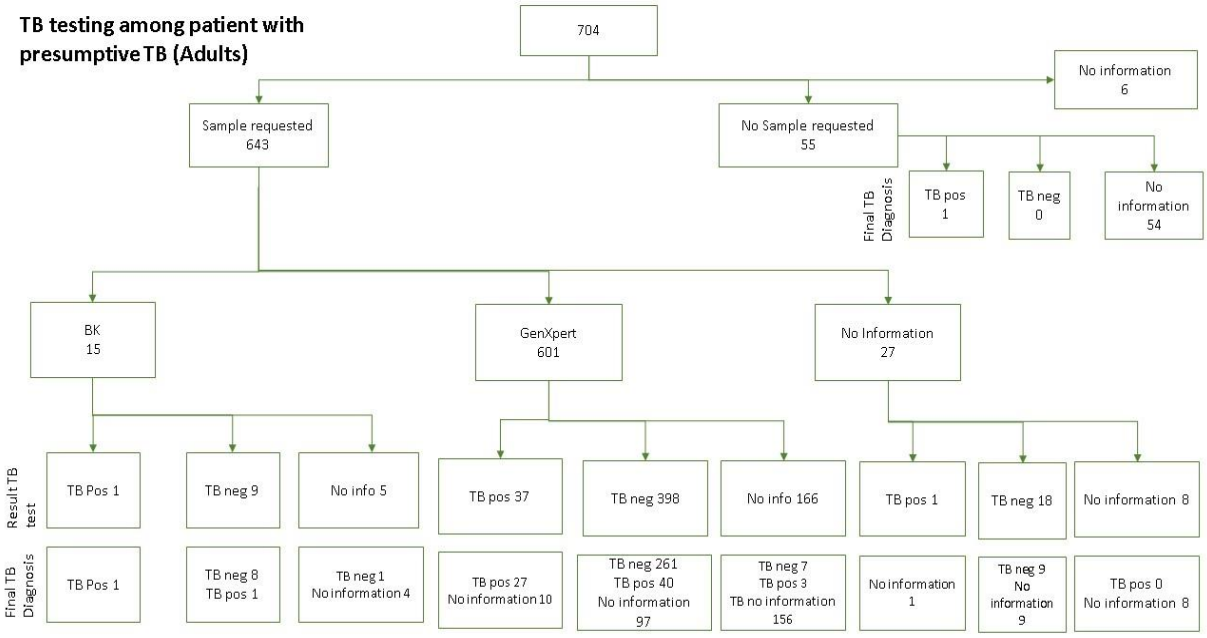

Figure 4. Flowchart for testing adult patients with suspected TB.

Of the 201 children with positive screening, 154 (77%) samples were requested, of which 122 (79%) for GeneXpert, only 1 (1%) for BK, and 31 (20%) were without information for which type of TB testing. Of the 154, 8 (5%) had a positive TB laboratory diagnosis and 19 (12%) had a positive final TB diagnosis (clinical and/or laboratory).

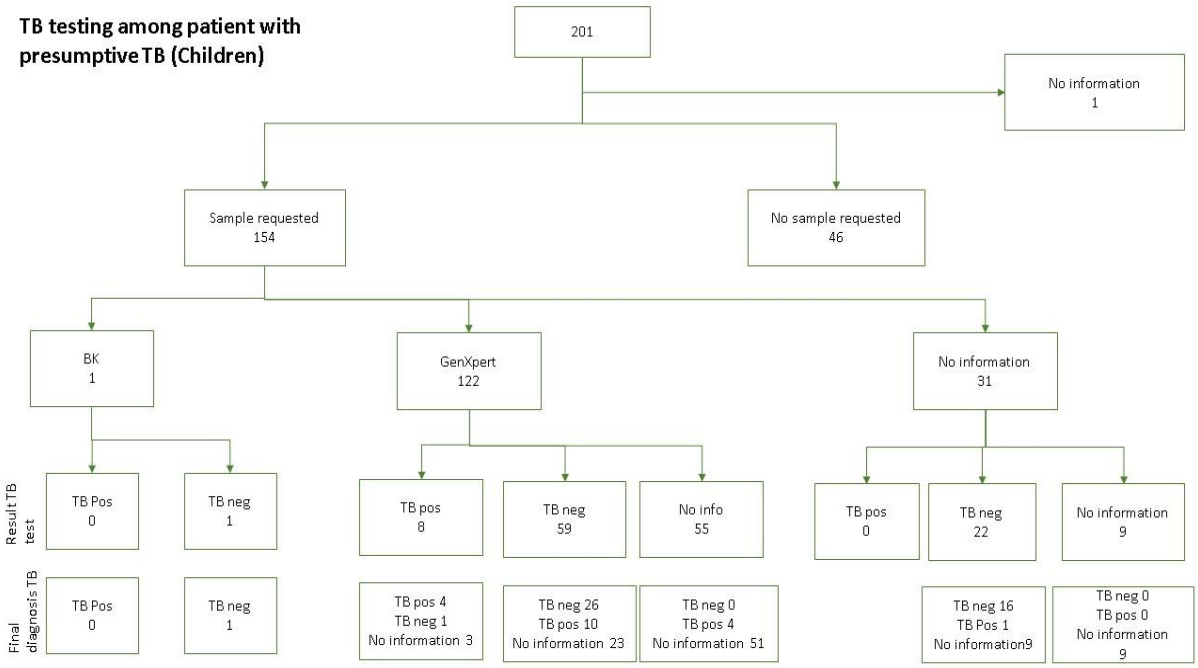

Figure 5. Flowchart for testing pediatric patients with suspected TB.

4. Linkage to HIV care for people with suspected TB

Of the 704 adults screened positive for TB, 133 (19%) had a previously known HIV-positive status, 321 had an unknown or HIV-negative serostatus registered in the tool, and for 250 (36%), no previous status was documented in the tool. Of the 571 patients with unknown, non-reported or HIV-negative status, 266 had a record of being HIV tested at the visit, and of these, 50 (12%) adults had an HIV-positive result. From the 133 previously known HIV-positive patients, 104 (78%) of 133 had their prior positive results registered at HIV services in the logbook, while for those persons newly diagnosed as being HIV-positive, 38 (76%) of 50 had their results registered at HIV services in the logbook.

Of the 201 children screened positive for TB, 16 (8%) were registered as having a known HIV-positive status, 12 (75%) of whom had a record for NID registration. Registration of unknown HIV status was found for 123 (61%) children, and no information on previous HIV status was found for 62 (31%) children. For the 185 children with unknown, non-reported or HIV-negative status, 144 (78%) HIV tests were done, of which four had positive test results (3%).

Among children, 12 (75%) of 16 previously known HIV-positive children had their registration in HIV services documented; 1 (25%) of 4 newly diagnosed children had their registration in HIV services documented as did 12 (9%) of 140 having HIV-negative or indeterminate results. Seven children were registered in HIV care services without having documentation of HIV testing.

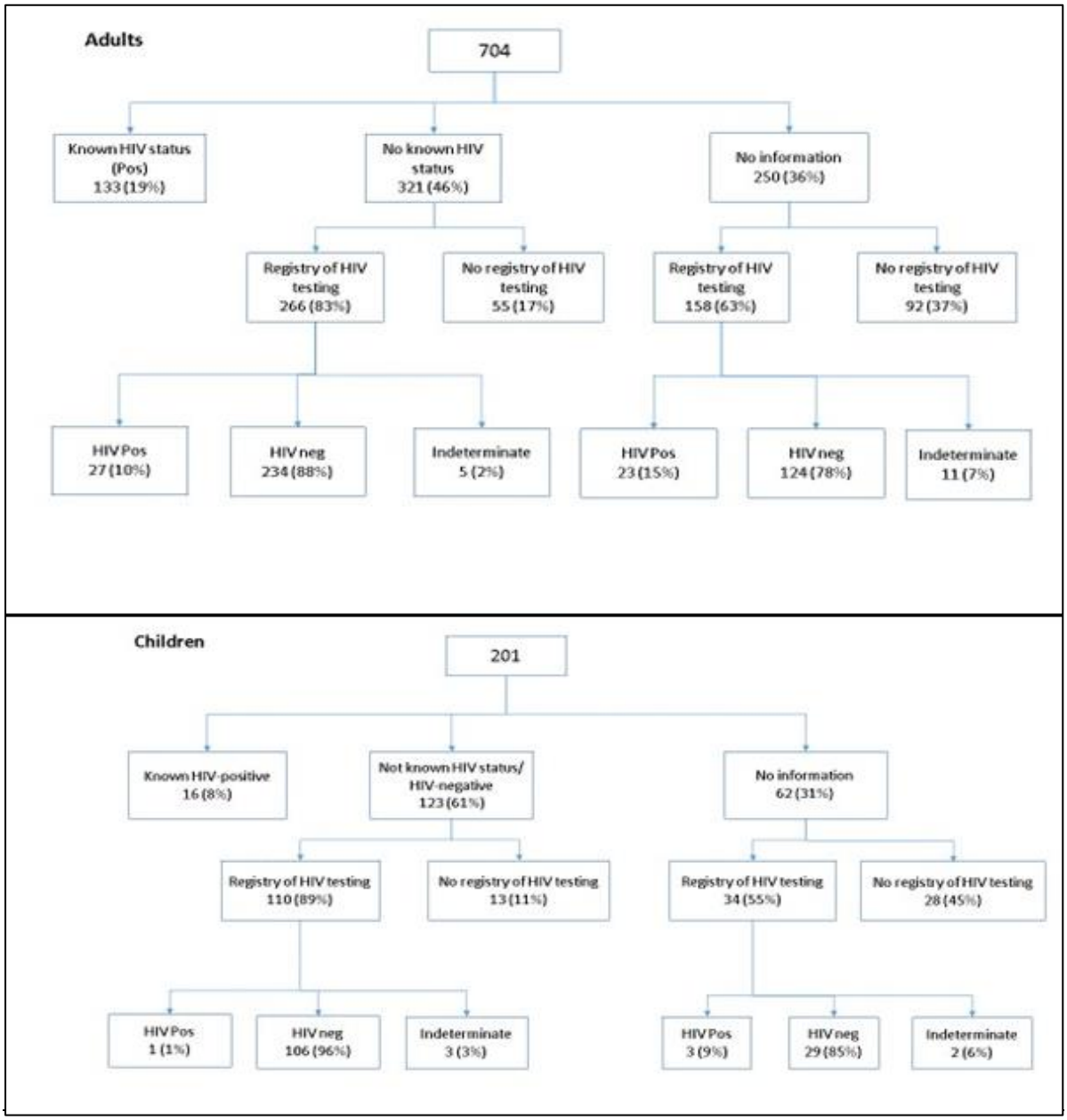

Figure 6. Linkage to HIV-care among adults and children with suspected TB

5. Linkage to TB care for patients, per HIV status

Of the total of 704 patients screened positive for TB (**Table 3**), 73 had a positive final diagnosis for TB and of these, 52 (71%) were registered in the National Programme of Tuberculosis Control ("*Programa Nacional de Controle de Tuberculosis, PNCT*"). Of the 183 HIV-positive patients, 16 (9%) had a positive final diagnosis for TB and of these 13 (81%) were registered in the TB clinic. Of the 358 HIV-negative patients, 42 (12%) had a positive final diagnosis for TB and of these 25 (60%) were registered in the PNCT

Table 3. Linkage to TB care in adults with suspected and confirmed TB diagnosis.

	N	TB diagnosis positive (Final Diagnosis)	Registry at TB services (Final diagnosis positive)	Registry at TB services (Final diagnosis not positive)
HIV positive	**183**	**16**	**13**	**3**
HIV negative	358	42	25	3
HIV indeterminate	16	1	1	0
No information	147	14	13	5
Total	**704**	**73**	**52**	**11**

Of the 201 children screened positive for TB (**Table 4**), 19 (9%) had a final positive TB diagnosis and of these 15 (79%) were registered in the PNCT Five children initiated TB treatment, but no documentation of final TB diagnosis (laboratory or clinical) was found. Of the 20 HIV-positive patients, 4 (20%) had a final diagnosis of positive TB and 3 (75%) were registered in the PNCT Of the 135 HIV-negative patients, 13 (10%) had a positive final diagnosis of TB and of those 10 (77%) were registered in the PNCT

Table 4. Linkage to TB care in children with confirmed TB diagnosis.

	N	TB diagnosis positive (Final Diagnosis)	Registry at TB services (Final diagnosis positive)	Registry at TB services (Final diagnosis not positive)
HIV positive	20	4	3	1
HIV negative	135	13	10	4
HIV indeterminate	5	1	1	0
No information	41	1	1	0
Total	**201**	**19**	**15**	**5**

Discussion and Conclusions

As part of a Quality Improvement project in Zambézia province, this evaluation was done to assess the feasibility of the use of the pilot instruments in documenting TB suspects along their cascade of HIV- and TB-diagnosis and linkage to care.

The pilot project was implemented between July 2018 and November 2019 in one health facility (Alto Molócuè Rural Hospital), and during this period, 905 health facility clients were registered with a presumptive diagnosis of TB in the logbook that was piloted, of whom 78% were adults and 22% were children.

A final diagnosis of tuberculosis was registered for a total of 93 (10%) persons, broken down as 73 adults and 20 children, showing the importance of active screening and individual follow-up at the different sectors of the HF.

Most cases with presumptive diagnosis of TB were found by clinicians (55% overall), Cough Officers (20% overall) and DOTS volunteers (19% overall).

Adults were mostly identified at the outpatient clinic, while most children were identified in the inpatient ward and in the community setting. We did not collect information on reasons for hospitalization so there may be a bias as respiratory infections are a common cause for hospitalization.

HIV testing among TB suspect patients was high among those with unknown serostatus (82% among adults and 89% among children). However, about a third of the patients did not have any registration of HIV testing (either previous or post-TB screening). Among all adult patients with suspected TB who were eligible for HIV testing (i.e., unknown, non-reported or HIV-negative status), our evaluation found HIV test results for only 47%. Though the HIV testing rate was moderately higher among all eligible pediatric patients with suspected TB (78%), this was still a much lower performance than the close to optimum (99%) HIV testing among pediatric TB patients found in a recent 2021 study assessing national pediatric HIV and TB program outcomes (Buck 2021). In the context of Zambézia province, our evaluation results underscore the remaining opportunity and need to strive toward optimal HIV testing performance among persons with suspected TB, especially considering that HIV positivity rate among those newly tested was found to be 12% among adults and 3% among children. Data on clinical diagnosis was not captured, which could explain why some children were registered at the HIV services without documentation of HIV test or with HIV-negative test result.

The results of this evaluation show that over a third of adult TB suspect cases were registered in outpatient clinics, nearly another third in TB clinics, and over a tenth from ART services. Nearly two-thirds of pediatric TB suspect cases were identified equally between community index case testing and inpatient pediatric services, with less than a tenth identified in pediatric outpatient services. Recently the MOH updated the pediatric outpatient logbook (*Livro da Triagem de Pediatria*, in Portuguese), which now includes the documentation of TB screening. This allows for assessment of the proportion of HIV positivity rate in children with a presumptive diagnosis of TB at the pediatric outpatient clinic. It also brings about the possibility of training and including health counselors as additional support for the implementation of this new logbook. However, this modification only happened in the pediatric logbook, whereas the logbook for adult outpatient clinic still does not include variables regarding the presumptive diagnosis of TB.

As the national TB program is currently conducting a revision of the all the TB tools, the results of this evaluation could provide additional insights to take into account when revising the national TB instruments. The HIV program included in the updated HIV clinical file (Master Card or "Ficha Mestre") the screening questions for TB in order to improve the quality of TB screening and thus improve TB diagnosis in ART-treated patients.

Apart from modifications to existing official instruments, the introduction of a separate logbook to register patients with presumptive diagnosis of TB could facilitate tracking of TB diagnostic testing, HIV testing, linkage to ART services as well as TB treatment initiation. However, the introduction of this tool can only catalyze improvements along the cascade of presumptive TB services, with strong commitment on the national level and strong leadership on the local level, with clear establishment of roles and responsibilities of the actors involved in each step of the cascade.

Orlando et al. report in their 2018 cost-effectiveness analysis of TB screening protocols that delays in TB diagnosis and TB treatment initiation contribute greatly to increases in newly transmitted TB infections in Mozambique (Orlando 2018). Offering high quality TB screening at every clinic entry point, using updated tools that allow for better tracking of patients in the cascade, and timely TB diagnostic and treatment services are critical for TB patients and for reducing incident TB infections.

Dissemination plan

In an effort to share best practices and lessons learned from this QI strategy, FGH collaborators have shared these results with employees and stakeholders from the Ministry of Health at the district and provincial (DPS-Z) levels.

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Appendices

Appendix 1: Supplemental Report Components

Approved protocol/ SOW

This secondary data analysis is covered under the protocol "*Quality Improvement for HIV Care and Treatment in Zambézia province of the Republic of Mozambique under the President´s Emergency Plan for AIDS Relief (PEPFAR)*", which has approvals from Mozambique ethics committee (CIBS-Z) and the VUMC Institutional Review Board (IRB). The approved concept note is submitted along with this final report for reference.

Informed consent

Informed consent was not required for use of data in this evaluation, as it was a secondary analysis of routinely collected, de-identified, programmatic data. A waiver of consent was approved, as the evaluation involved no more than minimal risk, would not have been possible without the waiver, and the waiver did not adversely affect the rights nor welfare of the patients whose data were included in the evaluation.

Bio-sketches

Not applicable.

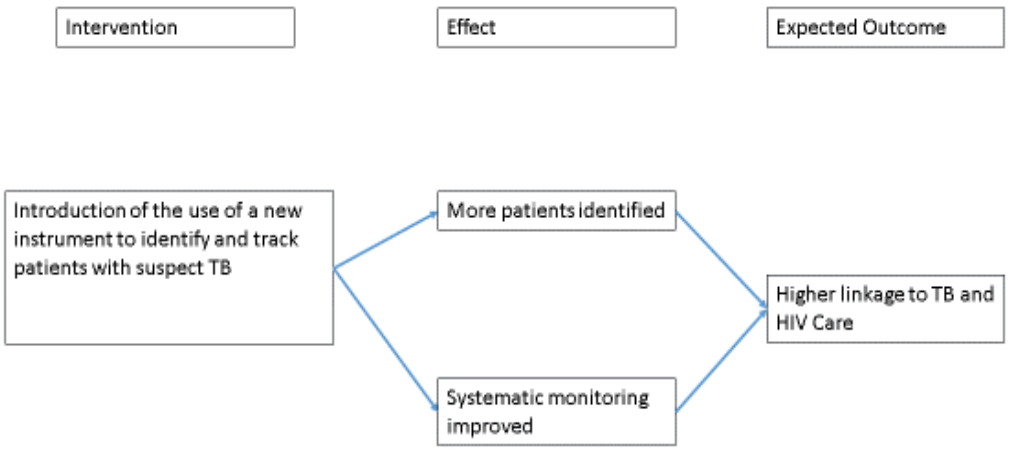
Conflict of interest statement

The collaborators in this evaluation have no conflicts of interest to declare.

Evaluation costs

Evaluation costs were limited to the personnel time required for extraction and analysis of routine secondary data, results review and discussion, and report preparation (anticipated expenditures equal to <1% of the total Avante Zambézia budget).

Logical Framework



Appendix 2: Pilot Presumptive TB tracking tool - Adults

Direção provincial de saúde da Zambézia - Ferramenta Piloto

FICHA DE REGISTO DE TUBERCULOSE PRESUNTIVA PARA ADULTOS

Distrito _____ Unidade sanitária _____ Sector de: _____

N de Ordem (1)	Data do rastreio positivo (2)	Nome do paciente (3)	Idade (4)	Sexo (5)		Com sinais e ou sintomas de TB(6)				Contacto de TB? (S/N) (7)	quem fez o rastreio? (1=oficial de tosse, 2=conselheiro, 3=clinico 4= voluntario DOTS-C, 5=PMT) (8)	conhecida com seroestado positivo? (S/N) (9)	Teste de HIV (10)			NID do paciente (11)	pedido de GeneXpert /BK? (12)		data de colheita (13)	Resultado (Pos/Neg/Invalido) (14)	Data de resultado (15)	Diagn. TB (16)	
				F	M	Tosse?	Febre > 2 semanas?	amagrecimento?	suores nocturnas?				Pos	Neg	Ind.		BK	Gene Xpert				S	N
1																							
2																							
3																							
4																							
5																							
6																							
7																							
8																							
9																							
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17																							
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19																							
20																							

INSTRUCOES DE PREENCHIMENTO

1= Número de ordem- é o número sequêncial de todos os adultos com rastreio de TB positivo
2 = Data de rastreio- escrever a data em que o paciente foi rastreiado para TB
3= Nome do paciente- escrever o nome completo do paciente
4 = Idade do paciente- escrever a idade do pecientes em anos
5 = Sexo do paciente- colocar um **X** no sexo do paciente (**M** se for masculino e um **F** se for feminino)
6 = Sinais e sintomas de TB- colocar um **X** se o paciente tiver um dos sintomas descritos na ficha (tosse, febre, emagrecimento, suores nocturnos)
7 = contacto de TB: coloca S se o paciente vive em casa com um paciente de TB e N se o paciente nao vive com alguem com TB em casa
8 = Quem fez o rastreio - escrever em numero quem foi que fez o rastreio (oficial de tosse **1**, conselheiro **2,** clinico **3,** DOTS-C **4,** PMT **5**). Os casos que chegaram no gabinete referido pelo PMT e na guia de transferencia foi riscado um ou mais destes motivos: tosse, febre e/ou emagrecimento, deve se escrever
9 = Seroestado HIV conhecido positivo: coloca S se o paciente ja foi testado positivo HIV antes do dia do rastreio TB e N se o paciente foi testada HIV negativo ou se nao foi testado
10 = Resultado do teste de HIV - Apenas escriver o resultado do teste de HIV para o paciente do seroestado desconhecido que foi feita neste dia do rastreio TB. Marcar com **X** o resultado do teste de HIV (**P** para positivos , **N** para Negativo)
11 = NID do paciente - caso o paciente HIV + tem/abriu processo clinico no dia de rastreio de TB, ha de colocar o NID atribuido ao paciente nesta coluna.
12 = Se foi pedido o GeneXpert - escrever um **X** no **SIM** se o paciente foi e no **NÃO** se não foi pedido um GeneXpert
13 = Data da colheita-escrever a data em que o paciente colheu a expectoração. Se não souber se colheu ou não, deve-se ir cruzar com o livro do laboratorio
14 = Resultado de BK ou de GeneXpert: escreve **Pos** se for positivo e **Neg** se for negativo e **inval** se for invalido.
15 = Data do resultado BK ou GeneXpert: Escreve **a data** que o resultado positivo ou negativo foi obtido
16 = diagnostico de TB - escrever **X** no **Sim** se o paciente foi diagnosticado TB e no Nao se **Não** foi diagnosticado TB. O diagnostico pode ser clinico, incluindo outros examens (RX, …) e/ou laboratorial (BK/GeneXpert/cultura)

Appendix 3: Pilot Presumptive TB tracking tool - Pediatrics

Direção provincial de saúde da Zambézia - Ferramenta Piloto

FICHA DE REGISTO DE DIAGNOSTICO PRESUNTIVO DE TUBERCULOSE PARA CRIANCAS

Distrito _____ Unidade sanitária _____ Sector de: _____

N de Ordem (1)	Data do rastreio positivo (2)	Nome do paciente (3)	Idade (4)	Sexo (5)		Com sinais e ou sintomas de TB (6)					Contacto de TB? (S/N) (7)	quem fez o rastreio? (1=oficial de tosse, 2=conselheiro, 3=clinico, 4 = voluntario DOTS-C, 5 = PMT) (8)	Crianca conhecida como infectada HIV? (S/N) (9)	Teste de HIV (10)			NID do paciente (11)	pedido de GeneXpert /BK? (12)		data de colheita (13)	Resultado (Pos/Neg/Invalido) (14)	Data de resultado (15)	Diagnosticado TB (16)	
				F	M	Tosse?	Febre > 2 semanas?	Perda de peso ou falencia crescimento?	Fadiga (crianca que nao brinca)	adenomegalia				Pos	Neg	Indet		Sim	Não				Sim	Não
1																								
2																								
3																								
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INSTRUCOES DE PREENCHIMENTO
1= Número de ordem- é o número sequêncial de todas as criancas com rastreio TB positivo
2 = Data de rastreio- escrever a data em que o paciente foi rastreiado para TB
3= Nome do paciente- escrever o nome completo do paciente
4 = Idade do paciente- escrever a idade do pecientes em anos
5 = Sexo do paciente- colocar um **X** no sexo do paciente (**M** se for masculino e um **F** se for feminino)
6 = Sinais e sintomas de TB- colocar um **X** se o paciente tiver um dos sintomas descreitos na ficha (tosse, febre, perda de peso ou falencia de crescimento, fadiga,
7 = contacto de TB: coloca S se a crianca vive em casa com um paciente de TB e N se a crianca nao vive com alguem com TB em casa
8 = Quem fez o rastreio - escrever em numero quem foi que fez o rastreio (oficial de tosse **1**, conselheiro **2** clinico **3** DOTS **4** PMT **5**). Sempre colocar o provedor ou voluntario que fez o primeiro rastreio. Os casos que chegaram no gabinete referido pelo PMT e na guia de transferencia foi riscado um ou mais destes motivos: tosse, febre
9 = conhecida como infectada HIV: Apenas aplicavel para criancas com seroestado já conhecido antes do dia do rastreio de TB: coloca S se a crianca ja tem diagnostico de infecao HIV e N se a crianca foi testada HIV negativa ou se nao foi testada
10 = Resultado do teste de HIV - Apenas preencher o resultado do novo teste HIV que foi feito, no dia de rastreio, para os casos com seroestado desconhecido. Não e obrigatorio de preencher o NID das criancas que ja vem em TARV. Marcar com **X** o resultado do teste de HIV (**P** para positivos , **N** para Negativo)
11 = NID do paciente - se o paciente HIV+ tem/abriu processo clinico, depois de ser testado, deve-se colocar o NID do paciente nesta coluna
12 = Se foi pedido o GeneXpert - escrever um **X** no **SIM** se o foi pedido pelo clinico e no **NÃO** se não foi pedido um GeneXpert
13 = Data da colheita-escrever a data em que o paciente colheu a expectoração. Trata-se da verdadeira colheita e não apenas do pedido feito
14 = Resultado de BK ou de GeneXpert: escreve **Pos** se for positivo e **Neg** se for negativo e inval. se for invalido)
15 = Data do resultado BK ou GeneXpert: Escreve **a data** que o resultado positivo ou negativo foi obtido
16 = diagnostico de TB - escrever **X** no **Sim** se o paciente foi diagnosticado TB e no Nao se **Não** foi diagnosticado TB. O diagnostico pode ser baseado no clinico e outros examens (Radiologia, …) tal como laboratorial (BK/GeneXpert/Cultura)