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An Evaluation of the Tuberculosis Prevention and Care Program in Gweru District, 2022: The Need to Increase Bacteriological Coverage

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ABSTRACT

Introduction: Tuberculosis remains a disease of public health concern. The national TB program has onsite laboratories (with Gene Xpert and CXR services) and is supported by a partner with mobile screening trucks that are equipped with the same equipment. Despite the availability of the xMTB-Rif, program data shows that the district has low bacteriological coverage (36.5%) in 2021-2022 instead of the expected 90%. Therefore, the study evaluated the TB control program in Gweru District to assess the inputs, processes, and outcomes of the program and determined the possible reasons for low bacteriological coverage.

Methods: A descriptive cross-sectional study design using the CDC logic model for program evaluation was conducted in Gweru district. A sample of 110 patient records was selected. Structured key informant interviews and checklists were used to collect data from the key informants and TB facility records. Data were analyzed using Epi Info 7.2.4 statistical package to generate, frequencies, means, and proportions. Health worker knowledge of the TB program was assessed and categorised as acceptable and poor using the modified Bloom cut-off point. A thematic analysis of qualitative data was performed.

Results: Patient-related reasons for low bacteriological coverage included failure to produce sputum and health system related included intermittent Xpert cartridge stockouts. Approximately fifteen (14.6) percent of presumptive TB patients missed the opportunity to submit sputa for bacteriological assessment and not all who submitted specimens received results. Bacteriological coverage was 68.1% which is below target. A high (10.0%) death rate was recorded, and 8/11 deaths were clinically diagnosed.

Conclusion: We concluded that low bacteriologic coverage poses multiple challenges including possible misdiagnosis which leads to unfavorable treatment outcomes and preventable costs to TB programs. Higher death rates were observed in clinically diagnosed compared to bacteriologically confirmed individuals. We recommended patient-level data analysis, ensuring that all presumed patients submit sputum, ensuring death audits are conducted.

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Introduction

Tuberculosis (TB) is a communicable disease and remains one of the major causes of death globally and the third leading cause of death in Zimbabwe by 2017 [1,2]. Zimbabwe remains one of the top eight countries in Africa on the world's top 30 list of countries heavily burdened by TB/HIV and multi-drug resistant (MDR-TB) and the economically productive males are the most affected group [2,3]. TB is common in mining communities and is even more prevalent (50%) in artisanal and small-scale mining environments [3].

The objective of tuberculosis control is to break the chain of transmission of infection. The use of sensitive diagnostic technology such as World Health Organization (WHO) recommended Xpert Mycobacterium TB-Rifampicin resistance assay (xMTB-Rif) has been adopted by the Ministry of Health and Child Care (MOHCC) to improve the yield of TB and enable the use of effective treatment regimens [4]. Strategies are in place to ensure timely and quality diagnosis and care within the National TB and Leprosy Control Program (NTP) which includes 230 TB diagnosing sites across its 10 administrative provinces. Some of the aims of the NTP through the 2021-2025

TB Strategic Plan Include:

- To increase the treatment coverage of drug sensitive TB from 83% in 2018 to 90% by 2025
- To increase the treatment success rate of patients with drug susceptible TB from 83% in 2017 to 90% by 2025
- To achieve universal HIV testing and ART coverage for TB cases by 2021 and sustain coverage through to 2025 [5].

Performance of the TB program is measured by the set indicators which are grouped into three main categories coverage, outcome, and impact indicators. These include:

Outcome

- Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and relapse cases.
- Treatment success rate of all forms of TB - bacteriologically confirmed plus clinically diagnosed, new and relapse cases (DS) (%)
- TB treatment coverage: Percentage of new and relapse cases that were notified and treated among the estimated number of incident TB cases in the same year (all form of TB - bacteriologically confirmed plus clinically diagnosed) (%)

Coverage

- Percentage of registered new and relapse TB patients with documented HIV status (%).
- Percentage of HIV-positive new and relapse TB patients on ART during TB treatment (%).
- Percentage of laboratories showing adequate performance in external quality assurance for smear microscopy among the total number of laboratories that undertake smear microscopy during the reporting period.
- Number of notified TB cases (all forms) contributed by non-national TB program providers – community referrals.
- Percentage of new and relapse TB patients tested using WHO recommended rapid tests at the time of diagnosis.

Impact

- TB incidence rate per 100,000 population
- TB mortality rate per 100,000 population [6]

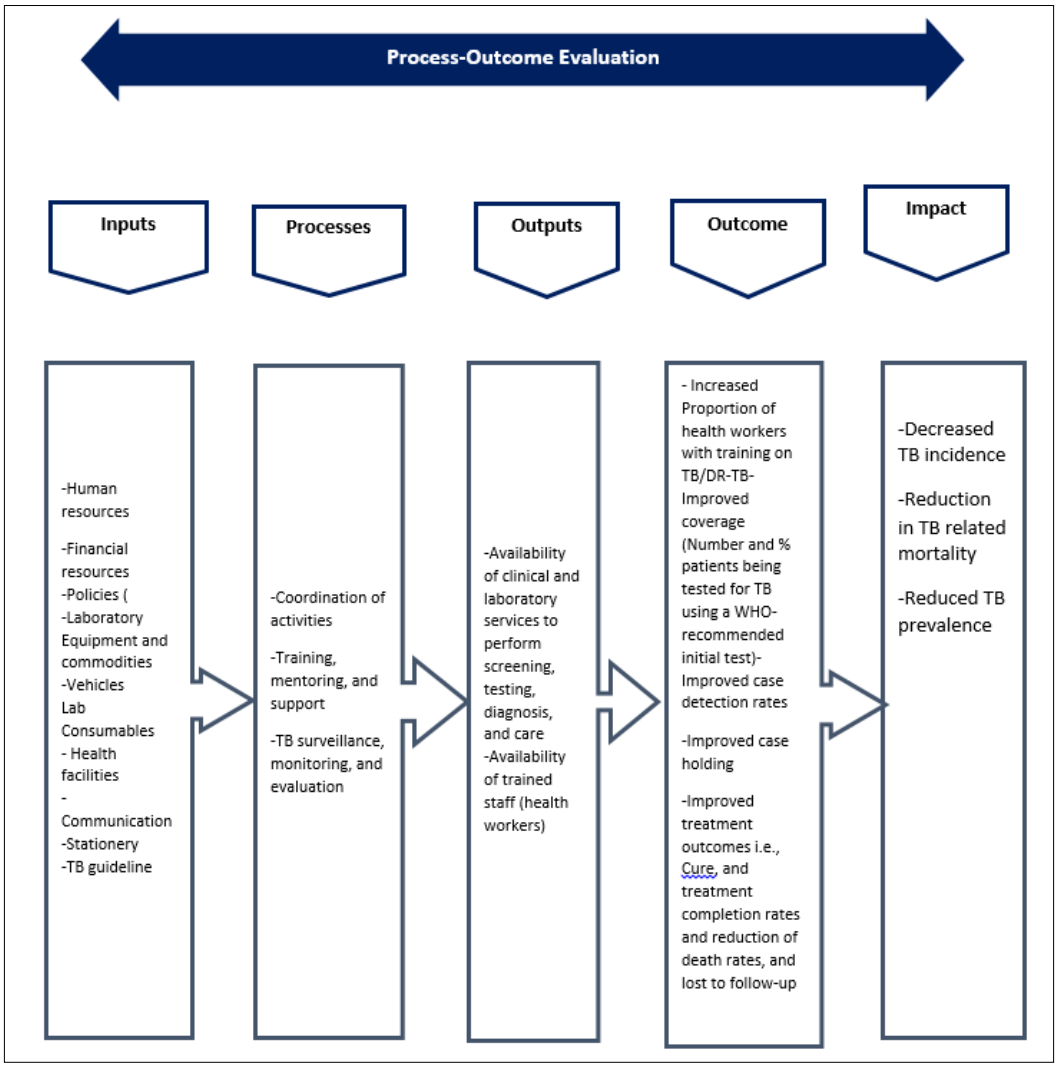

Figure 1: Logic Framework of the Evaluation of the TB Control Program (NTP) in Gweru District, 2021-2022

Source: National Strategic Plan, Monitoring and Evaluation Plan 2021-2015 [6]

Gweru is a mining district rich in artisanal and small-scale mining activities. A previous study in Gweru and Gwanda districts of Zimbabwe observed that at least a quarter of TB patients was potentially over-treated due to incorrect interpretation of chest x-rays [7]. The national TB program has onsite laboratories (with Gene Xpert and CXR services) and is supported by a partner with mobile screening trucks that are equipped with the same equipment. Despite the availability of the xMTB-Rif, program data shows that only 36.5% of the 364 ASMs diagnosed with TB were bacteriologically confirmed (2021-2022) instead of the expected 60-90%. A relatively new intervention (occupational health in artisanal and small-scale miners (ASMs)) is in place in this district. We evaluated the TB control program in Gweru District.

Research Question
Why are there fewer bacteriologically confirmed TB cases than expected in Gweru District, in 2022?

Broad objective
To evaluate the performance of the TB control program in Gweru District, 2022.

Specific objectives
1. To assess health worker knowledge of the TB control program in Gweru District, 2022
2. To determine the possible reasons for fewer bacteriologically confirmed TB cases than expected in Gweru District, 2022
3. To assess inputs of the TB control program in Gweru District, 2022
4. To assess the processes of the TB control program in Gweru District, 2022
5. To assess the outputs/outcomes of the TB control program in Gweru District, 2022

Materials and Methods

Study Type
A descriptive cross-sectional study design using the CDC logic model for program evaluation was conducted. The study was conducted to assess the inputs availed to the program, the processes carried out, the outputs realized and the outcomes. The logic model shows the links between inputs, process, outputs, and outcomes of a program.

Study Setting
The study was conducted in Gweru District the provincial capital of Midlands. Gweru is mainly a mining district with a population of 121 712. It is located 278km southwest of Harare the capital city.

Study Population
The study population were TB patient records, TB quarterly reports, TB presumptive registers, TB registers, charts, meeting minutes, and support and supervision exit meeting minutes. Key informants were nurses, primary care nurses, laboratory technicians, Environmental Health Officer (EHO), district TB coordinator (DTLC), provincial TB coordinator (PTLC) and artisanal and small-scale miner's representatives.

Study Unit
The study units were TB records, and any health worker (within the study population) who is involved in the TB control program in Gweru District within the selected health facilities.

Sample Size Calculation
The sample size was calculated using the Dobson formular from a study by Mngomezulu N. et al., 2015, where 93.6% of the records had smear results recorded [8].

Using the Dobson for calculation samples size for cross-sectional study

$n= (Z^2 (p (1- p)) \div d^2$

Where: Z=1.96 p=0.936 d=0.05 10%=nonresponse rate

$n= (1.96^2 x 0.936 x 0.064) \div (0.05)^2$

n=92 + (10%x92)

n=101 patient records

Sampling
Simple random sampling was used to select twelve (12) sites out of 35. All 25 key informants were purposively sampled based on participation in TB prevention, and case management and availability during the time of the study. Records (TB notification and quarterly reporting forms and registers) were purposively sampled from the randomly selected facilities. Patient records were selected using proportionate random sampling from the twelve sites.

Data Collection
Data from health workers (implementation key informants) was collected from face-to-face interviews using a key interview guide. Interviews were conducted to enquire reasons for fewer bacteriologically confirmed cases than expected and TB program inputs, processes and outputs and performance. The purpose of the of the key informant interviews was to get in-depth information about the TB control program as well as to validate (triangulate) data from the records. Tally Sheet 12 (T12), presumptive registers, Health facility TB quarterly reports, TB meeting minutes, TB support and supervision exit meeting minutes and TB registers were reviewed for information on the processes (screening, testing, results, etc.) and outputs/outcomes (treatment outcomes, coverage, case detection rates) of the program. The TB patient records were reviewed to assess investigations done and treatment outcomes. A checklist was used to assess inputs that were injected into the TB control program. Process observation was conducted for screening, testing and documentation activities.

Measurement of Variables
Inputs
Availability of TB policies and guidelines/SOPs/job aides was assessed through visualization of latest (2016) TB guidelines and all necessary addendums. A checklist was used to assess the availability of inputs required in the diagnosis of TB the inputs included presumptive TB registers, sputum pots, gloves, sputum request forms (Xpert), laboratory TB registers. X-ray facilities were inspected for service record and functionality. Health workers in post versus establishment were determined, as well as training needs documented. Availability of communication media and airtime balance of cell phones was determined to assess communication systems. Transport was assessed through availability and functionality of vehicles/motorbikes.

Outputs
Health worker trainings on TB/DR-TB was obtained by asking key informants during interviews where facility training coverage and training needs were determined.

Presumptive TB registers and quarterly reporting forms were used to determine the number of sputum specimens collected from various entry points. The lab registers and Xpert machine

registers were inspected to determine the number of specimens processed, and whether there were any specimen rejections and reasons why. Additionally, we inspected registers to determine whether there were any samples transported to other facilities for testing. The number of TB cases identified, number of contacts identified and number of contacts screened for TB were noted from the respective registers.

Outcome

The number of health worker trainings on TB/DR-TB was determined through interviews. Additionally, the training needs were determined through key informant recommendations. The number of patients being tested for TB using Gene Xpert MTB/Rif assay as the initial WHO recommended test and receiving results were determined by records inspection. The proportion was calculated by multiplying the fraction by 100. Treatment outcomes were assessed and presented as treatment success (cured and completed treatment), died, failure, and lost to follow up plus not evaluated

Data Analysis

Data was captured using Epi Info 7.2.4 statistical package. The same package was used to generate, frequencies, means and proportions. Health worker knowledge on the TB program was assessed. The modified Blooms cut off point was used to categorise knowledge into good/acceptable and poor, where an overall score of 60%+ signifies acceptable / good knowledge. An overall score <60% was regarded as poor knowledge. A thematic analysis of qualitative data was performed.

Ethical Considerations

The Midlands Provincial Ethics Committee reviewed and approved the study. The permission to carry out the study was obtained from the Provincial Medical Directorate's (PMD) office of Midlands Province and the Health Studies Office (HSO) within the Ministry of Health and Child Care. Every participant signed written informed consent form prior to participation in the study. No names were captured on the data collection tools. Confidentiality was assured and maintained.

Results

All 19-health facility-based health workers overall had good knowledge (got a score of >60% level modified Bloom's cut-off point) of the TB program. The health workers knew TB risk groups, signs and symptoms, diagnosis, and prevention. Health workers based at health facilities however did not know indicators tracked for TB diagnosis, but managers knew them (Figure 1.).

Health Worker Knowledge on TB Program in Gweru District

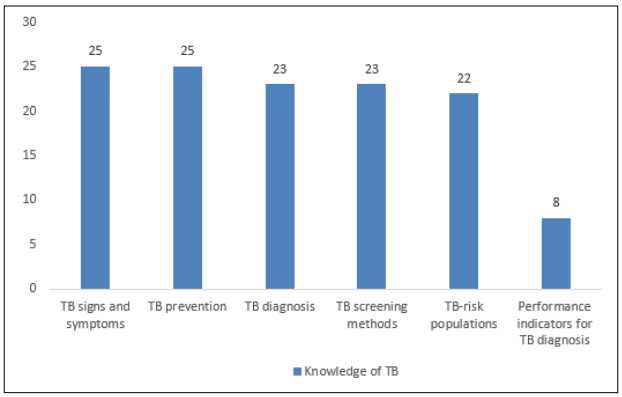

Figure 2: Health Worker Knowledge on the TB Program in Gweru district, 2022

Table 1: Reasons for Low Bacteriologically Confirmed TB Cases than Expected in Gweru District, 2022

Reason	Frequency n=25	Comments
Xpert cartridges out of stock	9	Intermittent stockouts for Xpert cartridges
Individuals fail to produce sputum.	14	Clients can be miners who are diagnosed during routine screening.
Sputum rejection at the laboratory (due to poor quality mainly saliva)	10	Rely on spot sputum specimen and difficult to get early morning sputum from miners.
Possibly TB-silicosis comorbidity	5	TB detection can be difficult in the presence of silica dust

Reasons given by key informants for fewer bacteriologically confirmed patients with TB than expected were intermittent stockouts for TB Xpert cartridges, individuals failed to produce sputum for investigation, sputum rejection at the laboratory (due to poor quality mainly saliva), and some patients will test negative due to possibility of TB-silicosis disease (Table 1.). The reasons why there is low bacteriologic coverage were grouped into two main themes which were patient related and health system related. Patient related reasons include that miners fail to produce sputum, produce poor specimen quality as they will be rushing to work, and they do not bring early morning sputum as highlighted in the key informant interviews:

Patient Related Reasons

One key informant reported that miners were usually in a rush and do not bring sputum as requested.

"TB in miners is usually diagnosed through X-rays because they fail to produce sputum. Miners will be rushing to go back to work so at times they do not bring the early morning sputum as instructed by the health workers". (Key informant 1)

Another key informant stated that there was a possibility of silicosis which has similar clinical presentation with TB.

"*Some clients test negative on the x-pert test yet their clinical presentation is suggestive of TB and I suspect that there is a possibility of silicosis coinfection yet they can be diagnosed as just TB because diagnosis can be tricky since both TB and silicosis clients usually have similar clinical presentations. It really requires a clinician who is diligent in their assessment and experienced too." (Key informant 3).*

Health System Related Reasons

At times the health system is not adequately prepared to provide the services.

"*We face challenges with x-pert cartridges stockouts especially last year there was a global crisis and sometime in 2021 there were rumors of a global crisis" (key informant 4).* "

The health system related reasons for low bacteriologic coverage include intermittent x-pert cartridge stockouts" (Key informant 2).

Inputs for TB Control Program

Only eight out of twelve health facilities had the latest TB guidelines (2016 version) available for use by health workers. Sputum mugs, gloves and registers were readily available at all

health facilities. All 12 facilities had at least two health workers with either formal or in-service training in TB control. Two facilities had unstable communication system where they were relying on personal mobile phones for communication. All facilities had access to sample transport through integrated sample transportation (IST). Majority (83.3%) of facilities did not have sample tracking forms and no other specimen tracking system was in use. If need arises, they make follow-up phone calls.

Processes in TB Control Program

Screening for symptoms was administered to all age groups, and children under 5 were screened through nutritional assessment. Patients with signs and symptoms suggestive of TB were identified following the screening. Approximately fifteen (14.6) percent of presumptive TB patients missed the opportunity to submit sputa for bacteriological assessment. Of the patients who submitted sputum specimens, not all received results. Both semesters performed below the expected positivity rate (possible over presuming). All assessed facilities submitted expected reports in DHIS2. The district conducted supportive supervision visits through multiple programs e.g., integrated support, integrated TB/HIV care (ITHC) site visits (Table 2).

Table 2: Processes Involved in TB Control Program, Gweru District, 2021-2022

Variable	Achieved 2021	Achieved 2022	Target	Comment
Persons screened for TB (all age groups	115794	103210		All age groups screened
Presumptive TB patients identified (All age groups)	2062	1964		Patients with signs and symptoms suggestive of TB were identified following the screening
Sputum specimens collected and sent for Xpert	1740 (84.4)	1681 (86.4)	100%	(14.6) percent of presumptive TB patients did not submit sputa for bacteriological assessment
Patients with Xpert results	1627 (93.5)	1456 (89.8)	100%	Not all results were received
Patients testing positive	120 (7.4)	130 (8.9)	10-15%	Low positivity rate (possibly over-presuming)
Support and supervision visits	4		4	Supportive supervision visits conducted through multiple programs e.g., integrated support, ITHC site visits

Outputs/Outcomes for TB Case Detection

Only one training was conducted for the district although each of the 12 assessed facilities had at least two (2) HWs trained (on job or formal). Cases bacteriologically confirmed were below the expected. One hundred and ten (110) cases records were reviewed for treatment outcomes. Of the reviewed records, no cases had treatment failure. Performance below target 2022 performance was lower than 2021 52.6% and 83.6% respectively. High (5.5% in 2021 and 14.5% in 2022) death rates were recorded. Of the eight deaths in 2022, six were clinically diagnosed while two were bacteriologically confirmed. Of the three deaths in 2021 two were clinically diagnosed while one was bacteriologically confirmed. Majority (36.1%) of treatment outcomes were not yet evaluated since patients were still on treatment on the time of evaluation. (Table 3).

Table 3: Outputs/Outcomes for TB Case Detection, Gweru District, 2021-2022

Output/outcome	Achieved 2021	Achieved 2022	Target	Comment
Total TB cases notified	267	305		
TB cases bacteriologically confirmed	148 (55%)	171 (56%)		Low coverage
TB cases reviewed	55	55		110 cases records were reviewed for treatment outcomes
Index cases with contacts investigated	29	43	55	
Number of contacts identified	87	172		
Number of contacts screened for TB	72	121	All identified	Suboptimal performance
TB treatment success	46 (84%)	29 (53%)	90%	Below Target
Died	3	8	0%	High death rates were recorded. Eight out of 11 deaths were clinically diagnosed
Lost to follow-up and not evaluated	5	20 (36%)	0%	Majority of outcomes were not yet evaluated for the 2022 semester since they were still on treatment

Discussion

The study's key findings were low bacteriological coverage, suboptimal contact investigation, the program generally had enough consumables though intermittent shortages were experienced. Other key findings were high unfavorable treatment outcomes such as death, and loss to follow up.

Low Bacteriological Coverage

The TB program has invested in World Health Organization recommended diagnostic tests like gene Xpert and Truenat. Integrating Xpert MTB/Rif with other molecular diagnostic tests increases bacteriological confirmation according to which is inconsistent with our study findings which indicate that despite availability of these tests, Gweru District still has low coverage (55%) of bacteriologically confirmed TB cases between July 2021-June 2022 [9]. The bacteriological coverage is low compared to the national performance of 92% within the same period. The low performance is despite support from a consortium of major partners in TB program within the district. Reasons given for low bacteriological coverage included that patients would test negative for mycobacterium tuberculosis yet they had symptoms suggestive of TB so they ended up being clinically diagnosed. Similar findings were observed by Abdullahi et.al., 2021 where 70% of clinically diagnosed patients had a negative sputum result [10]. The negative sputum result could be attributed to the paucibacillary nature of sputum for people living with HIV (PLHIV). Other reasons for low bacteriologic coverage were that "TB in miners is usually diagnosed through X-rays because they fail to produce sputum. Miners do not bring the early morning sputum as instructed by the health workers because they will be "busy" working and generally have poor health-seeking behavior so multiple hospital visits become a challenge". Low bacteriologic coverage was also attributable intermittent stockouts of Xpert cartridges. Desta et.al., also noted that intermittent supplies of laboratory consumables affected performance of the TB program. Another study conducted in Uganda highlighted stockouts of reagents, and lack of training on TB diagnosis as major barriers to uptake of diagnostic evaluation. Other reasons raised included cost of test, transport and time required until whole diagnostic process is completed [11].

Clinical diagnosis presents several shortcomings. According to Timire et.al., 2019 at least a quarter of TB patients were potentially over-treated due to incorrect interpretation of chest x-rays. This has a bearing on treatment outcomes due to the incorrect diagnosis [7]. Gweru District is a mining district, and the population is exposed to silica dust. The diagnosis of TB in the presence of silicosis poses challenges. Firstly, differential diagnosis is difficult since symptoms such as cough, wheeze, and chest pains are common in both TB and silicosis. Secondly, the interpretation of chest x-ray (CXR) films is difficult owing to the superimposition of silicotic nodules and TB infiltrations. Silicotic fibrosis prevents the discharge of mycobacteria tuberculosis into sputum specimens [12]. This negatively impacts on yield of TB in these specimens. Another challenge with low bacteriologic coverage is that without confirmation it is impossible to detect drug resistance therefore patients with drug resistant TB will be managed on first line TB medicines which are ineffective. The ineffective treatment then results in unfavorable treatment outcomes. If DR-TB is not detected there will be ongoing community transmission and therefore high disease burden. Misdiagnosis poses other challenges such as delayed treatment for other conditions like lung cancer as highlighted in studies by Masamba et.al., 2016 and Hammen et.al., 2015 [13-14]. Over diagnosis of TB can also cause psychosocial problems among patients and families due to stigma and concern over risk of exposure [10]. There are financial implications to overdiagnosis of TB to both the patients and the TB program. TB program will experience costs in contact investigation, medications among other costs and patients will experience costs while receiving incorrect treatment [15].

Processes for TB Program

Non-adherence to TB guidelines was possible since facilities did not have current copies of the guidelines and were initiating patients on treatment without early morning sputum. In Ethiopia not adhering to TB guidelines was one of the challenges in TB control [16]. Suboptimal contact investigation could be attributed to staff shortages where health workers (EHPs) were covering large areas. Resources like transport were inadequate since the motorcycles are old, poorly serviced, and intermittent supply of fuel for contact investigation activities. Funding for TB activities is another key area for TB control processes. Various studies found that TB programs are generally under-funded or are not on the top of priority lists for health care funding [17-19]. The suboptimal performance results in missed opportunities for case finding and prevention of progression to active TB disease [20]. Documentation, monitoring and evaluation are part of TB control processes. Underreporting of TB cases was noted in Tehran because laboratories in the private sector did not have means of reporting to the NTP [21]. Having no public private partnership (PPP) in Liberia led to low case detection due to lack of coordination between public and private institutions [19]. However, this study did not include any private facilities so PPP could not be compared.

Outputs/Outcomes for TB program

The district recorded high unfavorable treatment outcomes i.e., high death rates and lost to follow up. Of note death rate was higher in clinically diagnosed patients compared to bacteriologically confirmed patients in both 2021 and 2022. Our findings were consistent with Abdullahi et.al., 2021 who also found a 9.9% death rate among clinically diagnosed patients compared to 4.5% in bacteriologically confirmed patients [10]. The high death rate could be attributed to the possibility of misdiagnosis (incorrect reading of x-rays) [7]. Of those that died 7 (63.6%) were coinfected with HIV therefore the high death rate could be attributed to the TB/HIV and possibly silicosis. The patients are possibly artisanal and small-scale miners who are generally triple burdened by TB/HIV/Silicosis [22]. In Brazil high incidence and mortality were recorded and poor knowledge in TB was found in health workers in facilities covering small populations [23].

Limitations

This study had limitations. Perceptions of the actual beneficiaries of the program (patients, and ASMs) were not explored since mainly health workers and a few ASMs representatives were included in the study. Another limitation was the use of smaller sampler (12 health facilities) sample size than the calculated 23, however, the effect is minimized by the descriptive design.

Conclusion

We concluded that low bacteriologic coverage poses multiple challenges which include misdiagnosis which leads to unfavorable treatment outcomes, psychosocial and financial challenges to both patients and TB programs. Suboptimal contact investigation was due to inadequate resources (human and transport). Higher death rates were observed in the clinically diagnosed individuals compared to bacteriologically confirmed individuals. We recommended case based or patient level data analysis to

determine possible contributing factors to poor outcomes, an addendum to the TB screening algorithm in revised TB guidelines to involve community health workers in community-based sputum collection. Other recommendations were to conduct a further study to determine factors associated with higher death rates in clinically diagnosed compared to bacteriologically diagnosed TB patients, ensure that death audits are conducted within seven days of report of death, implement hybrid contact investigation and also emphasize investigation of non-household contacts. The NTP to scaleup electronic health record (EHR) to enable analysis of disaggregated data.

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Conflict of Interest
The authors declare no competing interests.

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