Title: A comparison of the yield and relative cost for Zimbabwean and WHO-recommended active case finding algorithms

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ABSTRACT

Setting: 10 districts and 3 cities in Zimbabwe

Objective: To compare the yield and relative cost of identifying a case of tuberculosis (TB) if the National TB Programme (NTP) used one of three World Health Organisation (WHO)-recommended algorithms (2c,2d,3b) instead of Zimbabwe's active case finding (ACF) algorithm

Design: Cross-sectional study using data from the Zimbabwe ACF project.

Results: 38,574 people were screened from April-December 2017 and 488 (1.3%) were diagnosed with TB. WHO-2d had the least number of people needing a chest X-ray (CXR) at 13,710 (35.5%) and bacteriological confirmation at 2,595 (6.7%). If the NTP had used the WHO recommended algorithms, fewer TB cases would have been diagnosed - 18% (88 cases) with algorithm 2b, 25% (122 cases) algorithm 2d, and only 7% (34 cases) with algorithm 3b. The relative cost-per-case of TB diagnosed for the Zimbabwe algorithm at $565 was over three times that of WHO 3b algorithm ($180) which was the cheapest.

Conclusion: The Zimbabwe ACF algorithm had the highest yield but at considerable cost when compared to WHO algorithms. The trade-off between cost and yield needs to be reviewed by the NTP and changing to use algorithm 3d considered.

INTRODUCTION

Tuberculosis (TB) is the leading cause of deaths among infectious diseases globally. In 2017, nearly 1.2 million died and 10 million people were affected. [1, 2] Zimbabwe is among the 14 countries globally having a high-burden of TB.[3] Despite the declining TB case notifications in the country, one-third of people with active disease were estimated to remain undiagnosed in 2017. [1]

Active case finding (ACF) among high-risk groups (HRGs) is effective in identifying people with undiagnosed active TB.[4-6] This leads to earlier initiation of appropriate treatment, which reduces the duration of being infectious and community transmission. [7] In high-burden countries, implementing ACF over a 10 year period has been estimated to reduce TB incidence and mortality by 27% and 44% respectively. [8] ACF is essential if global targets of the "End TB" Strategy are to be met. [8, 9]

The Zimbabwean National TB Programme (NTP) has been implementing an ACF project since 2016. The focus is to identify people with undiagnosed TB cases in areas with estimated high proportions of high-risk groups (HRGs) (see box). In a resource limited country with high HIV and TB prevalence, there is no clarity from the World Health Organisation (WHO) on the most appropriate algorithm to use for community-based ACF. [10] Countries are encouraged to select an algorithm that meets their primary objective for conducting ACF. They should also consider the prevalence of TB in their setting, HRGs being targeted and the resources available when selecting the algorithm.[4, 11, 12]

The NTP in Zimbabwe desired an algorithm that would identify the majority of people with undiagnosed TB and improve treatment coverage. Prevalence surveys have demonstrated that around 10% of people diagnosed with active TB are asymptomatic.[13-15] In addition, the country has a high TB-HIV co-infection rate of 71%. [1] TB among people living with HIV (PLHIV) can be paucibacillary hence the need for clinical diagnosis.[16, 17] Therefore, the algorithm designed by the NTP [18] was appreciably different from those recommended by WHO [4], with the intention of addressing these concerns (see table 1).

There is paucity of literature comparing the yield and cost of WHO-recommended algorithms under programmatic conditions. We could only find one study from China that used

data from elderly people from a TB prevalence survey.[19] However, the burden of both TB and HIV in their study population was much lower than that in Zimbabwe.

The ACF project in Zimbabwe is costly and the recurrent funding required was a concern for the NTP. They requested a review of their screening algorithm to determine if a comparable number of people with TB could be identified but at a reduced cost. Hence, the purpose of our study was to analyse the characteristics of the population screened in Zimbabwe and use the data to compare the yield and relative cost of identifying a case of TB if NTP had used one of the three WHO recommended algorithms.

METHODS

Study design

An analytic cross-sectional study using data from an active case finding project.

Setting

General country profile

Zimbabwe is a Sub-Saharan African country with a population of 17 million people in 2017.[1] It is a developing country with 22.5% of the population living in extreme poverty, defined as able to? afford per capita consumption less than 2100 calories?.[20]

The public health system has four levels; central (tertiary), provincial, and district hospitals, and primary health centres. Prior to introduction of the ACF project, diagnosis of TB was mostly based on passive case finding (PCF) in public health facilities. TB treatment is provided free of charge in all public health facilities in Zimbabwe.

Study sites

The Zimbabwe ACF project was rolled out in March 2017 and implementation is still ongoing. Data from 10 districts (Beitbridge, Bubi, Chimanimani, Chiredzi, Masvingo, Matobo, Mutare, Nkayi, Sanyati, and Zvimba) and three city-areas (Harare, Chitungwiza and Kwekwe) where the screening was conducted in 2017, was used in this study.

The screening teams used local knowledge to identify places within the selected districts and cities that were most likely to have high numbers of undiagnosed TB cases. Priority was given to poor overcrowded communities; places near mines; popular business centres; and areas with limited access to health services. People living within such places were sensitised and mobilised to come for free TB screening.

Screening for important co-morbidities for TB, namely diabetes and HIV, were offered as part of the package. Those diagnosed were linked with their nearest health facility for appropriate treatment. Isoniazid preventive therapy (IPT) was not provided during implementation of ACF to eligible TB contacts or PLHIV.

Study population

People screened for TB in Zimbabwe ACF project between April and December 2017.

Data source and variables

Data from the Zimbabwe ACF project stored in the central server was used. During screening, all data were entered electronically on a tablet by health care workers (HCWs). Data on age, sex, TB symptoms, chest X-ray (CXR) findings, bacteriological confirmation, HIV status, HRG, and TB diagnosis from the people screened were extracted. We also collected information on the operational costs for staff and the laboratory for the project.

Analysis and statistics

The data analysis was performed using STATA version 13.0 *(StataCorp LP College Station, Texas, USA)*. A logic check was used to identify files with encoding errors and seven records were excluded. We calculated the number diagnosed with active TB and prevalence among those tested and 95% confidence intervals (CI), by different characteristics and HRGs.

The Zimbabwe ACF project data were used to determine for each of the three WHO algorithms, the number and percentage of people that would be screened for TB symptoms and undergo CXR (table 4). We also determined the number of presumptive TB cases that would have been identified after symptom screening alone, CXR alone or both sequentially for the algorithms (table 4). From these presumed cases, we then determined the number who had active TB diagnosed (table 5).

A McNemar's test was used to determine if the number of people diagnosed with TB by each of the three WHO algorithms was significantly different from the Zimbabwe algorithm at 5% significance level. The number needed to be screened (NNS) to diagnose one case of TB was also calculated for each algorithm.

We estimated the average cost per person of conducting symptom screening, having a CXR taken, and bacteriological confirmation (see table 2). Only staff costs and laboratory consumables used were included. Other costs related to procurement of capital equipment, depreciation, maintenance and insurance were assumed to remain constant for all the

algorithms and thus not included. Patient costs were not included since TB screening was provided for free.

The relative cost-per-case diagnosed was calculated by dividing the total cost of the screening by the number of people diagnosed with active TB for each of the algorithms. A sensitivity analysis was also done to determine if our conclusions on the relative cost-per-case for the different algorithms remained the same if we changed the cost assumptions.

Ethics

Ethical clearance was sought and granted prior to the study by the Medical Research Council of Zimbabwe (MRCZ/E/198) and The International Union against Tuberculosis and Lung Disease Ethics Advisory Group (02/18).

Patient names were not used in this study as only anonymised data was abstracted from the electronic files. The electronic database was kept on a password protected computer of the principal investigator.

RESULTS

A total of 38,574 people were screened for TB in Zimbabwe (Table 3). Over half (61.6%) of them were females. The mean age (standard deviation) of the population was 48 (21) years. Active TB was diagnosed in 488 (1.3%) persons, of whom 370 (75.8%) were clinically diagnosed and 118 (24.2%) were bacteriologically confirmed.

The HGRs were not mutually exclusive. Over half (54.9%) of the people screened belonged to more than one HRG while 41.0% of people screened did not belong to any of the targeted groups. The prevalence of TB among people who were in more than one HGR was 1,839/100,000. This was significantly higher *($p < 0.001$)* than that of people who did not belong to any HRG. .

The most common HRGs among the people screened were being a TB contact and being HIV positive. The highest prevalence for TB was among people previously treated for TB, those who were HIV positive, and miners.

In all the algorithms, symptom screening was the initial step for all people except for WHO 3b where the CXR was used first (see Table 4). WHO 2d algorithm at 13,710 (35.5%) would have had the lowest number of people needing to have a CXR done and interpreted by a medical doctor. With WHO 2b algorithm, no CXR would be done.

The Zimbabwe algorithm had the highest number of presumptive TB cases that needed bacteriological confirmation, 39.6% (table 4). All the three WHO algorithms would have fewer numbers of presumptive TB cases identified compared to the Zimbabwe algorithm with WHO 2d at 6.7% being the lowest.

Table 5 shows that, compared to the number of TB cases diagnosed by the Zimbabwean algorithm, all the three WHO-recommended screening algorithms would have had a statistically significant lower yield of TB cases identified *($p <0.001$)*. WHO 3b, WHO 2b and WHO 2d had 7.0%, 18% and 25% fewer cases, respectively.

The lowest relative cost-per-case was with WHO 3b algorithm ($180). It would have been over three times cheaper than the Zimbabwe algorithm ($565). Sensitivity analysis

showed that despite varying the unit costs used in our model, WHO 3b algorithm had a consistently lower cost-per-case of TB diagnosed compared to the Zimbabwe algorithm.

DISCUSSION

To the best of our knowledge, this is the first study to use data from a TB ACF program to compare the yield and relative cost of the WHO-recommended ACF screening algorithms in a high TB and HIV prevalence setting.

The main finding was that the current Zimbabwe ACF algorithm gave the highest yield of TB cases diagnosed but this was at over three times the cost per case of TB diagnosed by the WHO 3b algorithm. However, 7% cases of active TB would be missed by WHO 3b algorithm. It is probable that these cases will be diagnosed later by routine passive case finding (PCF) at public health facilities. A study from Russia found that PCF had a median delay from onset of symptoms to diagnosis of TB of 6.9 weeks compared to 1week with ACF, so the delay in any missed case may not be that long. ACF should not replace PCF in public health facilities but both approaches should complement each other in finding active TB cases.[5, 11, 12, 21]

Table4 shows the reasons for the considerable variation in costs with each algorithm. The number of people needing symptom screening, CXR and bacteriological confirmation was different for the algorithms and this impacts on the relative cost-per-case. If the NTP were to adopt the WHO 3b algorithm, significant savings on staff and laboratory costs could be made.

The relative cost-per-case of TB diagnosed in this study are markedly different from a study carried out in China.[19] Though they used a similar method, only data from elderly people who participated in a TB prevalence survey were analysed. They also reported that the WHO 3b algorithm had the best yield, however they calculated it to be the most expensive. This is because they used direct smear microscopy for bacteriological confirmation which was markedly cheaper (and less sensitive) than GeneXpert. [22] A market cost for CXR was used in their calculations and this makes it more expensive than in our study. In addition, the NNS in the China study was more than double that from our study population. This reflects a lower TB prevalence setting. Despite the expense, the Chinese study recommended the WHO 3b algorithm to be used.

The strengths of our study were that it used all the available data from 38,574 people screened in the Zimbabwean ACF project. Data were collected electronically in the field and so minimized transcription errors. Our study also adhered to the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[23]

Limitations of this study were that the costings model we used only generated indicative costs for the different algorithms. It did not include capital costs or depreciation. This means the costs cannot be used for international comparisons or designing a new program. Also, the results are from areas in Zimbabwe with the highest estimated prevalence of TB. Care therefore needs to be taken when generalising the results to areas with lower TB prevalence where implementing ACF in such settings may not be cost-effective.[24] Furthermore, the prevalence figures must not be used as population estimates. The study population was purposively sampled high-risk communities, and selection bias is also obvious in the male/female ratio.

A trade-off could be considered by the NTP when selecting the most appropriate ACF algorithm. Savings from the project could be used to support other components of the program, particularly IPT which is recommended to eligible PLHIV when active TB has been excluded.[18, 25] Unfortunately, this was not being done in the Zimbabwe ACF project. This is a missed opportunity since IPT among PLHIV has been shown to reduce the overall risk of developing TB by around 35%. [8, 26] By integrating IPT within the ACF program, Zimbabwe could get additional benefits of reducing TB incidence among PLHIV.

Conclusion

Our study has demonstrated that the Zimbabwe ACF algorithm provides the highest yield of TB cases diagnosed. The WHO 3b algorithm will miss 7% of TB cases but is three times cheaper. The NTP should thus consider compromising between cost and yield and adopt the WHO 3b algorithm.

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CONFLICT OF INTEREST

None declared.

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TABLES AND FIGURES

High-risk groups for TB in Zimbabwe:

- People living with HIV infection
- Contacts of TB patients
- Miners
- Healthcare workers (HCWs)
- People with diabetes mellitus
- Prisoners
- The elderly (≥65 years)

Box: High risk groups for TB in Zimbabwe

Table 1: Comparison of the screening algorithm used in Zimbabwe in 2017 for tuberculosis with three recommended by WHO,

Algorithm	Step 1	Step 2	Step 3	Step 4
Zimbabwe	[a] **Symptom enquiry** *If negative or positive, go to step 2*	**CXR** *If **either one of steps 1 or 2** are positive, go to step 3*	[b] **Bacteriological confirmation** If positive = TB diagnosed *If negative go to step 4*	**Clinical review** Medical doctor reviews patient and can make a clinical diagnosis of TB
WHO 2b	[a] **Symptom enquiry** *If positive, go to step 2*	[b] **Bacteriological confirmation** If positive = TB diagnosed *If negative go to step 3*	**Clinical review** Medical doctor reviews patient and can make a clinical diagnosis of TB	
WHO 2d	[a] **Symptom enquiry** *If positive, go to step 2*	**CXR** *If positive, go to step 3*	[b] **Bacteriological confirmation** If positive = TB diagnosed *If negative go to step 4*	**Clinical review** Medical doctor reviews patient and can make a clinical diagnosis of TB
WHO 3b	**CXR** *If positive, go to step 2*	[b] **Bacteriological confirmation** If positive = TB diagnosed *If negative go to step 3*	**Clinical review** Medical doctor reviews patient and can make a clinical diagnosis of TB	

[a] Symptom enquiry was for cough of any duration, weight loss, fever, night sweats. The symptom enquiry in Zimbabwe did not include haemoptysis as recommended by WHO
[b] The GeneXpert was used as the diagnostic test of choice for bacteriological confirmation.
CXR – chest X-ray; TB – Tuberculosis; WHO – World Health Organisation

Table 2: Indicative cost per patient screened in Zimbabwe, 2017

Description	Indicative cost per patient screened (USD)
Symptom screening	$1.85
Chest X-ray	$0.93
[a] Bacteriological confirmation	$11.05

[a] *GeneXpert was used for bacteriological confirmation*

Table 3: Characteristics of the population screened and cases diagnosed with active tuberculosis in Zimbabwe, 2017.

Variable	Number screened for TB N (%)[a]		Number diagnosed with TB N (%)[b]		TB Prevalence /100 000 population N (95% CI)	
All clients	**38,574**	**(100)**	**488**	**(1.3)**	**1,265**	**(1,156 – 1,382)**
Gender						
Female	23,761	(61.6)	202	(0.9)	850	(737 – 975)
Male	14,813	(38.4)	286	(2.0)	1,931	(1,715 – 2,165)
Age group						
0 – 4 years	271	(0.7)	2	(0.7)	738	(90 – 2,640)
5 – 14 years	1,471	(3.8)	12	(0.8)	816	(422 – 1,421)
15 – 24 years	2,755	(7.1)	18	(0.7)	653	(388 – 1,031)
25 – 34 years	6,109	(15.8)	50	(0.8)	818	(608 – 1,078)
35 – 44 years	7,735	(20.1)	103	(1.4)	1,332	(1,088 – 1,613)
45 – 54 years	6,510	(16.9)	99	(1.5)	1,521	(1,238 – 1,848)
55 – 64 years	5,120	(13.3)	78	(1.5)	1,523	(1,206 – 1,898)
≥ 65 years	8,603	(22.3)	126	(1.5)	1,465	(1,221 – 1,741)
Number of HRGs						
People with no HRG	15,819	(41.0)	92	(0.6)	582	(469 – 713)
People with only one HRG	1,597	(4.1)	7	(0.4)	438	(176 – 901)
People with > 1 HRG	21,158	(54.9)	389	(1.8)	1,839	(1,662 – 2,029)
Type of HRG						
Previously treated for TB	2,462	(6.4)	80	(3.3)	3,249	(2,585 – 4,028)
HIV Status						
Positive [c]	6,562	(17.0)	174	(2.7)	2,652	(2,276 – 3,070)
Negative	29,471	(76.4)	296	(1.0)	1,004	(894 – 1,125)
Unknown	2,541	(6.6)	18	(0.7)	708	(420 – 1,117)
Miner	3,439	(8.9)	69	(2.0)	2,006	(1,564 – 2,532)
Prisoner	2,076	(5.4)	37	(1.8)	1,782	(1,258 – 2,448)
TB contacts	7,250	(18.8)	129	(1.8)	1,779	(1,488 – 2,111)
Health care workers	1,652	(4.3)	11	(0.7)	666	(333 – 1,188)
Diabetic [d]	911	(2.4)	3	(0.3)	329	(68 – 959)

[a] *Numbers in the brackets are column percentages*

[b] *Numbers in the brackets are row percentages*

[c] *HIV positive status was based on self-reported HIV positive status or confirmed status after testing*

[d] *Diabetics status was self-reported or a tested random blood glucose of more than 11.1mmol/L*

TB - tuberculosis, HIV - human immunodeficiency virus, HRG – High risk group

Table 4: A comparison of the number of each test that would be required for the four screening algorithms based on data from Zimbabwe ACF project??, 2017.

Algorithm	Total number screened	Number who had symptom screening N (%)[a]	Number of chest X-rays N (%)[a]	Number of GeneXpert tests N (%)[a]
Zimbabwe	38,574	38,574 (100.0)	38,574 (100.0)	15,260 (39.6)
WHO 2b	38,574	38,574 (100.0)	0 (0.0)	13,710 (35.5)
WHO 2d	38,574	38,574 (100.0)	13,710 (35.5)	2,595 (6.7)
WHO 3b	38,574	0 (0.0)	38,574 (100.0)	4,145 (10.8)

[a] *Numbers in brackets represent row percentages*

Zimbabwean – Zimbabwean algorithm: everyone is screened using both symptoms and chest X-ray and if either are positive, they go for bacteriological confirmation

WHO 2b – WHO algorithm: people are initially screened using symptoms and if positive they go for bacteriological confirmation

WHO 2d – WHO algorithm: people are initially screened for symptoms and if positive they go for a chest X-ray and if positive for bacteriological confirmation

WHO 3b – WHO algorithm: people are initially screened by chest X-ray and if positive go for bacteriological confirmation

Table 5: A comparison of the number of TB cases diagnosed, number needed to screen, and relative cost per case diagnosed using four different screening algorithms based on data from Zimbabwe, 2017.

Algorithm	Number screened N	Number diagnosed with active TB						Number needed to screen N	Relative cost per case (USD)
		All cases N (%)		Clinically diagnosed N (%)		Bacteriologically confirmed N (%)			
Zimbabwe	38,547	488	(1.3)	370	(75.8)	118	(24.2)	79	$565
WHO 2b	38,547	400[a]	(1.0)	294	(73.5)	106	(26.5)	96	$557
WHO 2d	38,547	366[a]	(0.9)	282	(77.0)	84	(23.0)	105	$308
WHO 3b	38,547	454[a]	(1.2)	358	(78.9)	96	(21.1)	85	$180

[a] *McNemar's test showed the number of active TB cases diagnosed was significantly different (p-value <0.001) compared to the Zimbabwean algorithm*

*Zimbabwean – Zimbabwean algorithm: everyone is screened using both symptoms and chest X-ray and if **either** are positive, they go for bacteriological confirmation*

WHO 2b – WHO algorithm: people are initially screened using symptoms and if positive they go for bacteriological confirmation

WHO 2d – WHO algorithm: people are initially screened for symptoms and if positive they go for a chest X-ray and if positive for bacteriological confirmation

WHO 3b – WHO algorithm: people are initially screened by chest X-ray and if positive go for bacteriological confirmation

USD – United States dollars