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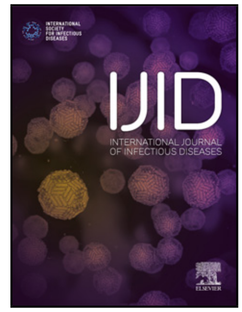

Population-based Screening for Pulmonary Tuberculosis utilizing Community Health Workers in Ethiopia

Yared Merid, Yimtubezinash Woldeamanuel Mulate, Mesay Hailu, Tsegaye Hailu, Getnet Habtamu, Markos Abebe, Daniel G. Datiko, Abraham Aseffa

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Title: Population-based Screening for Pulmonary Tuberculosis utilizing Community Health Workers in Ethiopia

Authors: **Yared Merid**[1,2,3], Yimtubezinash Woldeamanuel Mulate[2], Mesay Hailu[3], Tsegaye Hailu[1], Getnet Habtamu[1], Markos Abebe[1], Daniel G. Datiko[4,5], Abraham Aseffa[1].

Institutions: [1]Armauer Hansen Research Institute, [2]Addis Ababa University, [3]Hawassa University, [4]REACH Ethiopia, Hawassa, Ethiopia; [5]Liverpool School of Tropical Medicine, Liverpool, UK.

Corresponding Author:

Yared Merid (MSc., PhD candidate)

Hawassa, P.O. Box: 2154, Ethiopia

Phone number: +251 947 53 32 14

Email: meridyared@gmail.com

Presentations:

Part of this work was presented at the 12th TB Research Advisory Committee Conference that was held on March 23, 2017 at Addis Ababa, Ethiopia.

Highlights

- Household level symptom screening for active TB identified hidden burden rapidly
- Community health workers improved yield of active TB case finding in rural areas
- Health development army extensions enabled women better TB symptom screen access

- Community level TB symptom screen with Xpert diagnosis reaches underserved pockets

Abstract

Objective: To evaluate the utility of a volunteer health development army in conducting population screening for active TB in a rural community in Southern Ethiopia.

Methods: A population-based cross-sectional survey was conducted in six *Kebeles* (the lowest administrative units).Volunteer women community workers led a symptom screening program to identify adults ≥15 years with TB in the community. Individuals with cough ≥ 2 weeks had spot and morning sputum samples and were examined using AFB smear microscopy, culture and Xpert MTB/RIF.

Results: All 24,517 adults in the study area had a symptom screen performed; 544 (2.2%) had cough ≥ 2 weeks. Among a positive symptom screen, 13 (2.4%) had a positive sputum AFB smear microscopy, 13 (2.4%) a positive culture and 32 (5.8%) a positive Xpert MTB/RIF test. Overall, 34 TB cases (6%) were identified by culture and/or Xpert which corresponds to a prevalence of 139 per 100,000 persons.

Conclusion: We demonstrate the capability of community health workers (volunteer and paid) to rapidly conduct a large-scale population TB screening evaluation and highlight the high yield of such a program to detect previously undiagnosed cases when combined with Xpert MTB/RIF testing. This could be a model to implement in other similar settings.

Keywords: Community TB, Prevalence, Health development army, Ethiopia

Introduction

The fight against tuberculosis (TB) has been bolstered by the development of new molecular diagnostics, drugs, and a recent high-level United Nations meeting addressing the epidemic; however, many challenges to TB control remain. One of the most pressing challenges to eliminate TB is the high number of undetected cases. Only 6.4 of an estimated >10 million cases (64%) were officially notified in 2017, leaving a gap of > 3.5 million cases unreported and potentially undetected. Most of these missed cases occur in low-and-middle-income countries (LMICs) and among vulnerable populations (1). Rural settings are particularly challenging areas to detect and diagnose TB due to limited healthcare services, poor healthcare seeking behavior, and limited awareness and knowledge about TB (2, 3). Understanding the burden of TB in poor rural areas has large implications for TB control and is needed to design optimal case finding strategies (2, 3). Our study sought to evaluate the utility of a volunteer health development army (HDA) in conducting population screening for active TB in a rural state in Southern Ethiopia.

Active case-finding (ACF) for TB is influenced by individual (care-seeking behavior), social (access to health care), and biomedical (diagnostic capability) factors (4). In rural communities, ACF can help reach persons with no transport or limited mobility, scarce resources, and persons who rarely seek healthcare (5, 6). The Ethiopian national TB program (NTP) relies on passive case finding as most control programs NTPs globally; however, there is a recognized need to strengthen community screening given variations in disease epidemiology across diverse geographic and cultural settings (7).

Ethiopia is one of fourteen countries to be included on all three WHO high burden country lists for TB, TB/HIV and multi-drug resistant TB (MDR-TB). The TB incidence in Ethiopia in 2017 was estimated to be 164 per 100,000 population (1). The prevalence of smear positive PTB was 108 per 100,000 per population according to a national population-based TB survey which was conducted from October 2010 to June 2011, where the vast majority of those identified were newly diagnosed cases that had not been captured by the control program and most (55%) were among the younger age groups (15–34 years) (7). Additional studies across various rural settings in Ethiopia have found a range of smear positive PTB prevalence (from 30 to 174 per 100,000 population) suggesting disease epidemiology varies across different geographical locations of the country (8-13).

We evaluated the efficacy of a population screening program for active pulmonary TB using volunteer and paid community health workers in a rural area in Southern Ethiopia. As a brief background, Ethiopia launched a health extension program (HEP) in 2003 with the objective of increasing population access to basic health services including TB. The HEP consists of female health extension workers (HEWs) who receive one-year of training and then become salaried healthcare workers equipped to provide basic health services to the same community they were recruited from (5, 6, 14, 15). The HEWs are based at local health posts and provide health promotion to the community at a household level. In 2013, to further expand healthcare services and to ease the burden on HEWs, the Ethiopian government rolled out a program called the health development army (HDA) (16) which consists of female community-level volunteers who receive basic training on health by the HEWs. They are recruited based on their leadership qualities and their interest in being involved in the health of their community.They live within the communities and aid the HEWs at household level. They have regular meetings among themselves and with the HEWs to deal with health issues in the community. Our main goal was to assess the feasibility and utility of a population screening program for active TB led by HDAs.

Methods

Study setting/design

We performed a cross sectional study in the Hawassa Zuria woreda (a rural district), in the Sidama zone of Southern Ethiopia. Hawassa Zuria woreda has 23 *kebeles* (the lowest administrative units within Ethiopia each with an average population of approximately 5000 persons or 1000 households), and a total population of 153,190 persons, 79,858 of whom were ≥ 15 years (52%). The woreda has one hospital, four health centers, and twenty-three health posts serving the population. Each health center is associated with five satellite health posts and combined they form a primary health care unit (PHCU). The health service coverage of the woreda is 80% (accessible health service is defined as having a health facility within two hours walking distance). For our study, we selected three health centers in the district with functional PHUC. We randomly selected two *kebeles* from each of the three health centers, and thus our study area included six of the twenty-three *kebeles*. All households in the study *kebeles* were surveyed. Inclusion criteria were community members without known TB and had cough ≥2 weeks, ≥15 years of age and voluntary study participation with signed written consent. Exclusion criteria were patients currently on anti-TB treatment, those who were disabled or immobilized, patients with severe illness, unable to provide sputum sample, community members who were not available for screening at time of screening due to travel or hospitalization. The study was conducted from May 08, 2016 through June 09, 2016.

Data collection

Prior to the study, we convened meetings with *kebele* leaders, HEWs and members of the HDA to inform them of study objectives and procedures and to receive input and feedback. Subsequently, we conducted training with the field supervisors and HEWs at health posts.

Identification of presumptive TB cases (i.e., those with a positive cough screen) was carried out by members of the HDA. There were 30 to 58 HDAs in each *kebele* depending on population size and approximately 350 HDAs were involved in active TB case finding. Prior to the survey, community mobilization (creating awareness about the study) was done through religious institutions and schools in the community. Afterwards, the HDA conducted house-to-house visits to identify people who had cough of at least 2 weeks. Individuals with cough $\geq$2 weeks were considered a presumptive TB case and brought to the health post. At the health post, they were evaluated by field supervisors (health professionals who have experience in TB and community work) and HEWs. Those who met the eligibility criteria were interviewed and asked to submit two sputum samples (spot and morning). For all study participants, a pretested (validated) structured questionnaire was used to collect data on patient demographics, clinical presentation, and associated risk factors for the transmission of TB. Two field supervisors and the study principal investigator (YM) monitored the daily data collection process. The duration of patient screening and data collection was five days for each of the six *kebeles* between May 08, 2016 through June 09, 2016.

Laboratory

AFB smear preparation was carried out at the health posts by laboratory technicians assigned for the study. Slides were prepared on the same day of sputum collection and along with the remaining portion of the sputum samples were transported daily to a health center ~25 kilometers away. Here the slides were stained using Ziehl-Neelsen (ZN) hot staining technique and examined for acid-fast bacilli (AFB) using regular light microscopy (17). The remaining portion of the two sputum samples were pooled and stored at -20˚C until transported to Armauer Hansen Research Institute (AHRI) in Addis Ababa where culture was performed using Löwenstein-Jensen (LJ) media according to standard procedures (18).

HIV counseling and screening was offered to all participants diagnosed with TB and HIV serology was performed based on the national testing algorithm. Finger stick blood was tested for HIV (1/2) with the Antibody Colloidal Gold (KHB) test and positive results were confirmed with Stat-Pak while discordant results were resolved by HIV-1/2 Unigold Recombinant assay.

Definitions

A confirmed pulmonary TB case was defined as one in whom a sputum specimen was Xpert MTB/RIF test and/or culture positive. Clinical treatment outcomes were defined as per national guidelines (19).

Data management

All data were double entered into an online REDCap database (20) and analyzed using STATA software. Differences in categorical variables were tested using the Chi-square test and for continuous variables a two-sample t-test was used. A multivariable logistic regression model was used to evaluate the independent association of potential risk factors for TB. Model building and selection was based on the purposeful selection of covariates strategy as previously described, based on findings in univariate analysis and biological plausibility (21). A p-value of <0.05 was considered significant.

Ethical consideration

The study was approved by the Institutional Review Boards of Addis Ababa University and the Armauer Hansen Research Institute (AHRI) as well as the Ethiopian National Ethics Review committee. Study permission was also obtained from the Southern Regional Health Bureau, Zonal Health Department and the *woreda* health office. Patients diagnosed with active TB were referred to their catchment health center and hospital for treatment.

Results

All 24,517 adults in the six *kebeles* had a cough symptom screen for TB performed during the one-month study period and 544 (2.2%) were found to have cough of ≥2 weeks. All patients with prolonged cough submitted two sputum samples. Among the 544 adults with a positive cough screen, the median age was 36 years (interquartile range [IQR] 29-48) and the majority were female (n=354, 65%) (Table 1). There were 152 participants (28%) with a history of contact to a TB patient, 160 (29%) who reported previous anti-TB treatment and 12 (2%) with history of incarceration (Table 3). There were high rates of reported symptoms including fever (80%), night sweats (87%), weight loss (85%) and chest pain (81%).

Prevalence of pulmonary tuberculosis

A total of 34 (6%) persons with a positive cough screen were determined to have pulmonary TB (Table 2). All 34 cases were confirmed by Xpert MTB/RIF (n=32) and/or a positive culture result (n=12). Only 13 of the 34 cases (38%) had a positive AFB sputum smear microscopy result (Table 2). Two culture positive cases had a negative Xpert MTB/RIF test and negative sputum smear microscopy results. Two cases were rifampicin resistant by Xpert MTB/RIF testing with one of the cases having a prior history of anti-TB treatment. During the study period, only one case of a patient on anti-TB treatment was identified who was not included in our calculated TB prevalence. The overall point prevalence of confirmed pulmonary TB cases was 139 per 100,000 population (95% CI: 96 - 194) (Table 2).

Almost three fourths (25/34, 74%) of the confirmed TB cases were newly diagnosed while 9/34 were previously treated cases. There was similar distribution among females (53%) and males (47%) (Table 3). None of the 31 TB cases who had HIV testing performed had a positive result. A treatment outcome was available for 29 cases; 28 of whom were cured and one had completed treatment. Five persons with TB moved out of their *Kebeles* and outcomes were not available.

Risk factors for tuberculosis

In univariate analysis, longer duration of cough, older age and close contact to a known TB case was associated with an increased risk of having confirmed TB among persons with a positive cough screen (Table 3). In multivariate analysis, a cough of > 4 weeks (aOR = 4.23, 95% CI 1.94-9.23) was associated with risk of having bacteriologically confirmed TB while older age (aOR = 0.047, 95% CI 0.005-0.43) was associated with a reduced risk bacteriologically confirmed TB among those with a positive symptom screen (Table 4).

Discussion

Utilizing a large volunteer healthcare workforce in rural Southern Ethiopia, we were able to carry out a massive population-based screening program for active TB among > 24,000 adults in a short time period (~1 month) and were able to detect 34 previously undiagnosed active TB cases, primarily through the use of Xpert MTB/RIF. Our study demonstrates the feasibility of a large TB screening program using community health volunteers doing the initial symptom screen and referrals and paid community health workers for further testing and confirmation. The high prevalence of previously undiagnosed TB identified in the current study highlights the hidden burden of TB in rural settings and the need for additional active screening programs. In our setting, we show that an approach using community health workers can carry out an impressive large-scale screening program and this may be a useful approach to consider for other similar rural LMIC settings.

Innovative approaches using community health workers are growing in number aimed at increasing case detection rate (12) and in this regard practical changes were observed in the Southern Ethiopia by applying a community-based TB intervention. Community-based interventions at the village level using female community health workers (HEWs) made TB diagnostic and treatment services more accessible to the community and significantly improved

TB diagnosis and treatment in rural settings of Southern Ethiopia (5, 14, 15). In contrast to these existing studies in Ethiopia, and as part of the innovative approach our study used Health Development Armies (HDAs) in identifying symptomatic TB individuals in the community. Using HDAs, we identified a very high number of TB cases in a short period of time. Involving HDAs helped us reach the entire community and trace the symptomatic cases easily. HDAs live in the community and come across symptomatic neighbors in their daily routines. They also participate in community meetings and work closely with the HEWs on health-related issues. They are not paid but contribute voluntarily to improving the health of the community. A similar approach has been reported from among others in Uganda where voluntary Village Health Teams (VHT) are involved in improving and promoting health at the community level (22).

Improved screening is inadequate without appropriate diagnosis and treatment. Linking the HDAs with a rapid molecular diagnostic tool such as Xpert MTB/RIF has proved to be a successful approach in detecting presumptive TB cases early for rapid diagnosis and treatment, thus reducing the burden as well as the adverse social and economic consequences of TB. The HEP in Ethiopia employs salaried staff and has continued to be productive for over a decade and a half. The HDA extension is on the other hand relatively new and relies heavily on volunteer women raising issues of sustainability. The driving force for their active involvement needs to be investigated in terms of motivation. It was observed in Uganda for example that volunteer community health workers (CHWs) were actually participating with an expectation of future rewards (23). In contrast, a qualitative study from this region of Ethiopia suggested current dominance of intrinsic motivators (such as community recognition and appreciation) among the HEWs and their supporters (16).

We detected 544 individuals with a positive cough screen among >24,000 screened. The overall prevalence of laboratory-confirmed TB was 139 per 100,000 population, much lower than the national prevalence of 277 per 100 000 population (95%CI 208-347) (7). The prevalence of smear positive pulmonary TB was also lower than in several previous studies in Ethiopia including the national prevalence survey (7-10, 12, 13), but higher than a report from southwest Ethiopia (11). Direct comparison is difficult because of differences in study methodology, population and time. More than 50% of all confirmed TB cases in the national survey had no cough but were identified through chest X ray (CXR) screening (7), a method not included in this study; chest radiographs are not available at most health centers in Ethiopia and CXR is not routinely employed in the diagnosis of pulmonary TB. Ethiopia has overall shown a declining trend in tuberculosis in the last years (1).

We diagnosed 34 previously undetected cases of active PTB in just four weeks using a community-based ACF strategy. In contrast, only one PTB patient was identified by the routine passive case finding procedure in the same period in the study population. ACF has the added benefit of reaching those with limited access, the economically disadvantaged, elderly people and those with poor health seeking behavior (5, 6). The routine TB diagnostic method in the health facilities, including at our study site, is smear microscopy which is known for its poor sensitivity (24). Xpert MTB/RIF is being rolled out at many health centers in Ethiopia. We used a combination of smear microscopy, Xpert MTB/RIF and culture. Xpert MTB/RIF detected 94% of the TB cases whereas smear microscopy detected only 38%. In our study, culture yield was much lower than expected (38%). This may at least in part be due to loss of viability of *M.*

tuberculosis following repeated freeze and thaw of sputum samples following power failures in the field during specimen storage and transportation to AHRI for culture facility.

TB prevalence rates are higher in men than in women globally (25) and this is true for Ethiopia as well (1). However, unlike in health facility based passive case finding, the proportion of women with TB increased consistently when community-based screening was conducted in southern Ethiopia (5, 14, 15) due to probably improved access to women who would have otherwise remained undetected. In a case control study of communities where HEWs were employed in active case finding, the male: female ratio of TB cases changed from 1.3:1 to 1:1 following intervention (5, 14). The male to female ratio of 1:1.1 among newly diagnosed cases in our study seems to further confirm the value of community-based health intervention in accessing the hard to reach pockets among the rural population.

In multivariate analysis, cough of ≥4 weeks was an independent risk factor associated with a TB diagnosis among persons with a positive symptom screen while TB was less likely to occur among older persons (≥35 years of age) with a positive symptom screen. TB-HIV co-infection was not reported in our study and this could be related to the overall low prevalence of HIV infection in rural communities of Southern Ethiopia (26).

Low case detection rate remains a global challenge with 36% of prevalent cases missing (1). Community-based TB activities are increasingly reported from several high burden countries. Ethiopia is strengthening surveillance and improving the diagnostic capacity (27) of the TB control program with a rollout of Xpert MTB/RIF testing (19). In the experience reported here, the reach of the HEWs is extended deep into their communities through engagement of HDAs. Symptomatic screening at community level coupled with rapid diagnosis using Xpert MTB/RIF allows health system access to underserved rural community pockets more effectively. HEWs in Ethiopia are paid female professionals who bridge care and are extensively engaged in community service packages that link health with integrated development; satisfying three main principles recently proposed by Palazuelos et al as essential values for trust in the health system and a path to equitable outcomes of health coverage (28).

Conclusion

Our study identified a very high proportion of undiagnosed TB cases using volunteer women community workers in the rural community of Hawassa zuria wereda and allowed us to screen large communities (>24,000 persons) in a relatively short period of time with minimal costs. The use of volunteer community workers together with Xpert MTB/RIF has the potential of increasing TB case detection, reducing the pool of undetected cases and in curbing the transmission of TB in rural settings of Ethiopia. Implementation and scale up of this strategy could help LMICs increase case detection in rural settings.

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Conflicts of interest: none declared.

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Ethical Approval

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Authors' contributions

YM: contributed to the conception and design of the study, acquisition of data and interpretation, and drafting and writing of the manuscript; YW, MA, DD: contributed to the design of the study and supervision and revision of the manuscript; TH: contributed to data management and analysis; MH: contributed to data analysis and revision of the manuscript; GH: contributed to laboratory work; AA: contributed to the design of the study and supervision, interpretation of data and revising the manuscript. All authors approved the final version of the manuscript.

Data statement

I feel that the relevant data are included in the manuscript in addition to the questionnaire used in the study. In case, if other data are requested, it is ready to submit.

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Table 1. Distribution of population and confirmed tuberculosis cases by *Kebeles* of Hawassa Zuria Woreda, Ethiopia

Kebeles	No. of house holds	Total population			≥15 years			Positive Cough Screen			Confirmed TB		
		Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female
1	1,272	6,231	3103	3128	3,248	1,618	1,630	77	50	27	3	2	1
2	1,508	7,390	3680	3710	3,852	1,918	1,934	91	63	28	7	5	2
3	1,976	9,681	4821	4860	5,047	2,513	2,534	131	96	35	10	3	7
4	1,127	5,534	2756	2778	2,885	1,437	1,448	46	33	13	3	2	1
5	2,436	11,447	5701	5746	5,967	2,972	2,995	113	65	48	6	2	4
6	1,373	6,749	3361	3387	3,518	1,752	1,766	86	47	39	5	3	2
Total	**9,692**	**47,032**	**23422**	**23,609**	**24,517**	**12,210**	**12,307**	**544**	**190**	**354**	**34**	**16**	**18**

Table 2. Distribution of confirmed tuberculosis cases by *Kebeles*, Hawassa Zuria Woreda, Ethiopia

Kebeles	**≥15 years**	**AFB positive**	**Culture positive**	**Xpert positive**	**Confirmed TB**	**Rate**	**95% CI**
1	3,248	1	1	3	3	92	19.05-269.69
2	3,852	3	3	7	7	182	73.09-374.06
3	5,047	4	4	9	10	198	95.05-364.08
4	2,885	1	1	3	3	104	21.45-303.59
5	5,967	2	2	5	6	101	36.91-218.73
6	3,518	2	2	5	5	142	46.16-331.36
Total	**24,517**	**13**	**13**	**32**	**34**	**139**	**96.06-193.74**

AFB – Acid Fast Bacilli

TB – Tuberculosis

CI – Confidence interval

Table 3. Predictors of pulmonary TB among persons with a positive cough screen, Hawassa Zuria Woreda, Ethiopia

Characteristic	Total (n=544) n (%)	No TB (n=510) n (%)	TB (n=34) n (%)	Univariate analysis OR (95% CI)	*P*- Value
Female sex	354 (65)	336(66)	18 (53)	0.58(0.28-1.17)	0.12
Mean age (year)	38	38	31		
Age category in year					
15-24	68(12)	61(12)	7 (22)		
25-34	143(27)	132 (26)	11(34)	0.72 (0.26-1.94)	0.52
35-44	159 (29)	150 (29)	9 (28)	0.52 (0.18-1.46)	0.21
45-54	94 (17)	90 (18)	4 (13)	0.38 (0.10-1.38)	0.14
≥55	80 (15)	79 (15)	1(3)	0.11 (0.01-0.92)	0.04
Illiterate	401(74)	383(75)	18 (53)	0.37(0.18-0.75)	0.006
Unemployed	533 (98)	501(98)	32(94)	0.28(0.05-1.38)	0.12
Married	470 (86)	440 (94)	30 (88)	0.83(0.28-2.45)	0.74
Duration of cough in weeks					
2- 4	333(61)	321 (63)	12 (35)		
>4	211 (39)	189 (37)	22 (65)	3.11 (1.50-6.43)	0.002
Symptoms					
Fever	437 (80)	409 (80)	28 (82)	1.15 (0.46-2.85)	0.76
Night sweats	472 (87)	443(87)	29 (85)	0.87 (0.32-2.34)	0.79
Loss of appetite	288 (53)	268 (53)	20 (59)	1.28 (0.63-2.61)	0.47
Weight loss	464 (85)	433 (85)	31 (91)	1.83(0.54-6.15)	0.34
Chest pain	439 (81)	411 (81)	28 (82)	1.12 (0.45-2.78)	0.80
Shortness of breath	315 (56)	294 (58)	21 (62)	1.18 (0.58-2.42)	0.63
Previous anti-TB treatment	160 (29)	151 (30)	9 (26)	0.85 (0.39-1.87)	0.69
Contact with TB case	152 (28)	137 (28)	15 (44)	2.02 (1.00-4.10)	0.049
Presence of TB patient in the family	89(16)	80 (16)	9 (26)	1.99 (0.85-4.21)	0.11
Absence of window in the home	490 (90)	457 (90)	33 (97)	3.82(0.51-28.5)	0.19
Alcohol use	13 (2)	11 (2)	2(6)	2.83 (0.60-13.3)	0.18

TB - tuberculosis; OR- odds ratio; CI-confidence interval.

Table 4. Multivariate analysis of risk factors for pulmonary tuberculosis among persons with a positive cough screen, Hawassa Zuria Woreda, Ethiopia (n=544)

Characteristics	Multivariate analysis	
	aOR (95% CI)	*P* Value
Age category in year		
15-24	1.00	
25-34	0.70 (0.24-2.07)	0.528
35-44	0.29 (0.09-0.96)	0.043
45-44	0.22 (0.05-0.86)	0.031
≥55	0.047(0.005-0.43)	0.007
Duration of cough in weeks		
2-4	1.00	
≥4	4.23 (1.94-9.23)	<0.001
Close contact with known TB patient		
No	1.00	
Yes	1.99 (0.93-4.26)	0.073

aOR –Adjusted odd ratio