Accuracy of the chest x-ray in screening for tuberculosis in Uganda: A cross-sectional study.

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Research

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Abstract

ABSTRACT BACKGROUND: The WHO END TB strategy requires ≥90% case detection to combat tuberculosis (TB). Increased TB case detection requires a more sensitive and specific screening tool. Currently, the symptoms recommended for screening TB have been found to be sub-optimal. CXR as a screening tool for pulmonary TB was evaluated in this study, as well as factors related to its false positive results. METHODS: A cross sectional study of 4441 records of consented/assented participants ≥15 years. Participants with a cough ≥2 weeks and/or any abnormality in the lung on CXR were included in the study. Löwenstein-Jensen (LJ) culture was used as the gold standard. The CXR were categorised as Abnormal meaning presence of any CXR abnormality suggestive of active tuberculosis. Symptoms were categorised as abnormal meaning presence of any of cough ≥ 2 weeks, fever, weightloss or night sweats. RESULTS: The CXR had sensitivity 93%, specificity 65% compared to culture results while symptoms had sensitivity 76% and specificity 31%. The adjusted prevalence ratio (APR) of a false positive CXR result increased with age categories (years); 45 - 54, APR 1.18 (1.08, 1.29), 55 – 64 APR 1.18 (1.09, 1.29), 65+years APR 1.2 (1.10, 1.30).The APR was 0.93 (0.90, 0.96) among males and 0.86 (0.79, 0.93) among HIV positive individuals. CONCLUSIONS: The CXR is a fair tuberculosis screening tool and performed better than symptoms in Uganda.

Background

The WHO 2018 estimates show that Tuberculosis (TB) was responsible for 1.2 million deaths among HIV negative persons and 250,000 deaths among HIV positive persons.[1] Uganda has a high TB incidence of 201 per 100,000 population as well as high TB related mortality of 26 per 100,000 population. The TB case detection rate for Uganda is 72%.[2]

In order to combat tuberculosis, WHO has proposed three strategies ; intensified case finding (ICF), isoniazid preventive therapy (IPT) and infection control (IC).[3] The WHO END TB strategy indicates a need for ≥ 90% TB case detection among others to combat TB.[4]

The strategic plan for the Uganda national tuberculosis and leprosy programme (NTLP) seeks to achieve 85% case detection by 2019/2020. However, confirming TB is difficult. Currently TB culture is the gold standard but financial and logistic challenges make it difficult to scale up. There is need to explore more widely available, low cost screening and diagnostic tools and algorithms to aid TB diagnosis. The CXR is one such potential tool.

The currently employed symptoms screening tool for tuberculosis in Uganda has been observed to have sensitivity 40.7% and specificity of 81.3% according to a survey done in South Africa considering presence of any cough, fever, weightloss or Night sweats.[5] Systematic reviews done to assess the performance of the symptoms in high HIV prevalence regions have shown sensitivity 84% and specificity 74%.[6] The symptoms screening tool runs a risk of missing patients with tuberculosis as the patients do not seek care and do not have symptoms due to early TB disease.

The chest radiograph (CXR) was commonly used in mass screening campaigns in Europe and the US in the early TB chemotherapy era (1950s), but has not been widely used in screening TB in low-income countries because of high cost and lack of capacity.[7, 8] This CXR has been found to have sensitivity of 98% and specificity of 75% according to a systematic review. [6]

The recognition that bold new strategies are needed to control TB (END TB Strategy) has led to reconsideration of CXR as a potential tool, as innovative, lower costs strategies for performing CXR (digital radiography) and reading them (computer aided reading) have become available.[9, 10] The use of more sensitive tuberculosis screening tools increases the pool of presumptive TB cases hence increasing case detection as more individuals are exposed to the confirmatory test which ultimately leads to reduction in mortality and morbidity.[11]

The impact of false positive results in screening of tuberculosis.

The performance of screening tests is affected by the level of false negative and false positive results that are obtained as a result of using the test. The CXR and symptoms have been reported to have a very high number of false positive results hence challenges in their application as many individuals who would have been saved from a confirmatory test will still undergo the confirmatory test only to find them without the disease.[12, 13]

The identification of the factors responsible for false positive results is important as it guides the application of the test to individuals who are more likely to benefit from the test. A study done in Tennessee found a high rate of normal CXR among PLHIV with culture confirmed tuberculosis.[14] These factors if identified help guide the implementation of screening interventions in the various populations and countries.

Uganda carried out a national tuberculosis prevalence survey (UTPS) from 2014–2015 which screened for tuberculosis by collecting data on TB symptoms using questionnaires and performed CXR in all consenting participants.[15]

Therefore using the data from UTPS, we sought to evaluate the performance of the Chest radiograph in the screening of tuberculosis and factors associated with a false positive CXR.

Methods

Study design

We conducted a cross sectional study by secondary analysis of the data collected during the Uganda National Tuberculosis prevalence survey (UTPS).

Study design, setting and sampling method used in the UTPS

The Uganda National TB prevalence survey was conducted from October 2014 to July 2015 with the primary objective of determining the prevalence of Tuberculosis in Uganda. Villages (clusters) across the country were sampled using probability proportionate to size (PPS). The starting block was randomly selected by the village leader and then blocks were added in a clockwise manner around the original block until the required cluster size was achieved. Eligible respondents aged ≥ 15 years in selected blocks were invited to the survey[15].

Study procedures

Screening strategy

All eligible consenting/assenting individuals who were ≥ 15 years were screened for tuberculosis by research assistants in the community using a questionnaire which listed the symptoms and a CXR (Fig. 1). Parents/Guardians of individuals < 18 years also offered informed consent.

Participants with a cough ≥ 2 weeks and/or any abnormality in the lung on CXR were considered presumptive for TB and were requested to submit two sputum samples (a spot and an early morning sample).

Respondents who did not have a CXR taken were also eligible to submit sputa, even if asymptomatic.

All respondents eligible for sputum collection had HIV testing.

CXR reading

CXRs were read in the field by a trained technician and interpreted as normal or abnormal. Two experienced independent radiologists categorised all the abnormal CXRs as normal, suggestive of active TB disease, inactive/healed TB, and extra pulmonary abnormalities. A third radiologist adjudicated in case there were differences and the differences were resolved by consensus. All normal x-rays were read a single time.

The Gold standard

The culture results obtained with Löwenstein–Jensen medium and confirmed as survey TB were considered as the gold standard.

Study participants

Records of participants ≥ 15 years were included in the study. We excluded records that were missing data on culture and CXR results.

Sampling and sample size

All records in the electronic database that met the inclusion criteria for the study were analysed.

To estimate the sample size for performance of the CXR and symptoms. The modified Kish Leslie formula for diagnostic studies was used. We assumed 95% confidence level (CI), sensitivity 90%, specificity 83% [16]and TB prevalence of 401 per 100,000 population[15] to obtain the desired sample size for assessing the performance of the CXR in screening for tuberculosis.

Data extraction

We used a data extraction form to obtain variables of interest from the electronic database.

The CXR results were considered as abnormal (suggestive of active TB disease) or Normal (healed TB/inactive TB, other TB related lung abnormalities, other non-TB related lung abnormalities and extra pulmonary abnormalities, normal).

The symptoms screen encompassed presence of cough of ≥ 2 weeks, fever, weight loss and night sweats as recommended by Uganda Ministry of Health. Individuals with any of the above symptoms were considered presumptive for tuberculosis.

Data analysis

We used the STARD 2015 guidelines in reporting the results of this study[17]. Data was analysed using Stata version 13.0 (College Station, Texas, USA). In our study, records with any of the above symptoms i.e. cough ≥ 2 weeks, fever, weightloss or night sweats were analysed as positive for symptoms. Records indicating CXR abnormalities suggestive of active TB were analysed as positive by the CXR.

Variables were summarised using percentages and proportions depending on their distribution. Performance of the symptoms screening and CXR were reported as sensitivity, specificity, negative and positive predictive value, negative and positive likelihood ratios.

The chi square was used to determine the association between each predictor and false positive CXR results. These were reported as prevalence ratios due to the high prevalence of both CXR and symptoms false positive results in the population.

The Poisson multivariate regression model with robust standard errors was used to obtain factors that were independently associated with false positive CXR or symptoms. The results were reported as prevalence ratios because the prevalence of false positive results was greater than 10%. All factors with level of significance ≤ 5% were considered significant. Interaction was assessed using the chunk test and considered present at P-value < 0.05. Confounding was assessed and considered present at ≥ 10% difference in the prevalence ratio.

Results

Study Profile

A total of 40,539 participants were screened for TB in the UTPS. We excluded 35,690 records of participants that did not submit sputum to the laboratory. We excluded 348 records because they were missing data on culture results. 60 records were excluded due to missing data on CXR results. The remaining 4441 records were analysed (Fig. 2).

Characteristics of the study population

The study included individuals aged 15–65 years. Majority of the participants were between ages 25–34 years 832(19%) and 35–44 years 851 (19%). There was an equal number of females 2222(50%) and males (Table 1).

Table 1
Demographic, clinical and radiographic characteristics of the study population

Characteristic	N = 4441 N (%)
Age	
15-24yrs	753 (17)
25-34yrs	832 (19)
35-44yrs	851 (19)
45-54yrs	717 (16)
55-64yrs	468 (11)
65 + yrs	820 (18)
Female	2222 (50)
Education	
None	1364 (29)
Primary	2247 (47)
Secondary	939 (20)
Tertiary	212 (4)
Employed	3160(71)
Rural residence	2854 (64)
Smoking Status	
Never	3216 (72)
Current	643(15)
Past	582(13)
HIV	
Positive	415 (10)
Negative	3852 (80)
Missing	495 (10)
Abnormal Chest X-ray	1657(37)

Performance of the Chest radiograph or symptoms in screening tuberculosis in Uganda

Pulmonary tuberculosis was confirmed in 160 (3.6%) participants using LJ culture. The CXR had sensitivity 93% (95%CI; 87, 96), Specificity 65% (95%CI; 63, 66) compared to symptoms with sensitivity 56 (95%CI; 48, 64) and specificity 41% (95%CI; 40, 43).

The negative and positive predictive values of the CXR was 99% & 9% versus 96% & 3% of the symptoms. The positive and negative likelihood ratios of the CXR were 2.6 (95%CI; 2.5, 2.8), 0.1 (95%CI; 0.1, 0.2) compared to symptoms with positive and negative likelihood ratios of 0.9 (95%CI; 0.8, 1.1), 1.1 (95%CI 0.9, 1.3) (Table 2).

Table 2
Performance of the CXR or symptoms in screening culture confirmed pulmonary tuberculosis.

Diagnostic/ Parameter	Culture confirmed TB	Total Number	Sensitivity (95%CI)	Specificity (95%CI)	Positive Predictive Value (95%CI)	Negative Predictive Value (95%CI)	Positive Likelihood ratio (95% CI)	Negative Likelihood ratio (95% CI)
Prevalence	160	4441						
CXR	148	4441	93(87,96)	65(63,66)	9(8,10)	99(99,100)	2.6(2.5,2.8)	0.1(0.1,0.2)
Symptoms	89	4441	56(48,64)	41(40,43)	3 (3,4)	96(95,97)	0.9(0.8,1.1)	1.1(0.1,0.2)

Additional Tuberculosis cases obtained by screening with the CXR in addition to symptoms
A total of 160 cases of tuberculosis were diagnosed during the Uganda tuberculosis prevalence survey. Using the CXR in screening tuberculosis an additional 38 (23.8%) cases of tuberculosis were diagnosed. The results are shown in Fig. 3, below.

Factors associated with false positive results on screening with the CXR or symptoms.

A total of 1657 (37%) of all the participants had abnormal CXR results. Out of all participants with abnormal CXR results, 9% (148/1657) were confirmed to have tuberculosis.

On bivariate analysis, factors associated with a false positive CXR results included; age 45–54 yrs. PR 1.14 (1.04 ,1.24), 55–64 years PR 1.16 (1.07 ,1.27), 65 + years PR 1.2 (1.11, 1.30) and current smoking PR 1.08 (1.06, 1.10) (Table 3).

Table 3
Bivariate analysis of the factors associated with a false positive CXR result

Characteristic	True positive	False Positive	Prevalence Ratio	95% CI	P-value
	N (%)	N (%)			
Age					
15-24yrs	27(19)	116(81)	1.00		
25-34yrs	37(16)	191(84)	1.03	0.94–1.14	0.518
35-44yrs	38(13)	265(87)	1.08	0.99–1.18	0.101
45-54yrs	23(7)	288(93)	1.14	1.04–1.24	0.002
55-64yrs	11(6)	187(94)	1.16	1.07–1.27	0.001
65 + yrs	12(3)	462(97)	1.20	1.11–1.30	< 0.001
Sex					
Female	35(5)	661(95)	1.00		
Male	113(12)	848(88)	0.93	0.91–0.96	< 0.001
Employment status					
Unemployed	97(8)	1051(92)	1.00		
Employed	51(10)	458(90)	0.98	0.95–1.02	0.317
Setting					
Rural	73 (8)	901 (92)	1.00		
Urban	75(11)	608(89)	0.96	0.93–0.99	0.018
Smoking status					
Never	80(8)	981(92)	1.00		
Current	36(13)	240(87)	1.08	1.06–1.10	< 0.001
Past	32(10)	288(90)	0.97	0.93–1.01	0.191
HIV					
Negative	96(8)	1179(92)	1.00		
Positive	37(22)	133(78)	0.85	0.78–0.92	< 0.001

On multivariate analysis the factors found to be independently associated with a false positive result included age categories 35–44 year APR 1.11 (1.01, 1.22), 45–54 years APR 1.18 (1.09, 1.29), 55–64 years APR 1.18 (1.09, 1.29), 65 + years APR 1.2 (1.10, 1.30) while male sex APR 0.93 (0.90, 0.96), positive HIV status APR 0.86 (0.79, 0.93) reduced the false positive CXR outcome (Table 4).

Table 4
Multivariate analysis of the factors associated with a false positive CXR result

Characteristic	Adjusted prevalence Ratio (APR)	95% CI	P-value
Age			
15-24yrs	1.00		
25-34yrs	1.05	0.95–1.16	0.369
35-44yrs	1.11	1.01–1.22	0.028
45-54yrs	1.18	1.08–1.29	< 0.001
55-64yrs	1.18	1.09–1.29	< 0.001
65 + yrs	1.20	1.10–1.30	< 0.001
Sex			
Female	1.00		
Male	0.93	0.90–0.96	< 0.001
HIV			
Negative	1.00		
Positive	0.86	0.79–0.93	< 0.001

Factors associated with false positive symptoms screening results.

Multivariate analysis was also conducted to determine the factors associated with false positive symptom screening results. The factors included male sex APR 0.96 (0.94–0.97) and positive HIV status APR 0.92 (0.88–0.96) which are both associated with reduced false positive symptom results (Table 5).

Table 5
Multivariate analysis of the factors associated with a false positive Symptom result

Characteristic	Adjusted prevalence Ratio (APR)	95% CI	P-value
Sex			
Female	1.00		
Male	0.92	0.88–0.96	< 0.001
HIV			
Negative	1.00		
Positive	0.96	0.94–0.97	< 0.001

Discussion

This study is one of the first studies to compare the performance of the CXR or symptoms against culture confirmed pulmonary tuberculosis by LJ Method in a community tuberculosis screening setting such as the National Tuberculosis prevalence surveys.

Our results show that the CXR performs better than the symptoms in correlating with positive tuberculosis sputum culture results in community settings which agrees with other studies.[3, 12, 18–21] The positive and negative likelihood ratios of the CXR versus symptoms further indicate that the CXR performs better in correlating tuberculosis sputum culture results. The results indicate that the use of the CXR in tuberculosis screening in community settings may hence increase tuberculosis case detection rate in high tuberculosis prevalence settings. This may be due to the increased number of individuals that are taken for the confirmatory tests. This is especially important in the era of the new advanced TB diagnostic tools.

Our results indicate that individuals above 45 years are more likely to have a false positive CXR when screened for tuberculosis. This may be explained by the increase in respiratory pathology associated with increase in age including pneumonia, chronic obstructive pulmonary disease among others.[22] Therefore, the CXR is not a preferred TB screening test among these individuals.

HIV positive individuals and males are more likely to have a true diagnosis of tuberculosis with both the CXR and symptoms.[18] This is important in the diagnosis of tuberculosis since these populations have been shown to be at high risk for tuberculosis.[23] However, other studies have shown that PLHIV have been found to have a lot of abnormalities on CXR and hence the CXR not a good TB diagnostic tool among such populations.[13] Therefore further studies are required to investigate the discrepancy noted between our study and other studies.

The strengths of our study include community screening for tuberculosis as shown by the use of data collected during the UTPS. The study was reported according to the STARD (Standards for reporting of Diagnostics Accuracy Studies) 2015 guidelines.[17]

Our study is subject to limitations. The fact that sputum culture was only done for participants with abnormal CXR or tuberculosis symptoms could have led to selection bias hence over estimation of the sensitivity of the CXR. However, the large sample size improves our estimation of the performance of the CXR.

We only looked at culture confirmed pulmonary tuberculosis but not clinically diagnosed and not culture negative or Extra Pulmonary TB. This could greatly impact the performance of symptoms screening and/ or CXR to identify true TB.

The study was performed under community screening conditions and therefore the results may not be applicable to tuberculosis screening in the hospital setting.

This study shows that community tuberculosis screening using the CXR improves tuberculosis case detection. Therefore, the CXR should be considered in community tuberculosis screening programmes.

Conclusion

This study made use of data obtained during the Uganda National Tuberculosis prevalence survey to determine the performance of the CXR in correlating tuberculosis culture results and factors associated with a false negative tuberculosis screening result. The results indicate that the CXR is a good tuberculosis screening tool and may improve TB case detection when used in community tuberculosis screening on addition to symptoms assessment. Individuals with knowledge to observe TB defining pathology on the CXR are adequate to provide expertise for CXR interpretation.

The use of the CXR in screening tuberculosis may improve TB case detection among the PLHIV and the males who are important risk groups for tuberculosis. However, the elderly patients above 45 years are likely to have false positive CXR results. Additional studies are needed to investigate the impact of the CXR screening tool in the era of the molecular

diagnostic tests. The cost effectiveness of screening tuberculosis with the CXR in high TB prevalence settings also needs to be determined.

List Of Abbreviations

HIV Human Immune Virus

PLHIV People Living with HIV

IC Infection Control

ICF Intensified Case Finding

IPT Isoniazid Preventive Therapy

MoH Ministry of Health

NTLP National Tuberculosis and Leprosy Programme

PTB Pulmonary tuberculosis

SOMREC School of Medicine Research and Ethics Committee.

TB Tuberculosis

UTPS Uganda Tuberculosis Prevalence Survey

WHO World Health Organisation

Declarations

Ethics approval and consent to participate

Ethical approval of the original survey was granted by the institutional review boards of the Higher Degree Research and Ethics Committee at the Makerere University School of Public Health and the Uganda National Council of Science and Technology (reference IRB00011353).

The nested study obtained a waiver of Informed consent from the Makerere University School of Medicine research and Ethics Committee (SOMREC).

Participants in the primary study offered written informed consent and or assent. Permission to use the data was obtained from the Uganda NTLP, Ministry of Health.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

JN, IN, PL, FO, EK and JM contributed to conception, design, analysis, methodology, interpretation of data, drafting and revision.

FM contributed to conception, funding acquisition, data acquisition and writing.

RS contributed to the data curation, software acquisition and revision.

AK contributed to conception, funding acquisition, investigation, resources, supervision, validation, drafting and revision.

JBK contributed to conception, funding acquisition, investigation, supervision, validation, drafting and revision.

All authors read and approved the final manuscript.

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The authors declare no conflict of interest.

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Figures

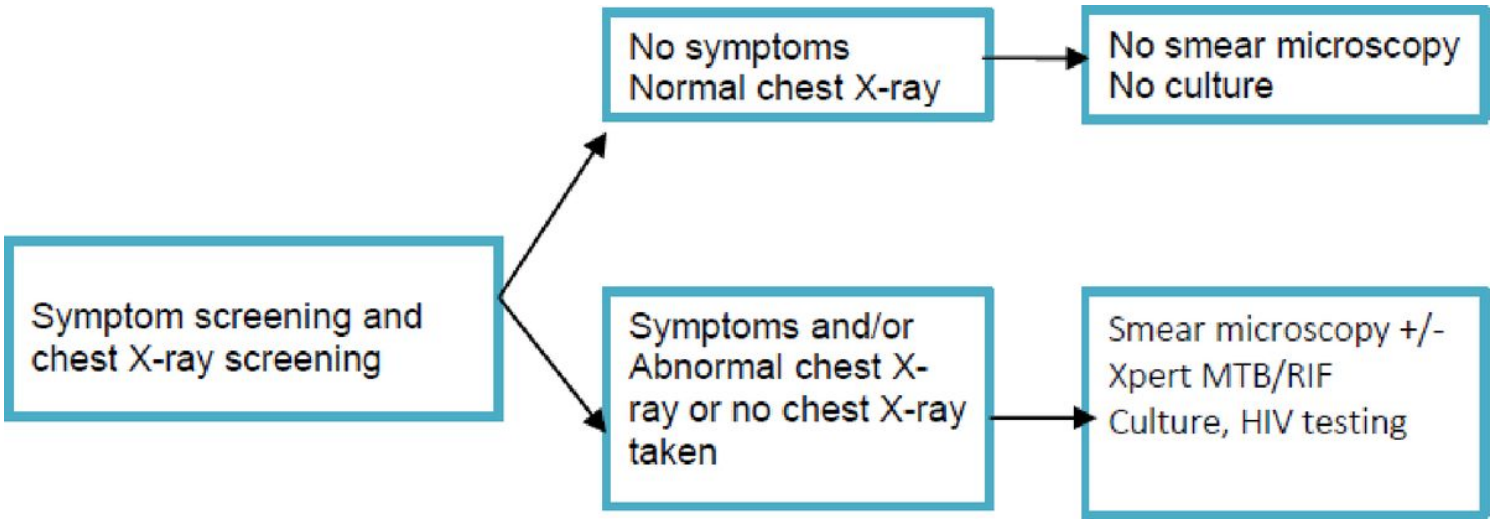

Figure 1

Diagrammatic representation of the combined symptom and chest x-ray screening strategy.

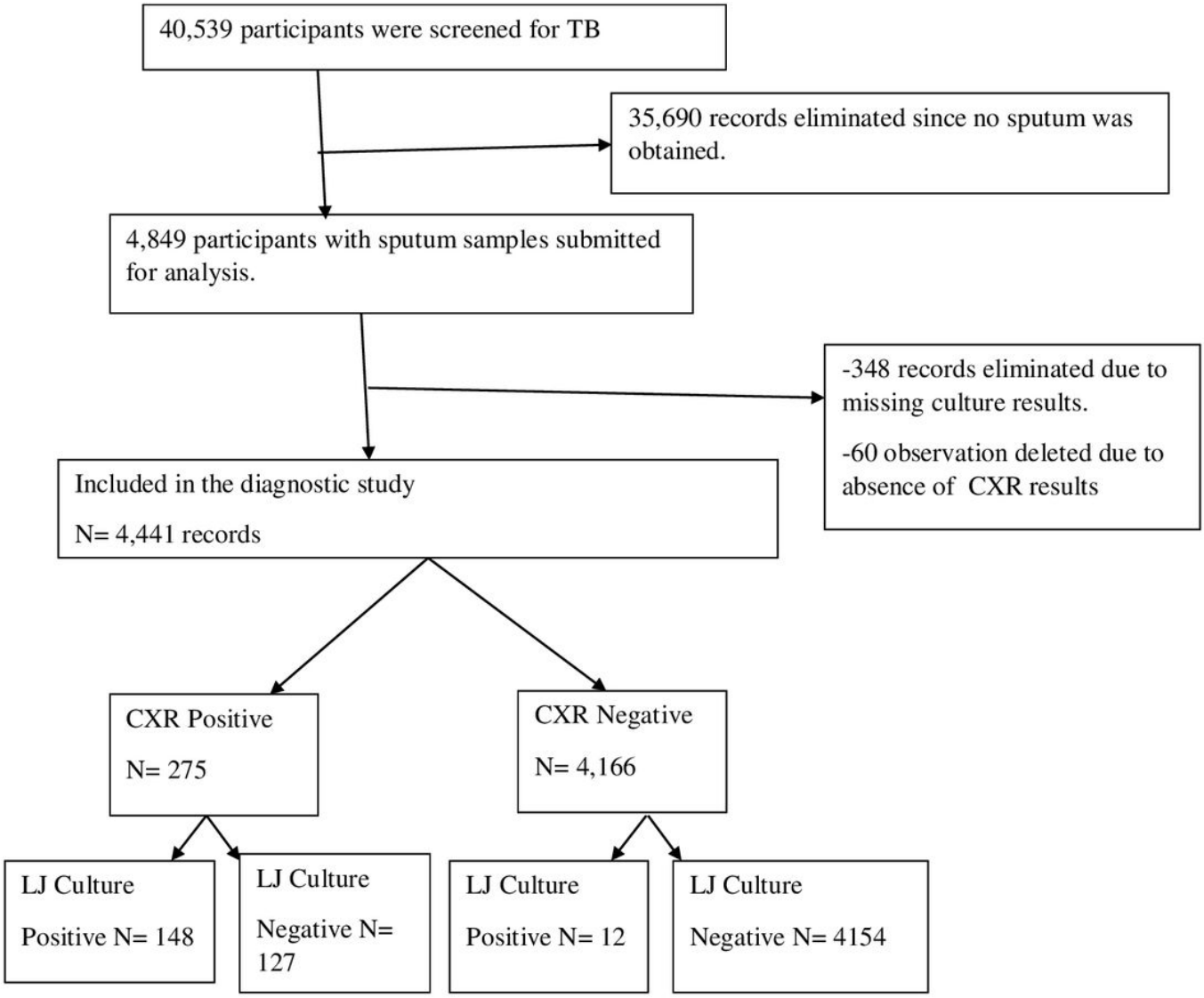

Figure 2

Study Profile

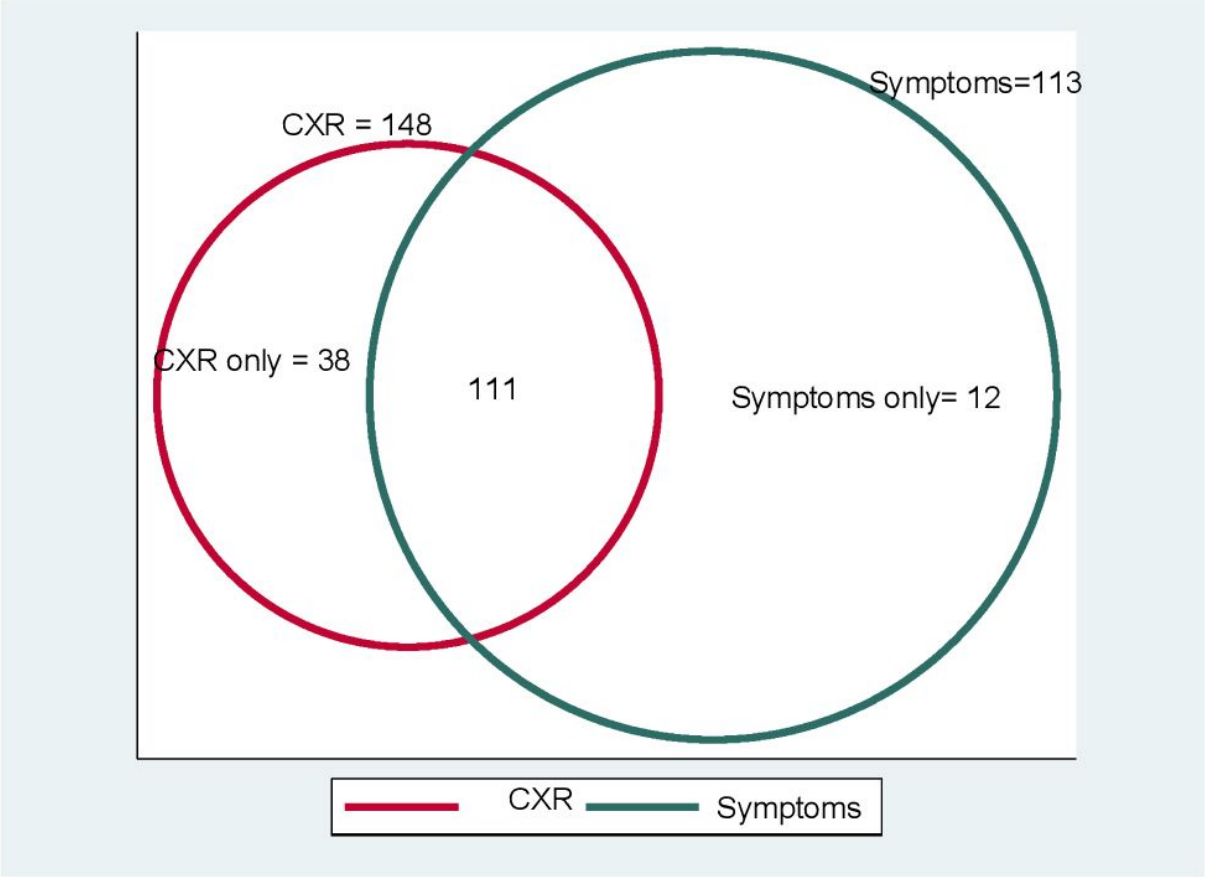

Figure 3

A Venn diagram of the culture confirmed Tuberculosis cases per screening tool.

Supplementary Files

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- AdditionalFile1.xls