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Tuberculosis disease and infection among household contacts of bacteriologically confirmed and non-confirmed tuberculosis patients

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Abstract

objective—To compare the prevalence of tuberculosis infection and disease in household contacts of patients with bacteriologically confirmed tuberculosis disease and contacts of non-bacteriologically confirmed disease in western Kenya.

methods—We enrolled newly diagnosed index patients and their household contacts from March 2014 to June 2016. All contacts were evaluated with a symptom questionnaire, tuberculin skin test (TST) and HIV test. Clinical evaluation and sputum testing were performed for those with symptoms, positive TST result or HIV infection.

results—We enrolled 1155 contacts of 330 index patients with bacteriologically confirmed tuberculosis and 192 contacts of 55 index patients with non-bacteriologically confirmed tuberculosis. 3.5% of contacts of patients with bacteriologically confirmed tuberculosis were diagnosed with tuberculosis, whereas no contacts of index patients with non-bacteriologically confirmed tuberculosis were. Of those diagnosed with tuberculosis disease, 58.5% reported symptoms, 34.1% reported no symptoms but had positive TST results, and 7.3% had neither symptoms nor positive TST but were HIV-positive. Among 872 contacts with a TST result, 50.9% of contacts of index patients with bacteriologically confirmed tuberculosis and 41.0% of contacts of index patients with non-bacteriologically confirmed tuberculosis had a positive result (prevalence ratio = 1.16, 95% confidence interval 0.92–1.48).

conclusion—In a high-burden setting, tuberculosis disease was more prevalent among contacts of patients with bacteriologically confirmed tuberculosis than contacts of patients with non-

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bacteriologically confirmed disease. TST was feasible to perform and helped to detect cases that would have been missed had only symptomatic contacts been evaluated.

Keywords

tuberculosis; contact tracing; Kenya; tuberculin test; HIV

Sustainable Development Goals (SDGs):

SDG 3 (good health and well-being); SDG 17 (partnerships for the goals)

Introduction

It is estimated that 10 million people develop tuberculosis (TB) each year, and over 1 million die from it [1]. As TB transmission occurs via inhalation of aerosolised droplets, people who are in close contact with people with TB are at high risk of getting the disease themselves. Thus, WHO recommends that household contacts of TB patients need to be identified and screened for TB to diagnose TB early and prevent further transmission within the household [2]. A meta-analysis of 95 studies from low- to middle-income countries showed that 3.1% of household contacts of TB patients were diagnosed with TB and 45.4% were diagnosed with latent TB infection [3].

Kenya is a country with a TB prevalence of 558 per 100 000 population [4]. Many countries with high TB burdens, including Kenya, have historically recommended contact investigation for sputum smear-positive TB cases only [5]. While the increased infectiousness of sputum smear-positive disease *vs.* smear-negative disease is well established [2], around 15% of transmission in TB patient cohorts from low-incidence settings has been attributed to smear-negative but culture-positive TB [6,7]. Additionally, since the first person in the household to be diagnosed (i.e. the index patient) may not be the first one to have become sick with TB, contact investigations are also useful for identifying previously undiagnosed source cases. These points suggest that restricting contact investigation to patients with sputum smear-positive disease may result in missed cases among contacts of patients with smear-negative disease in high-burden settings. However, there are few published data from sub-Saharan Africa that provide information about the magnitude of this issue [8–10]. Furthermore, many high-burden countries now use the more sensitive Xpert MTB/RIF assay (Cepheid, CA, USA) instead of sputum smear microscopy for bacteriologic confirmation; it is unclear whether this improvement in sensitivity is sufficient to avert the missed cases that might result from using smear positivity as a requirement for contact investigation.

We sought to assess the policy of prioritising bacteriologically confirmed cases for contact investigation in Kenya, which has scaled up the use of Xpert MTB/RIF in place of sputum smear microscopy [11,12]. We conducted a study to compare the yield of TB disease and infection between contacts of index patients with bacteriologically confirmed *vs.* non-bacteriologically confirmed TB.

Methods

Study design and population

We conducted a prospective cohort study of household contacts of bacteriologically confirmed and non-bacteriologically confirmed TB index patients, nested within a cluster-randomised study to compare different combinations of case-finding interventions. In the cluster-randomised study, 12 of 24 study areas were randomly assigned to receive contact investigations alone or in combination with other interventions; the other 12 study areas were randomised to not receive contact investigations. The cohort study aimed to perform contact investigations for all newly diagnosed TB patients who lived in the 12 designated study areas. Hence, TB index patients who had been on treatment for fewer than 30 days and their household contacts were eligible to enrol in the contact investigation study component if they lived within those areas. We identified eligible index patients from 49 health facilities and laboratories in Kisumu and Siaya counties (western Kenya) between March 2014 and June 2016.

Index patients were categorised as having bacteriologically confirmed disease if they had a positive result based on smear microscopy, Xpert MTB/RIF assay or culture. Index patients were categorised as having non-bacteriologically confirmed disease if the results of all recorded laboratory tests were negative. It was not possible to further classify index patients according to mode of diagnosis for several reasons: different patients received different tests due to the gradual replacement of sputum smear microscopy with Xpert MTB/RIF during the study period; mycobacterial culture is not a routine procedure in Kenya; and the basis on which non-bacteriologically confirmed diagnoses are made (e.g. radiography, symptoms) is not systematically recorded [12].

Procedures for contact evaluation

We invited enumerated contacts to the clinic for evaluation by requesting their phone number from the index patient or calling the index patient while he/she was at home, or by making a home visit. At either the clinic or the home, a symptom questionnaire was administered, a tuberculin skin test (TST) for TB infection was placed and read 48 to 72 h later, and HIV testing was offered. A sputum sample was collected and clinical evaluation performed for contacts who met any of the following criteria: (i) reported cough, night sweats, fever, hoarseness or weight loss (or decreasing growth or failure to thrive for children under 15) in the last 4 weeks, (ii) had a positive TST result, defined as an induration of 5 mm or larger, or (iii) was HIV-positive or had an unknown HIV status. Sputum samples were tested by Xpert MTB/RIF assay, with additional tests such as culture and drug susceptibility testing performed if clinically indicated. TB diagnoses were made based on a positive bacteriologic test result or a clinical diagnosis by the clinician. These procedures were consistent with TB evaluation algorithms recommended by the Kenya national guidelines, except that TST is not routinely used for adults in Kenya [12]. All contacts diagnosed with TB were referred to a health facility for treatment, and contacts under 5 years old in whom TB had been ruled out were referred for isoniazid preventive therapy [12].

Statistical analysis

To assess whether bacteriologic confirmation of the index patient was predictive of the risk of infection and disease among contacts, we compared the prevalence of TB disease and TST positivity between contacts of patents with bacteriologically confirmed *vs.* non-bacteriologically confirmed disease. We excluded from these analyses index patients who reported no household contacts. We assessed the association between bacteriologic confirmation of the index patient and prevalence of TST positivity among contacts with a TST result. This analysis was stratified by age group of the contact since the likelihood of a contact having been infected in the household *vs.* in the community was likely to vary by age, with young children most likely to acquire TB infection in the home. We also assessed the association between bacteriologic confirmation of the index patient and prevalence of TB disease among all evaluated contacts. For both analyses, we used a modified Poisson regression with generalised estimating equations and robust variance estimates to account for clustering among contacts of a single index patient. In multivariable analysis, we adjusted for sex, HIV status and rural *vs.* urban residence of the contacts. For all analyses, we interpreted *P*-values < 0.05 as indicative of statistical significance. Analyses were performed with SAS 9.4 (SAS Institute, Cary, NC, USA).

Ethical considerations

The study was approved by Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (SERU) institutional review board. CDC relied on the review and oversight of KEMRI SERU. The Walter Reed Army Institute for Research reviewed the protocol and determined that their engagement did not constitute human subjects research.

Results

The study enrolled 330 index patients with bacteriologically confirmed TB and 55 index patients with non-bacteriologically confirmed TB who reported at least one household contact (Table 1). Of those with bacteriologically confirmed TB, 277 (83.9%) had a positive sputum smear microscopy result recorded. For index patients with bacteriologically confirmed TB, 1334 contacts were enumerated, of whom 1155 (86.5%) were enrolled. For index patients with non-bacteriologically confirmed TB, 232 contacts were enumerated, of whom 192 (82.7%) were enrolled. Among contacts of index patients with bacteriologically confirmed TB, 271 (23.5%) were children aged under 5 years old while among contacts of index patients with non-bacteriologically confirmed TB, 42 (21.9%) were children under 5 years old (Table 2).

A total of 284 (24.6%) contacts of index patients with bacteriologically confirmed TB and 42 (21.9%) contacts of index patients with non-bacteriologically confirmed TB reported at least one TB symptom. A TST was completed for 872 (75.5%) contacts of index patients with bacteriologically confirmed TB, and 161 (83.9%) contacts of index patients with non-bacteriologically confirmed TB (Figure 1). Common reasons recorded for not completing a TST were logistical challenges in scheduling the reading within the necessary timeframe after placement (n = 95, 30.3%), stock-out of tuberculin (n = 78, 24.8%) and participants declining the procedure (n = 50, 15.9%). Contacts of non-bacteriologically confirmed TB

were significantly more likely to have completed a TST than contacts of bacteriologically confirmed TB ($P = 0.011$), but TST completion did not vary significantly by age group ($P = 0.709$), sex ($P = 0.773$) or HIV status ($P = 0.419$). Of contacts with a TST result, 444 (50.9%) contacts of index patients with bacteriologically confirmed TB and 66 (41.0%) contacts of index patients with non-bacteriologically confirmed TB had a positive TST result.

A total of 41 (3.5%) contacts of patients with bacteriologically confirmed TB were diagnosed with TB disease, with 18 (43.9%) of these diagnoses bacteriologically confirmed. Of the contacts diagnosed with TB disease, 9 (22.0%) were children under 5 years old and 12 (29.3%) were people living with HIV. Moreover, 24 (58.5%) reported at least one TB symptom, 14 (34.1%) reported no symptoms but were evaluated because they had positive TST results, and 3 (7.3%) reported no symptoms and did not have positive TST results but were evaluated because they were either HIV-positive or had an unknown HIV status (Table 3). Bacteriologic confirmation of TB diagnoses was more common for contacts with symptoms than those without (50.0% *vs.* 35.3%) and less common for those with a positive TST result compared to those without (36.7% *vs.* 63.6%); TB diagnosis was bacteriologically confirmed for 4 (28.6%) of those who reported no symptoms but who had a positive TST result. The highest yields of TB disease were diagnosed in people with HIV, regardless of whether they reported symptoms. The only subgroup of contacts with HIV in which no TB cases were diagnosed was that with no symptoms and a negative TST result.

No contacts of index patients with non-bacteriologically confirmed TB were diagnosed with TB disease. It was not possible to estimate a prevalence ratio for this difference using methods that account for household-level clustering due to the absence of the TB disease outcome in one group. As an approximation of the statistical significance of the observed difference, when household-level clustering was ignored, a Fisher's exact test yielded a two-sided *P*-value of 0.003. While the prevalence of TST positivity was higher among contacts of bacteriologically confirmed TB (Figure 1), this difference was not statistically significant (crude prevalence ratio [PR] accounting for household clustering = 1.16, 95% confidence interval 0.92–1.48; adjusted PR = 1.17, 95% confidence interval 0.92–1.49; Table 4). For children <5 years old, positive TST results were 88% more frequent among contacts of index patients with bacteriologically confirmed disease, although this association also did not achieve statistical significance (adjusted PR = 1.88, 95% confidence interval 0.84–3.73).

Discussion

Our results support the assertion that contacts of patients with bacteriologically confirmed pulmonary TB are at higher risk for developing TB than contacts of patients with non-bacteriologically confirmed TB. We found no TB cases among contacts of index patients with non-bacteriologically confirmed TB. Although the comparisons did not achieve statistical significance, we observed a higher prevalence of TST positivity among contacts of patients with bacteriologically confirmed TB, with the difference more pronounced among younger children. Notably, around 40% of contacts diagnosed with TB disease reported no symptoms and were evaluated because of a positive TST result or because of their HIV

status. Thus, although our study did not originally set out to evaluate contact evaluation algorithms, our results suggest the limitation of symptom screening as a triage step in contact investigations and support HIV testing for contacts and the consideration of TST in high-burden settings.

The high proportion of TB cases diagnosed among contacts who reported no symptoms is concerning in light of the fact that Kenya's guidelines, like other high-burden countries' guidelines, rely on symptom screening alone as the initial step in determining whether to evaluate a contact for TB [12]. Prevalence surveys have shown that many people with bacteriologically confirmed TB do not report symptoms [4,13]. Furthermore, studies where chest radiography was performed on all household contacts yielded substantial TB diagnoses among contacts reporting no symptoms in high-burden settings, including 3% of asymptomatic child contacts in Uganda [14] and 1.5% of asymptomatic contacts of all ages in China [15]. Given barriers to accessing chest radiography in Kenya, one way to programmatically find cases that would be missed by symptom-based screening alone would be to improve HIV testing coverage among household contacts of TB patients and perform diagnostic and clinical evaluations on all people with HIV [2]. While reducing the reliance on symptoms for the screening of household contacts will not fully address the issue of improving TB case detection among people who do not perceive or report symptoms, it would help to ensure that cases are not missed among in this particular vulnerable group.

Another method of increasing the yield of contact investigations over that achieved by symptom screening would be to consider routine use of TST. In this study, TST helped to identify contacts for evaluation who would have been missed by symptom screening alone. TST may also have helped doctors to make clinical TB diagnoses; although we do not know the basis on which doctors made clinical diagnoses, the lower proportion of bacteriologically confirmed cases among contacts with positive TST results suggests that the TST result may have been a factor in the decision. We found TST administration for household contacts of TB patients to be feasible in the context of this study, as the infrastructure for storing tuberculin under cold chain conditions already exists; the additional resource required was study nurses who could administer the TST in patients' homes for maximum coverage of all contacts. While this additional staffing comprised a deviation from routine programmatic conditions, it is worth noting that nurses make home visits both in other health programs in Kenya and in other middle-income countries [16–18].

Our findings generally support prioritising contact investigations for index patients with bacteriologically confirmed pulmonary TB. Contained within our category of patients with bacteriologically confirmed TB are those with sputum smear-positive TB, which has been established to carry a higher risk of transmission [2]. Although the number of non-bacteriologically confirmed index patients in our study was relatively small, the absence of TB cases among their nearly 200 contacts and the suggestion of a lower risk of infection in young children are strongly suggestive of lower transmission risk. On the other hand, studies from Malawi and Ethiopia have demonstrated a non-negligible risk of TB disease among contacts of index patients with smear-negative TB [8,10], and studies from the United States and the Netherlands have estimated that between 10% and 20% of transmission events are attributable to patients with smear-negative but culture-positive disease [6,7]. Therefore,

while a decision to restrict household contact investigations to bacteriologically confirmed cases may be programmatically reasonable because of the reduction in required resources, it is necessary to acknowledge the possibility that cases will be missed.

This study had several limitations. First, the lack of cases among contacts of index patients with non-bacteriologically confirmed TB prevented us from robustly quantifying the relative risk of TB disease between contacts of bacteriologically confirmed *vs.* non-bacteriologically confirmed TB. Possible contributors to the lack of cases we observed include small sample size; the fact that index patients with positive GeneXpert MTB/RIF results who might have been smear-negative were categorised as having bacteriologically confirmed TB; and the high proportion of index patients with extrapulmonary TB in the non-bacteriologically confirmed group. Our study data did not allow us to evaluate the differing contributions of disease site and bacillary load on contact TB risk. Second, not all contacts received a TST, potentially resulting in a lack of accuracy in the reported prevalence of TB infection in both groups. However, because contact characteristics did not systematically differ between those who completed a TST and those who did not, we expect that the comparison of TST positivity between contact groups is likely to be valid. Finally, we did not perform the more sensitive diagnostic procedures of gastric lavage and sputum induction for children, which could have led to missed TB diagnoses.

In conclusion, our results support a policy of focusing contact tracing on households of patients with bacteriologically confirmed pulmonary TB in resource-limited settings, particularly where Xpert MTB/RIF is being used for bacteriologic testing. In addition, our findings caution against a reliance on symptom screening to identify household contacts requiring evaluation. Our experience suggests that routine performance of TST for household contacts is feasible in a high-burden setting and that expanding its programmatic use in similarly resource-limited settings could maximise the yield of household contact investigations.

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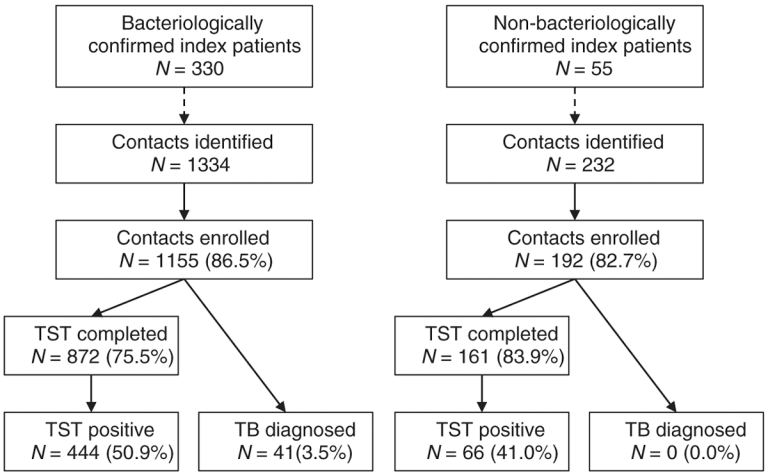

Figure 1.

Evaluation of contacts of index patients with bacteriologically confirmed TB (by sputum smear microscopy, Xpert MTB/RIF or culture) and contacts of index patients with non-bacteriologically confirmed TB. TST, tuberculin skin test for TB infection.

Table 1

Characteristics of enrolled index patients with bacteriologically confirmed TB (N = 330) and non-bacteriologically confirmed TB (N = 55)

	Bacteriologically confirmed TB, *n* (%)	**Non-bacteriologically confirmed TB, *n* (%)**
Type of TB		
Pulmonary	325 (98.5)	35 (63.6)
Extrapulmonary	4 (1.2)	20 (36.4)
Sex		
Male	169 (51.2)	32 (58.2)
Female	161 (48.8)	23 (41.8)
Age in years		
0–4	7 (2.1)	6 (10.9)
5–14	17 (5.2)	6 (10.9)
15–34	197 (59.7)	24 (43.6)
35–54	89 (27.0)	14 (25.5)
55+	20 (6.1)	5 (9.1)
HIV status		
Positive	173 (52.4)	35 (63.6)
Negative	156 (47.3)	18 (32.7)
Unknown	1 (0.3)	2 (3.6)
Residence		
Rural	240 (72.7)	34 (61.8)
Urban	90 (27.2)	21 (38.2)

Table 2

Characteristics of contacts of index patients with bacteriologically confirmed TB (N = 1155) and contacts of index patients with non-bacteriologically confirmed TB (N = 192)

	Contacts of index patients with bacteriologically confirmed TB *n* (%)	**Contacts of index patients with non-bacteriologically confirmed TB *n* (%)**
Sex		
Male	469 (40.6)	66 (34.4)
Female	685 (59.3)	126 (65.6)
Age in years		
0–4	271 (23.5)	42 (21.9)
5–14	380 (32.9)	72 (37.5)
15–34	327 (28.3)	52 (27.1)
35–54	108 (9.4)	18 (9.3)
55+	69 (6.0)	8 (4.2)
HIV status		
Previously known positive	106 (9.2)	21 (10.9)
Newly	diagnosed positive	12 (1.0)
2 (1.0)		
Negative	603 (52.2)	89 (46.4)
Unknown	434 (37.6)	80 (41.7)
Residence		
Rural	420 (36.4)	70 (36.5)
Urban	735 (63.6)	122 (63.5)

Table 3

Yield of TB diagnosis among contacts of index patients with bacteriologically confirmed TB, by contact symptoms, HIV status and TST status (N = 1155)

	HIV-positive, *n*/*N* (%)	**HIV status unknown, *n*/*N* (%)**	**HIV-negative, *n*/*N* (%)**
Symptomatic	7/45 (15.6)	11/105 (10.5)	6/134 (4.5)
Asymptomatic, TST positive	4/24 (16.7)	6/126 (4.8)	4/184 (2.2)
Asymptomatic, TST not done	1/17 (5.9)	0/92 (0.0)	0/108 (0.0)[†]
Asymptomatic, TST negative	0/32 (0.0)	2/111 (1.8)	0/177 (0.0)[†]

[†]Not eligible for sputum and clinical evaluation according to screening algorithm.

Table 4

Prevalence ratios of positive tuberculin skin test results among tested contacts of index patients with bacteriologically confirmed TB compared to tested contacts of index patients with non-bacteriologically confirmed TB, by age of contact

Age group of contacts	Positive TST results, *n/N* (%)		Prevalence ratio† (95% CI)	Adjusted prevalence ratio† (95% CI)
	Contacts of index patients with bacteriologically confirmed TB	Contacts of index patients with non-bacteriologically confirmed TB		
0–4	83/211 (39.3)	8/34 (23.5)	1.80 (0.87–3.70)	1.88 (0.84–3.73)
5–14	136/282 (48.2)	25/61 (41.0)	1.16 (0.81–1.68)	1.14 (0.80–1.62)
15–34	141/244 (57.8)	20/44 (45.5)	1.20 (0.87–1.65)	1.18 (0.87–1.61)
35+	84/135 (62.2)	13/22 (59.1)	1.08 (0.73–1.59)	1.08 (0.73–1.59)
All ages	444/872 (50.9)	66/161 (41.0)	1.16 (0.92–1.48)	1.17 (0.92–1.49)

†Prevalence ratios and confidence intervals account for household clustering. Adjusted prevalence ratios are adjusted for contact sex, contact HIV status and rural *vs.* urban residence