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THE LANCET

Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Corbett EL, Bandason T, Duong T, et al. Comparison of two active case-finding strategies for community-based diagnosis of symptomatic smear-positive tuberculosis and control of infectious tuberculosis in Harare, Zimbabwe (DETECTB): a cluster-randomised trial. *Lancet* 2010; published online October 4. DOI:10.1016/S0140-6736(10)61425-0.

Information leaflet given to participants

PLEASE READ CAREFULLY BEFORE PROVIDING SPECIMENS

Sputum examination for TB and the DETECTB research project

We have recommended a sputum test for TB because you (or a member of your household) have told us that you have been: -

- Coughing for the last 2 weeks or more
- Or have other TB symptoms such as coughing up blood, sweating at night, pain in the chest, weight loss and poor appetite

People with TB can have only mild symptoms but be infectious for many months or even years, putting their families and friends at risk of catching TB

What is TB?

- TB is an infection that is spread by coughing
- Not everyone who catches TB becomes sick
- TB is curable, but it is possible to die or become disabled from TB

How can I tell if I have TB?

- You can only tell if you have TB by having tests
- The first step is to look in the sputum for TB bugs – the test we will be doing

This test is routinely recommended for everyone with a cough lasting three weeks or more to help reduce the spread of TB

What does it mean if the sputum test is positive?

If TB bugs can be seen in sputum using strong light then it means

- That you have TB affecting the lungs
- That you are infectious to other people
- That TB is the likely cause of any TB symptoms that you have
- That you need to be treated for TB

TB treatment is provided for free by the government

What will happen to me if the sputum test is positive?

- We will contact you in the next 4 days to tell you of a positive result
- We will take more sputum to confirm the result, and will then refer you for free TB treatment by Harare City Health
- You will be offered an HIV test as well as TB treatment – but you do not have to have this if you do not want to and no-one will test you for HIV without your knowledge and written permission

What does it mean if the sputum test is negative?

- We will not tell you if the sputum test is negative

If we do not contact you within the next 4 days then your test was negative

- A negative sputum test does NOT mean that you do not have TB
 - You could still have TB deep in the lungs or elsewhere in the body

- This type of TB is much less infectious to other people
- This type of TB still needs to be treated, but is more difficult to diagnose

Take the ticket to Beatrice Road Hospital and we will do more TB tests

Why is the DETECTB research study doing sputum tests for free?

We are responding to the increasing problem with TB

- We want to see if we can improve the control of TB by providing extra services to pick up infectious people more quickly, so reducing the spread of infection
- We want to see which is more effective - mobile clinics or household enquiries?

Who is doing the DETECTB study?

BRTI, City Health Harare, London School of Hygiene & Tropical Medicine, UK, funded by the Wellcome Trust, a medical charity. We are working with Ministry of Health & Child Welfare.

Could having the sputum test harm me in any way?

The test itself will not harm you. The only risks would be from

- Mistaken (false) positive results. To reduce this risk as low as possible we will confirm all positive tests before referring for TB treatment
- Bad reactions from other people if the sputum test shows that you have TB. This is a risk, but we will keep your results confidential, so that it is up to you who you tell

What if I do not want to participate in this study?

- You do not have to participate in any way if you do not want to
- Simply return the sputum pots empty or tell the study team that you do not want to have your sputum test carried out and we will not trouble you again

For more information contact the DETECTB team on (Tel)

IF YOU WANT YOUR SPUTUM TO BE CHECKED FOR TB

- Use the two pots provided
- Rinse your mouth with water and then go outdoors
- Take a deep breath and cough deeply
- If you bring up sputum (like jelly) into your mouth then spit it out into the pot
 - To do this test we need sputum and NOT just watery spit from the mouth
- If you don't bring up sputum keep on taking deep breaths and coughing until you do, or keep the pot with you and wait until you cough and bring up sputum naturally
- Make sure that the lid is fastened tightly when you have finished
- Take one specimen **first thing in the morning before eating or drinking**
- Leave the pots at home to be collected, or take them to the mobile clinic if there is one in your neighbourhood. **Be sure to leave your correct address**

Procedures

To monitor delivery of the intervention, one in 20 households in door-to-door clusters were chosen at random and revisited by a supervisor immediately after completion of each cluster-round to ensure that all households had been visited as planned. Unannounced supervisor spot visits (at least twice per month) were used to monitor the activity of the mobile van team. Patients diagnosed with TB through both arms had check of residential address at the time of delivering results (with reassurance that there would be no penalty for being non-resident), and again through cross-check of the address given to municipal services for registration of treatment. A community liaison system and advisory board was in place.

Smear-positive participants in both intervention groups were referred to the DETECTB clinic, situated within the main TB registration centre in Harare for chest radiography and collection of two further sputum specimens. Patients were referred to adjacent Municipal services for treatment of TB and HIV management. HIV testing and care were not part of the community-level active case-finding intervention, but diagnostic HIV testing was offered to all participants attending for facility management. Patients testing HIV positive were started on cotrimoxazole and referred to an adjacent HIV care clinic. Treated TB patients were asked to return for assessment one month into treatment and on treatment completion, with active follow-up of defaulters. Transportation fares were refunded at each clinic attendance.

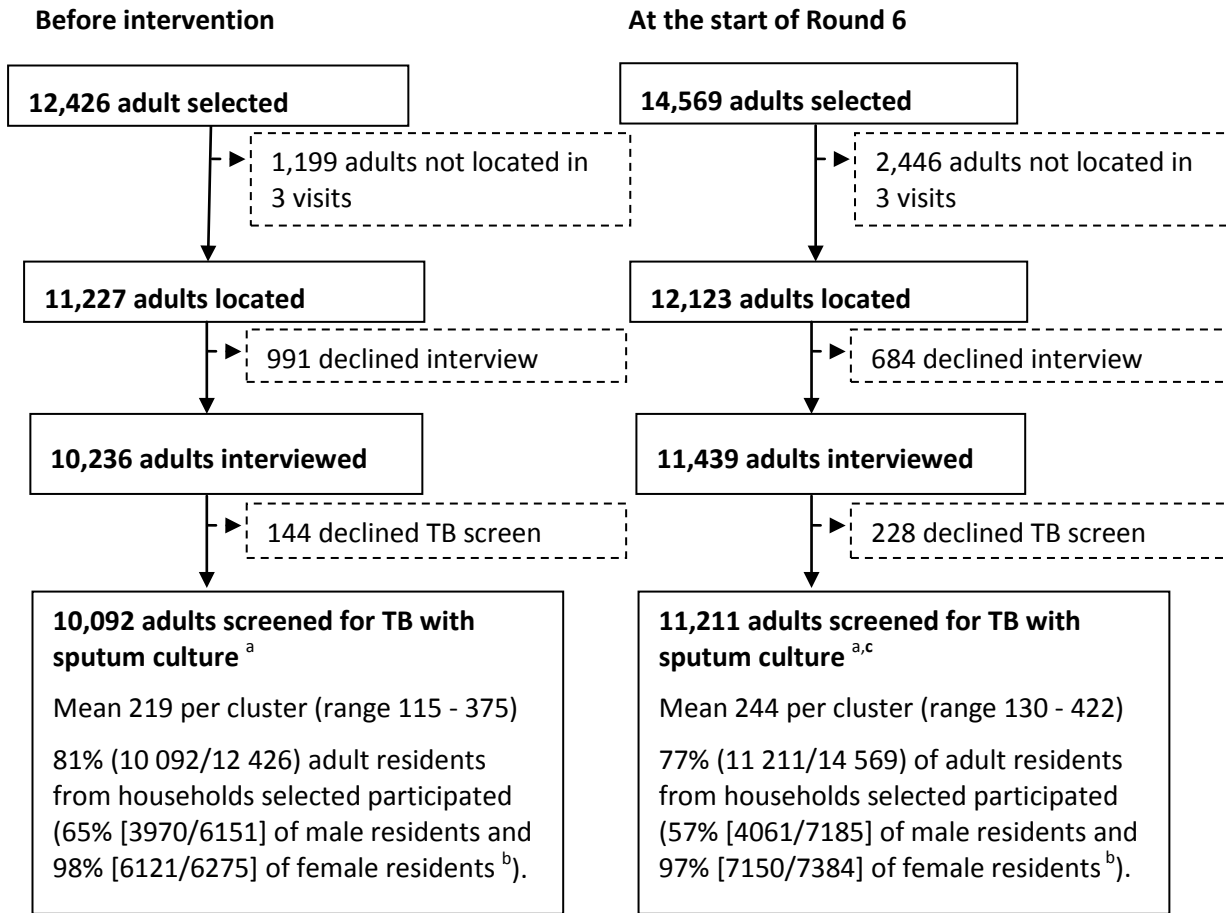
All patients diagnosed with TB during the study had confirmatory sputum microscopy and culture and chest radiography at the time of referral for TB treatment. The primary outcome analysis was restricted to patients with positive smears on ≥ 1 specimen collected through active case-finding, residing in an intervention cluster, and with TB disease confirmed on microscopy and culture of follow-up specimens.

All specimens from the two prevalence surveys were cultured for TB. Slides for microscopy were prepared from all specimens, but only stained and read if a) the participant had reported symptoms of TB, or b) there was growth on culture. All positive and 10% of negative slides were re-read by a second reader. Positive slides were confirmed with Ziehl-Neelsen staining. Culture used Lowenstein-Jensen (LJ) slopes, with residual concentrate stored at -20°C for re-culture in case of contamination. *M.tuberculosis* was identified through colony morphology, cording, and growth characteristics. Patients with non-tuberculous mycobacterial isolates had repeat specimens taken for microscopy and culture to minimise misclassification errors.

Findings of the pre-intervention survey have been described previously in more detail (1).

1. Corbett EL, Bandason T, Cheung YB, Makamure B, Dauya E, Munyati SS, Churchyard GJ, Williams BG, Butterworth AE, Mungofa S, Hayes RJ, Mason PR. Prevalent infectious tuberculosis in Harare, Zimbabwe: burden, risk factors and implications for control. *Int J Tuberc.Lung Dis* 2009;13(10):1231-7.

Participation rates for the two prevalence surveys (secondary outcome)



a. Included in analysis of change in prevalence of culture-positive TB for secondary outcome

b. Based on enumeration of men and women in households selected.

c. 403 (3.7%) individuals screened for TB in the end-intervention prevalence survey had participated in round 6 of the study intervention, 6 of whom had culture positive TB.

Characteristics of participants providing sputum specimens in the two prevalence surveys included in the analysis of secondary outcome

Variable	Pre-intervention N=10,092 ^a	End intervention N=11,211 ^a
Gender		
Male	3,970 (39.3%)	4,061 (36.2%)
Age in years		
Overall mean (SD)	31.2 (13.0)	31.9 (13.2)
<25	4,132 (40.9%)	4,183 (37.3%)
25-44	4,472 (44.3%)	5,259 (46.9%)
≥45	1,488 (14.7%)	1,695 (15.1%)
HIV testing and antiretroviral therapy		
Tested for HIV	9,062 (89.8%) ^b	9,851 (87.9%)
HIV-positive (% of those tested)	1,916 (21.1%)	1,845 (18.7%)
On antiretroviral therapy (% of HIV +ve)	Data not collected	83 (4.7%)
Smoking		
Current	867 (8.6%)	893 (8.0%)
Former	196 (1.9%)	255 (2.3%)
TB treatment		
Previous TB treatment	334 (3.3%)	370 (3.3%)
Currently on TB treatment	74 (0.7%)	65 (0.6%)
Number of household members with TB in past 2 years		
None	8,775 (86.9%)	10,036 (89.5%)
1	1,102 (10.9%)	891 (8.8%)
≥2 years	215 (2.1%)	194 (1.7%)
Education level		
None or primary	1,644 (16.3%)	1,543 (13.8%)
1-2 years secondary	1,040 (10.3%)	1,051 (9.4%)
3-6 years secondary	6,956 (69.0%)	7,868 (70.3%)
Higher level	446 (4.4%)	730 (6.5%)

a. Answered symptom questionnaire and, irrespective of symptoms, provided sputum for culture. Includes 31 and 29 participants in pre- and end- surveys who consented to provide sputum specimens, but were asymptomatic and unable to expectorate and so are assumed to be culture-negative.

b. Two participants tested for HIV had indeterminate infection status.