PAPER III
Tuberculosis case-finding through a village outreach programme in a rural setting in southern Ethiopia: community randomized trial

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Objective To ascertain whether case-finding through community outreach in a rural setting has an effect on case-notification rate, symptom duration, and treatment outcome of smear-positive tuberculosis (TB).

Methods We randomly allocated 32 rural communities to intervention or control groups. In intervention communities, health workers from seven health centres held monthly diagnostic outreach clinics at which they obtained sputum samples for sputum microscopy from symptomatic TB suspects. In addition, trained community promoters distributed leaflets and discussed symptoms of TB during house visits and at popular gatherings. Symptomatic individuals were encouraged to visit the outreach team or a nearby health facility. In control communities, cases were detected through passive case-finding among symptomatic suspects reporting to health facilities. Smear-positive TB patients from the intervention and control communities diagnosed during the study period were prospectively enrolled.

Findings In the 1-year study period, 159 and 221 cases of smear-positive TB were detected in the intervention and control groups, respectively. Case-notification rates in all age groups were 124.6/10^5 and 98.1/10^5 person-years, respectively (P = 0.12). The corresponding rates in adults older than 14 years were 207/10^5 and 158/10^5 person-years, respectively (P = 0.09). The proportion of patients with >3 months’ symptom duration was 41% in the intervention group compared with 63% in the control group (P<0.001). Pre-treatment symptom duration in the intervention group fell by 55–60% compared with 3–20% in the control group. In the intervention and control groups, 81% and 75%, respectively of patients successfully completed treatment (P = 0.12).

Conclusion The intervention was effective in improving the speed but not the extent of case finding for smear-positive TB in this setting. Both groups had comparable treatment outcomes.

Keywords Tuberculosis - prevention and control; Disease notification; Tuberculosis - diagnosis; Ethiopia (source: MeSH, NLM).

Mots clés Tuberculose - prévention et contrôle; Notification maladie; Tuberculose - diagnostic; Ethiopie (source: MeSH, INSERM).

Palabras clave Tuberculosis - prevención y control; Notificación de enfermedad; Tuberculosis - diagnóstico; Etiopía (fuente: DeCS, BIREME).

Introduction A successful tuberculosis (TB) control programme should be able to answer three key questions: what proportion of cases has been identified? How quickly have cases been identified? And what proportion of patients has successfully completed treatment? Case-finding, an important element of the DOTS strategy, is influenced by individual (care-seeking behaviour), social (access to health care), and biomedical (diagnostic capability) factors. Improved diagnostic setting (better diagnostic tests and well trained staff) and procedures may yield little increase in case-finding without mechanisms to improve access to these services.

Case-finding in most TB programmes is less than the global target of 70%. In the developing world, many people with TB live and die without the disease ever being diagnosed, or face delay in diagnosis and treatment. Studies from sub-Saharan Africa have reported delays in case-finding ranging from 50 to 180 days.

Early detection is key in reducing the duration of infectivity and thus the transmission of bacilli. Intensified case-finding among household members of infectious TB cases is an effective approach. However, in areas with high TB incidence, the principal source of infection may be contacts outside the household, thus a broader perspective is needed to improve case-finding in such communities.

In Ethiopia, which ranks 7th of 22 countries with a high burden of TB, many patients live far from health facilities and usually present very late for investigation and treatment. The
government has launched a community-centred health service initiative, a health extension package that emphasises disease prevention and health promotion. Health extension agents — well trained and well paid community health workers — are key elements in this initiative. How best to coordinate health facility and community-based activities for effective control of diseases such as TB, malaria, and waterborne diseases needs to be assessed.

We aimed to ascertain whether case-finding through a community outreach programme has an effect on case-notification rate (CNR), pre-treatment symptom duration, and treatment outcome of smear-positive pulmonary TB in rural Ethiopia.

Methods

Study population

The study was conducted in Lemo and Misha woredas (rural districts) of Hadiya zone in southern Ethiopia (Fig. 1) in 2003–04. Five health centres and seven health stations served the two districts; 55% of the population lived within 2 hours’ walk of a health facility. The health facilities were distributed equally across the study districts; seven were able to do sputum microscopy for acid-fast bacilli (AFB). TB patients were diagnosed and treated under the DOTS programme.

There were 87 rural kebeles (lowest-level administrative units) in the two districts. We clustered these into 32 communities, with an average cluster size of 11 000 people. The community was our unit of randomization and analysis since we aimed to assess the effect of the intervention at the community level.

Intervention

Before launching the intervention programme, we discussed the objectives and procedures of the programme with the local government and community leaders in the intervention areas. The zonal TB programme office identified 14 health workers (12 nurses and two health officers) from the seven health facilities with AFB microscopy. The health workers received 4 days of training on case-finding, diagnostic procedures, outreach coordination, handling of sputum specimens, interview techniques, and record-keeping. The outcome measures of the study were not disclosed to the health workers to reduce measurement bias during interviews or outcome assessment.

In consultation with the diagnostic centres, we identified ten community promoters: six had primary and four had secondary education. The promoters, all with previous experience in community outreach activities such as child-immunization and community-based distribution of contraceptives, received 4 days of training on basic facts about TB: its cause, transmission, symptoms, diagnosis, prevention, treatment, and outcomes. They also received training on societal perceptions about TB, on how to identify and refer a symptomatic TB suspect, and on how to communicate basic and locally understandable messages about TB. The community promoters were provided with leaflets and posters from the regional TB control programme and were assigned to the intervention communities. The leaflets described the cause, transmission, and main symptoms of TB, and contained the information that TB is curable with proper treatment.

The community promoters held discussions with community leaders to establish a suitable monthly date for the diagnostic outreach clinic in each kebele. Every month, before the outreach day, the promoters went around the villages for 3–4 consecutive days visiting houses, distributing TB leaflets, and discussing the possible symptoms of TB with individuals, households, and community groups. They also promoted messages about TB in schools and popular gatherings in the intervention areas. They encouraged symptomatic TB suspects to visit the outreach team or a nearby health facility if preferred.

Fig. 1. Map of the study communities, Hadiya, southern Ethiopia

SNNPR = Southern Nations, Nationalities and Peoples Region.

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.
The health workers made monthly outreach visits to each intervention kebele. Symptomatic TB suspects submitted the first spot sputum specimen at the outreach site. Specimens collected at outreach sites were coded and transported in an icebox to a diagnostic centre. The early-morning and second spot specimens were collected at the diagnostic centre the next day. All confirmed cases of smear-positive TB received free treatment at the diagnostic centre or at the nearest treatment centre preferred by the patient. Smear-negative symptomatic individuals were advised to seek further medical attention if their symptoms persisted. Each outreach site kept a logbook to record the number of suspects, the number that gave sputum for examination, and the number with a positive smear.

The intervention programme was implemented from 1 May 2003 to 30 April 2004. In the control communities, cases were detected through passive case-finding among symptomatic suspects reporting to health facilities. New smear-positive TB patients residing in the intervention and control communities and diagnosed during this period were prospectively enrolled in the study. Health workers obtained data from patients on social and demographic background, place of residence, mode of referral (self-referred versus diagnosed through community outreach) and pre-treatment symptom duration.

**Outcome measures**

Patients were followed up throughout treatment, and outcomes were recorded. Follow up was completed in November 2004. Primary outcome measures were CNR, pre-treatment symptom duration, and treatment outcome (success, default, death). Treatment success was defined as cure (smear-negative at treatment completion and on at least one previous occasion) plus treatment completion without confirmation by smear-microscopy. Default was defined as treatment interruption for more than 8 consecutive weeks after a minimum of 4 weeks on treatment. Treatment failure was defined as remaining or becoming smear-positive again at 5 months or later during treatment.

**Sample size**

The sample size calculation was based on the coefficient of variation among communities (K), study power, cluster size, and expected outcome. With the community as the unit of analysis, we calculated that with ten communities per group we could detect a 50% increase in CNR based on an average annual rate of 99.2 per 105 during 1997–2001 and 90% power; and a 50% reduction in the proportion of patients with pre-treatment symptom duration of >3 months based on an estimated delay beyond 3 months of 60%.

The sample size for case notification was calculated for a population of 7500 people per community. Since there were no data available on between-community variation in the rates, we estimated K to be 0.25. For pre-treatment symptom duration and treatment outcome, the calculation was based on an estimated ten smear-positive TB patients per community. We increased the number of intervention communities by one-fifth to account for possible loss to follow up, and doubled the number of control communities to include all communities in the study districts to increase the power of the study.

**Analysis**

Data were processed and analysed using SPSS for Windows version 12.0.1 (SPSS Inc., Chicago, IL, 2003) and Microsoft Excel. We analysed the data on the basis that all symptomatic TB suspects in the intervention communities intended to use the community outreach services. With the community as the unit of analysis, weighted means of CNR, percentage of patients symptomatic for >3 months, median duration of illness, and treatment outcome (success, default, death) were compared using independent sample t-test and Mann-Whitney U test.

The intra-cluster correlation coefficient (ICC) for each variable was calculated from the output of one-way analysis of variance (ANOVA) using the method suggested for estimating ICC from more than one group and that for binary outcome variables.

The study was approved by the Regional Committee for Medical Research Ethics in Western Norway (REK Vest) and the Ethics Committee of Southern Nations, Nationalities and Peoples’ Regional State Health Bureau in Ethiopia.

**Results**

Fig. 2 shows the flow of communities and individuals through the study. The 2003 mid-year population of the 32 study communities was 352 891, of which 127 607 were in the intervention group. During the 1-year intervention period, 159 and 221 cases of smear-positive TB were detected in the intervention and control groups, respectively. The communities and individual patients in both groups had similar baseline characteristics; no differences were significant (Table 1).

Table 2 shows primary outcome measures. The CNR in intervention communities was 27% higher than in control communities: 125 compared with 98 per...
The rate among adults older than 14 years was 31% higher in intervention than control communities: 207 compared with 158 per 10\(^5\) person-years. However, neither of these increases was significant (Table 2).

The proportion of patients with >3 months’ symptom duration was 41% in intervention and 63% in control communities; a 35% reduction in delay beyond 3 months. There was a significant difference in the weighted mean of median pre-treatment symptom duration between the intervention (89 days) and control (136 days) communities (Table 2).

During the 1st quarter of the intervention (1 May 2003 to 31 July 2003), the average median duration of pre-treatment symptom duration was similar in both groups (Table 2). However, in the remaining three quarters, the symptom duration in the intervention group fell by 55–60% compared with 3–20% in the control group. The differences in the weighted mean duration between the intervention and control communities during the 2nd, 3rd, and 4th quarters of the intervention were all significant (Table 2). The difference remained when we compared the geometric means for the log-transformed pre-treatment symptom duration (94 versus 123 days; effect size = 0.76 (95% confidence interval = 0.63–0.93; \(P = 0.001\)).

Treatment success in the intervention communities was 128/159 (81%) compared with 165/221 (75%) in the control communities (Table 2). In the intervention group, 26 of 159 (16%) defaulted compared with 48 of 221 (22%) in the control group defaulted from treatment. One patient in the control group had treatment failure. Five of 159 (3.1%) patients died in the intervention group; seven of 221 (3.2%) died in the control group. None of these differences was significant.

### Discussion

Our results show that case-finding through community outreach improved the speed, but not the extent, of case-finding for smear-positive TB. Although the CNR among adults in the intervention communities was one-third higher than in the control communities, this increase was not statistically significant (\(P = 0.09\)), possibly due to inadequate power to detect the effect. Another explanation is that the intervention did not have an effect on case-finding and that the observed difference is purely the role of chance.

The average CNR of smear-positive TB among all age groups in the study area during 1997–2001 (after the introduction of DOTS) was 99.2 per 10\(^5\), which is similar to the CNR of 98.1 in the control group.\(^{23}\) The estimated incidence of new smear-positive TB in 2003 in the country was 155 per 10\(^5\).\(^{16}\)

A more interesting finding is the reduction in pre-treatment symptom duration in the intervention communities after the 1st quarter of the intervention programme. Duration in the 2nd, 3rd, and 4th quarters was one-third to half that of the 1st quarter. With a monthly outreach clinic and continuous mobilization by the community promoters it was possible to reduce delay in TB diagnosis by at least half. The symptom duration in the control group showed little variation over the year.

A weakness of cluster-randomized allocation that does not allow for stratification or matching is that if the clusters are few, they tend to be distributed among the groups in an unbalanced manner with regard to baseline characteristics. In our study, the number of clusters was large enough for unrestricted randomization, and both groups had comparable baseline characteristics. In addition, to minimize measurement errors, questionnaires were standardized and pre-tested, and interviewers received training and were not told the expected outcome measures to avoid measurement bias.

TB patients from the intervention communities had comparable treatment outcomes (slightly higher treatment success and slightly lower default rate) with the control communities. Patients detected by community surveys might be less symptomatic, less infectious, and more reluctant to start or complete treatment.\(^{26}\) Patients detected through community outreach in our study were, however, symptomatic and infectious cases, and the findings were consistent with those of other studies. Chowdhury and colleagues reported that a successful TB control programme by community health workers in Bangladesh improved case-finding and treatment compliance.\(^{29}\) A similar achievement was reported from the Philippines.\(^{35}\) However, no data have
so far has been published on the effect of such interventions on pre-treatment symptom duration.

In the 1960s and 1970s, periodic symptomatic case-screening and use of mass, miniature radiography as means of active case-finding were reported to be less effective than expected in middle- and high-income settings.\(^{30–34}\) Further, it has been concluded that 90% of smear-positive TB cases happen to be symptomatic and most seek treatment from health services.\(^{35}\) Conversely, studies from Kenya on alternative approaches to improving case-finding identified many untreated smear-positive TB cases.\(^{36–40}\) Yet there appears to be no consensus on the role of active case-finding in low-income settings. Some disparage it for increasing the workload and cost of health services, while others believe it is highly cost-effective in countries with high prevalence, low case-finding, and moderate-to-high treatment completion.\(^{41}\) Nevertheless, all agree that current trends in case detection are less than satisfactory and need to be improved.\(^{1,2}\)

Our intervention could be classed as a variation of active case-finding. It did not involve house-to-house symptomatic screening; instead, symptomatic patients reported to community diagnostic outreach sites. However, it included regular house visits by community promoters to encourage symptomatic suspects to see a health provider. Furthermore, it involved a monthly outreach clinic by health workers to bring the service nearer to patients. Our use of symptom inquiry and sputum microscopy has been reported to be highly efficient in the detection of infectious TB cases.\(^{42,43}\)

Although our study had a remote, rural setting, most smear-positive TB patients sought medical care from a public health service at one point in the course of their illness. The most important effect of poor access to health-care services was an unacceptably long delay before diagnosis and treatment. Half the population had to travel for more than 2 hours to obtain care in a public health facility. Private clinics are scarce, and delays in diagnosis and treatment occur while seeking care from alternative providers such as traditional healers.

In an effort to reduce the access gap, the government has started a new community-based initiative called the “health extension package”. Thousands of health extension agents have been identified and trained and might help to enhance TB case-finding and case-holding under the DOTS programme in the region.

The general applicability of our results is uncertain. Our approach could be tried in other settings with poor access to health services where TB is a real public-health concern, case detection is low, there are considerable delays in diagnosis, treatment completion is above 70%, and there are established voluntary or paid community health workers. Furthermore, despite a notable difference

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<p>| Table 2. Case notification rate (CNR), pre-treatment symptom duration, and treatment outcome |
|-----------------------------------|-----------------|-----------------|-----------------|-----------------|</p>
<table>
<thead>
<tr>
<th></th>
<th>Weighted mean(^a)</th>
<th></th>
<th>Difference (95% CI)(^b)</th>
<th>(P^c)</th>
<th>Intraclass correlation coefficient(^d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNR per 10(^5) person-years (all)</td>
<td>125 (159/127 607)</td>
<td>98 (221/225 284)</td>
<td>27 (–19 to 72)</td>
<td>0.12</td>
<td>0.00027(^*)</td>
</tr>
<tr>
<td>CNR per 10(^5) person-years (adults &gt; 14 years)</td>
<td>207 (153/74 012)</td>
<td>158 (207/130 665)</td>
<td>49 (–27 to 123)</td>
<td>0.09</td>
<td>0.00042(^*)</td>
</tr>
<tr>
<td>Proportion (%) per quarter of intervention duration symptomatic for &gt;3 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st quarter</td>
<td>58</td>
<td>59</td>
<td>–1 (–19 to 16)</td>
<td>0.44</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>2nd quarter</td>
<td>24</td>
<td>60</td>
<td>–36 (–59 to –12)</td>
<td>0.002</td>
<td>0.00027(^*)</td>
</tr>
<tr>
<td>3rd quarter</td>
<td>34</td>
<td>75</td>
<td>–41 (–57 to –23)</td>
<td>&lt;0.001</td>
<td>0.00027(^*)</td>
</tr>
<tr>
<td>4th quarter</td>
<td>38</td>
<td>62</td>
<td>–24 (–41 to –6)</td>
<td>0.005</td>
<td>0.00027(^*)</td>
</tr>
<tr>
<td>Total</td>
<td>41</td>
<td>63</td>
<td>–22 (–32 to –12)</td>
<td>&lt;0.001</td>
<td>0.00027(^*)</td>
</tr>
<tr>
<td>Median symptom duration (days) per quarter of intervention duration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st quarter</td>
<td>183</td>
<td>157</td>
<td>26 (–48 to 99)</td>
<td>0.24</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>2nd quarter</td>
<td>71</td>
<td>136</td>
<td>–65 (–104 to –26)</td>
<td>0.001</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>3rd quarter</td>
<td>78</td>
<td>152</td>
<td>–74 (–101 to –46)</td>
<td>&lt;0.001</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>4th quarter</td>
<td>83</td>
<td>123</td>
<td>–40 (–73 to –8)</td>
<td>0.009</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>Total</td>
<td>89</td>
<td>136</td>
<td>–47 (–76 to –19)</td>
<td>0.001</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>Treatment outcome</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment success (%)</td>
<td>81</td>
<td>75</td>
<td>6 (–4 to 15)</td>
<td>0.12</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>Treatment default (%)</td>
<td>16</td>
<td>22</td>
<td>–6 (–14 to 3)</td>
<td>0.11</td>
<td>0.000027(^*)</td>
</tr>
<tr>
<td>Death (%)</td>
<td>3.1</td>
<td>3.2</td>
<td>–0.1 (–4 to 4)</td>
<td>0.49</td>
<td>0.000027(^*)</td>
</tr>
</tbody>
</table>

\(^a\) Weighted by the number of cases in each community.  
\(^b\) Confidence interval.  
\(^c\) Independent sample t-test.  
\(^d\) Using analysis of variance model.  
\(^e\) From binary data.
that might be important, the increase in CNR was not statistically significant. Larger studies in multiple settings might be helpful in establishing whether such interventions could have a significant effect. Such studies should include cost-effectiveness analysis and baseline CNRs in order to measure an independent effect of the intervention.

Acknowledgements
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Competing interests: none declared.

Résumé
Recherche des cas de tuberculose grâce à un programme à grand rayon d’action, visant à atteindre les villages d’une zone rurale du Sud de l’Éthiopie : essai randomisé en communauté

Objectif Déterminer l’effet d’une recherche des cas reposant sur une action communautaire de proximité en zone rurale sur le taux de notification des cas, la durée des symptômes et l’issue du traitement de la tuberculose (TB) à frottis positif.

Méthodes 32 communautés rurales ont été affectées au hasard dans des groupes d’intervention ou des groupes témoins. Dans les communautés bénéficiaires de l’intervention, des soignants appartenant à sept centres de santé ont tenu une fois par mois des dispensaires de proximité pour le diagnostic de la TB, dans lesquels ils ont recueilli des échantillons d’expectoration chez des personnes suspects de TB symptomatiques. En outre, des membres de la communauté formés aux activités de promotion ont distribué des dépliants et évoqué les symptômes de la tuberculose à l’occasion de visites à domicile et de rassemblements populaires. Les individus symptomatiques ont été incités à consulter l’équipe de diagnostic sur le terrain ou à se rendre dans une installation de santé de proximité. Dans les communautés témoins, on a déterminé un certain nombre de cas par recherche passive parmi les suspects de TB symptomatiques s’étant présentés dans des installations de santé. Les membres des communautés bénéficiaires de l’intervention et des communautés témoins chez lesquels on avait diagnostiqué une TB à frottis positif au cours de la période étudiée ont été recruts prospectivement dans l’étude.

Résultats Pendant la période étudiée d’un an, 159 et 221 cas de TB à frottis positif ont été détectés respectivement dans les groupes d’intervention et dans les groupes témoins. Les taux de notification des cas dans l’ensemble des tranches d’âge étaient respectivement de 124,6/105 et de 98,1/105 personnes-années (p = 0,12). Les taux correspondants chez les individus de plus de 14 ans étaient respectivement de 207/105 et de 158/105 personnes-années (p = 0,09). La proportion de malades présentant des symptômes sur une durée supérieure à 3 mois était de 41 % dans le groupe d’intervention, contre 63 % dans le groupe témoin (p < 0,001). Dans le groupe d’intervention, la durée des symptômes pendant la phase préliminaire du traitement avait baissé de 55 à 60 %, tandis qu’elle avait diminué de 3 à 20 % pour le groupe témoin. La proportion de malades ayant terminé avec succès leur traitement (p = 0,12) était respectivement de 81 % et de 75 % dans les groupes d’intervention et les groupes témoins.

Conclusion Dans la zone étudiée, l’intervention a permis d’améliorer la rapidité de la détection des cas de TB à frottis positif, mais non son amplitude. Le traitement a donné des résultats comparables dans les deux groupes.

Resumen
Detección de casos de tuberculosis mediante un programa de extensión a aldeas en un entorno rural del sur de Étiopía: ensayo comunitario aleatorizado

Objetivo Determinar si la detección de casos mediante actividades de extensión comunitaria en un entorno rural tiene algún efecto en el número de casos notificados, la duración de los síntomas y lo que se logra con el tratamiento (cfr. bacilífera) en condiciones de proximidad.

Métodos Asignamos aleatoriamente a 32 comunidades rurales al grupo de intervención o al de control. En las comunidades objeto de intervención, profesionales sanitarios de siete centros de salud organizaron consultorios de extensión diagnóstica en las comunidades para detectar los casos de TB. Los profesionales de extensión distribuyeron folletos y analizaron los síntomas de TB a lo largo del periodo de estudio. En las comunidades testigo los casos se detectaban de forma pasiva entre las personas sintomáticas que visitaban los centros de salud.

Resultados A lo largo del periodo de estudio, 1 año, se detectaron 159 y 221 casos de tuberculosis bacilífera en los grupos de intervención y control, respectivamente. Las tasas de notificación de casos en todos los grupos de edad fueron de 124,6/105 y 98,1/105 casos por persona-ano, respectivamente (p = 0,12). Las tasas correspondientes en los adultos mayores de 14 años fueron de 207/105 y 158/105 casos por persona-ano (p = 0,09). La proporción de pacientes que arrastraban síntomas desde hacía más de 3 meses fue del 41% en el grupo de intervención, frente al 63% en el grupo control (p < 0,001). La duración de los síntomas antes del comienzo del tratamiento en el grupo de intervención cayó un 55% - 60% en comparación con el 3% - 20% en el grupo control. En los grupos de intervención y de control, un 81% y un 75% de los pacientes, respectivamente, finalizaron satisfactoriamente el tratamiento (p = 0,12).

Conclusión La intervención mejoró eficazmente la rapidez, aunque no el alcance, de la detección de casos de tuberculosis bacilífera en esas circunstancias. Los resultados del tratamiento fueron comparables en los dos grupos.
TB case-finding in southern Ethiopia

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References

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