**A community-based Isoniazid preventive therapy for the prevention of childhood tuberculosis in Ethiopia.**

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**Abstract**

**Background:** Children in contact with adults with tuberculosis should receive Isoniazid preventive therapy (IPT) but this is rarely implemented.

**Aim:** To assess whether a community-based approach providing IPT at household level improves uptake and adherence in Ethiopia.

**Methods:** Contacts of adults with smear-positive pulmonary TB (PTB+) were visited at home and examined by Health Extension Workers (HEWs). Asymptomatic children <5 years were offered IPT and followed monthly.

**Results:** 5,345 (87%) of 6,161 PTB+ cases identified by the HEWs in the community were visited, identifying 24,267 contacts. 7,226 (29.8%) contacts were children <15 and 3,102 (12.7%) of them were <5 years old. 2,949 contacts had symptoms of TB and 1,336 submitted sputum for examination. 92 (6.9%) had PTB+ and 169 all forms of TB. Of 3,027 asymptomatic children, only 1,761 were offered (and accepted) IPT due to isoniazid shortages. Of these, 1,615 (91.7%) completed the 6-month course. The most frequent reason for discontinuing IPT was also Isoniazid shortages.

**Interpretation:** contact tracing contributed to detection of additional TB cases and provision of IPT for young children. Delivery of IPT in the community alongside community-based TB interventions resulted in better acceptance and improved treatment outcome.

**Key words**: Tuberculosis, children, preventive therapy, Health Extension Workers, Ethiopia

**Introduction**

Children in contact with adults with smear-positive pulmonary Tuberculosis (PTB+) have a high risk of infection and disease progression and contact investigation is critical to diagnose additional cases and to prevent vulnerable individuals from progressing from infection to overt disease. Nearly all National TB Control Programmes (NTP) recognise this risk and recommend screening contacts, especially children, for the presence of symptoms. According to international recommendations, symptomatic contacts should be investigated for active TB, while asymptomatic children < 5 years old should receive isoniazid preventive therapy (IPT) [1].

Although IPT reduces the risk of disease progression [1], very few NTPs in Low and Middle Income Countries (LMIC) implement this recommendation [2, 3]. This is because Isoniazid is often unavailable; staff have the perception that the risk of disease progression is low, that mono-therapy promotes the risk of drug resistance if active TB is not excluded and reluctance to take on additional work [4, 5]. Parents are also reluctant to give pills to their asymptomatic children and adhere poorly to the 6-month course [3, 6, 7].

We have implemented a novel community-based approach to enhance TB case finding and treatment outcome in southern Ethiopia since 2010. The project trains female Health Extension Workers (HEWs) to identify individuals with symptoms of TB, collect sputum specimens and prepare and fix smears for examination in kebeles (equivalent to a village with an average population of five thousand people) [8]. HEWs are supported by supervisors who transport the smears to the nearest diagnostic laboratory and bring the drugs to initiate treatment at home or at the kebele health post. Contacts of adult TB cases are supposed to be screened for TB. However, as it was unlikely contacts would attend the health facilities or bring their children for screening [8], we initiated contact tracing and the provision of IPT in the community through the HEWs. We report the acceptability of and adherence to IPT of children in contact with adults with PTB+ identified and managed in the community by the HEWs.

**Methods**This was a prospective community-based cohort study of individuals residing in the household of adults who had been diagnosed with PTB+ in Sidama Zone, in the Southern Nations Nationalities and Peoples’ Regional State (SNNPR) of Ethiopia. The project covered the entire zone, which has a population of 3.2 million residing in 19 rural districts and two town administrations. In the zone, three hospitals and 104 health centres provide health services to 524 rural and 39 urban *kebeles*  [9]. The project was implemented within the Ethiopian Health Extension Programme (HEP), which provides health services at village level since 2003. The HEP trains women who have completed secondary education for one year and HEWs are salaried cadres responsible for routinely conducting household visits to implement 16 basic health packages [10].

Adults with PTB+ reported here were diagnosed between May 2011 and March 2013, as previously described. Briefly, individuals with cough of two weeks or more were identified by the HEWs during routine household visits. Symptomatic individuals were requested to provide two sputum specimens over two consecutive days. Smears were prepared and fixed by the HEWs and were transported by supervisors to the nearest laboratory. If the smear was positive, the supervisor brought anti-TB drugs to the village and initiated treatment at home or at the health post, depending on the patient’s preference [8].

All household members were considered contacts of the index case. The index cases were asked to list the household members and their age at the time the supervisor or HEW visited the household to disclose the diagnosis of PTB+ and initiate treatment. This list was used to ask for the presence of symptoms suggestive of TB among contacts. Houses of index cases reporting symptomatic household contacts not present at the time of the first visit were revisited to examine the contacts. However, asymptomatic contacts absent from the household at the time of preparing the list were not systematically revisited.

Presumptive cases among contacts were defined as individuals who reported to have cough of two weeks or more with or without chest pain, shortness of breath, fever, weight loss, failure to thrive or night sweats. Presumptive cases able to expectorate were requested to submit sputum specimens. Children unable to produce sputum were referred to the nearest health facilities for further clinical examination and chest x-rays. Transport subsidies were provided, as needed, for household members who could not afford to travel to ensure they were able to access the services. TB cases diagnosed among symptomatic contacts were provided treatment in the same manner as the index cases. Children considered to have other infections were given broad spectrum antibiotics and were followed by the health facilities.

Asymptomatic children under 5 years of age were offered 6-month Isoniazid at a dose of 5 mg per Kg daily. Children were not tested with the Tuberculin Skin Test or Interferon-Gamma Release Assays, as these are not locally available and are not indicated by the Ethiopian TB guidelines [10]. Parents and guardians of the children were instructed to break the tablets into two (or four) pieces to provide the most approximate dose possible. Parents of children < 2 years old or unable to swallow tablets were advised to crush the pieces into a powder. Parents were advised on the symptoms of TB, the importance, purpose and side effects of IPT and to seek the HEWs advice if the child developed symptoms or side effects. Adult contacts received health education about TB, its transmission, symptoms and what to do if symptoms developed in the future.

Index cases receiving anti-TB drugs and children receiving IPT were followed by the HEWs and volunteer TB treatment supporters. Follow up was conducted by monthly home visits or at the health post, at the same time the index case was receiving anti-TB treatment. During each visit parents/guardians were asked by the HEWs about the presence of symptoms, adverse effects and compliance. The parents of children with minor side effects were advised to continue the IPT and to immediately report any changes. Children with major IPT side effects or TB symptoms were told to discontinue IPT and were referred to the nearest hospital, where they were investigated and monitored. Refusal to accept IPT was defined as a parent refusing to initiate IPT. IPT ‘’discontinuation’’ was defined as a child initiating IPT but stopping the medication for more than 2 continuous months in the absence of side effects or medical advice.

Parents or guardians were informed about the importance of IPT and adherence and children took their medication under their supervision. Parents or guardians visited the local health posts for refills and discussed any concerns with HEWs or supervisors about the medication, side effects and TB related symptoms. Monthly meetings between HEWs, supervisors and health centre staff were held to discuss progress in implementation of IPT in the community. Children receiving IPT were registered in health post IPT registers and data were updated monthly and at the time of drug refills.

Semi structured questionnaires were used for symptom screening among household contacts. TB and IPT registers were used to collect data related to diagnosis for active TB and IPT outcomes. Questionnaires were checked for completeness and consistency and data was entered by a data officer into Excel and exported to SPSS for Windows 20. The main outcomes of the study were the number of children who completed 6-month IPT and the number who discontinued or were lost to follow up. Secondary outcomes were the number of children initiating ITP who developed minor and major side effects and the number of children diagnosed to have TB or who died during the 6-month follow up. We conducted a univariate analysis for categorical variables. P-value less than 0.05 was considered statistically significant. Children under 5 were categorized by age group to identify risk factors for IPT discontinuation.

The Federal Ministry of Health of Ethiopia and the Southern Regional Health Bureau provided written support for the implementation of the study. The study protocol was submitted for consideration to the Liverpool School of Tropical Medicine Ethics Committee. The Committee waived the need to obtain ethical approval as it considered the project was implementing an internationally accepted treatment. Parents were informed that the service was part of the National TB Guidelines and were informed that data monitoring was required to document the proportion of children who completed the treatment.

**Results**A total of 10,066 PTB+ cases were reported from Sidama zone from November 2010 to March 2013. Of these, 6,161 (61%) had been identified by the HEWs. Contact tracing was mostly conducted for the index cases identified by the HEWs. A total of 5,345 index cases (53%) had their contacts enumerated, generating a list of 24,267 household contacts. Of these, 7,226 (29.8%) were children <15 years old, including 3,102 (12.7%) children < 5 years old. A total of 2,949 (12.2%) of the 24,267 contacts had symptoms of TB (including 523 [7.2%] of 7,226 children <15 and 75 [2.4%] of 3,102 children <5 years old). Forty-five percent (1,336) of the 2,949 symptomatic contacts submitted sputum for examination.

Ninety-two (6.9% of 1336 symptomatic contacts with smear examinations) had smear-positive TB and 169 (12.7%) had all forms of TB, as shown in Table 1. The median age of the 75 symptomatic children under 5 years old was 39 (range 1 - 72) months compared to 47 months for the 1730 asymptomatic children under 5 (31 had missing age).

 Only 472 (93.4%) of the 523 symptomatic children under 15 examined had symptoms recorded, compared to 100% of the 864 symptomatic adults examined. The commonest symptoms identified in these children were cough (66.3%), fever (63.8%), shortness of breath (55.7%) and constitutional symptoms including night sweats, loss of appetite and weight loss. Only a few children had haemoptysis. These frequencies were similar to those recorded among symptomatic adults, except cough, which was more common among adults (p<0.01, table 2).

There were 3,027 asymptomatic children < 5 years old who were eligible for IPT. Of these, 1,761 (58%) were offered IPT (888 [50.4%] male, 867 [49.4%] female and sex was missing in 6). The remaining 1,266 (42% of the 3,027 eligible) were not offered IPT due to shortage of Isoniazid. All parents offered IPT accepted the therapy.

In total 1574 (89.3%) completed the 6-month course (table 3). Infants appeared to be more likely to discontinue IPT than 1-2 year and 3-5 year old children (89.0 versus 90.8% and 92.1%, respectively) and to do so within one month of prophylaxis initiation. However, frequencies are small and do not reach statistical significance. The proportion of children adhering to IPT at monthly intervals by age is shown in figure 1 (age missing in 103 children). The most frequent reasons for discontinuing IPT were Isoniazid shortages (N=133), the death of a parent or the index case (N=4) and side effects (N=3). The characteristics of the children completing or discontinuing IPT and those who became symptomatic during follow up are shown in Table 4. The main side effects of IPT reported included nausea and vomiting, which resolved spontaneously. One child developed symptoms compatible with hepatitis and required hospitalisation. As the hospitals do not have diagnostic capacity to exclude other common causes of jaundice such as viral hepatitis, IPT was discontinued in this child as a precaution. A further 6 developed symptoms compatible with TB, and underwent chest x-ray examinations. Three (0.17 %) were diagnosed as having TB and 3 (0.17 %) died from other medical illnesses (two were malnourished children and were considered to have sepsis and one, whose parents had HIV, developed abdominal distension and severe oedema.

**Discussion**Despite the universal recognition of the value of the systematic screening and provision of IPT for children in contact with adults with TB [11-14], very few NTPs in LMICs implement this service at health facility level [12, 15, 16] and even fewer programmes are able to provide the service at the community level in poor, remote and rural communities. The reasons for not implementing contact investigation and IPT range from lack of prioritization by TB programmes, logistic problems to secure Isoniazid supplies, the time required to initiate and monitor IPT, staff perception that the risk of disease progression is minimal and the risk of developing drug resistance [12, 17-20].

We report here our experience implementing IPT for children at the community level within the framework of the HEWs of the Ethiopian Health Extension Programme. Children and adults exposed to adults with pulmonary TB were visited at home and questioned for the presence of symptoms and symptomatic individuals were asked to provide sputum samples. Of the 7,226 children less than 15 years old, 523 were reported to be symptomatic and 35 had TB. All parents with children <5 visited by the HEWs who were offered IPT accepted the therapy and attained high adherence, with over 90% of the children completing the 6-month course. Despite the acceptability of the approach, an important shortcoming of the intervention was that, despite a close partnership with the TB programme, we faced major logistic problems for the procurement of isoniazid. Before the intervention, the TB programme had only implemented IPT at health facility level and on a small scale and the relatively large scale of our project led to major national procurement problems. The government also requested to register the child by proxy at the nearest health centre before the isoniazid was released. These resulted in bottlenecks and a protracted process to release the drugs to the community, which took several months to resolve.

Our study has methodological limitations that need to be explicit to facilitate interpretation. The intervention was conducted under operational conditions, with the purpose of developing a system to provide TB services close to the community. As such, we were limited by the amount of information that could be collected to avoid overburdening the system. We were unable to obtain sputum from about 55% of contacts who initially reported having symptoms. This was due to contacts being unable to expectorate, having no cough, or symptoms resolving before the HEW had examined them. Furthermore, children unable to expectorate were referred for chest radiography, but not all parents were able to attend the clinic and some TB cases were likely missed. A further limitation is the underrepresentation of selected age groups, as only 29.8% of the contacts identified were children. This is in contrast to the national population statistics that estimate that 44% of the population is <15 years old. Their deficit may reflect the working pattern of the HEWs, as household visits were conducted during working hours, and children may have been missing due to their behaviour patterns, such as herding and school activities. Finally, child friendly formulations, as recently developed, would have simplified the delivery of prophylaxis, but these were not available at the time of the study [21]. The INH dose used (5 mg/Kg) might have also been too low, as the WHO increased the recommended dose to 7-10 mg/Kg after the study had been implemented for 2 years.

Despite these limitations, the approach presented here suggests that partnership with HEWs to provide community-based screening of contacts and provision of IPT can achieve a high degree of acceptance and adherence. To our knowledge, this is the highest adherence level ever reported from this continent [22, 23] suggesting that a large component of the lack of acceptability and adherence reported by most studies may be the poor accessibility of the service.

Although these results are encouraging, a major precondition to the provision of the service without incurring major health service expenses was the availability of community-based services with the deployment of multi-purpose HEWs at the village level. As these cadres are selected from and by the community, they are likely to remain in the village and have trusting relationships with the community. Several evaluations of the programme have demonstrated their impact in other health areas [24, 25], and the acceptability of the TB packages.[26] A further constraint is the inherent ineffectiveness of contact investigation as a method of early detection of TB cases, as secondary TB cases typically develop after a lag-time of several weeks in the first 2 years after infection. Thus asymptomatic contacts could develop TB at a later time, and less secondary cases will be detected if contacts are only interviewed for symptoms immediately after the diagnosis of the index case. Furthermore, symptom-based screening can miss many TB cases, as it is increasingly recognised that this method has poor sensitivity. Consequently, children receiving IPT may be re-exposed to TB when older members of the household develop TB and parents need to be aware of the need to maintain vigilance for symptoms for a long time.

We had reported earlier that very few children in contact with adult TB cases initiating IPT completed the 6-month prophylaxis in the SNNPR [22] and that adherence was poor, with very few parents continuing beyond the first few weeks. Contact investigations at health facilities are often conducted days or weeks, after initiation of treatment of the index case and once the therapy is established. This delay separates the processes of treating the patient and preventing further disease in the family, potentially contributing to lower IPT uptake and adherence. In this study, we have observed that initiating TB treatment and IPT together creates a better mind imprint of the importance of adherence and that it is convenient for the parents to collect the drugs at the same time of receiving treatment. This temporal association could be one of the reasons for the high adherence rates attained, alongside the client-friendly characteristics of the community-based approach implemented, but we are unable to separate these factors.

In conclusion, this innovative intervention demonstrates that implementing a community-based contact tracing and provision of IPT for children is feasible under programme settings and can attain high adherence and completion rate in Ethiopian context.

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Table 1. The yield of household contacts screening and IPT provision in southern Ethiopia.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Age (in years) | All household members | Contacts with symptoms | Symptomatic contacts examined 2 | Children examined who initiated IPT | Smear-positive TB | All forms of TB5 |
| 0 – 4 | 3,102 | 75 (2.4%1) | 74 (98.7%3) | 1,761 (58.2%4) | 4 (5.4%) | 8 (10.8%) |
| 5 – 14 | 4,124 | 448 (10.9%) | 431 (96%) | NA | 19 (4%) | 27 (6.3%) |
| ≥ 15 | 17,041 | 2,426 (14.2%) | 864 (35.6%) | NA | 69 (8%) | 134 (15.5%) |
| Total | 24,267 | 2,949 (12.2%) | 1,336 (45.3%) | NA | 92 (6.9%) | 169 (12.7%) |

1 Percentage of contacts with symptoms among all household members of the specific age group.

2 Number examined at the time of the household visits who submitted sputum.

3 Percentage of contacts with symptoms who were examined

4 Percentage of children < 5 years oldwhoinitiated IPT

5 Includes smear-negative and extra-pulmonary TB cases diagnosed among the contacts examined.

Table 2. Most frequent symptoms reported among contacts of index pulmonary TB cases who submitted sputum (N = 1336).

|  |  |  |
| --- | --- | --- |
| N = 1336 | < 15 years N= 472 | ≥ 15+ YearsN= 864 |
| Presence of  |  |  |
| Cough  | 313 (66.3%) | 844 (97.6%) |
| Fever | 301 (63.8%) | 562 (65%) |
| Shortness of breath  | 263 (55.7%) | 539 (62.4%) |
| Night sweats  | 226 (47.9%) | 369 (42.7%) |
| Loss of appetite  | 208 (44.1%) | 369 (42.7%) |
| Weight loss  | 168 (35.6%) | 289 (33.4%) |
| Blood in sputum  |  12 (2.5%) |  20 (2.3%) |

Table 3. Characteristics of asymptomatic children < 5 years old who received IPT.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Completed IPT | Discontinued IPT | Treated for TB on follow up | Died |
| All (N=1761)\* |  | N = 1574 | N = 142 | N = 3 | N= 3 |
| Median age (months)  |  | 36 (1 -60) | 48 (2-60) | 24 (9.6-48) | 9.6 (1-54) |
| Age group (years)\* |  |  |  |  |  |
| < 1  | N = 164 | 146 (89.0 %) | 15 (9.1 %) | 1 (0.6%) | 2 (1.2%) |
| 1 to 2  | N = 263 | 239 (90.8 %) | 24 (9.1 %) | 0 | 0 |
| 3 to 54  | N = 1190 | 1,096 (92.1 %) | 93 (7.8 %) | 0  | 1 (0.8%) |
|  Male: Female (% male)\*\*\* |  |  802:766 (51.1 %) **\*\*** | 58:84 (40.8%) | 0:3 (0%) | 1:2 (33%) |

\* Outcome missing in 41. \*\*Age missing in 103. \*\*\*Gender missing for 6 children.

Figure 1. Proportion of children who adhered to IPT by age group and month of treatment