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Each year millions of pilgrims perform the annual Hajj from more than 180 countries around the world. This is one of the largest mass gathering events and may result in the occurrence and spread of infectious diseases. As such, there are mandatory vaccinations for the pilgrims such as meningococcal vaccines....

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8. The Implementation of Early Detection in Tuberculosis Contact Investigation to Improve Case Finding

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The Roll-out of Child-friendly Fixed-dose Combination TB Formulations in High-TB-Burden Countries: A Case Study of STEP-TB

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Research Article

The Implementation of Early Detection in Tuberculosis Contact Investigation to Improve Case Finding

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ABSTRACT

The early detection of Tuberculosis (TB) among TB contacts is a strategy to find TB cases in earlier stage and to stop the transmission. This study aimed to assess the implementation of early detection in TB contact investigation to improve TB case finding. This was an operational research study conducted in Badung District, Bali, Indonesia. The samples were TB contacts, identified in the period July through September (third quarter) 2017. Contacts were household members who were living and sharing a room at least for 3 months with infectious TB patients and were not previously diagnosed with TB. Data were collected through face-to-face interview using structured questionnaires and registration reviews using a checklist. We visited 124 TB patients and successfully identified 498 contacts, thus the ratio of contacts to cases is 4:1. All TB contacts were invited to participate in TB screening and evaluation program. A total of 100 (20.1%) contacts have attended at least one examination session and 41 contacts have completed all sessions. Ten TB cases were found among the contacts, of which four of them were adults (three bacteriologically confirmed and one clinically confirmed) and six were children (aged under 15 years). The positivity rate among children was higher (46.2%) compared with adults (14.3%). The positivity rate of confirmed TB among contacts with any TB symptoms was 43.8% and that without symptoms was 12.0%. The contribution of early detection in TB contact investigation to improve TB case finding was 8.1% through all TB patients. The early detection in TB contact investigation yielded additional notified cases, especially among children. A comprehensive education, covering cognitive and psychological aspect, is needed to encourage TB contacts to completely participate in early detection program until their diagnosis is confirmed.

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1. INTRODUCTION

Indonesia is one of the countries with the highest tuberculosis (TB) burden in the world. TB prevalence was estimated at 660 per 100,000 population, which means that there would be more than 1,600,000 people with TB in Indonesia [1]. According to TB global report 2017, the TB incidence rate in Indonesia was 395 per 100,000 population and the mortality rate was 40 per 100,000 per year. The target of TB program in Indonesia is to achieve TB incidence rate of <10 per 100,000 population and mortality rate of <2 per 100,000 population by 2030 [2]. The main strategy of TB program is to prevent its transmission by optimizing case finding and treating people with TB. However, to date, the case finding rate is very low. The national Case Notification Rate (CNR) in 2016 was 128 per 100,000 population). The Case Detection Rate (CDR) was very low at 32% in 2015 and 33% in 2016. In Badung District, the

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TB case finding was lower compared with that of national level. The Badung CNR was 60 per 100,000 population in 2015 and 65 per 100,000 population in 2016. Meanwhile, the CDR was extremely low at 15% in 2015 and 19% in 2016, which were still far lower compared with the national CDR target of 70% [3,4].

The household contacts of TB patients (index case) are at the highest risk for TB infection. Around a quarter (25%) of household contacts have been infected at the time the index case was diagnosed [5]. The TB active case finding program among at-risk population has already been administered based on The Regulation of The Minister of Health Indonesia Number 67 in 2016 as a strategy to improve case finding [6,7]. Active case finding among TB contacts is a systematic, efficient, and effective strategy to look for new TB cases [8], including a home visit in contact investigation. A home visit aims to actively identify TB contacts and to interview them for TB symptom screening [7]. However, screening TB using symptoms, particularly chronic cough to identify presumptive TB cases, may cause missed opportunity. As per the Indonesia

TB prevalence survey in 2014, 42.5% TB cases were found without showing common symptoms (i.e., cough for 2 weeks or longer) [1]. Alternately, chest X-ray examination and other sensitive methods for TB screening are needed to reduce missed opportunities [9]. The chest X-ray examination may be able to find any abnormalities in lung parenchymal that is suggestive of TB as an early detection of presumptive TB cases, especially before symptoms occur.

The Ministry of Health of the Republic of Indonesia has initiated family approach for Healthy Indonesia Program where TB is part of its priority. The main objectives of the family approach in TB program are to increase the coverage of TB services among family members and to involve family members in TB case finding. The family of TB patients should provide support for TB treatments and participate in active TB case finding. All TB household contacts should participate in the TB screening and evaluation at public health centers (PHCs) [10].

The Indonesian National TB Program has been implementing contact investigation, however, its implementation was lacking evaluation. There were no indicators available for TB recording and reporting system to evaluate the performance of contact investigation [7]. This study aims to assess the implementation of TB early detection in contact investigation, its result, and contribution in improving TB case finding.

2. MATERIALS AND METHODS

2.1. Design

This was a descriptive exploratory study, which was integrated into previous TB program, aimed at providing evidence to increase its performance. The household TB contacts during home visit in contact investigation were advised to join TB early detection and their participation in screening and evaluation for TB were regularly followed up to 2 months.

2.2. Study Settings

The study was conducted in 6 months, from July until December 2017 in Badung District, Bali Province, Indonesia. The estimated population in 2017 was 643,500 people with the density of 1531.8 people per km². Badung District has the highest local revenue compared with other districts and city in Bali. Most of the revenue comes from tourism sector, particularly at the southern part, whereas at the northern part most of the people work in the agricultural sector [3].

The health facilities in Badung are well distributed, with good quality, and well-developed insurance system. It has 13 PHCs, 54 satellite PHCs, one public hospital, and six private hospitals. Since 1 January 2017, Government of Badung District has initiated universal health coverage and national health insurance.

The TB program in Badung is delivered by following the national guidelines. All bacteriologically confirmed TB and childhood TB were home visited by PHC's TB officers for treatment adherence support and contact investigation. Since third quarter of 2017, they have implemented TB early detection in contact investigation to improve case finding. TB early detection was evaluation using chest X-ray for adult contacts without cough and Tuberculin Skin Test (TST) for all child contacts.

2.3. Study Population and Samples

The study population was the household contacts of index cases who were diagnosed at the third quarter of 2017 at PHCs in Badung District. Household contacts were people who lived in the same house, shared enclosed space (bedroom, living room, dining room, kitchen, and other rooms in the same house), and frequently interacted with the index cases for 3 months and had not been previously diagnosed with TB [11]. Household contacts were identified through interview with index cases during a home visit in contact investigation.

2.4. Variables, Data Collection, and Analysis

We collected data on household contacts' sociodemographic characteristics (age, sex, education level, marital status, and health insurance), family relationship to index case, TB symptoms, participation in TB screening, evaluation (TB examination), and the results. Contacts' characteristics and their TB symptoms were collected through face-to-face interview using a structured questionnaire. Interview with child contacts was conducted with their parents. Contacts' participation for TB screening, evaluation, and the results were obtained from TB register book and collected using a checklist by trained enumerator.

Screening for TB started from the home visit in contact investigation. Contacts were interviewed regarding TB symptoms and those with cough were given two sputum pots (for collecting random and early morning sputum) and were advised to participate in TB evaluation at PHC. Contacts with other symptoms or without symptoms were also advised to visit PHC for further screening and evaluation. Evaluation for TB at PHC was following the National TB Program's guidelines. Adult contacts were evaluated using sputum examination (microscopic, Gene X-pert, culture) for bacteriological confirmation and signs, screening symptoms, and chest X-ray examination for clinical confirmation. Meanwhile, evaluation among children was conducted using a scoring system.

We trained 12 interviewers to perform the data collection. They were trained to identify TB contacts during home visit, deliver interviews, follow-up contacts, assist contacts for TB screening, evaluate, and review contacts' participation at TB register book. We did double data entry using Epi Data Entry 3.0 and certified duplicate file for validation. The implementation of early detection in contacts investigation was assessed using the indicators of contact investigation performance. The indicator comprised of the number of index cases found, the number of contacts identified, the ratio between contacts and index cases, the proportion of contacts who participated in TB screening and evaluation, the new TB cases found from contacts, and the positivity rate. The contribution of early detection was assessed using the proportion of new cases found from contact investigation among all TB cases in the same period. Frequency distributions and cross tabulations were used for data presentation.

2.5. Ethical Consideration

The ethical clearance was obtained from The Ethical Committee of the Faculty of Medicine, Universitas Udayana, Indonesia.

3. RESULTS

We found a total of 124 index cases. The study team had successfully home visited all of them. On the basis of interviews of index cases, we identified 498 contacts, thus the ratio contacts to cases was 4:1 Figure 1. Among the 498 contacts, 122 (24.5%) were children (under 15 years), 254 (51.0%) were female, and 328 (65.9%) were the nuclear family of index cases. All contacts were interviewed regarding the TB symptoms. There were 114 (22.9%) of contacts who had one or more TB symptoms with the most frequent symptoms being cough (15.9%), breathing difficulty (6.8%), and fever (6.4%) Table 1.

On the basis of the contacts' follow-up results we found 100(20.1%)out of 498 who attended at least one TB examination session at a health facility (PHC or hospital) Figure 1. Twenty-two of them were children and 78 were adults. Anamnesis and physical examination were completed for all contacts that visited PHC. The most common symptoms found were cough, fever, and breathing difficulty. Twenty-one adults were requested to provide sputum smear for examination and three (14.3%) of them were found positive. There were 13 children undergoing TST, five (38.5%) of them were found positive. Seventeen children and 70 adults were undergoing chest X-ray examination in Badung local hospital, 14 (82.4%) children and 55 (78.6%) adults were found have lung parenchymal abnormalities Table 2. Out of 100 contacts that attended at least one examination session, there were 41 contacts that completed participation until diagnosis was confirmed. The participation was higher among children compared with adults (46.2% vs 14.3%), among nuclear family compared with extended family (9.0% vs 1.9%), among contacts with education level \leq 9th grade compared

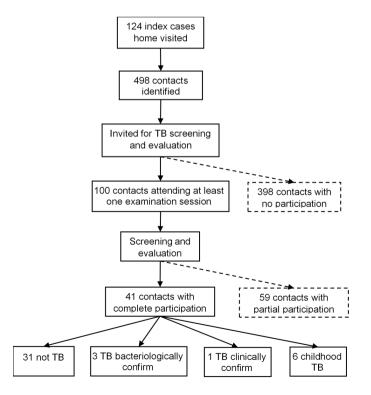


Figure 1 Flow diagram describing the implementation and result of contact investigation in Badung District, Bali Province, Indonesia. The dotted boxes indicate potential missed opportunities for tuberculosis case finding.

 Table 1 | The contacts' characteristics and tuberculosis symptoms based on home visit interview

| | 400 |
|--|-----------------|
| Variable | <i>n</i> = 498 |
| Age (years) mean ± SD | 38.6 ± 14.1 |
| <15 years old (children) | 122 (24.5) |
| ≥15 years old (adult) | 376 (75.5) |
| Sex | |
| Female | 254 (51.0) |
| Male | 244 (49.0) |
| Family relationship to index cases | |
| Nuclear family | 445 (89.4) |
| Extended family | 53 (10.6) |
| Education level | |
| ≤9th grade | 130 (26.1) |
| >9th grade | 368 (73.9) |
| Have health insurance | |
| Yes | 418 (83.9) |
| No | 80 (16.1) |
| Marital status | |
| Married | 289 (58.0) |
| Unmarried | 209 (42.0) |
| Confirming that they have tuberculosis | |
| symptoms when home visited | |
| Cough | 79 (15.9) |
| Coughing up blood | 4 (0.8) |
| Sweating at night | 10 (2.0) |
| Fever | 32 (6.4) |
| Weight loss | 16 (3.2) |
| Breathing difficulty | 34 (6.8) |
| Chest pain | 20 (4.0) |
| At least one tuberculosis symptom | 114 (22.9) |

Table 2The results of tuberculosis examination among contacts whoattended at least one examination session in Badung District, BaliProvince, Indonesia

| X7 . 11 | Age group | | |
|--|-----------------------------------|--------------------------------------|--|
| Variables of tuberculosis examination (<i>n</i> = 100) | <15 years old (<i>n</i> = 22) | \geq 15 years old (<i>n</i> = 78) | |
| Anamnesis and physical examination | | | |
| Cough | 6 (27.3) | 16 (20.5) | |
| Coughing up blood | 0 (0.0) | 3 (3.9) | |
| Sweating at night | 2 (9.1) | 3 (3.9) | |
| Fever | 3 (13.6) | 8 (10.3) | |
| Weight loss | 2 (9.1) | 6 (7.7) | |
| Breathing difficulty | 1 (4.6) | 10 (12.8) | |
| Chest pain | 1 (4.6) | 6 (7.7) | |
| Extra pulmonary TB sign (lymph nodes) | 1 (4.6) | 0 (0.0) | |
| Following sputum smear | NA | 21 (26.9) | |
| Smear positive | NA | 3 (14.3) | |
| Smear negative | NA | 18 (85.7) | |
| Following chest X-ray | 17 (77.3) | 70 (89.7) | |
| Lung parenchymal abnormalities | 14 (82.4) | 55 (78.6) | |
| Normal | 3 (17.6) | 15 (21.4) | |
| Following TST | 13 (76.5) | NA | |
| Positive | 5 (38.5) | NA | |
| Negative | 8 (61.5) | NA | |
| Following examination until confirmed diagnosis | 13 | 28 | |
| Tuberculosis bacteriologically confirmed | NA | 3 (10.7) | |
| Tuberculosis clinically confirmed | NA | 1 (3.6) | |
| Childhood tuberculosis | 6 (46.2) | NA | |
| No tuberculosis | 7 (53.8) | 24 (85.7) | |

TST, tuberculosis skin test; NA, not available (because the examination was not designated for children or < 15 years).

| Table 3 | The participation of | f contacts on following examination and | the results of diagnosis among wh | o followed up examination completely |
|---------|----------------------|---|-----------------------------------|--------------------------------------|
| | | | | |

| | Participation $(n = 498)$ | | | Diagnosis $(n = 41)$ | |
|----------------------------|---------------------------|------------------|------------------------|----------------------|------------------------|
| Characteristics | Complete n (%) | Partial n (%) | Not participated n (%) | TB n (%) | Non-TB <i>n</i> (%) |
| Age (years) mean ± SD | | | | | |
| <15 years old | 13 (10.7) | 9 (7.4) | 100 (82.0) | 6 (46.2) | 7 (53.8) |
| ≥15 years old | 28 (7.5) | 50 (13.3) | 298 (79.3) | 4 (14.3) | 24 (85.7) |
| Sex | | | | | |
| Female | 21 (8.3) | 35 (13.8) | 198 (77.9) | 4 (19.1) | 17 (80.9) |
| Male | 20 (8.2) | 24 (9.8) | 200 (82.0) | 6 (30.0) | 14 (70.0) |
| Family relationship to ind | ex case | | | | . , |
| Nuclear family | 40 (9.0) | 55 (12.4) | 350 (78.6) | 10 (25.0) | 30 (75.0) |
| Extended family | 1 (1.9) | 4 (7.5) | 48 (90.6) | 0 (0.0) | 1 (100.0) |
| Education level | | | | | |
| ≤9th grade | 17 (13.1) | 12 (9.2) | 101 (77.7) | 8 (47.1) | 9 (52.9) |
| >9th grade | 24 (6.5) | 47 (12.8) | 297 (80.7) | 2 (8.3) | 22 (91.7) |
| Have health insurance | | | | | . , |
| Yes | 32 (7.7) | 56 (13.4) | 330 (78.9) | 6 (18.8) | 26 (81.2) |
| No | 9 (11.3) | 3 (3.7) | 68 (85.0) | 4 (44.4) | 5 (55.6) |
| Marital status | | | | | |
| Married | 17 (5.9) | 39 (13.5) | 233 (80.6) | 2 (11.8) | 15 (88.2) |
| Unmarried | 24 (11.5) | 20 (9.6) | 165 (78.9) | 8 (33.3) | 16 (66.7) |
| Confirm one or more tube | · / | × / | | × / | |
| Yes | 16 (14.0) | 20 (17.5) | 78 (68.4) | 7 (43.8) | 9 (56.2) |
| No | 25 (6.5) | 39 (10.2) | 320 (83.3) | 3 (12.0) | 22 (88.0) |
| Smoking | | | | | . / |
| Yes | 3 (4.9) | 3 (4.9) | 55 (90.2 | 0 (0.0) | 3 (100.0) |
| No | 38 (8.8) | 56 (13.0) | 338 (78.2) | 10 (26.3) | 28 (73.7) |
| With diabetes mellitus | ` ' | × / | | × / | |
| Yes | 2 (28.6) | 1 (14.3) | 4 (57.1) | 1 (50.0) | 1 (50.0) |
| No | 39 (8.0) | 58 (11.9) | 392 (80.2) | 9 (23.1) | 30 (76.9) |

TB, Tuberculosis.

with those with higher education (13.1% vs 6.5%), and among contacts who had at least one or more TB symptoms identified during home visit compared with those without symptoms (14.0% vs 6.5%) Table 3.

Those TB evaluations had successfully found 10 additional new TB cases consisted of six childhood TB, three bacteriologically confirmed TB, and one clinically confirmed TB. There was a child who had TST result negative but diagnosed as TB by the physician at PHC because the chest X-ray result showed bilateral bronchopneumonia and perihilar lymph, and the score was 6. The positivity rate was higher among children compared with that in adults (46.2% vs 14.3%), among males compared with females (30.0% vs 19.1%), among contacts with education level \leq 9th grade compared with higher education (47.1% vs 8.3%), among contacts who had at least one or more TB symptoms identified during home visit compared with those without symptoms (43.8% vs 12.0%) Figure 1 and Table 3. The overall contribution of early detection in contact investigation to improve TB case finding was 8.1% or an increase from 124 to 134 cases Table 4.

4. DISCUSSION

This study found that the ratio of contacts to index cases was 4:1, similar to other studies that found the ratio of 3–5:1 [12–14]. This result indicated that most of the identified contacts were a nuclear family to index cases. The contact identification should

 Table 4 | The actual and estimated contribution of TB early detection in contact investigation to improve case finding

| Indicators | Children and adults with TB symptoms | Adults without TB symptoms | |
|---|--------------------------------------|-------------------------------|--|
| Number of index cases | 124 | | |
| Number of contacts identified | 210 | 288 | |
| Number of contacts with complete participation | 22 (10.5%) | 19 (6.6%) | |
| Number of additional TB cases found | 8 | 2 | |
| The contribution to improve TB case finding | 8.1% | | |
| Positivity rate | 36.40% | 10.50% | |
| Expected participation | 100% | 50% | |
| Expected contacts with com- plete participation | 210 | 144 | |
| Expected additional TB cases to be found | 76 | 15 | |
| Expected contribution to improve TB case finding | 73.4% | , D | |

TB, Tuberculosis.

be optimized because most of the people in Bali including Badung District are living with extended family. The ratio of contacts to index cases was relatively low compared with the target stated on The Regulation of The Minister of Health Indonesia No. 67 in 2016, where contact investigation should identify 10–15 contacts from one index case [6]. Based on review toward the TB register 01 book, technically the number of rows to put contact tracing results was limited. Only five rows were provided and it led the officer to provide only a maximum five identified contacts, even though there were more contacts that could be found. The trouble also came from index cases. They had experienced fear of infection, loneliness, and isolation from society, which delayed them to seek healthcare [15]. The stigma experienced by index cases prevented them from declaring their close and household contacts during the investigation [16]. The TB officers at PHCs should be trained to improve their capacity in delivering TB education, building trust, and interviewing people with TB to trace more contacts.

The proportion of TB contacts who had cough in this study was similar to another study (15%); however, the proportions for other symptoms were found to be fewer [17]. The proportion of contacts with at least one TB symptom in this study was 22.9%, a lot fewer compared with that in another study (45%) [17]. This result shows that the awareness about the TB symptoms among contacts, except for cough, was still low. The TB officer when conducting home visit should perform with a good skill on how to ask, explain, and describe (giving examples) TB symptoms clearly. The questions should also be clear toward duration and other characteristics of the symptoms. For example, fever in TB is low grade or <38.5°C [5,18]. Further education about TB symptoms will help contacts to be aware, to remember, and to reveal the symptoms that occurred.

The implementation of early detection in contact investigation had two points of missed opportunity, causing a low participation (8.2%). First was the participation of contacts attending PHC and second was the participation of contacts to complete TB evaluation until diagnosis is confirmed Figure 1. An earlier study regarding barriers to adherence with TB contact investigation found that knowledge, attitudes, and practices were associated with a contact's participation [19]. Another study also found that the barriers among index cases and contacts in contact investigation were their lack of TB knowledge, perception to related TB stigma, and fear of TB diagnosis [16]. Both studies showed that the greatest challenge of the TB early detection participation was health behavior [20]. This finding implicates the importance of health education for contacts, which can be delivered while conducting a home visit. The factors associated with health-seeking behavior on TB include knowledge, perception regarding TB, TB-related stigma, fear of TB diagnosis, and their previous experience visiting health facilities. Therefore, the health education material and method should comprehensively address the cognitive and psychological aspects of contacts [21,22].

The implementation of early detection in contact investigation yielded 10 additional new TB cases among 41 contacts that completed participation. It means one additional TB case was found for every four contacts evaluated. Other study found that for one index case, the number required to screen contacts was at least 11 household members/contacts [23]. The prevalence of TB among contacts in this study (24.4%) was higher compared with that from a previous study in the Philippines (12.8%) [24]. Higher positivity among contacts with at least one TB symptom indicates that they should be made as a priority for screening. In addition, a result of 12% TB positive among contacts without symptoms was similar to positivity rate among presumptive TB in the general population (5–15%) [7]. This indicates that TB early detection using chest X-ray was feasible to be implemented. Moreover, this result shows that the early detection among contacts was an efficient and effective strategy

for TB case finding. The strategy should be continued and initiated in other districts and provinces in Indonesia [17,25,26].

It has potential to improve the contribution of early detection in TB case finding (8.1%), especially if the contacts' participation level can be optimized. A previous study found that the contribution of systematic contact investigation with a home visit to improve case finding was 63%. The high contribution in this study was due to the high level of contacts' participation in TB evaluation (66%) [23]. Furthermore, we also estimated the expected contribution by calculating the expected contacts' participation multiplied by the positivity rate based on symptoms and age groups. We expected that if the complete participation among child and adult contacts with TB symptoms can achieve 100% and adults without TB symptoms is 50%, then the expected additional new TB cases found will be 91 people in quarter of a year or 73.4% expected contribution to improve case finding Table 4.

The contribution of early detection in TB case finding was high among child contacts. In the third quarter of 2017, the program found two index cases of children, meanwhile the early detection program among child contacts found six children to be TB positive. It means that the strategy has improved childhood TB case finding about three times in the same period. The finding of a total of eight children with TB was close to the 10% target of total TB patients found. Other studies also reported a high level of TB case finding among children during contact investigation [27,28]. The prevalence of childhood TB among child contact tracing was also high [29]. This finding has an important significance in increasing the TB program's performance. As the childhood TB case finding is mostly low in Indonesia, therefore this strategy can be offered as a solution.

The indicators of contact investigation calculated from this study should be continued and integrated into the TB reporting system. It is important to maintain a good standard in implementing contact investigation, establish systematic evaluation, and determine the next strategy to improve the TB program's performance. Those standard indicators will also lead the TB officers at PHCs and at district level to be more concerned about the performance of contact investigation. Another study proved that the use of standard indicators had improved the program's performance [23].

This study has some limitations. The participation of contacts in screening and evaluation was very low. The contacts with complete participation might indicate a self-selection bias. They participated because of their condition and a close relationship to the index case. Contacts with any TB symptoms and from a nuclear family of index cases were more likely to complete participation and thus might have caused an overestimation of positivity rate in this study. The officers' capacity and facilities in each PHC to support contact investigation, TB screening, and evaluation varied among PHCs. This might have caused missed opportunity to find new TB cases.

5. CONCLUSION

The early detection in contact investigation is feasible to be implemented perpetually and can be adopted also by other districts/ cities and provinces. This strategy showed to be effective and efficient in finding new TB cases, especially among children, and thus contributed to the increase in TB case finding. The main challenge was the poor participation of TB contacts to undergo TB screening and evaluation. A comprehensive education covering both cognitive and psychological aspects is needed to encourage contacts in participating in the TB screening until their diagnosis is confirmed.

CONFLICTS OF INTEREST

The authors declare that they have no potential conflicts of interest with respect to this research, authorship and/or publication of this manuscript.

AUTHOR CONTRIBUTIONS

I.W.G.A.E.P. designed the study, developed methodology, and data collection tools, conducted data analysis, and drafted the manuscript. N.M.D.K. contributed to the design of the study and the data collection tools, conducted the data collection, imputation, and drafted the manuscript. N.P.E.P.D. provided background information about the TB program in Badung District, coordinated the implementation of early detection in contact investigation, and data collection. I.K.S. contributed to the development of methodology and data collection, provided TB-related epidemiological information, and assisted in data collection. I.M.K.D. and I.K.H.M. contributed to data collection and imputation. P.R. critically reviewed the study protocol and supervised the research implementation. B.A. critically reviewed the study protocol, supervised the research implementation, and assisted in drafting the manuscript. A.P. critically reviewed all aspects of the study and assisted in drafting the manuscript. H.B.N. assisted in drafting the manuscript, and C.U.W. critically reviewed all aspects of the study and assisted in drafting the manuscript. All of the authors have approved the final manuscript.

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