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Issues to be considered when implementing the standardized tuberculosis contact investigation in a setting with routine tuberculosis contact invitation: an experience from the Kisumu County, Western Kenya, 2014-2015

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Abstract

Introduction: Persons in close proximity with Tuberculosis (TB) patients are at risk of TB infection. Contact investigation (CI) has not been scaled up to full implementation by the National Tuberculosis Program in Kenya. As part of a TB household CI study, we documented key concerns that the TB program in Kenya need to consider when transitioning from routine contact invitation to standardized contact investigation. **Methods:** A mixed methods evaluation, using participant documents, databases and meeting notes, was conducted between 2014 and 2015 in Kisumu County, Kenya. Qualitative data were manually coded as per emerging themes. Quantitative data was summarized into proportions of participants that received specific services. **Results:** Of 554 TB index cases recruited, 95% listed at least one household contact and a total of 1974 contacts; 2,068 contacts were however identified during a home visit (median no. of contacts per index 5 IQR 3-7). Of 98% (1,907/1945) of contacts scheduled for eligibility assessment, 1,855 (99%) were "household contacts" and 1519 (82%) assented enrolment. Of 346 (23%) child contacts (aged <5years), 82% had tuberculin skin test done; only 71% of symptomatic child contacts had Chest x-ray examination. Isoniazid Preventive Therapy initiation and completion rates were 15% and 20% respectively. Study procedures required the use of relational databases and a huge resource investment. **Conclusion:** TB programs should take into account the size of the proposed target population and infrastructure to support screening and treatment of contacts prior to transitioning to standardized contact investigation.

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Introduction

Tuberculosis (TB) is a highly infectious disease; a person with active TB can infect up to 15 persons a year through close contact [1]. Persons in close proximity with TB patients (e.g. household members) and persons with lowered or impaired immunity (e.g. children or immunosuppressed persons), are therefore at risk of TB infection [2, 3]. Contact investigation (CI) of TB patients, though not widely practiced in resource limited settings, is usually recommended as a means of case finding [3]. CI is done to either determine whether a contact has TB and requires TB treatment, or does not have TB but is likely to have latent TB infection (LTBI) or asymptomatic infection and therefore requires TB chemoprophylaxis with Isoniazid Preventive Therapy (IPT) [4]. Contacts should be invited within 7 days of a TB diagnosis of an index case for screening; repeat screening of the contacts should be done after 2 months of initial screening [3]. This is to cater for the window period of infection [4]; in the literature among contacts who screened smear negative at initial screening, 49% were still symptomatic at month one of follow up and 12% of them were diagnosed with TB [5]. In 2006, The Wolfheze conferences of the World Health Organization (WHO), International Union against Tuberculosis and Lung disease (IUATLD) and Koninklijke Nederlandse Centrale Vereniging tot bestrijding der Tuberculose (Dutch Tuberculosis Foundation-KNCV) Tuberculosis recommended that; 90% of TB index cases should have at least one contact screened for TB, 90% of high priority contacts should be evaluated and 80% of all contacts should be screened within 3-4 months of a TB diagnosis in the index case and 85% of contacts with LTBI should be put on chemoprophylaxis with at least 75% of them completing treatment [1]. In 2012, the WHO provided recommendations for investigating contacts of persons with infectious tuberculosis in low and middle income countries [6]. The WHO however, did not issue detailed guidelines on how to conduct contact investigation or how to prioritize contacts except in, children aged less than 5 years and HIV infected individuals [7]. There were no specific guidelines to be followed on the circle of contacts to be invited for screening, or upon inviting a contact of a known case of TB. The appropriate rescreening rate of contacts, based on the rate of reactivation rate of latent TB (which is also unknown), was also not recommended. However, for ethical reasons, if a TB diagnosis could be excluded at initial screening, effective preventive therapy could be administered [8].

TB programs worldwide have therefore faced challenges in implementing this program. In a systematic review on contact investigation in China between 1997 and 2007, written national guidelines on contact investigation did not exist. There was no standard definition of contacts, no prioritization of contacts to be screened or types of screening tests to use. TB screening programs had employed different investigations with varying yields. "Contacts" had been defined contacts as persons living in the same household with the TB index case; this definition may have (or may have not) stated the duration of contact [7]. In 1991, the guidelines for contact investigation in Victoria, Australia, were neither updated nor adhered to, patients were not appropriately screened and IPT was not administered to all eligible contacts of TB patients [4]. The Indian National TB program recommends IPT administration for childhood household contacts aged less than 6 years; however the TB treatment cards of index cases did not have details of their household contacts and health care workers were not aware of the policies for CI [9]. The TB program in Kenya recommends IPT administration to all household contacts of TB patients who are either, aged less than five years or, HIV-infected and subsequently screen negative for TB [10, 11]. However, Contact investigation has not been scaled up to full implementation (Malika, T, Deputy Provincial Leprosy Tuberculosis and Lung Diseases Coordinator, The former Nyanza Province, Personal Communication, 30th August, 2012). Contact investigation is resource-intensive; it requires funds to track all contacts, test them for TB and initiate them on preventive or curative therapy [3]. The TB program in Kenya therefore practices Contact invitation. (Malika, T, Deputy Provincial Leprosy Tuberculosis and Lung Diseases Coordinator, the former Nyanza Province, Personal Communication, 30th August, 2012). Data on contact investigation in Kenya is limited. Of the 11,886 cases reported in The former Nyanza north in 2012, only 2% (281) were by contact investigation (Malika, T, Deputy Provincial Leprosy Tuberculosis and Lung Diseases Coordinator, The former Nyanza Province, Personal Communication, 30th August, 2012). In Kenya, there is no current documentation of the total number of household members eligible for screening (Program Coordinator, Clinical Services, HIV Implementation Science and Services Branch, Kenya Medical Research Institute, Personal Communication, 30th June, 2012). As part of a Tuberculosis household Contact investigation study, we documented key concerns that The TB program in Kenya could to take into consideration when transitioning from routine contact invitation to standardized contact investigation.

Methods

Design and settings: A mixed methods study design was employed to document issues that would facilitate or hamper the implementation of TB household contact investigation. A document checklist was used to collect qualitative data concerning experiences of study staff conducting a TB household contact investigation study [12]. Study participant's record review was then conducted to support the findings from the qualitative data [13]. The TB household contact investigation study was a prospective cohort study conducted for all TB incident cases at 27 public and privately owned health facilities within Kisumu County between 2014 and 2015. This study was conducted at health facilities that were randomized to "TB household contact investigation" within a larger TB case detection study. Kisumu County located in Western Kenya, is a high TB burden, densely populated region. In 2015, the TB incidence was 105 per 100,000 and the TB prevalence was 306 per 100,000 [14]. It has a population of 952, 645 of whom 20% are aged less than 5 years living in an area of 2,086 square kilometers (population's density 464.5 per square kilometer) [15]. The county has 109 TB treatment sites, 75 drug resistant TB treatment sites and 80 TB diagnostic sites [14].

Study population recruited for the Tb household contact investigation study: All consenting incident cases of smear-positive TB identified by the TB program and their contacts residing in the study area were eligible for inclusion.

Research Study staff working in the TB household contact investigation study: The study was conducted by a team of 46 persons; there was an overall study coordinator, a clinic manager, 2 clinical officers, 5 nurses, 10 community interviewers (4 field based and 6 office based) and 27 community health volunteers. This does not include health workers who worked at the TB clinics and laboratories of participating health facilities.

Procedures for the TB household contact investigation study: Study participants underwent the following procedures; TB index cases were interviewed by a study staff member. This was followed by chest radiograph examination, culture of respiratory specimens for M. tuberculosis and HIV testing. All household contacts any age known to be HIV+ were interviewed after which they underwent tuberculin skin test (TST) screening. All household contacts aged less than 15 years with unknown HIV status were interviewed after which they underwent tuberculin skin test (TST) screening and were tested for HIV. All household contacts aged 15 years or older with unknown HIV status underwent interview and TB symptom screening and HIV testing. Chest radiograph examination was done for all contacts that either screened positive for TB symptoms or had a positive TST result. Data was abstracted from laboratory and medical records for TB index cases and their household contacts. A home visit was conducted for TB index cases to identify and refer additional household contacts for TB screening. All new cases of active TB detected during contact investigations or follow-up were referred to the local TB control program for further evaluation and treatment. All HIV+ contacts and all children < 5 years of age were referred to the local TB control program for further evaluation and consideration for treatment according to national policies and guidelines. Decisions on treatment, selection of treatment regimen and clinical management during treatment were carried out by the TB program according to national policies and guidelines and were not a part of this project.

Data collection for this evaluation: Data were collected from Consent cover sheets, participant tracking sheets and minutes of weekly meetings with the study staff. The Consent cover sheet contains participant demographic details, participant comprehension, literacy level, details of the consenting process and any other additional details that the persons obtaining informed consent wished to document about the process. The participant tracking sheet accompanied the participant as he or she moved from one point within the clinic, to another and was filled at each point. It helped track the service delivery points where the participants had been seen as well as summarized all the documents that were filled at each point e.g. triage, clinician's desk, laboratory, pharmacy etc. During each meeting, an agenda item for "Challenges and Successes" was allocated for the study team members to discuss their experiences. Supporting data was also collected from the participant databases.

Data analysis: A document checklist was used to collect qualitative data from each of these sources. Information was manually coded as per emerging themes [12]. SAS 9.2 was used to summarize proportions of participants that received specific services [16]. The results from quantitative data analysis were used to triangulate the findings from qualitative data whenever possible [13].

Ethical considerations: Ethical approval to conduct this study was granted by the Kenya Medical Research Institute Senior Scientific Committee (KEMRI SSC # 2408).

Results

Issues that were encountered during the implementation of the study with regards to contact investigation included:

Identification and recruitment of index cases and their household contacts: Only 554 (19%) of the 2,936 TB index cases that were diagnosed in Kisumu County during the study period, were recruited into the study; of these 527 (95%) listed a total of 1974 household contacts. However, upon home visit, 2,068 household contacts were found. The median number of household contacts per index case was 5(3-7). A total of 652 home visits were made in attempt to reach 1,945(94%) household contacts. Upon tracing 1,183 (61%) were interviewed, 544 (28%) scheduled an interview at a later date, 100(5%) were not found at home, 84(4%) declined participation, 18(1%) had out-migrated, 15(1%) were unreachable on phone and 1(0%) had died. Upon screening of 1,907(98%) contacts who were linked to 509 of the TB index cases, only the 1,855(99%) that had spent more than 7 consecutive nights in the household of the TB index case were eligible for enrolment. The 22 (1%) who were ineligible for enrolment either declined participation (n = 11), did not fit the definition of household member i.e. had not spent more than seven consecutive nights in the home with the index case (n = 4), were untraceable (n = 4), had out-migrated from the study area (n = 2), and one contact (n = 1) was mentally handicapped and could not give consent to participate. Only 1,519 (82%) household contact that were linked to 445 index cases were enrolled into the study. The 366 who were not enrolled either declined participation (n = 286), could not be traced (n = 48) or the reasons for non-enrolment were not documented (n = 32). Over one fifth of contacts (n = 346; 23%) were aged less than 5 years of age. The majority (n = 445; 80%) had at least one household contacts; of these the 243 (55%) that had at least one household contacts aged less than 5 years comprised of 44% of all the TB index cases in the study.

The requirement to adhere to multiple appointment schedules: As a requirement of the study, all potential study participants had to adhere to all study procedures which included a minimum of five visits over a three month period to the health facility. During these visits, the TB index case would undergo additional tests if required and household contacts would be screened and depending on their screening results, the appropriate treatment would be commenced. Participants had also to adhere to appointment schedules for TST readings and to travel in the event of referrals to higher level facilities in the event their primary facilities did not have the infrastructure and personnel to conduct Chest x-rays and skills for TST inoculation and reading. The number of visits may have therefore exceeded the required minimum.

Completion of the TB screening and treatment cascade: There was a decrease in the number of contacts from the point of identification to completion of the screening cascade and subsequent follow up. All participants aged less than 5 years ought to have had a HIV test done and TST inoculated, read and interpreted. Moreover, symptomatic participants and those with a positive TST should have had a chest X-ray done. However, only 82% of contacts had a TST done and of those who were eligible for Chest X ray (i.e. 48%); only 71% had a chest x-ray done. There were also challenges in completion of the TB treatment cascade for both LTBI and active TB disease. Only 15% of contacts eligible for IPT initiation were put on IPT and only one fifth completed IPT.

Database management: A relational database was used during the study. An index case had eight data tables; these were Patient eligibility, Patient information, Patient interview, TB index HIV test results, TB index Lab results, TB index Chest X ray results, Household contact identification and Household visit. Each contact had eight data tables; these were Contact tracing, Contact eligibility, Contact interview, Contact TST, Contact lab results, Contact HIV test results, Contact Chest X ray results, Contact follow up interview. A TB index case was identified by a unique number linked to the screening center. E.g. "KI", for Kisumu County followed by a four digit code (index identifier), a hyphen, and another two digit code (contact identifier). For instance, "KI-0001-0" would be the first index case recruited in Kisumu County. All household contacts would subsequently be identified with a suffix added to the index identification number e.g. for index case "KI-0001-0", contacts would be listed as ""KI-001-1", "KI-001-2", "KI-0001-3"....."KI-0001-n". The index identifier was the unique identification number that was used on all index data tables (which contained 554 observations one for each index case), except the Household contact identification data table. In this table, study staff would enter all identification details of all the household contacts of a TB index

case; this data table had 1974 observations (one for each contact). Upon visiting the home to trace other contacts, 2068 were identified and this was entered in the Contact tracing data table. However, upon screening, only 1945 were found during tracing and were entered into the Contact eligibility data table. Upon interview only 1,855 met the definition of household contact and were entered in the Contact interview data table. These contacts then appeared on the Contact HIV test, Lab results, TST and Chest X-ray and follow-up data tables if they were retained in the study. This implies that the final database would have a number of unique identification numbers dropped during the screening and identification cascade.

Resource implications : This study was conducted over a 2 year period in several facilities in Kisumu County. The study budget (that included salaries of additional staff that were hired to conduct the study, transport and screening costs, tracing costs etc.) was in hundreds of thousands of US dollars (KEMRI CGHR TB Program Strengthening section head, Personal communication, 30th June 2016). However, it was still not possible to place a study staff at each facility. Field study personnel therefore had to shuttle between participating health facilities to implement study procedures. Additional costs were incurred to make 625 home visits to transport all the contacts from their homes to the health facilities for screening for at least 2 visits (for both inoculation and TST readings) and possibly treatment, to purchase TST kits, to pay for chest x-rays and other laboratory tests. The furthest distance the study team had to travel to transport study participants from their homes to the TB clinics was a round trip of approximately 100 kilometers. The institutional vehicle costs approximately USD 1 per kilometer. A maximum of three home visits were to be made before declaring a participant untraceable. The study team also incurred costs of telephone charges to track down participants and invite them for an interview or remind them to attend a scheduled clinic appointment.

Discussion

The issues were identified during the study period, i.e the identification and recruitment of contacts, completion of the screening cascade, database management, and resources implications, are discussed in subsequent paragraphs. Similar to studies conducted in other parts of Kenya, the majority of index cases had at least one household contact [17]. Most households had approximately 5 household members; analogous to the average Kenyan household size [18]. Approximately 44% of all index cases had a household contact aged less than 5 years; this was higher than that in Benin (23%) where CI was successfully implemented in an urban center [19]. With a higher TB burden in Kenya in comparison to Benin, (Tb incidence 348 per 100,000 vs. 59 per 100,000 in 2016), the implementation of household contact investigation may prove more challenging in Kenya [20]. By defining Household contacts as persons who had spent more than 7 consecutive nights in the same household as the index case in three months preceding a TB diagnosis [1], 1% (43) of potential household contacts were excluded. In Uganda, the extension of contact screening to non-household contacts that were first degree relatives of the index cases, increased the yield of CI [21]. Extending the radius of within which to draw contacts for screening to 50 meters may also increase the number of cases detected [22]. So does screening all persons sharing the same residential address, as opposed to only persons who shared eating arrangements [23]. Since the relationship between ineligible household contacts and TB index cases or, the radius around the index case was not documented, the proportion of persons who may have been excluded by our definition that may have had TB could not be determined. The success of household contact investigation depends on the willingness of TB index cases and their household contacts to consent to participate. A refusal rate of 4% (n = 84) potentially translates to 3 cases of active TB and 39 cases of LTBI who would remain diagnosed; based on a prevalence of active TB of 3.1% and of 45% of LTBI among household contacts in low and middle income countries [24, 25]. This unwillingness may have linked to the stigma associated with TB, the communities' perceived link between TB and HIV [26] and due to the high TB/HIV co-infection rate in this region, the likelihood of an inadvertent disclosure of a HIV diagnosis [24]. The rights of a participant to decline participation in a research setting are well defined [27]. However, similar to TB index cases, contacts are also likely to have TB and are thus potentially infectious. They therefore maybe regarded as "TB suspects" by the TB program [11]. There exist Laws and regulations regarding the management of persons with notifiable diseases (like TB) [28] and in this instance, public health laws may infringe on individualism [29]. Furthermore, the TB index case may have not had an influence on their screening and treatment decisions of contacts who were not directly related to them [17].

We were able to trace 94% of the household contacts identified. Residences in Kenya are not clearly identified by their physical addresses making it difficult to visit patients' homes and account for all persons who live at that address [30]. The study limited its scope to only study participants that could be found within the study area. Those that had migrated or lived outside the study area were excluded. It would be important to ensure that the TB program in a particular region can contact the TB program in neighboring regions to track and screen all eligible contacts. We demonstrated a very high screening rate but sub-optimal IPT initiation and completion rates. Our screening rates (90%), documented in a research setting, were higher than those documented a programmatic setting in Ethiopia where only 55% of the contacts were screened. However, the fact that the clinical care of all study participants occurred within in routine programmatic settings, this may partly explain the low IPT initiation and completion rates [31]. Poor uptake and completion rates may have been due to attendance of different clinics by the index case and the contact, and different clinic visit schedules [32], the erratic supply of IPT and the need to adhere to a six month schedule of daily medication [33, 34]. At the time of the study there were not tools to support CI within routine clinical care. All the details of household contacts, their tracing and screening outcomes and details of subsequent management ought to be documented by TB programs using a relational database that can turn disparate pieces of information into a valuable resource [35-37]. The regular monitoring and evaluation of programmatic activities has been shown to facilitate the effective implementation of TB programmatic activities [17, 38]. The introduction of linked IPT family cards and IPT registers, supported by health worker training, led to a three-fold increase in the proportion of contacts screened for TB. Health workers reported that the documents were easy to complete and that it helped them complete their tasks according to programmatic guidelines [9]. Despite paper-based tools having been used to implement TB contact investigation [9, 17, 19], the use an electronic database supported by a clinical decision support system will be more efficient and effective in monitoring this kind of data [39]. This study received external funding to support contact investigation in addition to already existing funds allocated to the TB program. Contact investigation is resource intensive [31] and requires a huge investment in infrastructural support. Although research has shown that the absence of Chest x rays and TST should not be a deterrent to screening and management of children [19], this will require clear guidelines on long term monitoring of contacts who initially screen negative for TB [40]. There also costs borne by TB program in tracking all contacts based on its TB burden and the average number of contacts per case [41] as well as the costs of community health education [41]. If the program does not cater for these costs, they will have to be borne by the patients and their families. This presents a challenge since the costs of transport, chest x ray and facility registration are higher than the daily wage of most patients in Kenya [17]. We were unable to accurately verify the contact details of the index case and for this reason our screening rates may have been under or over estimated. We were also unable to follow up persons who had declined participations; such persons who have provided suitable controls to assess the benefit of TB screening among household contacts.

Conclusion

To optimize the effectiveness of household TB contact investigation, the TB program ought to avail of all the required infrastructures at all points of the screening and treatment cascade (point of care TB diagnostic facilities and continuous supply of Isoniazid at no cost) based on the TB burden and number of persons in households in different regions. This will decrease attrition at each point and make the TB household contact investigation program more cost effective. We also recommend the use of an electronic relational database ingrained with a clinical decision support system to aid the monitoring of index case-contact dyads. TB programs ought to implement contact investigation within existing community health systems with a possibility of home screening and delivery of isoniazid and incorporate community health education. An economic evaluation should also be conducted to assess the actual costs of contact investigation incurred by patients and their families.

What is known about this topic

- Tuberculosis is a highly infectious disease which is spread airborne and persons in close contact with TB patients are therefore at risk of infection;
- Contact investigation is an evidence-based method recommended for TB case finding;
- Monitoring and evaluation, has been vital to the success of TB programs.

What this study adds

- In high TB burden regions where majority of TB patients have at least one household contact, TB programs will have to invest more in the screening and treatment of a larger population of household contacts;

- TB programs should consider waiving user charges for household contacts to undergo screening in resource limited settings;
- TB Contact investigation has huge data demands and requires rapid access to information: the investment in an effective health management information system is crucial to the success of this program.

Competing interests

The authors declare no competing interest.

Authors' contributions

Barbara Kabai Burmen participated in data collection, analysis and manuscript writing. Thadeaus Ochieng Ochieng participated in data collection reviewed the manuscript. Timothy Malika provided study oversight and technical review of the manuscript review. All the authors have read and agreed to the final manuscript.

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