

Effects of Programmatic Interventions to Improve the Management of Latent Tuberculosis: A Follow Up Study Up to Five Months After Implementation.

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Abstract

BACKGROUND: Less than 19% of those needing tuberculosis (TB) preventive treatment complete it, due to losses in several steps of the cascade of care for latent TB infection. A cluster randomized trial of a programmatic public health intervention to improve management of latent TB infection in household contacts was conducted in Rio de Janeiro. Interventions included contact registry, initial and in-service training, and a TB booklet. We conducted a follow-up study starting one month after the conclusion of this trial, to measure the effect of interventions implemented, and to identify remaining barriers and facilitators to latent TB infection treatment, from different perspectives.

METHODS: In two health clinics in Rio de Janeiro, that received the interventions in the intervention trial, data for the latent TB infection cascade of care for household contacts was collected over a five-month period. The number of household contacts initiating treatment per 100 TB index-patients was compared with cascade data obtained before and during the intervention trial. Semi-structured open-ended questionnaires were administered to healthcare workers, household contacts and TB index-patients regarding knowledge and perceptions about TB and study interventions.

RESULTS: In this follow-up study, 184 household contacts per 100 TB index-patients were identified which was 65 fewer per 100 TB index-patients, (95% CI -115, -15) but the number of household contacts starting latent TB infection treatment was sustained (difference 2, 95% CI -8,5). A total of 31 TB index-patients, 22 household contacts and 19 health care workers were interviewed. Among TB index-patients, 61% said all their household contacts had been tested for latent TB infection. All health care workers said it was very important to test household contacts, and 95% mentioned that possessing correct knowledge on the benefits of latent TB infection treatment was the main facilitator to enable them to recommend this treatment.

CONCLUSION: In this follow-up study, we observed a persistent effect of interventions to strengthen the latent TB infection cascade of care, on increasing the number of household contacts starting latent TB infection treatment.

Introduction

According to the World Health Organization (WHO), tuberculosis (TB) is still one of the top 10 causes of death worldwide. Although Brazil has an estimated TB incidence rate of 45 per 100,000 people, making it one of the 30 countries with the highest TB burden, the incidence rate in Rio de Janeiro is more than double the national estimate (93.7 per 100,000 thousand). (1, 2)

Before the COVID-19 pandemic, worldwide incidence of TB was falling due to intensified efforts to reduce the spread of the disease. However, given the impact of the pandemic on health services, it is estimated that there will be an increase of 10.7% in TB cases and 16% in TB deaths over the next 5 years. (3) In order to reach the targets of the End TB strategy of reducing deaths by 95% and cases by 90% by 2035, (4) TB programs need to make significant efforts to provide continuous essential TB services, including

preventive and curative treatment for TB. Tackling the reservoir of latent TB infection (LTBI) has been estimated, from modelling studies, to be the most effective way of reducing TB incidence. (5) As such, one of the pillars of the End TB strategy is integrated patient-centred TB care and prevention, which includes identifying and treating high-risk individuals with LTBI in order to reduce progression to active disease. Household contacts (HHC) of TB patients are included among this group of high-risk individuals. (6) During the 2018 United Nations High Level Meeting on TB, world leaders agreed on a resolution to identify and provide LTBI treatment to 4 million children under 5 years of age and 20 million other HHC by 2022. (7) However, currently, less than 19% of those needing LTBI treatment complete it, with many losses throughout the cascade of care, including at the stages of identification, diagnosis and treatment. (8)

To better inform setting-specific strategies, research from the perspective of health care providers and patients is needed. In a preceding trial (ACT4), (9) interventions were implemented to strengthen key steps in the LTBI cascade of care with the goal of increasing the number of HHC initiating LTBI treatment in Brazil. (10) The primary objective of this follow-up study was to compare the number of HHC identified and initiating LTBI treatment after the trial interventions had ceased, to the number identified and initiating LTBI treatment before the trial, and during the intervention phase of the trial.

Additional objectives were to identify current barriers and facilitators for linkage to care, and for accepting and initiating LTBI treatment from the perspectives of HHC, health care workers (HCW) and TB index-patient's, as well as identifying the acceptability of trial interventions from a HCW perspective.

Methods

Study setting

Under Brazilian guidelines LTBI care is provided to child and adult HHC who have a positive tuberculin skin test (TST) or positive Interferon-Gamma Release Assay (IGRA). All treatment for LTBI is self-administered and LTBI is not a compulsory notifiable condition. (11)

This study was carried out in two clinics where the intervention trial had previously been implemented.

Study periods

The intervention trial was conducted from May to October of 2018. The follow-up study consisted of two components. Firstly, we conducted a retrospective analysis of the cascade of LTBI care of HHC of TB index-patients diagnosed between November 1, 2018 to March 31, 2019. Secondly, questionnaires were administered to TB index-patients, HHCs and HCWs between May 7, 2019 to July 4, 2019.

Intervention trial

The intervention trial consisted of a rapid public health evaluation to identify barriers to LTBI treatment for HHC of TB index-patients, followed by site specific selection of strengthening activities and implementation of interventions to the barriers. (10)

In Rio de Janeiro, Brazil, LTBI program strengthening interventions consisted of: (i) initial training covering all steps of the cascade of care in LTBI, (ii) intensified in-service training provided by a TB physician (weekly visits for the first two months, then every two weeks for two months, then once a month), (iii) development and use of a contact registry to facilitate a cascade analysis to support the in-service training of HCW, (iv) leaflets with educational information for TB index-patients and their contacts and (v) educational material developed for health care workers (TB booklet). (10)

After October 2018, all trial interventions were stopped. This meant cessation of in-service training, provision of leaflets to HHC and index patients, provision of the TB booklet to HCW, and no further on-site visits by research staff.

Follow-up study

For the cascade of LTBI care, we abstracted information from the TB registry at each clinic regarding the number of people recorded at each of the following steps: TB index-patient diagnosis, HHC identification, medical evaluation (including TST), and HHC initiating treatment. Only HHC of new microbiologically confirmed pulmonary TB patients (using acid fast bacilli (AFB) smear, TB culture, or Xpert®MTB/Rif) diagnosed between November 1, 2018 and March 31, 2019 were included in this cascade analysis. We excluded HHC with a diagnosis of active TB.

In the follow-up study, interviewer-administered open-ended structured questions were applied to TB index-patients, HHC and HCW. TB index-patients were eligible to be interviewed if they had confirmed (as defined above), or clinical pulmonary TB. HHC was defined as someone who slept in the same house at least one night per week, or spent more than one hour in the house at least five days per week, on average, with a TB index-patient, over the preceding three months. HCW were defined as doctor, nurse, auxiliary nurse or community health agent that assisted TB patients in either of the two clinics.

For the questionnaires on barriers and facilitators, a consecutive sample of all TB index-patients and their HHC presenting to both clinics from May 7, 2019 date to July 4, 2019 were invited to participate. The health clinic directors identified HCW from the TB programs; all were approached and accepted to participate.

For the questionnaires, semi-structured knowledge, attitudes and practices questionnaires were adapted from those used in the ACT4 trial. For HHC and TB index-patients, questions focused on perspectives and perceptions about the identification of contacts and reasons why linkage to LTBI care was or was not achieved. For HCW open ended questions related to motivation for contact tracing and continuation of activities implemented in the intervention trial were used. All questionnaires were interviewer-administered in the participating health clinics. All interviewees were 18 years of age or older. Written informed consent was provided by all participants prior to data gathering.

Outcomes

The two primary outcomes were the number of HHC identified and the number of HHC initiating LTBI treatment within three months of diagnosis of the TB index-patient. Both outcomes from the follow-up study (November 2018 to March 2019), were compared to: (i) the pre-trial intervention period (July-December 2017) of the intervention trial, and (ii) during the intervention period of the trial (May-October 2018). Outcomes were presented per 100 TB index-patients.

Secondary outcomes included: current barriers and facilitators to LTBI linkage to care, and acceptance and initiation of treatment identified by TB index-patients, HHC and HCW; and identifying the acceptability of study interventions from a HCW perspective.

Analysis

A Poisson regression model with identity link, accounting for over dispersion when necessary, was used to compare cascade of care data between the three time periods.

For questionnaire responses, open-ended questions were transcribed from audiotapes and coded by two independent reviewers (MYL, MLB) into common themes. Disagreements were resolved by consensus. The results from these common themes are presented as frequencies and proportions. We compared the responses of HHC and TB index-patients from the intervention trial questionnaires to the follow up study questionnaires using the Mantel-Haenszel method for adjusted odds ratio and Wald method for the confidence intervals.

Data analysis was performed using the statistical package R version 3.5.1 and Microsoft Office Excel 2016.

Ethical approval

The study was approved in Rio de Janeiro by the Municipal Health Ministry (CAAE 38278214.3.1001.5279) and by the McGill University Health Centre ethical review board (15-291-MUHC).

Role of funding source

This study was funded by the Canadian Institute of Health Research, grant number FDN-143350. The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Cascade of care analysis:

A total of 38 TB index-patients and 70 of their HHC (184 HHC per 100 TB index patients) were identified for the cascade of care in the follow-up study. This was similar to what was found in the pre-intervention period (difference -6, 95%CI -46.5 to 34.5), however it was 65 less (95%CI -114 to -15) per 100 TB index-

patients compared to the cascade during the intervention trial. From the 70 HHC identified (184 HHC per 100 TB index-patients), 18 (47 per 100 TB index-patients) initiated LTBI treatment (rate difference 137 per 100 TB index-patients). When comparing the number of HHC initiating LTBI treatment in the follow-up study to the pre-interventions period, we observed an increase of 42 HHC (95%CI 22 to 63) per 100 TB index-patients. When comparing the follow-up study to the intervention period, there was a similar number of HHCs initiating treatment (difference -2, 95%CI -8 to 5) per 100 TB index-patients (Table 1).

Table 1. Effectiveness of the intervention on different outcomes in the cascade of care.

Measurements	Pre-interventions period (July-December 2017)	Intervention trial (March-October 2018)	Follow-up study (November-March 2019)
Number of confirmed pulmonary TB patients (mean, SD)*	21 (4)	29 (6)	19 (11)
<i>Total number of HHC identified</i>	78	142	70
Number of contacts identified per 100 confirmed pulmonary TB patients (mean, SEM)**	190 (14)	249 (18)	184(19)
Difference between follow-up study and specific period (95% CI)	-6 (-47,34)	-65 (-115,-15)	—
<i>Total number of contacts initiating LTBI treatment</i>	2	28	18
Number of contacts initiating LTBI treatment per 100 confirmed pulmonary TB patients (mean, SEM)**	5 (3)	49 (2.1)	47(1.2)
Difference between follow-up study and specific period (95% CI)	42 (22,63)	-2 (-8,5)	—

*Mean and SD of observed data; ** Mean and standard error of the mean weighted by number of TB patients.

The cascades of care for the pre-intervention period, intervention trial, and follow-up study are shown in Figure 1.

Questionnaires:

A total of 31 TB index-patients, 22 HHC and 19 HCW were interviewed during the follow-up study.

The main barriers and facilitators identified by TB index-patient HHC and HCW are summarized in Table 2.

Table 2. Barriers and facilitators identified in TB index-patient questionnaires, HHC questionnaires and HCW questionnaires.

Barriers and facilitators identified in TB index-patient questionnaires		
Step in the cascade of LTBI care	Barriers n(%)	Facilitators n(%)
HHC identification	Not encouraging HHC to be tested 3 (10%)	Counselling from health professionals on LTBI testing in HHC 30 (97%)
	Disbelief in LTBI 2 (6%)	Concern about HHC falling ill with TB 29 (93%)
		Correct knowledge of TB transmission 24 (77%)
Completion of initial assessment and medical evaluation of HHC	Too busy, inconvenient location or working times of the clinics 4 (13%)	Knowledge of TB (as a precaution/fear) 13 (42%)
	Disbelief in LTBI 2 (6%)	Advice by a health professional 6 (19%)
LTBI treatment initiation	Disbelief in LTBI/ no symptoms/ not a priority 7 (23%)	Advice by a health professional 2 (6%)
Barriers and facilitators identified in HHC questionnaires		
HHC identification		Correct knowledge of TB transmission 18 (82%)
		Concern about falling ill with TB 18 (82%)
Completion of initial assessment and medical evaluation of HHC	Too busy/not a priority 8 (37%)	Advice by a health professional 12 (55%)
LTBI treatment initiation	Lack of trust in health professionals 1 (5%)	Concern about falling ill with TB 7 (32%)
		Knowledge of TB (prevention/ protection) 21 (95%)
Barriers and facilitators identified in HCW questionnaires		
HHC identification		Correct knowledge of LTBI identification in children <5 years 9 (50%)
		Correct knowledge of the importance of LTBI testing

		19 (100%)
Completion of initial assessment and medical evaluation of HHC	Not having access to TST, chest x-ray and INH	1 (5.5%)
LTBI treatment initiation	Correct knowledge of the benefits of LTBI treatment	18 (95%)

When asked if all their HHC had been tested, 39% of TB index-patients said no, the main reasons being that HHC were too busy to get tested, that they will get tested later and that their HHC do not believe in the disease or do not feel sick. Among TB index-patients, 87% said that all or most of their questions regarding TB had been answered by a health professional, and 90% said that they had encouraged their HHC to be tested. When HHC were asked if they had been checked for LTBI or if they were planning on getting checked, 37% said no, the main reason being that they were too busy, could not get time off work or that they would do it later. When asked if they would take LTBI treatment if recommended, only one HHC said that they would not, because they do not like going to the doctor or taking medication. The main facilitator identified by HCW was attitude of HCW towards LTBI. All (100%) of HCW said it was very important to test HHC for LTBI. Almost all (95%) mentioned that possessing correct knowledge on the benefits of LTBI treatment was the main facilitator to enable them to recommend this treatment.

When comparing the answers from the TB index-patient and HHC questionnaires from the follow up study to the intervention trial, we observed that a non-significantly higher proportion of HHC were willing to be tested (63.6% (14/22) vs 52.6% (10/19)) and to take treatment for LTBI if necessary (95.5% (21/22) vs 85% (17/20)). A non-significantly higher proportion of TB index-patients was also informed about HHC testing for LTBI (96.8% (30/31) vs 87.5% (21/24)). (Supplementary Table 1).

With regards to the acceptability of the interventions, the majority of HCW (61%) considered the TB booklet to be an accessible tool for solving day to day queries on LTBI diagnosis and treatment. Initial (56%) and in-service training (39%) were considered important for changing the attitude and beliefs about LTBI. The main themes identified in the open ended questions from HCW questionnaires can be found in Supplementary Table 2. Almost all (95%) of HCW said it was useful to have a member of the research team helping in daily activities regarding LTBI. Sixty-eight percent said that they felt more prepared to treat TB and LTBI patients after interventions had been implemented.

Discussion

This study evaluating the long term effects of programmatic public health interventions showed a persistence in the number of HHC initiating LTBI treatment, up to five months after the interventions had been stopped by research staff. The main facilitator to linkage to care, acceptance and initiation of treatment identified by HCW, TB index-patient and HHC was knowledge of LTBI diagnosis and treatment.

In this follow-up study, we identified losses of HHC at the identification step of the cascade of care. However, this did not affect the number of HHC initiating LTBI treatment, which remained similar to the intervention trial. Previous studies of the cascade of LTBI care in Brazil had also demonstrated the highest losses in the initial steps (identification and investigation). (12, 13) As mentioned by HCW in the questionnaires, interventions such as training, TB booklet and in-service training helped improve contact identification and treatment initiation. Notwithstanding, HCW also mentioned that clinics are understaffed and have a high demand from the public, which may have limited the capacity for contact identification once the intervention trial ended.

The quantitative assessment of the cascade of care, which shows ongoing losses at the identification step – despite its improvement from the pre-interventions period, contrasted with the qualitative assessment from the interviews, in which very few barriers towards HHC identification were found among all the interviewed groups. This may be due to the effectiveness of the interventions in overcoming previous barriers, although social desirability and selection biases cannot be ruled out, as all questionnaires were interviewer-administered and only patients who attended the clinics were interviewed.

From the TB index-patient questionnaires, we see that most of the patients interviewed encouraged their HHC to get tested and that most of them were worried that someone else in their household would get sick with TB. Both the findings from HHCs and TB index-patients indicate that a strong support network, including family and HCW, is an important enabler for linkage to LTBI care, and acceptance and initiation of treatment, as has been shown in other studies. (14-16)

Given that a shift in HCW knowledge, attitude and practices plays a vital role in decreasing the losses at different stages of the cascade of care, (17, 18) it may be warranted to include interventions focused on continuous training tailored to site-specific context, (19) within all TB prevention programs.

This study is not without its limitations. Firstly, it was not possible to interview the same participants from the intervention study. However, our objective was to measure the effects from the interventions, which is reflected in the cascade of care as well as in responses from new participants. The power to detect statistical differences is limited by our sample size, which in itself is limited by the total number of HCW, TB index-patients and HHC at each clinic. The period of time between end of the intervention trial and measurement of the cascade of LTBI care may not be long enough to capture long term effects of said interventions. Nonetheless, we consider that the time period between end of interventions to the new questionnaires provides a washout period that allows us to evaluate the persistent effects of interventions.

One of the main strengths of this study is that we were able to evaluate the effects of interventions under programmatic conditions, thus providing useful information for National TB programs (NTP). Another strength of this follow-up study is that HCW, HHC and TB index-patients were included to gain an understanding of the LTBI cascade of care from the perspective of all parties involved. (8)

Noteworthy, the way people interact with health services, as well as health services delivery, has changed due to the coronavirus pandemic. Notwithstanding, it is imperative that NTP take action towards protecting vulnerable populations who may be at greater risk of developing TB during this time, this includes HHC of TB index-patients.

Conclusion

In summary, the number of HHC initiating LTBI treatment, adjusted to the number of TB index-patients, in the five months after the termination of a programmatic trial, was similar to the number during the intervention period of the trial, and significantly higher than the pre-interventions period of the same trial. This suggests a persistent effect of the interventions.

List Of Abbreviations

AFB Acid fast bacilli

HCW Health care worker

HHC House hold contact

IGRA Interferon-Gamma Release Assay

LTBI Latent TB infection

TB Tuberculosis

TST Tuberculin skin test

WHO World Health Organization

Declarations

Ethics Approval and Consent to Participate

The study was approved in Rio de Janeiro by the Municipal Health Ministry (CAAE 38278214.3.1001.5279) and by the McGill University Health Centre ethical review board (15-291-MUHC). All participants provided written informed consent.

Consent for Publication

Not applicable

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

We declare no competing interests or conflicts of interest.

Funding

This study was funded by the Canadian Institute of Health Research, grant number FDN-143350. The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Authors Contributions

DM and OO acquired the funding. DM, OO, AT and MYL designed the study. MYL and NR collected the data and interviewed participants. MYL and MB carried out the analysis and data synthesis. MYL wrote the initial draft of the manuscript. All authors interpreted the data, provided critical revision, contributed important intellectual content, and approved the final version to be published.

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Figures

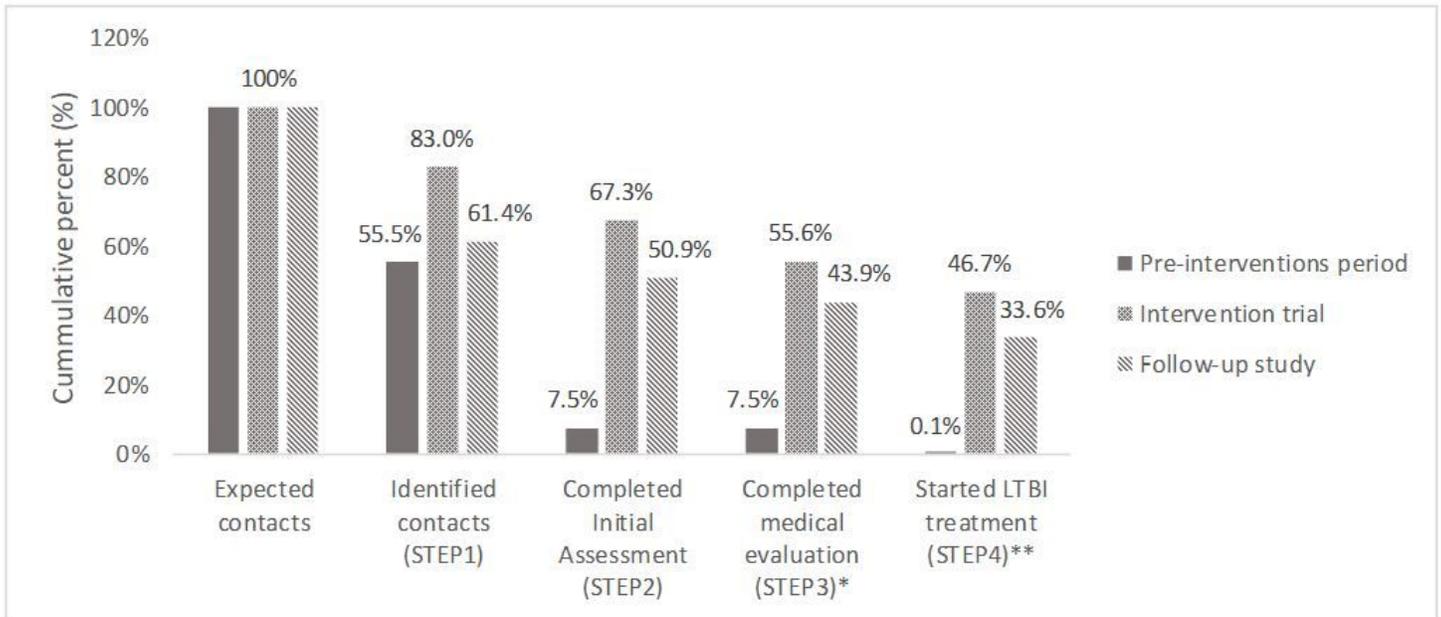


Figure 1

Cumulative percentages of contacts of all ages retained in the cascade at each step, during the pre-interventions period, intervention trial, and follow-up study. Notes: * proportion who completed a medical evaluation over total who needed medical evaluation (for age under five, TST positive, prior TB, symptoms with TST negative); ** taking into account a 6% possible active TB among contacts who completed medical evaluation. We estimated that for each TB index-patient there would be three HHC, this was used to calculate the number of expected contacts.

Supplementary Files

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