Wave 10 Quarterly Narrative Report

TB Preventive Treatment Projects

Project Information	
TB REACH Project Short Code	10429
Grantee organization	Rede Brasileira de Pesquisa em Tuberculose, Rede TB
Country	Brazil
Report Period	01.01.23 – 31.03.23

Activities

1. Describe the activities that were implemented this quarter.

- How are you reaching out to and identifying persons with TB infection and diagnosing persons with active TB who are excluded from TPT?
- Are you using any tests for infection this quarter?
- What treatment regimens are you using?
  (indicate if and when there were changes in the test or treatment regimen used?

Q1 2023 was dedicated to (i) preparing training material, (ii) preparation of research data collection tools (questionnaires) and seeking for ethical approval of the implementation research component of the project, (iii) engaging with the municipal and state TB managers in the five intervention cities to achieve consensus on the project activities, (iv) baseline data validation (BDV), (v) agreement on which data to collect prospectively and preparation of an updated cohort registry book and an updated registry analysis tool (RAT), (vi) selection of personnel who will work in the project (data managers, administrative personnel, focal points in each city, and community advisory board - CAB) and (vii) preparation of protocols of cost-effectiveness analyses. No field activities were implemented in Q1, they have started in April (virtual training). The project lead participated in the Stop TB Partnership TB Reach Wave 10 meeting from 6 to 10 March 2023 in Bangkok, with the project's funding.

i. Training material

Audiovisual material for virtual training was prepared in agreement with the NTP. Two types of training were prepared: one for community health agents (https://docs.google.com/presentation/d/1mPY53Gs1x3-wVg-Fk_e3d3nVAxPCW8ev/edit?usp=sharing&ouid=102944331555646687031&rtpof=true&sd=true) and one for nurses/medical doctors (https://docs.google.com/presentation/d/1Z41N0rOuwc8MA5F8ze8fJppMVWeMvdWQ/edit?usp=sharing&ouid=102944331555646687031&rtpof=true&sd=true). Training sessions are being conducted in the 5 cities (April and May), and the material is being improved based on feedback of the community advisory board, of the audience and on our own perception. The NTP and the project leader are conducting jointly this training.

Printed material was prepared for healthcare workers (HCW). For clients (people living with TB – PLWTB – and their contacts), the proposed material is being revised by the community advisory board. All material is available upon request.

ii. Ethical clearance

After gathering letters of agreement from all the city's managers and building the questionnaires for HCW, the project was submitted to the principal investigator's University Hospital IRB (Hospital Clementino Fraga Filho, Federal University of Rio de Janeiro) on Feb 1st, 2023. It was approved on March 10th, 2023 (in annex). Clearance in Manaus, Rio de Janeiro, São Paulo and Recife was obtained subsequently (only Porto Alegre still pending). However, only research activities involving human beings (such as acceptability by HCW of the tools used in the project) need ethical clearance. The submitted project clearly states that training activities and cost-effectiveness analyses based on public data will not wait for approval.

iii. Engagement with local TB managers

We have held meetings with state and city managers, the NTP and the project lead in January (and many others in April, Q2). We have also discussed with local managers and selected personnel the need for the letters of

agreement, selection of trainers in the city (for future sustainability of the activities) and indication of a focal point who would be responsible for overseeing the project's activities and checking for data quality control. Those focal points were indicated and are now fully engaged in the project implementation. It was agreed that 10% of data would be checked monthly in each participating clinic in Q2 and Q3, and thereafter, only in clinics where there is still a problem with data quality. Because the cities have hundreds of primary health clinics, and some treat very few TB patients monthly, we have decided to concentrate efforts in clinics here at least 2 new people living with TB (PLWTB) monthly, in average. This will also avoid wasting of PPD in the country.

iv. Baseline Validation (BV)

The NTP, project lead and data managers have exchanged information with the project's reviewer in Q1. We have received the final report for Q1. Among the problems depicted are having planned activities and projected numbers for a 15-month period, while the project activities are expected to last for only 12 months. In addition, the IL-TB information system will be the only source for comparison of EP and CP. This system does not contain information in all cascade steps, and as observed in the BDV, delays in notification are expected. Finally, because there is no randomization, control cities are far from perfect. They were chosen among those who regularly TPT and we tried to have geographical representativity, in four of the five regions in the country. Most notifications in IL-TB are in the EP cities, which was of course the reason why the NTP chose to invest more in them. Only two control cities had more than 1000 notified TPT up to end 2022. We expect that the analyses of trend will show the increase in the TPT uptake during the project implementation, and beyond.

v. Data collection during the project

We have adapted the contact registry book and the registry analysis tool (RAT) previously used in the ACT-4 project, to include TPT outcomes, TB detected and date of notification. Data managers proposed an automatic tool to aggregate individual clinic data to be analyzed monthly by the NTP, city and clinic managers and the project lead, in order to take quick actions in case bottlenecks are observed in any step of the cascade. Data managers have built in the platform RedCap an interface for data entry and analysis.

vi. Selection of project personnel/community engagement activities

We have prepared description job and terms of reference for each type of personnel, most were hired and started in Q1. The local NTP indicated the focal point HCW for their cities.

Ezio Tavora, our community engagement expert, has engaged 13 TB community activists (from the 5 cities) to constitute the CAB, they have read the project, made relevant suggestions including for the training (presentation) material and are currently working on the educational material for clients. The term of reference for the CAB is attached.

vii. Preparation of cost-effectiveness protocols

In collaboration with Dr. Jonathon Campbell, from The McGill TB WHO Collaborating Centre, we have developed protocols for the cost-effectiveness analyses of TST training and mTST quality control.

2. a. Describe any operational successes or challenges you had implementing your TPT program.

- How have you built health care worker capacity for identifying persons with infection and providing TPT?
- Were there any concerns for program staff or health care workers providing the services?
- Were there any notable benefits or challenges for persons screened, tested, or treated?
- Describe any procurement challenges or successes?
- Is TPT adequately recorded and reported in your evaluation population?

b. How has the project adjusted to maximize these successes and mitigate the challenges described in 2a above?

The program implementation started Q2 (April 10 was the first training). We foresee a couple of issues. Firstly, there is a shortage of PPD. The final vials are about to be used and the new arrival is planned for June, distribution in this continental country may be an additional issue, PPD expected to be available in services in July. QFT-Plus is available for PLH and children from 2 to 10 years of age in some areas of the 5 cities. For children under 1 or between 10-15 and for PLHA that do not have access to IGRA tests, TPT is being recommended up to July without TBI testing for children up to 15 and PLHV.

However, some positive changes are expected for Q2. The Nurse Federal Council and the Ministry of Health have approved the ability of nurses to request TST/IGRA and CXR and to prescribe TPT within a protocol algorithm. That might have a positive effect in intervention and control cities.

Training activities are highly appreciated by the public, they will be detailed in the Q2 report.

3. Did activities result in the identification of persons with active TB disease and TB infection? • Did the activities result in TPT initiation and completion for those with TB infection? • What interventions are being done to improve TPT initiation and completion? • How are persons on TPT being supported and assessed for adherence and side effects?
Data not yet available.

4. Describe how the numbers of persons across the cascades- those identified with active TB, TB infection, who initiated, and/or completed TPT- have changed in your evaluation population since the beginning of your activities (data from GMS tables) • How do these numbers compare to your control areas?
Non-applicable

5. In the next quarter, what will the project do differently to improve / maintain impact?
Project activities started in Q2. We do not expect to achieve the predicted overall increase (35%) of screening and TPT initiation in the first quarter of project activities, as we believe this will be a gradual process. Likewise, we expect to see the true results on TPT completion with some delay. Planned activities for Q2 are virtual training on the National recommendations (we have already surpassed the 1500 planned HCW), implementation of the registry book and the registry analysis tool, which will be implemented in May/June, and TST training in July 2023, when PPD will be available.

6. Describe any internal or external factors* which may have influenced the identification of person with TB, TB infection, TPT initiation or TPT completion in your EP and CP (both positively or negatively). What changes were observed? How did they influence your results?

* Internal factors are related directly to project activities e.g. staff capacity and motivation; availability of commodities. External factors are more health systems related and can include political unrest, health care worker strikes, national stockouts of commodities, initiation or termination of service delivery activities by other organizations, changes in reporting units, and implementing new/improved diagnostics by others, etc.

Not yet applicable, as there were no project activities in Q1. However, in Q2, we have started to hold regular meetings with the focal points in the 5 cities and have identified that in São Paulo (the largest city with the highest absolute numbers of new TB clients and notified TPT), there will be a lot of resistance to accelerate this training. We are negotiating with the NTP solutions to this sensitive issue, which may be a substantial bottleneck for the program.

Shortage of PPD is another obvious bottleneck, PPD is expected to be available in all cities at the beginning of Q3. During Q2, IGRA is available in some areas for PLHA and children 2-10 years, otherwise, TPT is recommended without TBI testing for all children under 15 and PLH, regardless of CD4 count (currently, recommendation is to test for TBI if CD4 is ≥ 350/mm^3).

7. Comment on how data quality was assessed during the reporting period.

Not available. We are just transcribing, for the moment, the IL-TB information system. We know from previous studies that there are substantial delays in reporting, thus we are updating the previous trimesters. Data in the intervention cities will be collected through the registry book and transcription to the RedCap platform, and 10% of books will be checked. Comparison between the intervention and control cities, however, will only be possible through the IL-TB information system, which only gathers data from treatment, not the whole cascade of care, as explained in the baseline validation document.

Health Systems Strengthening

8. Describe how your project contributed to health systems strengthening. • **Describe which building blocks your project contributed to and how? (Leadership and governance, service delivery, financing, workforce, medical products and technologies, information systems, and community engagement)** • **Describe any challenges related to implementing HSS activities and how these were mitigated.**	Leadership, Governance, and Accountability: We have been working jointly with the NTP/MoH, the community and professional categories to discuss the evidence generated by this project with the regulatory and incorporation organs. In Q1, the Federal Nurse Regulatory Council has approved the right of nurses to request TBI tests/XCR and prescribe TPT. Negotiations involved the NTP and the ExpandTPT project lead. This may have deep implications in the health system and in the expansion of TPT (both in intervention and in control cities). Our activities will include training of HCW, training of trainers, evidence generation and evaluation of preparedness for new technology incorporation, including acceptability, feasibility, cost-effectiveness and budget impact analyses. Output are meeting reports, manuscripts, conference presentation. The CAB has been working closely with us, addressing relevant issues, reviewing and producing educational material and participating in the training sessions and municipal meetings (Q2). Health Financing: Also in Q1, Rede-TB and the NTP participated in the negotiations that lead to an inter-ministerial agreement to work together to end TB. This will include the scaling up of TPT in the country, and lessons learned in the ExpandTPT program can be applied to the country expansion of TPT. However, the project is not providing any kind of incentive or financial support for clients or HCW. Access to diagnosis: We expect to increase the number of contacts entering the cascade of care, the number of TST applied and read, and the number of TPT started (and % completed). A CAD solution (free of charge for the public health system) to replace radiologists for TBD exclusion will be installed in 5 clinics in Rio. Outputs are number of TPT applied in contacts, number of TPT started and percentage completed, time between TST reading and TPT initiation in clinics with CAD. PS: We will not collect costing data for clients or clients' satisfaction, as the scope of the planned project is already ambitious for the timeline and funding available Health Information Systems: A cohort-based registry book accompanied by an innovative tool (the registration analysis tool) will be used in the facilities, local managers will be trained to complete the data and analyze its output for quality improvement of all steps of the cascade. We will perform QC of these data and compare with the IL-TB system. We will train HCW to include data directly on the notification system (currently this activity is highly centralized in the administrative/surveillance services, resulting in substantial delays, which jeopardize the principle of M&E (surveillance for action). Outputs are collected through the registry books and RedCap and through the IL-TB. Healthcare force: the project will not hire people for the routine activities, as our goal is to allow the activities to be sustainable after the end of the project. We have hired focal points (all female) in each city to organize and help in the implementation and M&E activities. All were indicated by the municipal TB control program. However, we will train 1500 HCW of different categories to act in the contact cascade-of-care. Outputs are number of HCW trained (by category) and number of trainers trained, satisfaction with training tools and QC (mTST). Up to the moment, we did not have major challenges regarding the HSS activities.

Implementation Research

9. If your project is conducting implementation research, describe any activities related to implementation research this quarter and what you are planning for next quarter.

Implementation research, as planned, will include acceptability of the used training and quality control tools and of the CAD **by HCW**, as well as cost-effectiveness of these technologies. This is planned for Q3 and Q4, when all activities will have been fully implemented. The evaluation of the training activities, mainly for TST placing and reading, are highly relevant to the country, as there is a common non-evidence-based practice to require 100 induration readings with 80% concordance with the trainer to certificate a HCW to independently read TST. This has been one of the major limitations for TPT scaling up in the country.

During Q1, we finalized the questionnaires and informed consents, submitted the project to the ethical committees of the involved cities. Clearance was obtained in 4 of 5 cities.

We are preparing a simplified questionnaire for a client satisfaction survey. This will be a quality control activity, not needing ethical approval.

Advocacy for Awareness, Sustainability, and Scale-Up

10. Describe your advocacy activities including your partner engagement (especially with the NTP and CCM), results sharing/dissemination and advocacy efforts during the quarter.

- How has your project promoted and improved awareness among health care providers and the community on the importance of initiating and completing TPT?

This is a joint project with the NTP. We have been holding meetings since the project writing. Activities are planned jointly. During Q1, the NTP has invited the state and municipal TB programs to participate in a meeting to present the activities and to explain that this is a national priority, a governmental program, not a research project (although there will be a small research component). The NTP has been actively participating in the training activities in Q2 and we are planning joint (project lead and NTP) technical visits to the municipalities in Q3.

During Q1, our community engagement expert also selected a group of community leaders in the five cities to compose the CAB. The CAB has been actively working since April, details will be reported in Q2 report.

We have produced educational material for HCW (in annex) and are finalizing, with the CAB, educational material to the client as well. The training of HCW includes the reinforcement that contacts and index patients should be educated to understand the importance, efficacy, and safety of TPT.

Women's Empowerment Activities

Please describe activities that you conducted to provide gender responsive services and/or empower women?

Except for the community engagement expert, ALL the hired personnel are women (they were not chosen because they are women but based on their skills).

Most of the TB district (sub-municipal level) are women, and are being empowered to act as monitors in the district clinics.

We are training CHW to identify all household contacts, with special attention to women, as most of TB contacts are female (TB is more common in men). We are gathering data disaggregated by sex and will see the impact of the training.

We acknowledge this is not a strong component of our project. We consulted the CAB for ideas to empower women. Their suggestions are attached.

Story from the Field

11. Provide a story from either persons who accessed services that you provided under this TB REACH grant or from program staff/ health care workers who worked under this grant about their experiences and how their lives have been changed due to your program? Please insert relevant photos if available and be sure to get permission from the persons profiled for use of their photo. Stop TB Partnership will use these stories and photos to promote grantee's work.	
	Not yet available.