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Experiences and Learning Systematization Study Multicountry Grant:

"Strengthening of the Tuberculosis Laboratory Network in the Americas Region"

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EXPERIENCES AND LEARNING SYSTEMATIZATION STUDY MULTICOUNTRY GRANT: "STRENGTHENING THE TUBERCULOSIS LABORATORY NETWORK IN THE AMERICAS REGION"

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Content

Acronyms

BK	Sputum Smear
COMISCA	Council of Health Ministers of Central America and the Dominican Republic
GDF	Global Drug Facility
GLI	Global Laboratory Initiative
ITM	Institute of Tropical Medicine, Amberes (Belgium)
InEDR	Institute of Epidemiological Diagnosis and Reference - Mexico
NIID	National Institute of Infectious Diseases – Argentina
PHI	Public Health Institute - Chile
LPA	Line Probe Assay - for rapid detection of mutations associated with resistance to anti-tuberculosis drugs
SNL	Supranational Laboratory
NRL	National Reference Laboratory
WHO	World Health Organization
PAHO	Pan American Health Organization
ORAS-CONHU	Andean Health Organization - Hipólito Unanue Agreement
NTP	National Tuberculosis Control Program
DST	Anti-TB Drug Susceptibility Test
RR	Rifampicin Resistance
SECOMISCA	Secretary of the Council of Health Ministers of Central America and the Dominican Republic.
DR-TB	Drug Resistant Tuberculosis
MDR-TB	Multidrug-resistant tuberculosis
XDR-TB	Extremely resistant tuberculosis
TAV	Technical Assistance Visit
XPERT MTB-RIF	Rapid molecular test that detects Tuberculosis Complex and rifampicin resistance in the same study.
GeneXpert®	Equipment that uses closed cartridges and simplifies the execution of the molecular method because it integrates and automates the three processes - sample preparation, DNA amplification and tuberculosis detection.
Genotype®	Proof that based on linear probe hybridization (LPA) detects the resistance of M. tuberculosis to anti-TB drugs.

I. Presentation

I Presentation

➡ To date, tuberculosis continues to be a crucial public health problem in Latin America because there are factors that allow it to remain an epidemic, affecting thousands of people. These factors tend to be, first of all, the great inequalities that characterize most of the countries of the continent; the HIV; antimicrobial resistance, which increases cases of multidrug-resistant tuberculosis (MDR-TB) and extremely resistant (TB-XDR); and its relationship with other pathologies.

Although the fact that the number of deaths due to TB has decreased dramatically in the region, this disease continues to mainly affect impoverished populations, which have barriers to the exercise of the right to health and access to decent public services. Prevalence and mortality from tuberculosis are associated with poor living conditions, weak health systems, and social protections, in general, to detect and monitor cases until recovery. The low quality of the diagnosis and the delay in the identification of the infection, influence the treatment to be late or the drug-resistant cases are not detected -on time, which contributes to MDR or XDR tuberculosis spreading by not receive a timely and accurate diagnosis, making its control more difficult, and increasing the possibility that the infected person will deteriorate, develop the disease and spread to others in their environment, expanding the epidemic.

Accordingly, the laboratories responsible for diagnoses in each country have a central role in the success of national tuberculosis control programs (NTP-). PAHO / WHO has a network of laboratories in the Americas in the perspective of strengthening them based on their articulation and exchange dynamics, sharing knowledge, updates, and contributions to the fight against TB. For more than two decades, PAHO / WHO and the countries themselves financed the training, the production of technical documents and quality control. However, as funds were scarce and external financing priorities moved to regions of low-income countries and with more cases, it was not possible to sustain the strengthening of the laboratory network. Therefore, since 2009 an attempt is made to promote a plan to strengthen the laboratories of America, which had difficulties in resources to be implemented.

To this is added, in the last decade a different technological scenario emerged, new methods were developed that substantially reduced the time of diagnosis of TB and the identification of drug resistance. Its incorporation requires the purchase of equipment and supplies, software, training in its management, biosafety conditions and the modification of algorithms for the identification, reference and performance of tests according to the different cases.

The situation before the start of the grant was as follows: The laboratories had an acceptable performance in the diagnosis of TB by microscopy and culture. Besides, nineteen of the twenty countries had rapid molecular tests. Fifteen performed second-line drug sensitivity tests, but, of them, only six had commercial liquid media systems (BACTEC-MGIT) which is a method recommended by WHO as a test for the diagnosis of tuberculosis by culture and identifies resistance to first and second-line drugs. On the other hand, the technical manuals for performing conventional diagnostic tests and for new techniques were lacking in the networks or out of date[1].

Likewise, the laboratories showed deficiencies in biosafety systems, since only 10 national reference laboratories (NRL) had certified biosafety cabin, nine had directed air and eleven laboratories had antechambers[2].

In terms of operation, of the 20 countries in the America network that would later benefit from the Global Fund Regional Grant, fourteen performed external quality control, thirteen received technical visits and training, and only eight had a stable provision of reagents and supplies[3] for rapid molecular tests. More than fifty thousand cases remained unreported in America.

[1] Results taken from the 2016 diagnostic document: Structure and operation of the National Laboratory Networks of tuberculosis in the Americas region. / Program "Strengthening the Network of Tuberculosis Laboratories in the Region of the Americas" - Lima: ORAS - CONHU; 2017.

[2] Op. Cit.

[3] Op. Cit.

Aware of this situation, in 2015 PAHO proposed a three-year regional project and sent the expression of interest to the Global Fund, after whose acceptance the concept note was formulated jointly with the ORAS-CONHU. This concept note was consulted with all the laboratories in the region and was refined taking into account the diversity of regulations and the reality of the twenty countries that ratified their willingness and commitment to participate. Approval was achieved in 2016, but Global Fund grants establish that PAHO cannot act as the main recipient, so that ORAS CONHU was designated as such, with PAHO and the Executive Secretariat of COMISCA as sub-recipients (SECOMISCA). The grant started in January 2017 and concludes on December 2019.

The main objective is to strengthen 3 supranational Laboratories (SNL) in Latin America (Argentina, Chile, and Mexico) and the NRL of 17 countries in the region, generating positive results in their respective national tuberculosis laboratory networks. Therefore, the grant aims to optimize the diagnosis of TB made by all NRL of the participating countries, improving its quality and opportunity, expanding its coverage, thereby reducing the diagnostic gap.

The grant-maintained the articulation design matrix of the laboratory network with which it had operated in previous years under the leadership of PAHO and continued with many activities carried out in the past maintaining the same style in many cases, however, increased the frequency and linkage between activities to generate cumulative synergistic results. Also, advocacy activities were added to promote the sustainability of the actions developed.

PAHO was responsible for the technical component of the grant. COMISCA has led the coordination of the countries of Central America and the ORAS of those of South America. The latter played a central role as governmental integration agencies in political advocacy in the countries that are within their jurisdiction. However, there have been many activities with scope in its execution for all twenty countries, coordinated by any of the three instances.

II. Executive Summary

II Executive Summary

➡ Between January 2017 and December 2019, the Regional Tuberculosis Grant, financed by the Global Fund in The Americas, works to improve the diagnostic capacity of laboratories and detect more quickly and quality to reduce the gap between the number Annual estimated and reported TB cases.

This Grant is the continuation of PAHO's efforts to strengthen laboratories. It covers 20 countries and focuses on TB NRL and SNL that act as network heads, located in Argentina, Chile, and Mexico.

The resources are managed by the Andean Health Organization - Hipolito Unanue Agreement, as the main recipient, and has two sub-recipients: The Secretariat of the Council of Health Ministers of Central America and the Dominican Republic, and the Pan American Health Organization. Among these three institutions: ORAS, SECOMISCA, and PAHO, all activities are coordinated and executed.

Below, the most relevant results of the consultancy are present to systematize the experiences and what has been learned.

The training, the updated technical documents, the extension of the molecular diagnosis, the advice, and the quality controls, strengthen the laboratories and contribute to the reduction of the diagnostic gap in Tuberculosis.

- A synergistic impact was achieved between the grant update activities that strengthened the laboratories, under the technical guidance of the PAHO liaison point.

- The technical guide and standardized manuals helped to unify diagnostic criteria and practices of TB Laboratories in The Americas. At least 70% of the countries declare to have them as references for their national standards.

- Training development improved laboratory performance and expanded the participation of technicians and professionals. In five countries, NRL have assigned quotas to other national network personnel, to expand the benefits of training.

- The grant boosted the incorporation of molecular fast methods, and improved procedures, or placed them on the agenda of investment in technological improvements, although advances differed according to the resources of each country.

- Internships and technical visits facilitated access to diagnostic expertise that is not obtained through instructions or online information from the teams.

- In the majority of the NRL, where the use of rapid and molecular methods was strengthened, the diagnostic time was reduced, and in some countries, changes were generated about the transfer of samples and reference systems.

- The participation of the NRL in the activities of the grant redefined their role and leadership before their respective national networks, training and improving their articulation with the laboratories of other levels.

- The implementation of the benefits was not the same in the countries and also not homogeneous, not all developed the activities that derive from the investment in documents and training.

New equipment and training for the 3 SNL strengthen their technical advisory capacity and revitalize networking.

- The supervision, recommendations, and assistance provided to the SNL, guided by PAHO / WHO, generated processes of updating and acquiring cascading skills of the SNL towards the NRL, which influenced the strengthening of laboratories and these towards their national networks.

- The acquired equipment allowed enhancing the diagnostic capacity of the SNL and expanding the specialized technical assistance they provide to the NRL, boosting external quality control.

- Participation in congresses and internships in centers of excellence meant a permanent challenge for SNL, who have all the updates in TB diagnostic procedures.

- The accompaniment and advice of the SNL to the NRL was sustained and fluid during the grant, building bonds of trust and exchange between them.

- The technical visits expanded the knowledge of the SNL about the conditions of the laboratories in their network and the national and local epidemiological characteristics, focusing pertinently their advice to the countries.

- Links and relationships were built between the members of the network, which resulted in horizontal exchanges of social media expertise and collaborations with inputs.

The bureaucratic difficulties for the operation of TB laboratory networks in the Americas partially overcome.

- The cumbersome procedures for permissions permits were a frequent obstacle, due to the bureaucratic structure and/or the lack of timely communication of the Ministries of Health to the NRL or the weak relationship between the National TB Program and the Laboratory.

- The rhythms and procedures were refined along the way, through mediation efforts by ORAS-CONHU and SECOMISCA, in front of the authorities and the laboratory for the management of permissions and authorizations.

- The main limitation to enhance the benefits of the grant was the lack of resources at the national level or within its networks: for the incorporation of personnel, purchase of supplies, and improvement of laboratory infrastructure.

- The average transport time of the strain panels and their clearance varies from one week (minimum 3 days) to 20 days (with a maximum of 38). Most of the difficulties of the first year were resolved in the following. Only one country has not received the panels, due to conditions external to the grant.

Tuberculosis laboratories gain relevance as a pillar in disease control, but more investment is required to improve their conditions.

- The involvement of NTPs in the technical meetings of the grant in most countries tightened ties between NTPs and NRL. However, in 25% of the countries, a dissociation persists between the two.

- The grant helped to make visible the contribution that laboratory diagnosis means to the fight against TB, which highlighted the relevance of laboratory networks.

- The recognition of NRL in TB public policies did not translate equally into budget support. Some countries bought equipment, supplies or incorporated more personnel. Others, on the other hand, do not support laboratories financially.

- It is observed that not all laboratories have the leadership required to reverse the conditions of infrastructure and resources, requiring legal skills.

The fulfillment of the commitments derived from the grant is uneven, and it is necessary to sustain and advance the achievements obtained.

- Nine countries incorporated in their budget some activities derived from the grant (purchase of GeneXpert and supplies, centrifuges, staff training) although in several the little predisposition to prioritize public spending remains.

- In seven countries, the country grant (FM de TB) or international cooperation financed the purchase of supplies or equipment for laboratories, as a result of actions promoted by the regional grant or in confluence with it.

- There is a lot of disparity in the commitment of governments to continue training, technical assistance and quality control of diagnostic activities.

- The governments of Mexico and Argentina program resources by 2020 to maintain compliance with the criteria that give their laboratories supranational character.

In Chile, variants are analyzed according to their capacity to cover 2020 to all their countries, two of which are being assumed by other laboratories in 2019.

- There has been more progress to date, in the countries of Central America than in South America in supporting the future sustainability of the laboratory network, since they achieved the signing of a multilateral agreement.

III. Objectives and Methodology of Systematization

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• 3.1 Objectives

- Identify how the grant has strengthened the network of tuberculosis laboratories; through the analysis of the components of technical standardization, equipment, capacity development, information systems, certification and optimization of biosafety and improvement in the quality management of the SNL and NRL.

- Analyze whether the implementation of the grant favored that national reference laboratories gain relevance within the national public policy to fight tuberculosis; identifying if they were most valued by the national program and by health authorities.

- Know if the TB Laboratories made technical and biosafety improvements based on technical visits, control recommendations, supervision, advice, or as a product of the internships of laboratory members.

- Inquire if the interventions and activities proposed in the concept note respond to the current needs of the tuberculosis laboratory network for its proper functioning.

- Identify the main critical nodes that emerged during the implementation of the grant and the proposed solution alternatives.

- Analyze what is required for advances in laboratory strengthening to be sustained over time after the grant is completed; placing special emphasis on high-level political commitment so that the laboratory network does not decline.

• 3.2 Instruments, samples and procedures

- Coordination and orientation meetings with the institutions responsible for grant implementation.

- Review of the documentation, manuals, technical guide, and communicative products developed within the framework of the grant, including all the information or official data accessible on the Monitoring and Evaluation Plan.

- 50 semi-structured interviews conducted with key actors of the National TB Programs, officials of the Ministries / Secretaries of health, responsible for the SNL, the NRL, and members of CARLAC.

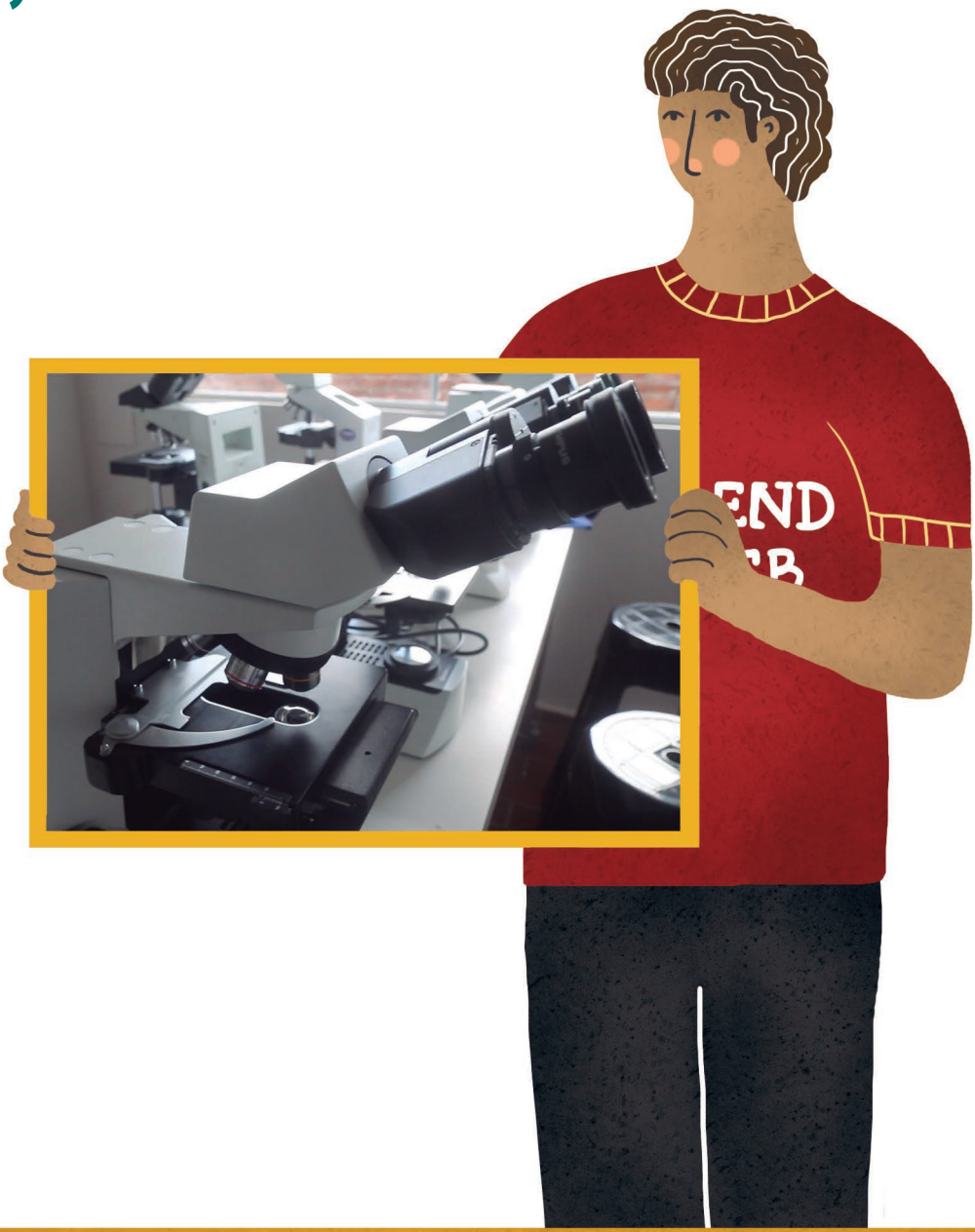
- 28 semi-structured online questionnaires filled out by key actors of the National TB Programs, responsible for the NRL and focal points of the CARLAC.

- Analysis and triangulation of the information obtained from the different perspectives of the key actors and grant participants.

- Observation of technical coordination meetings and workshops organized by the grant.

- Presentation of preliminary findings to the coordination team and grant partners.

IV. Main Results of the systematization



IV Main Results of the systematization

➡ In this chapter, we present the results of the interviews, meetings, and observations. We have divided the results into 6 points that group the areas that we believe may show the observed changes and the synergistic consequences of the activities implemented by the grant.

• 4.1. The synergy between training, updated technical documents, internships, and technical meetings

➡ To respond to the need for updating, training, internships, participation in congresses and technical documents were developed, in the perspective of having the new recommendations and guidelines of WHO in the fight against tuberculosis. The emphasis has been on driving the use of rapid and molecular diagnostic methods. The coordination and technical advice of these activities were carried out by PAHO as a subrecipient.

The technical documents were one of the first products of the grant. Diverse efforts have been making since 2009 to update, for example, the Susceptibility Testing Manual, but the constant technological advances or lack of budget had delayed its preparation. The grant was an opportunity for experts to systematize and standardize the processes based on WHO recommendations and that, in the opinion of Dr. Ernesto Montoro, Technical Coordinator, "WHO itself had not yet compiled, putting the region of the Americas ahead of the world in terms of the availability of some documents", as is the case of the Manual for external quality assessment. The grant developed, translated and published a Technical Guide and 3 manuals[4], in a very short time. To date, 1394 copies have been distributing among the 20 countries participating

[4] These were the following: "Technical guide for the bacteriological diagnosis of tuberculosis: Part3 Susceptibility tests"; "Manual for the bacteriological diagnosis of tuberculosis: Part 1 Manual for updating the smear test"; "Manual of algorithms for the diagnosis of tuberculosis"; "Manual for the bacteriological diagnosis of tuberculosis: Part 5 Manual of procedures for external quality assessment of bacteriological methods".

in the grant, in addition to sending the electronic versions to reach the majority of professionals working in TB laboratories in the countries.

The capacity development component has been one of the highest points of the grant. Training workshops[5] were held; medium-term training processes[6]; internships of SNL staff in centers of excellence and NRL staff in their respective SNL; assistance of SNL and NRL professionals to international courses[7] and congresses. Likewise, the grant continued with the good practice of promoting interaction in technical meetings for the fight against TB[8] between the heads of laboratories and TB programs.

All the interviewees of the SNL and the NRL agreed that the central contribution of the grant to the strengthening of the laboratories was based on the update and the transmission of the "Know-how".

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[5] Regional workshop on maintenance of laboratory equipment (B. Aires, 17-21 / Sept 2018); Regional Workshop on New Tools for the Diagnosis of TB (Chile, 9-13 / July 2018); Leadership and Governance Workshop (Lima, 2017 and Buenos Aires 2018); Workshop for training TB laboratory consultants (Mexico, March 11-15, 2019); Information Systems Workshop (Panama, March 2018)

[6] Training of certifiers of biological safety cabins

[7] Regional Course on Biosafety and Management of Biological Risks and Safe Transportation of Infectious Substances (Chile, 27-31 / Ag 2018); Remote Regional Course on Quality Management and Good Laboratory Practices; National Quality Management Courses in TB laboratories.

[8] Attendance of the LSN chiefs at the GLI Annual Meeting; I GRTL-TB meeting with heads of Lab. Guadalajara Oct 2017; II GRTL-TB Meeting with heads of Lab. Guatemala Nov 2018; Follow-up Meeting on policies and mandates Guatemala Nov 2018; CARLAC meetings March 2018, October 2018, April 2019; I Meeting of Ministers, Lima February 2018; II Meeting of Ministers, Quito, Nov. 2018; II Meeting of Ministers / Secretaries COMISCA and Mexico, Santo Domingo June 2018; II Technical Meeting of Lima Sept / 2018; Meeting of Ministers / Secretaries COMISCA and Mexico, Antigua Guatemala, June 2019; III Regional Technical Meeting on Tuberculosis and Leadership and Governance Workshop; Antigua Guatemala, June 2019.

Standardized technical guides and manuals

➡ The technical documents were timely because the technological changes are driving new tests and diagnostic procedures, and the laboratories required updated information in their language to analyze their procedures and standards. Nine countries used the technical guides to develop their national standards or update the ones they already had (for example, Argentina, Bolivia, Colombia, Costa Rica, Peru).

"Those documents have been and are the basis for ours, which we are currently taking out. Right now, we are taking out documents and a course, for example, of smear microscopy for the entire network, based on those documents of the Regional Grant "(NRL).

Before having the manuals, there was a high degree of uncertainty because the laboratories were not sure if the diagnostic procedures they used were correct. Besides, these new materials allowed them to have an updated scientific-technical framework of diagnostic practices that unify their daily work (as recognized, for example, Uruguay, Panama, and Nicaragua). Therefore, the staff gained security in their work and used the recommendations in the manuals to unify internal criteria and train their staff (manifested by Belize, El Salvador, and the Dominican Republic).

"The technical guides that developed the project helped in updating the procedures, which were not reviewed since 2008. For this reason, the development and updating of technical personnel have been favored" (NRL).

"The Guides and Manuals received during the project help us to have bibliographic support, to know more about the tests that are currently being carried out, whether they are or are expected to be implemented in the NRL and the laboratories of the Network (also the guides were distributed to them)" (NRL).

These documents were key to advancing the incorporation of molecular diagnostic methods that had already been discussed at the meeting organized by the grant in

Guadalajara in 2017[9]. From the technical guides, some laboratories reviewed their work algorithms[10] by introducing changes in their procedures (for example, Chile, Costa Rica, El Salvador, Dominican Republic, and Honduras), which in some cases had not been reviewed since 2008 and incorporating LPA tests.

"We change the algorithms, we optimize them, we extend the use of the new tool, for example, if we are going to do an Xpert ultra that can already replace the smear, let's stop doing double methods that only lead to overloading the equipment and it will not contribute more information and opportunity" (SNL).

For some laboratories, which experienced resistance or doubts about the use of molecular methods, having the standardized manuals served to endorse their technical opinions and to support the need for the use of molecular tests for the detection of LPA and Xpert resistance or to plan their incorporation and/or enlargement (as in Peru, Bolivia, and Honduras). That is to say, they became scientific support for discussion at the national level with other experts who advocate focusing on smear microscopy or that condition the incorporation of molecular methods to their validation with national studies.

"Many times, the professionals here say that: "So we do this in Peru, we have another characteristic of the bacteria, so first you have to do an investigation here in Peru to be able to implement a method. What was done in Africa, what was done elsewhere, does not work for Peru", so sometimes there is resistance to what is implemented" (CARLAC).

Also, the NRL had a compiled documentation that reduced the time of bibliographic research each time they had to technically support their work before the authorities or manage the purchase of supplies or equipment, as they had the support of an international document (thus Honduras, Argentina, and El Salvador recognize it).

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[9] From October 8 to 11, 2017, the "Regional Meeting of Chiefs of National Reference Laboratories (LRN) of Tuberculosis of the Americas" organized by the grant was held.

[10] Set of successive instructions to achieve the objective of making a rapid and accurate diagnosis of TB and TBDR (OPS, 2018).

At the same time, the technical guides served to articulate the work that was had with the national networks, reproducing them or sharing with them in order to update and standardize the diagnostic methods of the laboratories belonging to the network of each country (for example, Colombia, Costa Rica, Honduras, El Salvador, Paraguay and Nicaragua).

"The guides allow the updating of the work protocols at all levels of the network, the basic ones received via sputum smear manual and all those who do sensitivity tests received the documents in physical." (NRL)

Capacity development, internships and conference attendance

➡ Before the grant, PAHO conducted training workshops with a periodicity of between 3 to 4 years, which were preferably attended by the heads of laboratories, while the grant extended the training to other professionals, who also needed to improve their knowledge and performance.

For most staff, the opportunity for technical training was very remote. Few laboratories have financial resources to go abroad, internship or to attend international conferences, and these types of training are not proved in their countries regularly. For many professionals, it was the first time they trained internationally, and it meant a personal motivation that resulted in a greater commitment to their institution.

"Yes, that is another thing I have to say, the motivation of the staff, too. Sometimes these meetings are suddenly held that, let's say, are specific to a boss and they see that one goes out, but I feel that obviously, the opportunity is given to several, of course, that has motivated them, has given them security to attend the internships, they gain more confidence in what they are doing. Definitely if yes, personal motivation is important too." (NRL)

"The training had previously been scarcer, the possibilities of training were more limited, it had to be that one applied, that there were scholarship possibilities to then be able to go out to train, receive a course, or that you would had a research project with funding to receive international training." (NRL)

Of all the training that the grant developed, the interviewees highlight one in particular: The workshop on "New Tools for the Diagnosis of TB". For most countries, diagnostic training using molecular methods meant innovation in diagnostic practices and made it possible to know the feasibility of incorporation or expansion in their respective countries (as expressed, for example, by Cuba, Belize, and Paraguay).

"Last year I went to receive training in LPA because I am the one who will do the LPA now when the microcentrifuge is put on. This technique will offer a rapid result of resistance in the country, because it is not the same to do it with culture-based methods that require 4 to 6 weeks than to use a molecular biology method, with less biological risk, faster results." (NRL)

Some interviewees underlined as central learning to have incorporated into their practice the criteria for the use and sequence of phenotypic and molecular methods for the first and second-line drug sensitivity tests, depending on the characteristics of the samples arriving at his laboratory (as is the case in Honduras and Paraguay).

"The training, internships and technical assistance mean a very important contribution in the laboratory for the implementation of new techniques and the commitment of the trained professional". (NRL)

Certainly, the capacity of laboratories for molecular diagnosis varies according to their geographical, institutional and epidemiological conditions. In some countries (for example, Belize and Bolivia) these teams are now available in decentralized public laboratories, to identify cases and address them earlier or to reduce sample transfer problems. In other countries, this type of diagnosis is centralized in the National Reference Laboratory, due to the low prevalence of TB, or the lack of a network of laboratories (e.g., Uruguay), lack of resources, or resistance to incorporate these diagnostic methods due to the high cost of inputs and the technological dependence of massifying their use.

In the grant items, the equipment and supplies were not provided for the NRL (except for Cuba after a first reprogramming with the efficiencies generated). However, the training and activities of the grant directly or indirectly motivated the purchase of

GeneXpert equipment. These purchases were made with public funds or from the Global Fund country-grant or with donations of cooperation[11] (for example, in Peru and Bolivia). On the other hand, other countries, such as Panama, already had equipment for molecular diagnosis at the beginning of the grant. In these cases, the training served to make better use of the equipment and to improve the diagnostic procedures and their standardization.

"These events and activities provided new information and knowledge to improve diagnosis. For example, the Xpert MTB / RIF was acquired and implemented based on the information received at these events and activities." (NRL)

As a balance, we can see that the laboratories gained confidence and skills and had technical documentation that supported the introduction of improvements in their procedures. This expertise also allowed, in some cases, to convince the authorities to incorporate the new diagnostic techniques learned in training and internships.

"We have been able to update knowledge about the different diagnostic techniques, indicators, diagnostic algorithms, and in this way, with foundation, make the procedures before the pertinent authorities for the application and implementation of the different techniques." (NRL)

However, not all countries, to date, we're able to incorporate the new diagnostic methods, most of the time due to budget constraints. However, motivated by the grant and having the existing human capacities in the laboratories, some of them are managing the incorporation or expansion of these methods (for example, Ecuador, El Salvador and Honduras), others require a management capacity major policy, which is often lacking from laboratories.

Another of the training very well valued by the interviewees was the course of "Biosafety and Management of Biological Risks and Safe Transport of Infectious Substances". This workshop helped the NRL to take stock of the biosafety situation

[11] In Peru, a GeneXpert device was purchased for DISA-Sur https://vital.rpp.pe/salud/equipos-diagnostican-tbc-multidrogo-resistente-en-48-horas-noticia-805088

of their laboratories. Many of them took steps to solve some biosafety problems in their laboratories or their national network (case of Honduras). These courses were reinforced by the technical assistance visits that the SNL and PAHO experts made, making suggestions for changes in air and workflows, or proposing improvements in the cabins or space layout.

""Concerning Biosafety, the resource, the person who received training in this subject, has repeatedly reproduced what has been learned. Also, what has been improved on this issue in the Section has been done". (NRL)

In other cases, the needs exceeded the laboratory's response capacity, since the infrastructure requires a major change because the buildings where they operate are very old constructions or were improvised as laboratories (for example, Bolivia, Guatemala, Uruguay, and Venezuela). The grant, therefore, has contributed to highlighting biosafety measures and positioning them on the laboratories' agenda. In those who are changing buildings or remodeling, airflows and other biosafety recommendations are being considered (for example, El Salvador, Dominican Republic, and Nicaragua).

As for the internships that the NRL laboratories carried out in the SNL, several interviewees indicated that it was very different to observe the demonstrations developed by the SNL experts than to read it in the manufacturer's manuals since such expertise was not found in these Not on the Internet. The interns were helped to adapt procedures, to reproduce the techniques, to observe the results, and to incorporate the care and solutions to the resources and conditions existing in their reference laboratories.

"Internships are an important instrument to have direct knowledge about new laboratory techniques. Attendance at conferences and events allows the laboratory to express their opinions and receive new information, in addition to having a space to share criteria with other countries." (NRL)

In general, the internships served for the professionals to gain security in the processes, acquiring a "know-how to do" that the interviewed themselves reported that are

not found in other sources. The training allowed them to find solutions to situations that are not present in the academic literature or to infrastructure difficulties, and to implement innovative solutions.

"I was there, I saw all the controls, I did not imagine the number of controls that had to be taken into account to do the process. Plainly I was located in following a protocol, but all controls, all the flow, it is not the same to read it than to see it in the same a place that is done, understand how everything flows, learn from all the quality management that they have a whole quality management system based on that technique." (NRL)

In the case of the SNL, the trainings strengthened their knowledge that also meant a substantive contribution to the diagnostic tests that, but also served to give better technical assistance to the NRL. The SNL did not perform the same diagnostic tests as the NRL, due to the different characteristics that TB takes in each country. But, following the grant, other evidence was incorporated to provide better advice, as was the case of the SNL of Argentina.

For the professionals, the participation in international conferences and internships at centers of excellence increased in the level of their expertise and familiarization with procedures and protocols whose discussions did not directly benefit SNL staff. Like the NRL internships, these training had an impact on everyday processes.

"I also went to Milan to see all the environmental issues at level 3 containment. And that has been spectacular because it turns out that one has the training or training in general, in molecular biology, but not applied to mycobacteria. So, of course, I can study, but it will take me much longer. Going there where they already have the experience, the competences, they have a lot of trainers, in the background… So it's easy to absorb it, fast, and try to implement it here and adapt it to other countries. (SNL)

However, grant management sometimes could not overcome the old difficulties for participation in training. Partly because the relations between the program and the laboratory did not flow properly, or because the communications made by PAHO have their official channels, addressed to the central authority of the ministries of health, and these public agencies do not take into account the profile suitable and

send staff following other criteria, or simply do not process authorizations on time, so some laboratories lost the opportunity to take advantage of these benefits.

"In some of the trainings, the personnel working with Tuberculosis were not taken into account and people from other dependencies were sent, so I suggest that when they make the invitations, they must be directed to the profile of the professional working in the Tuberculosis Laboratory." (NRL)

Indirect results of technical documents and trainings

➡ Although the grant did not contemplate as a direct result of the trainings the strengthening of national laboratory networks on specific replication issues, this was a very positive unintended result. The capacity development implemented by the grant improved the network of national laboratories, also, it allowed to optimize the diagnostic processes and reinforce surveillance and, therefore, the contribution of laboratories to the fight against TB at the national level (as highlighted by example, Ecuador and Dominican Republic)

"The technical guides are valuable in the laboratories across the country and the printed guides reach the places where we don't have Internet. We need the guides printed and in electronic format to be updated. Also, by replicating what some of us had the opportunity to learn, we are giving more technical level to our national networks." (NRL)

One of the activities included in the grant consisted of the replicas that the LRN should make in their national networks of the Course of Quality Management and Good Laboratory Practices of TB (today, they have been accomplished in Nicaragua, El Salvador, Mexico, Argentina, Paraguay, Guatemala, Panama, Uruguay, Bolivia, Dominican Republic, Honduras, Peru, Colombia, Venezuela, Ecuador; and the other countries have them programmed in the remainder of 2019.

Beyond that, several NRL trained the laboratories of their national network using the training received in the workshops without being planned as a grant activity (for example, Belize, Bolivia, Ecuador, and Honduras), even some countries incorporated

substantive changes[12] in the operation of its network (for example, Nicaragua, Honduras and The Salvador). A case to highlight is Ecuador, as they made the replicas of almost all the trainings received and therefore the benefit of the training was significantly expanded.

"We as a reference laboratory in front of our network, we always have seminars programming, trainings to the network to replicate all these things that we learn and, in fact, last year we did one of November, November 15 and 16, where all were exposed these chats of all these workshops." (NRL)

"Topics learned in training and internships have been reproduced with the network. Also, with the completion of external quality control of smears with microscopy panels, it is expected to have a better overview of the capabilities of network professionals and thus determine the interventions if they merit." (NRL)

It should be stressed that, although the technical meetings where the heads of laboratories or directors of the national TB program participated, do not constitute training processes in themselves, they contributed to the development of a network of laboratories in the Americas. The meetings allowed sharing experiences, recommendations, the construction of cooperation and trust bonds among the attendees (they show it, for example, Costa Rica, Belize, and Colombia).

According to some laboratory professionals, the main learning was to "function as a network", because, before the grant, the regional network was disjointed, depended on the activities that PAHO promoted. Participating in regional activities, served as a template to boost their national network (for example, Uruguay, Belize, and Bolivia). But, above all, the grant allowed the implementation of a national technical assistance model, influenced by the technical assistance model that SNL provide to NRL, as another cascade.

[12] Fluorescence Microscopy; Lateral immunochromatographic; Database improvement of the Information System of the Regional Laboratory; Internal quality controls (culture media)

• 4.2 Contribution of advice, technical visits and quality controls to the strengthening of the NRL

➡ The technical supervisions carried out by the WHO or GLI experts, as well as the acquisition of the equipment for the SNL, generated a close dynamic of coordination, advice, and visits to the laboratories, with the active involvement of the heads of the laboratories and the Permanent support of the PAHO Technical Coordinator. Also, the main team of the Principal Recipient has constantly monitored the actions to improve management efficiency.

Before the grant, the SNL received technical and monitoring visits from PAHO, WHO or GLI sporadically. Due to the lack of funds for the transfer and internships in the SNL, many consultations were given by telephone or via email, which did not allow a comprehensive transfer of the "know-how to do" about diagnostic procedures, or biosafety measures.

This situation changed completely with the regional grant from the Global Fund, as technical assistance visits and supervision intensified. The three SNL received visits from the GLI or the Supranational Network of WHO Laboratories of 2017 and 2018, the SNL of Chile already received that of 2019 (scheduled for Argentina and Mexico of 2019), being evaluated as compliant with the terms of reference that give them supranational character. For their part, the three SNL made 17 technical assistance visits to the NRL scheduled for the first and second years. To date, 12 of the 17 visits of the SNL to their NRL corresponding to 2019 have been making. The remaining ones are scheduled. In other words, out of 60 VAT during the entire grant, 53 have been carried out. And of the 20 supervisions to be carried out by PAHO to each of the countries, 11 are counted so far[13].

The distribution of the countries that each SNL has in charge was carried out at the request of PAHO, and was the following: The TB laboratory of the National Institute of

[13] During 2018, six 6 visits were made and as of June 2019, four 4 visits; The remaining 10 are pending for the second half of 2019, which certainly agglomerate towards the end of the subsidy.

Infectious Diseases of Buenos Aires, Argentina, covers - in addition to its own country - to Guyana, Paraguay, Peru, Venezuela (and Brazil, which does not participate in the regional grant); the TB laboratory of the Institute of Public Health of Santiago de Chile, is a reference for Chile and serves Bolivia, Colombia, Cuba, Ecuador, Dominican Republic and Uruguay; and the TB laboratory of the Institute of Diagnosis and Epidemiological Reference INDER of Mexico assumes -apart from Mexico-, Belize, Costa Rica, The Salvador, Guatemala, Honduras, Nicaragua, and Panama.

Certain contexts hinder or delay the implementation of the new diagnostic methods. One of them is the feasibility of buying cartridges and reagents because there are no suppliers in some countries; another is the absence of companies that certify biosafety cabins. The grant has advised laboratories for the management of purchases through the GDF and the PAHO Strategic Fund, to address the problems of suppliers and costs. Also, it financed the training of BSC certifiers so that, from the SNL of Argentina and Mexico (who designated two professionals to train, with a public service commitment of five years or more), the service is provided to the countries.

Advice and technical assistance visits developed by the SNL

➡ There was a close communication from the PAHO liaison point with the three SNL to guide the development of the consultancies and technical assistance, which was highly valued. The three SNL had as an explicit purpose, on the recommendation of PAHO, to expand the incorporation of molecular diagnostic methods in the NRL that were in charge. Therefore, they focused their technical assistance to this end, in negotiation with the laboratories.

The procedure used by the SNL was to prepare together with the NRL an agenda for the visit of the experts on the topics of interest. Aspects to be deepened were included on the topics of the training received or which could not be attended. In several cases, members of the national network were included in the training (as in Colombia and Bolivia).

A range of activities was also scheduled such as the analysis of the physical conditions of the laboratory and biosafety recommendations, demonstrations of diagnostic

methods, training on certain procedures or advice for the purchase of equipment and supplies for sensitivity tests (for example, in Honduras and Ecuador).

The type of assistance was adapted to the needs of each laboratory. The technical visits allowed the SNL experts to understand the conditions where the NRL operated and the needs of the type of epidemic they attended. Knowing in situ the infrastructure conditions of the NRL facilitated providing concrete solutions on how to manage air and workflows.

The SNL experts were able to better understand the epidemiological conditions in each country and guide their advice based on each national reality. Recommendations were made to improve diagnoses, taking into account the characteristics of the country visited and its applicability to the national network of TB laboratories (the case of Ecuador). These processes would not had been possible with the previous scheme, of distance advice and time-space.

"It has been enriching, not only from a professional point of view but also as person because it is another idiosyncrasy, they are other cultures, so you learn how to do things differently, with other resources, with another mentality. Many times you have to adapt and that allows you to open your mind because you are accustomed to your own." (SNL)

"The project, really, supported the laboratory to really know the other laboratories it serves, because sometimes one from their country does not have the same vision and already being with them is that you understand. Because one asks for things and maybe they don't necessarily have that in their countries as such, so I feel that it places us a little more, in reality, to be able to support." (SNL)

"¿Do you know how Peru is doing in terms of tuberculosis? ¿Does the experience accumulate in resistance? There is much learning there. And you can understand what Guyana is, such a different culture? You also learn in those ways. It has nothing to do with anything one and the other! They are always big challenges. Then, those of us who were, we found different realities for which we had to make different proposals and agreements, work agreements, agree on some things and see the realities of totally different laboratories. That enriched us a lot" (SNL).

It should be stressed that for laboratories, the realization of technical assistance consultations and visits involved a redistribution of functions, since the activities that were carried out by the experts who traveled for VAT, had to be assumed by other professionals, adapting their skills or the usual dynamic of a workweek. Also, those responsible for VAT had to learn about techniques[14] that they do not develop daily in SNL (due to different epidemiological characteristics of each country). It is because of the questions of the NRL that the experts had to exercise certain techniques to be able to provide advice. A situation that illustrates is the high number of MDR-TB cases that are processed in Peru, so the Peruvian NRL constantly performs tests with LPA from a long time ago, while its SNL, from Argentina, performed it sporadically.

"Our reality is different, we handle a general flow for all patients, as a quick test to have the timely diagnosis, so they came to see, more or less they took a good picture of the handling we have because we have been working with that something from seven to eight years with LPA." (NRL)

The SNL staff became involved and valued the efforts of the NRL that frequently work in adverse material and political conditions, finding innovative solutions.

The technical assistance visits for each country that financed the grant focused on various topics, including molecular biology, use of the Xpert MTB / RIF, biosafety and risk control, management and algorithms, quality control, lamina panels BK and LQAS, PSD 1L and 2L in BACTEC-MGIT, registration systems, and equipment maintenance. (For more details see annex II).

Changes or innovations generated by visits and technical assistance

➡ We found changes generated from the development of the grant. In some countries, technical assistance visits directly helped update diagnostic procedures that were reflected in the improvement of methods for the identification of second-line drug resistance, or in the incorporation of the Lowenstein-Jensen medium for

[14] For example, the molecular methods expert learned the format of crop yield.

PSD (as in The Salvador) or the use of the proportion method (the case of Honduras) and improvements in the use of BACTEC-MGIT equipment (Ecuador).

"Thanks to these visits this year we will begin to carry out DST of the second line and we will begin to perform the external quality control of smear microscopy through panels by microscopic" (NRL)

One of the processes highlighted by the interviewees has been that the grant generated external quality control for three consecutive years through strain panels that send the SNL to their NRL. Continuity in control has been a stimulus for countries to strive to improve their diagnoses. Although not everyone has accepted levels of efficiency, quality controls made the NRL understand their importance, need and commitment to improving their procedures.

PAHO technical assistance put a lot of emphasis on the adoption of rapid molecular methods and the reduction of the investment in diagnostic smear equipment and procedures. The SNL in their technical visits, especially in Argentina and Chile, promoted the adoption of molecular methods, which does not imply discarding the installed capacities for performing smear microscopy and cultures.

In countries that already had molecular diagnostic equipment, its use was improved and, in some cases, GeneXpert is used for the diagnosis of multiple diseases such as TB, HIV or Hepatitis C, as a common platform that depends on the type of cartridge to run. The model of training supervision promoted by PAHO and implemented by the SNL, improved the technique of application of the tests, transferring criteria and specific know-how to do. It happens that some countries that already did rapid and molecular tests had not received training so that they did not know the threads, but during the visits, the SNL could help them refine their procedures.

"And besides, it was all a trick at the time of the techniques, and it is not the same when you have a person who is already trained, with enough experience that tells you: "Look, this is here, don't trust this because this can happen to you, you can't ignore this detail"; then one has the possibility to train and see everything, it is how I really see it, just like when they

went there to our laboratory to train us in GeneXpert and we had been doing GeneXpert for 2 years, but we had not received any training, it was just what we had read." (NRL)

"With the issue of the LPA test, there was a point at the end that was the subject of the patients when an outcome came out indeterminate for a resistance issue that did not match the other susceptibility test, the issue of sequencing was missing." (NRL)

Despite the acquired capacities, not all countries incorporated the new diagnostic procedures, due to budgetary limitations or the lack of feasibility analysis. To date, some do not have the centrifuge, or a Tween incubator, or an adequate safety cabin is not available, or the purchase of the cartridges has not been guaranteed by 2020, once the grant ends and they are finished financed stocks purchased in these years. However, in many of these countries, the political will has been secured for the incorporation and continuity of these new methods, which will require intense political management (for example, Ecuador, The Salvador, Honduras, and the Dominican Republic).

Likewise, during the VAT the SNL staff also guided on how to articulate laboratory diagnostic practices with other procedures and problems of disagreements, which resulted in adjustments to the algorithms used.

"We have improved our algorithms, we do many repetitive things that make us spend more inputs and with these visits we then refined our algorithms, incorporating, adding methodologies for the confirmation of tests." (NRL)

It should be noted that monitoring the impacts of changes generated in disease control is not part of the grant indicators. Because the objective of the grant is simply to strengthen the laboratories that contribute to the fight against TB, the financed activities did not involve improving the process of transporting samples at the national level, registration or reference and counter-reference systems, operational research, or drug management and its articulation with the diagnosis; Although these aspects continue to represent extremely vulnerable points in the fight against TB.

"Yes, the transport of the samples is bad, each health area is an independent executing unit, then it is the one that costs, and the systems are varied, it depends on the steps that each health area performs." (PNC)

It should be stressed that eleven of the twenty countries have a Global Fund country-grant at different stages, and some have resources from other sources for the fight against TB, which include this health system strengthening activities in relation to TB The grant, rather, focused on this little attended link in the chain, which are the laboratories.

Per biosafety training, the VATs of SNL emphasized the analysis of biosafety conditions. This supervision highlighted substantive changes that should be made in the laboratory infrastructure so that they meet the requirements.

"The grant allowed us to visualize and identify strengths, weaknesses, and opportunities, which because we are immersed in the laboratory, we do not identify them. On the other hand, advice and technical visits allow us to make changes in the areas based on the recommendations of the experts." (NRL)

In some cases, the NRL were able to commit the decision-makers in the investment for the remodeling of the smear area (the case of Belize) or the transfer to other facilities (for example, The Salvador and the Dominican Republic) or the same staff delimited the area of containment to avoid risks for personnel (Venezuela, for example), but in other countries, more intensive management is required.

"After several recommendations it has been achieved that at present the removal of the laboratory infrastructure is executed, to meet the necessary standards in the reliable and timely diagnosis." (NRL)

"There are some things like the structure of the laboratory, that from the biosafety point of view the building does not meet the requirements and that is no longer up to us, but we have been given very complete and very rich reports on all the information that have given us." (NRL)

VAT also generated other results related to the diagnostic management model, such as improvements in documentation, data collection and workflow organization and in general having a situational balance of the laboratory operation (for example, Belize, Venezuela and Nicaragua), which has resulted in a better efficiency of the NRL in the quality and timing of its diagnoses.

Difficulties in implementing the results of technical assistance

➡ The difficulties differed from one country to another. The main limitation, certainly, was the lack of resources to make the suggested changes in the technical reports. This was expressed in the lack of budget to remedy the infrastructure deficiencies of laboratories that did not comply with the basic biosafety standards (for example, Belize, Dominican Republic, Venezuela, Colombia, and Nicaragua) and whose solution requires a firm political will.

"When the recommendation is due to efforts that do not correspond to the area coordinator (in our case we refer to the biosafety and adequacy of the physical infrastructure of the laboratory), this is a priority, but for the value it has in resources and the dimension of the activity, is something that scales to the highest level of management." (NRL)

"In our laboratory, the main problem is biosafety deficiency, for which it has been requested every year before our authorities the reconditioning of the containment area and in all the technical assistance made is the recommendation that is repeated." (NRL)

Many laboratories are kept on the premises where they were founded five or six decades ago. As we have already pointed out, the VAT reports - as documents of an international expert opinion - was a useful tool to convince the authorities to invest in improving the laboratory, whether these are partial improvements, a total remodeling or a new headquarters (for example, The Salvador, Dominican Republic, Uruguay, and Belize).

In another sense, some recommendations could not be implemented due to the cost of the cartridges for the Xpert MTB / RIF, as the price for countries that do not receive grant is extremely high, while low-income countries and those that are going

through economic crises (Venezuela and Argentina, for example) have difficulties in expanding the existing budget. In some cases, it was decided to channel the purchases through the country fund.

" The biggest difficulty is that we do not have a budget to implement these recommendations immediately. Our country does not have budget-based sustainability for inputs and reagents." (NRL)

Another critical problem is the lack of personnel, to the extent that some laboratories expanded their activities, for example, strengthening their national network, or incorporating other diagnostic methods. The time available to implement all recommendations or procedures is not consistent with the human resources available in some cases due to the low number and in others due to the low workload (for example, Belize, Uruguay, Costa Rica, Honduras, and Paraguay).

"It has cost in the sense that in parallel that we receive the visits we cannot leave the assistance task, but see if people will be happy with the technical visits that were left after time to be able to be listening all day to the professionals of Chile whom they came." (NRL)

"I feel that the staff is not enough, because there are many activities that we have to comply with and sometimes due to lack of staff we leave them a little behind, for example, the quality control of smear microscopy." (NRL)

In some countries, the lack of staff time brought difficulties, including, for the implementation of the external performance evaluation (Honduras, for example). The regular activities of the laboratory were maintained, but participation in the grant demanded a greater dedication of time, and the limitation of staff prevented applying everything learned at the speed they wanted.

Some countries postponed the implementation of the new methods after the end of the regional grant, and plan to develop an incorporation plan, but they anticipate that their main limitation, too, will be human resources, because even in several countries there is access to resources to finance equipment, but not to incorporate new personnel.

"We work with a lot of freedom, we do not have serious budgetary problems for the purchase of equipment and supplies, but unfortunately, human resources are very limited and that prevents us from complying with some activities that are also critical for the country." (NRL)

"The recommendations basically go towards strengthening the laboratory staff, appointing more staff, because we really were very few and still are, we still need staff to complete all our functions, and really what is in reagents and supplies we have not had problems." (NRL)

On other occasions, the difficulties come from the management systems of each country. In Cuba, for example, the blockade imposed by the United States hinders the purchase of equipment and supplies, and even the shipment of strain panels from the SNL for external quality control. Some other countries also experience problems due to slow or cumbersome efforts or lack of coordination between program and laboratory, however, the administrative unit of the regional grant of ORAS-CONHU found solutions, changing suppliers or carriers and improving processes. In other cases, the equipment or supplies are not available in the country.

""It is also difficult because companies do not have the representation of some equipment and reagents suggested in the training." (NRL)

There is a limitation in PAHO for the management of consent and authorizations, as an international organization it is obliged to communicate through the PAHO representations of each country with the ministry or secretariat of health, and cannot do so directly with laboratories or institutes. This causes that the information takes a long time to arrive at the laboratory or simply never arrives, or that the ministry designates a person outside the laboratory to attend the training or coordination activities even though the letters of invitation sent specify participant profile. On the other hand, ORAS-CONHU and SECOMISCA did not have this restriction when they implemented the activities under their charge, they communicated directly with the NRL, in addition to respecting the previous channels with the ministries or secretaries of health. They also made bridges between the NRL and the NTP, and on some occasions, they made a direct dialogue with the authorities to unlock the efforts.

However, when the grant ends, the management will return to a situation similar to the previous one.

"The communication of ORAS and COMISCA to the ministry was always communicated (no matter how redundant) to the laboratory and it was possible to follow up. However, PAHO strictly communicates to the ministry and in that case because the laboratory could not follow up on what is unknown, and opportunities were lost." (NRL)

There are specific cases that depend on how the organization chart is structured, where the laboratory is dissociated from the program or the administrative processes of the ministry, where the decisions go through the secretariat of international relations and the procedures were so slow that they prevented the participation of professionals in training.

"This had different edges, in some cases, it was due to the lack of articulation between the laboratory and the agency in charge, in some cases to the program, in others, to international relations, in others to a dependency of the ministry" (PAHO).

• 4.3 Strengthening the network of laboratories of the Americas

➡ A strong investment was made in the equipment of the SNL, providing them with capabilities for molecular diagnosis. Also, participation in international conferences with scientific papers and internships to international institutions of the highest level was financed. Consecutively for two years evaluated, the three SNL meet the criteria established by WHO to be supranational laboratories.

The grant opted for a strengthening in cascade, having the first line of benefit in the SNL, which then revert in the NRL through advice and technical visits, which is directly reinforced with the documents and training addressed to the NRL.

Likewise, the grant financed the hiring of two professionals in Argentina and Chile to redistribute the burden of the dedication of their expert staff to the training and technical assistance activities energized by the grant. In the case of Mexico, this was not possible due to internal regulations that prevented hiring new staff with external

funds, but the SNL assumed its roles and activities with its capabilities and resources. At the end of the grant, Argentina absorbed the new staff, remaining in the regular staff of the institution. On the other hand, the Public Health Institute of Chile gave up hiring the two professionals (one should be hired this third year and the other when the regional grant ends), due to government policies restricting domestic spending.

The core activity of the grant was in the control of the diagnostic quality of the twenty laboratories. Strain panels were sent to be analyzed to see if their DST diagnoses were correct. Shipments were annual and transportation was financed. Only Cuba has not been able to receive the samples, so efforts are made to attempt the shipment directly from the SNL of the IMT of Belgium, where the WHO coordinating laboratory that supplies the SNL is located.

Strengthening of SNL through the grant

➡ The donation of equipment was concentrated in the 3 SNL (Mexico, Argentina, and Chile) and exceptionally in Cuba. For the SNL they meant an enhancement in the ability to meet the demands of the NRL and their national networks. These donations improved biosafety conditions, expanded the types and capacity of diagnostic tests.

Molecular diagnostic capabilities were also reinforced in Chile and Argentina, with the purchase of GeneXpert equipment and higher capacity servers to perform more complex molecular analyzes that identify mutations of multi-resistant strains. Although some SNL already had equipment for genotypic analysis, the technology acquired by the regional grant allowed them to make complete genomics, a cutting-edge technology that they did not have before.

"The acquisition of the equipment allowed us to evaluate resistance profiles, second-line, first-line drugs with a complete profile, both molecular and phenotypic." (SNL)

Also, it meant an advance in their knowledge and abilities, especially regarding rapid and molecular tests. Before the grant, not everyone had implemented the constant use of rapid tests and rather the training and internships at the centers of excellence allowed them to acquire skills to be able to transfer them to America's network.

For example, the SNL of Mexico had GeneXpert equipment but did not have many cartridges, which were used in special cases. The use and skill of these methods were enhanced with the grant.

"We had not done so much in the molecular diagnosis before and now we have already implemented it, we already have rapid molecular tests to identify resistance for both first and second lines, as a result of the project, it was something that the country had pending." (SNL)

In Argentina and Mexico, the purchase of equipment for the certification of cabins expanded the laboratory's capacity to provide technical assistance. The equipment was parallel with the training of engineers in the CSB certification, which was a necessity of the NRL, funded by the grant, whose training culminates in 2019.

However, it should be noted that, in some NRL that did not receive equipment, a synergistic effect was generated between training in molecular diagnostic techniques, technical visits, and internships in SNL, which consisted of boosting the purchase of equipment to carry out rapid and molecular tests. This was done with public funds, with funds from the FM country grant or sometimes with cooperation donations.

The incorporation of GeneXpert in some countries redefined the diagnostic processes, the reference, and counter-reference of the cases and the system of transfer of samples to the interior of the countries. Besides, it involved adjusting the algorithms and therefore had to work more closely with national programs.

"Our work algorithm will change we are already in discussion with the national control program, adjust the laboratory work algorithm based on this tool that we will have available" (NRL).

External Performance Evaluation

➡ This is one of the central aspects of laboratory strengthening. The SNL closely coordinated the sending of panels with their networks, an activity managed by the ORAS-CONHU. This task has been carried out for years with direct financing from PAHO, but the reduction of funds imposed a strain on ensuring external quality controls so that the grant eased this concern. Also, not all countries had technical biosafety conditions (certified CSB) to perform these techniques, so not all received the panels. Since 2018, shipping from the WHO laboratory in Belgium to SNL has a cost, which had hitherto been free.

"The last thing we did was in 2014, but in this case it was not so much because of a conditioning for the contract issue of a suitable company, which we achieved through the project, but because many of the laboratories to which we had to send the panels did not have the appropriate technical conditions to perform these techniques." (SNL)

The grant expects to close with quality controls carried out in all countries, pending an alternative for Cuba, which is attempted in 2019.

The mechanism used has been the following: The Belgian laboratory prepares the strain panels that it sends to the three SNL, and these, in turn, prepare the panels for their NRL, always with an earlier round, whose results are already available. During the implementation of the grant, the transport of the samples has been fully financed, but in the future, each country will have to finance this process. The countries carry out the DST to the samples, identifying the sensitivity patterns and the results are sent to the senders so that they determine if their diagnoses are correct through the calculation of sensitivity, specificity, reproducibility, and efficiency.

In the first year, transportation and customs clearance (or nationalization) was a recurring obstacle. The changes in the air transport regulations of biological samples make the transfer of this type of infectious biological material even more difficult. There are countries in which the national authorities are late in disbursing the corresponding counterpart, since the shipment is paid by the grant, but not the customs clearance. The characteristics of the samples demand additional procedures

and sometimes due to the lack of coordination between the authorities, the customs clearance was delayed, and the cost of its withdrawal increased. From ORAS-CONHU, the steps were taken and coordinated with a single supplier to expedite transport and customs clearance. However, once the grant is completed, this problem will remain.

According to the monitoring data, 50% of the NRL obtained, in the first year (2017), an external evaluation of the quality control to acceptable PSD, that is, the same performance observed in 2015. The goal could not be reached planned 70% of laboratories. In the interviews, it is argued that the breach of the minimum levels of diagnostic quality was due to deficiencies in biosafety and lack of personnel, but from the perspective of PAHO it was fundamentally "because there was no certification of biosafety cabins", an essential requirement for sending strains from the SNL to the NRL.

Currently, there are no data regarding the results of 2018, but it should be added that the grant has financed the training of engineers who are already evaluating the CSB as part of their training and also provided the SNL with instruments for measuring the biological risks. From 2020 the SNL will be able to provide the certification service of the biological safety cabins.

The efficiency of the diagnosis in some laboratories is a great concern, but also the financing of the processes that are in charge of the SNL, which have committed themselves to include personnel, supplies, and resources for the preparation of the control panels. However, this commitment has to pass some critical barriers, especially in Argentina, where economic conditions reduce the ability of the State to buy supplies, it will be very difficult for the endowments to be sustained, in the past, there were situations of unavailability of inputs, and the grant had to solve it.

"For me, there is uncertainty, because equipment has been acquired, but now they let go of our hands. And how do we buy their consumables in dollars? How do we solve the shipments of panels? And no matter how much we put at will and express with a correct argumentation the best and ask for the budgets, for the economic conditions that we have expressed before, they will tell us: "No, it is impossible" "(SNL)

As of the date of preparation of this report, the countries of Central America and the Dominican Republic have agreed with the Council of Health Ministers of the subregion (COMISCA) to allocate resources to cover these needs, while in South America the meeting where financing and sustainability of the operation of the TB laboratory networks will be at the end of the second half of 2019.

Network construction: Relationship between SNL and NRL

➡ In general, it is appreciated that the technical assistance provided by the SNL is highly valued by the NRL. Especially since the frequent shipments of the panels have been fulfilled and the technical visits and internships have increased.

"All technical assistance processes are more advisory to achieve the goals of the country and the region in the framework of the elimination of tuberculosis, in reality, this process is always very high quality by our SNL, I do not I would modify anything."(NRL)

Also, the increase in technical assistance improved the relationship between SNL and NRL. It also had an effect of personalizing the assistance, being able to meet face to face facilitated the relationship between the experts of the SNL and the professionals of the NRL. This meant greater confidence and a better flow of communication. However, not everyone was able to take advantage of technical assistance in all its potential, given that its infrastructure and lack of personnel and resources limit them.

"It has been requested every year before our authorities the reconditioning of the containment area and, in all technical assistance performed, is the recommendation that is repeated. As long as the problem is not solved, it is difficult to request technical assistance on other issues." (NRL)

The incorporation of new methods generates doubts that arise day by day and is often urgent and may not necessarily wait for technical visits. However, in some cases when these consultations were made to the SNL the responses were not quite fast. Certainly, the SNL also has a recharge because it must meet the needs of its national network and at the same time devote time to fulfilling the activities of the grant.

However, some maintain direct and constant communication with NRL who are responsible.

"We have created support networks, for example, for the implementation of new methods, for biosafety, for different things, and we already have some confidence, at the beginning there was a distance, now no, we have WhatsApp open almost 24 hours, so they ask, it's very rewarding."(SNL)

In other cases, the SNL struggled to devote time to the questions and demands of the laboratories. This difficulty was compensated by the NRL themselves by creating a WhatsApp network constituted by them, the technical manager of PAHO and the one of SECOMISCA. In this social environment, laboratories make inquiries and exchanges with each other and in that way doubts and questions are cleared more quickly.

In addition, the SNL had to implement, at the request of the NRL, more practical than theoretical assistance and operational follow-up processes, for example, by sending the technical reports of the visits in a shorter period, since at the beginning some delayed sending up to three months In fact, the SNL argue that experts prepare the reports after making the visits, then that report is reviewed with the head of the laboratory. Subsequently, it is sent to PAHO and SECOMISCA, who sends it to the authorities of the ministries or secretariats, and these are sent to the laboratories; although, after these steps, the SNL also send directly to the NRL, because sometimes the reports do not come down from the higher instances.

The demand for some NRL (for example, Dominican Republic, Honduras, and Nicaragua) is that the technical assistance views be longer (usually five days) to better develop the practical implementation of their recommendations.

"In some cases, a longer stay of the technician is required, since some assists require a transfer of theoretical/practical skills." (NRL)

The network of laboratories is conceived as a "star" with a center that is PAHO and 3 nodes or bridges constituted by the SNL, plus 17 subnodes, corresponding to the national laboratories that receive technical assistance from their SNL, and then

transfer those you strengthen your networks within countries. This network model pays attention to a pyramidal structure of the centers towards the peripheries, with few relations between the nodes. Some laboratories have had to redirect their training needs with other NRL or SNL that is not necessarily to which they are attached, and this presupposes more complex coordination.

After meetings and training, exchanges and collaborations between NRL increased. In this way, collaborative processes between NRL were initiated without necessarily going through SNL.

"We have a WhatsApp group that (…) helps us a lot to make inquiries and we always find someone's prompt response, from Lucia Barrera, Ernesto Montoro, and others. Also, and product that attending meetings we get to know and appreciate, we have email addresses of each of the NRL bosses, which also allows us to share experiences and pass on tips." (NRL)

The links built throughout the grant have resulted in collaborative processes that go beyond a virtual relationship. Currently, several NRL exchange solutions, absolve questions or even share inputs so as not to stop laboratory work or receive visits (for example, Peru, Guyana, and Venezuela). This was an unplanned result, but it could be considered as a "good practice" to ease the burden on SNL tasks since sustainability is not entirely guaranteed.

"We have even supported supplies from laboratories in other countries, they have also asked us for help to implement Genotype, for example. They have also come here to do internships at the laboratory, they have come with their money, Nicaragua, Bolivia has come… " (NRL).

This concept of the horizontal fabric of the network has not been directly driven by the grant, but some of its members perceive it as a strength of the network and that it can increase and improve the design of "targeting" proposed from PAHO, making it more dynamic.

"It would be very good to have a more formal and exclusive group to attend technical queries and in general the task, that is not segregated as we are now with the SNL, since they all work differently and that the consultations can be attended by those who most prepared or have more experience" (NRL).

• 4.4 Relevance of laboratories and impact on national TB policies

➡ Boosting the relevance of the reference laboratories was not the result of direct activities as an advocacy process, as this was not explicitly contemplated for the national level, but has been a result of a synergistic process, generated by various components of the grant: The technical documents allowed specialized support in the interlocution for changes in procedures and acquisitions. The technical reports of the visits facilitated the management of improvements in infrastructure and services (maintenance). The involvement of the directors of national TB programs in regional coordination meetings gave cohesion and force to disease control.

This set of activities has positioned the work of the laboratory and valued the capacity of its members and the centrality of the diagnostic quality before the authorities and before the program, although this has not always translated into greater support for the laboratory.

Advocacy in public policy to combat TB

➡ The investment in the strengthening of laboratories has had three circles of benefits. The first has certainly been the laboratory itself, which has improved its diagnostic methods, has gained confidence, has standardized its procedures, has consolidated its technical support and has more trained staff. However, the level of benefit has not been the same for everyone, in the technical visits made by PAHO it is expressed that not all laboratories have reversed what they have learned towards their staff or have improved their processes.

The second circle of benefits can be seen in the improvements introduced in the national laboratory network. Although these were also unequal, it should be noted

that several NRL promoted the updating of laboratories at other levels in their respective countries. Also, they disseminated the technical documents or made replicas to the members of their network, or even involved them in the technical assistance activities developed by the SNL experts during the visits.

"Some people in the network were invited to training, which became an incentive for their work. Everything that is received from recommendations or adjustments to processes is always socialized with the network, so the update processes are replicated favoring the capabilities of human talent." (NRL)

For some laboratories, the dynamization of the Americas network helped them to redefine their role as NRL, now thinking of themselves as an active agent for capacity development, improvement in biosafety, update of tests and control of diagnostic quality.

"In a very important way, he gave the Laboratory the relationship and direct contact that was missing from the network. In addition to being able to see the reality of many members of the network know their needs and strengths." (NRL)

Several NRL were encouraged to establish or strengthen their national network of laboratories using the assistance and supervision model that operates at the level of the Americas. In general, the dynamics developed allowed laboratories to have a different view of the network, with a wider diagnosis, a better understanding of what can be done with different levels. For some NRL it was impossible to strengthen their national network further because this competition depends on the National TB Program or another instance.

"The program, above all, is the one that performs the supervision, the technical assistance of the laboratories of the network. We stayed for a while without a grant, when it was up to the laboratory to absorb the staff did not assume it, so the national program is the one that absorbs the staff with its funds" (Program)

It should be stressed that the grant only contemplated the realization of a replica of the workshop on "Quality Management and Good Laboratory Practices". Therefore,

additional activities at the country level were part of the motivation of the NRL to transfer the benefits to their networks.

"According to the most recent satisfaction survey, the NRL is in a position of excellence. We have a network of 110 laboratories that frequently consult us, so that even centers with high turnover, receive immediate advice." (NRL)

There is a third circle of benefits that is outside the direct reach of laboratories, which consists of improvements that can be introduced in the health system from increasing the quality of diagnostic procedures. The laboratories that managed to generate changes in the management of the fight against tuberculosis had good relations with TB programs or improved in the development of the grant. It was achieved, in some cases, to change or update the algorithms of care, referral, laboratory diagnosis, etc., which is only possible when there is good coordination with the instances related to health care.

"Communication between laboratories improved greatly, although we must continue working on this issue with doctors, nurses, etc." (NRL)

For most laboratories, the incorporation of rapid and molecular methods driven by PAHO meant a reduction in diagnostic time, because the use of GeneXpert can yield results in 2 hours, in contrast to 30 days or more than last traditional methods. Consequently, the grant will indirectly contribute to reducing the incidence, while a patient identified earlier and treated in time, reduces the transmission of the disease in its immediate environment, in the community and the impacts on the family economy, labor costs and loss of opportunities.

In Central America, the incorporation of molecular methods, in some countries, meant reducing the cost much more, since before the samples were sent to the SNL in Mexico, which was delayed and complicated because the amount of the transfer was increased due to the biological risk. Also, because of the delay, the diagnosis was no longer so timely. The implementation of these methods represents a considerable saving.

Along these same lines, other secondary aspects of the grant have to do with the improvement of the sample transport system for the diagnosis. One of the problems was always the transport conditions and speed so that the samples are not altered, and the diagnosis is timely and accurate. This aspect was not contemplated in the goals of the grant, but it is a constant source of concern for laboratories. Some have opted for the decentralization of the diagnosis, with the purchase of GeneXpert equipment to have a timely result in the regions, provinces or departments.

"The transport of samples from the sample collection units to the health areas and hospitals is not adequate or in the time required, this is a recurring problem at the national level." (NRL)

Another aspect of public policy to combat TB is related to information systems. This is dissociated, since the way of registering the health system or the NTP is based on cases and the registration of the laboratories is based on diagnoses made, on the number of samples processed. In most countries, the absence of a nominal registry of patients and the health services provided is critical, creating duplication and atomization of the records. At this point, we do not see major advances, as they are complex processes that depend on health care models and are beyond the reach of laboratories but have been included in the agenda of laboratories and NTP. At least it was done as part of the regional grant, a survey of the current state of information systems in the TB laboratory networks of the twenty countries, a training workshop, consultancy to the three SNL and a proposal for strengthening.

"The change has also been in understanding that we have to monitor the things we do, it is not only to make 30,000 culture a year, but it is who! Because (…) then it has been more about how to collect data that we did not have to manage, because in reality without data we cannot manage." (NRL)

The development of reliable statistics, through the national network, around the identified cases of TB-DR, TB-MDR and TB-XDR, contributed to the policies because it generated interest from some authorities on the evolution of the situation epidemiological and monitoring of TB cases. Since the guard on tuberculosis had been lowered by the emergence of other epidemics such as HIV, bird flu, dengue,

Zika or Chikungunya, TB statistics facilitated the alert, especially on the number of cases not notified.

"The activities helped strengthen the national network particularly in terms of data collection to generate useful information for the country. There was no detailed information before 2017 as it is now." (NRL)

"The implementation of new techniques has opened the possibility of having better data on the reality of tuberculosis; this allows the authorities to have more knowledge about the pathology." (NRL)

On the relevance of diagnosis in the fight against TB

➡ In all countries, the grant helped to make visible the contribution that laboratory diagnosis means to the fight against TB, which highlighted the relevance of laboratory networks.

The grant continued the policy developed by PAHO in the past to involve those responsible for NTP in the coordination activities organized by the grant, only on this occasion the program-laboratory involvement was more frequent over time. The chiefs of NTP became even more aware of the importance of the quality of the diagnosis and in most countries, the links between the program and the laboratory were strengthened. Understanding their needs in some cases facilitated the management of funds from the national grant for the purchase of supplies or equipment.

"Some authorities had a change of attitude, at first they only said "yes, we are going to do it… "but then they got involved. The people who offered some resistance later were facilitators, for example, my director assumed responsibilities to favor the consent" (SNL).

These results were most evident in countries where there was a close link between the program and the laboratory, in some cases due to a functional organization of the system itself (for example, Uruguay, Cuba, Costa Rica), in others due to close coordination. and trust between both instances (for example, Chile, Mexico).

"We meet frequently, so they are aware and share criteria with the Health authorities. As a Commission, we promote country strategies."(NRL)

However, in the fourth part of the countries (for example, Bolivia, The Salvador, Dominican R., Ecuador, and Belize) there is still a lack of coordination between the laboratory and the national health system or the program, which hindered the optimization of the strengthening of the NRL that the grant promoted. Close coordination is required to improve algorithms, reference systems, information and monitoring mechanisms, etc.

"The joint work of the laboratory and the program is not what is expected." (NRL)

It should be noted that the difficulties that laboratories currently have to improve their infrastructure, equipment, expand their staff or buy supplies go through political management. The recognition of NRL in TB public policies did not translate equally into budget support. Some countries bought equipment, supplies or incorporated more personnel; others, on the other hand, do not support laboratories economically as described above.

The idea persists in some laboratories that their role is purely technical, and political management exceeds their capabilities. Indeed, during the data collection, several interviewees stated that they had no information on budgetary matters, or the future sustainability of the diagnostic activities incorporated as a result of the grant. However, the grant introduced this discussion in meetings with ministers, bringing technical teams closer to them, and with regional training on leadership and political management.

The concept note did not include activities for advocacy actions by laboratories, these activities were focused on the high-level management of ORAS-CONHU and SECOMISCA. This multilateral management has paid off, the two institutions advocated expediting procedures, permits and obtaining political support. In Central America, also, it was achieved that the ministers of all member countries sign an agreement to finance the strengthening activities of the NRL. However, it would have

been desirable that in the post-grant scenario, the NRL were better equipped for advocacy actions.

The capacity of the recipients allowed them to overcome difficulties and facilitate activities, as they are external actors and administrative management independent of government procedures, together with PAHO as an international expert institution. However, once the grant ends, the laboratories will not have these organisms alongside with the same intensity and commitment observed in the three years of the grant. Despite the efforts, most laboratories will have difficulties in political management, especially in those where the cooperative relationships between the laboratory and the program are not optimal.

• 4.5 Compliance with the commitments derived from the grant

➡ Sustainability has been a concern of the grant and a condition of Global Fund financing. Various activities were carried out in anticipation of this goal: As of 2019, twelve meetings had been held with the ministers/health secretaries and the laboratory managers, sponsored by ORAS-CONHU and SECOMISCA, where mechanisms to guarantee the financing of network activities were discussed. Also, ORAS-CONHU and SECOMISCA made visits to the countries of their respective regions and met with ministers and vice-ministers of Health to guarantee laboratory support and continuity of commitments.

However, the challenges facing laboratories are dense. There is a need to give "internal" sustainability to the positive results of the grant within countries. The continuity of the introduction of the new diagnostic methods must be guaranteed; the preventive and corrective maintenance of the equipment and the update of the software of diagnosis, purchase of supplies and materials, certification of the cabins. Also, those countries that did not meet the biosafety requirements have to advocate for infrastructure improvement. Others, who have planned the adoption of molecular methods, have to manage the purchase of new equipment and supplies. Not to mention the problem of the lack of human resources to meet the needs of its national network and the quality control of the laboratories that depend on them.

Likewise, it is necessary to give continuity to the network of laboratories of The Americas in support of the quality, updating and improvement of the diagnostic practice of the NRL. This "external" sustainability relies mainly on quality control through the dispatch of strain panels, but also on advice and technical visits, in the internships of professionals in SNL and trainings.

Sustainability of the changes incorporated in the NRL

➡ In nine countries, some activities derived from the grant were incorporated into the public budget (for example, Ecuador, Honduras, Nicaragua, and Panama), for example, for the purchase of GeneXpert equipment, cartridges, and supplies, although in others the resistances are maintained to prioritize public spending. The political management developed by ORAS-CONHU and SECOMISCA, the involvement of TB policy officers, meetings with authorities and direct advocacy with health ministers/secretaries contributed to the success achieved in some countries.

In some cases, the mechanism to guarantee to finance in 2020 was the development, together with the ministry, of a sustainability plan for the fight against TB or inclusion in the AOP or in national strategic plans, or renegotiation of the country grant with the Global Fund, where some laboratory needs were included. In other cases, it was a management that followed the established channels, with meetings between the authorities of the health sector and the planning unit of the secretariat or ministry of health, to formulate the request for the budget item for next year (the case of Honduras). Another path was the construction or strengthening of the relationship between the head of the laboratory and the relevant authority on the issue of TB (as in Paraguay). Another way was through the change of the regulations, or the modification of the algorithm (for example, Costa Rica and Nicaragua) that implied the commitment for the incorporation of molecular methods and consequently that the health sector generates the obligation of the purchase of equipment and supplies.

"In the new National Standard, the algorithm for laboratory diagnosis begins with the Xperts, so they will have to comply with it." (NRL)

Instead, in seven countries the country grant of the Global Fund or international cooperation financed the purchase of supplies or equipment for laboratories. This occurred in some cases as a confluence between the TB program and the improvements observed in the laboratories. In others, it was a consequence of efforts promoted by the regional grant.

There are countries where it is not clear how the purchase of inputs for molecular tests will be financed (Dominican Republic; Venezuela) and active management by the laboratory is required, either by generating a transition plan or by doing advocacy to obtain financing. Many laboratory managers are aware that the financial sustainability of the changes operated depends on political management.

Not all countries have budgetary or cooperation restrictions for the purchase of equipment, supplies, and materials (for example, Peru, Panama, Costa Rica), but like the rest they have difficulties to incorporate new staff to help consolidate the learning of the laboratory and extend the benefits of the grant to your national networks.

Sustainability of The Americas laboratory network

➡ The post-grant scenario is challenging as long as external funds will no longer be available, but neither will PAHO-WHO resources to finance the technical visits of SNL, nor for sample transport.

Regarding the sustainability of the activities of the SNL, there is a commitment from the governments of Mexico and Argentina to support the leading role of their laboratories, and for this, they have programmed resources by 2020 to fulfill the activities that confer their character supranational. In Chile, the picture is more complicated, since the two people whose hiring has been covered by the grant were not assumed in the public budget basically, due to transversal austerity policies. The Chilean health sector is considering alternatives to maintain activities such as SNL, but from now on two of the countries (Cuba and Bolivia) that were in charge would not receive their support in technical assistance or internships in 2019, having to be assumed by other NRL (Colombia and Peru) with a high level of expertise in the topics of interest to the referred countries.

On the other hand, in Central America significant progress has been made in financing the activities of the network that corresponds to the NRL. Thanks to the management of the SECOMISCA, a second meeting was held on June 2019, in Antigua Guatemala. There it was achieved that the ministers/health secretaries agree to finance the main activities for the maintenance of the Central American network. That is, to allocate a special amount, in each country, to finance the transport and clearance of strain panels, to finance the technical visits made by the SNL of Mexico and to pay for the internships of the NRL personnel to the SNL of Mexico.

This management was a process initiated in a previous inter-ministries meeting, where the subject was put on the agenda, but no agreement was reached. The success was based on the experience of SECOMISCA in political negotiation, having had legal advice for the formulation of the proposed agreement, the existence of a regional network of laboratories, the laboratory network, and which was also consulted and drafted the resolution together with the head of laboratory and program of Central America and with the recipients of the grant.

One of the critical knots facing sustainability is staff training. The possibility of financing this type of training abroad is more difficult in countries where fiscal austerity plans are in force (such as in Chile and Costa Rica) or due to corruption scandals that Latin America is going through, so locks were put to travel abroad. These restrictions are more critical in countries with high inflation (the cases of Venezuela and Argentina). But regardless of the availability of resources, some laboratories cannot send their staff to train due to the low institutional weight to manage resources in the central government.

On the other hand, there are cases of countries that do have public resources for this training. In some (such as Colombia or Panama), funds are available for the formation of the public servant, but they must be managed promptly. In others, these activities are leveraged with research resources financed by private funds or cooperation.

"In a collaborative project we have with England, what have I done? All that money is on the side of England and so they pay us. When we want to go out to train, they pay for the trips." (NRL)

On the other hand, in other countries the national guidelines (in the case of Chile) prohibit the financing of private individuals for the training of public personnel, in addition, there are restrictions to receive research funds, to guarantee decision-making autonomy and avoid the influence of transnational laboratories, but this limits the availability of funds for training. There are also countries where the possibilities of financing training are remote, due to the absence of funding sources.

"No, there was no money for that. Now having this project, the truth is that it has given us many opportunities to strengthen our capacities." (NRL)

For countries in South America that have not yet managed to finance with ministers and health secretaries, there is still concern about how to cover technical visits, quality control, cabin certifications. The grant invested in a long training of two engineers in-cabin certification who from 2020 would be able to perform certification to the NRL cabins, but it is necessary to design the formula so that the recipient country pays the expenses of the specialist and the transport of certification instruments, since in some countries the contracting of services from external third parties is prohibited without going through a public tender.

In the last three years, SNL visits to NRL were funded by the grant through the main recipient and sub-recipients. Now the challenge is how to finance them since the regulations of some countries (such as in Colombia, Chile) prevent the cost of external people that are not in the public return.

"It is not possible that as a state entity, per diem or travel is paid to people who are not officials of the entity, so this will not have the expected sustainability." (NTP)

As we can see, the normative characteristics of each of the 20 countries present us with a complex panorama, which has to be addressed with a political management before the authorities, for which the laboratories are not fully prepared, since not all have the leadership, or the time or resources sometimes required by a good advocacy plan.

Perspectives of sustainability and political management

➡ There is a perception that before the grant the laboratory network worked by inertia, and rather due to the grant it has been reactivated and energized. Thanks to the technical guidance of PAHO, intensified by the grant, there is now greater clarity of the current trend in diagnostic practices and its contribution to the "End to TB" strategy. Laboratories now have a clear path to concentrate their efforts to strengthen and contribute to national policies.

In fact, in the three years of the grant, laboratories and their staff received a set of very concentrated benefits and, that with different intensities, were processed and translated into improvements to their diagnostic processes and changes in TB control policies. Many of the good results were facilitated by the technical leadership of PAHO and the political and administrative management (external) of SECOMISCA and ORAS-CONHU. The scenario on the situation of internal and external sustainability, after the grant, has generated uncertainty in laboratories.

"So, I don't know what exactly, what will happen once the participation of ORAS-CONHU ends because the support we have received and its impact, we had not had before." (NRL)

However, the concern is focused on the implementation of the changes generated by the update and on the continuity of the already advanced. The deepening of the diagnostic improvement is pending, as it is a changing scenario, due to the constant technological progress and the epidemiological characteristics of the countries that are being affected by migratory, climatic changes and other agents. Therefore, a longer-term vision is required to deepen the improvement of laboratories in their diagnostic practice, but also in their influence on public policies. The laboratories today are more aware of that.

""The knowledge is very changing, at least in the east field of tuberculosis, new knowledge is generated every day, in fact, it is something that we have seen now in the conferences that leave some standards, some guides come out and at 2 years this it changes and changes again, that is, that knowledge is something that must be renewed." (NRL)

"I would like to optimize as a region and do those studies, a dream for me is to have a sequencing center where only DNA that is like what Italy does with Africa could be transported. They do not have the methodology, or the resources, or anything, but where they are, they send, send the DNA and all the studies are done and have the latest technology. We could do it in our countries." (SNL)

To the extent that internal sustainability has not been fully resolved in Central and South America, neither internal nor external, this remains in the field of political management. However, the process of generating political will is not very clear to laboratory professionals and many SNL and NRL bosses perceive it as difficult and complex or outside their capacities. In some countries, political management is more likely to succeed when there is an articulation between the TB Program and the laboratory. Where this relationship is fractured, political advocacy becomes less attainable.

Many of the laboratories see the post-grant scenario with pessimism, due to the financial restrictions of the governments, to the difficulties of doing political management, to give continuity to the update or simply to have the technical assistance of the SNL and PAHO with the same intensity of the last three years.

Likewise, it is demanded and expected to have a focal point in PAHO that is dedicated to the strengthening of laboratories, as was the case during the grant. The role that the liaison played in the technical design of the grant and in the technical assistance visits it carried out was highly valued.

While it is aware of the financial difficulties in maintaining the intensity of the consultancies, laboratories hope that through social and virtual media the link can be maintained and continued with them as much as possible.

Some believe that the strengthening process is only at an early stage and the end of the grant has been very sudden since the third year the number of activities has increased with the national replicas of the quality course. From the majority, the grant had to contemplate an intermediate phase with a "bridge project" that consolidates the advanced and guides the autonomous operation of the network.

• 4.6 Grant design and management

➡ In the Concept Note prepared by PAHO and ORAS-CONHU, agreed, also, with a good part of laboratories, it is particularly emphasized that there is a low detection of cases in some countries, especially MDR-TB. Among the problems listed are the limited ability to perform second-line DST. Infrastructure and biosafety problems, insufficient management of quality control of diagnostic procedures, slow implementation of new molecular methods that could make diagnosis timely.

The context analysis reveals the management difficulties in the political structures of each country, of health systems in particular, that prevent coordinated attention.

"Latin American health systems are, in general, segmented and fragmented systems with weaknesses in the rectory and governance that limit the coordinated and integrated actions of the different institutions, service networks and actors of health systems." (Concept Note)

Public health institutes and, within them, TB NRL, are no stranger to this reality. Sometimes these do not belong to the same unit to which the NTP belong, making coordination difficult, sometimes they have independent budgets and the information systems are divided, although efforts are made to articulate between the programs and the laboratory networks, in particular, related to network planning or evaluation activities.

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The document emphasizes that one of the main challenges or a critical activity for strengthening laboratory networks is at the political level. In other words, it is essential to establish diagnostic policies in countries that include, in addition to the incorporation of new techniques, training plans, and quality assessment, as well as

laboratories with managerial capacity that can develop a work coordinated with the programs nationals.

"The slow implementation of the new rapid methods for a timely diagnosis of sensitive TB and MDR / XDR TB persists in all 20 countries. One of the central elements for the adoption of these new technologies is the existence of diagnostic policies, which include both the incorporation of these techniques in the diagnostic algorithms and the establishment of training plans and external evaluation of the quality of the incorporated techniques." (Concept Note)

Another point that stands out, and that would be one of the main problems for any intervention project related to the improvement of TB laboratories, is the absence of information systems of the real situation of the laboratory network and also the poor standardization between the different types of information that is recorded, even within the same national network.

This problem, in practice, has many consequences such as the absence of continuous epidemiological surveillance, and higher issues such as resistance to tuberculosis drugs.

"In the information systems of the different countries, there are missing variables that allow monitoring the diagnosis, the quality of the data, the opportunity of the diagnostic services (date of receipt of the sample, processing, and delivery of results)". (Concept Note)

Despite the existence of international recommendations on the periodicity of the flow of information, it varies in different countries and data are collected with little standardization. The deficits of the information systems of both the RNL and the NTP and the lack of connection between them have critically hindered the establishment of continuous monitoring of resistance to tuberculosis drugs. This endangers monitoring the magnitude of this problem in the region since most countries have discontinued the periodic surveys of the prevalence of resistance.

Did the design meet the needs of the laboratories?

➡ As can be seen from various interviews, the design of the grant was well articulated, the actions are linked to each other and lead to other synergistic processes. Especially at the technical level, the leadership of PAHO stands out, which articulated the production of documents, training, and advice and technical visits to strengthen laboratories.

One aspect that the laboratories valued was the efficiency with which ORAS-CONHU implemented the activities, the care that was taken with the management of the consent and the efforts made so that the tickets and logistics were on time. Also, the transparency with which the grant was implemented was appreciated, as the results achieved were constantly reported in the meetings, the results achieved, and to whom they were addressed.

"Another thing that stood out in that project in which ORAS-CONHU was the administrator, is the transparency with which everything was handled, which rarely says:" We had access to all the information "and that was something very good." (NRL)

Also, respondents appreciated the expertise and effectiveness of SECOMISCA in high-level policy management, achieving inter-ministerial agreements to finance external sustainability.

In general, most of the interviewees considered that in terms of training, the grant met their expectations, partly because few laboratories had resources for staff training or it was reserved for the head of the laboratory. However, the objective of cascading training to the national laboratory network after what was learned in training or internships was not met in all countries, as stated by the interviewees, and this should be an initiative of the country independently of the regional grant.

Supervision visits and internships have been considering by NRL and SNL staff as a pillar in the implementation of new diagnostic tests and new expertise[15]. In this regard, a criticism found particularly among laboratory staff is that the functions and responsibilities of SNL should have been better defined, although, on the other hand, also the relative flexibility they had later appears in this same text as a virtue of design, maybe not planned.

In addition to good project planning, the design also allowed flexibility. The adaptation to the needs was carried out by the SNL, which agreed with the NRL, according to their needs, a work plan to develop technical visits and advice." (SECOMISCA)

In principle, the grant had planned to develop the same scheme in the different countries, since a situational diagnosis of each one was not available. From the most recent survey on the Structure and functioning of national tuberculosis laboratory networks in 2016[16] there was a situational diagnosis[17]. However, the technical implementation of the grant was successful in being flexible and the three SNL tried to adapt to the needs of each laboratory, diversifying their assistance:

"As for the design of the project, the activities were designed in a standard way for all the NRL, certainly there was a lack of a study on the needs of each laboratory that allowed an ad hoc design for each one or a cluster work. (SECOMISCA)

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[15] It is interesting to have found the opinion that the visits, beyond their importance for strengthening the capacities of NRL personnel, also serve in some way to pressure the authorities to fulfill certain commitments.

[16] This study contrasted the progress with the previous 2012 study, and at the same time served as the baseline of the subsidy.

[17] However, this study was given at a precise moment (it was not constituted in a periodic practice) and only released general data, so the opinion persisted in many that there was no updated and more accurate information on the state of the networks domestic nationals. An interesting recommendation in this regard was given by a PAHO representative who proposed with this grant to fill this gap with a systematization of the supervision that is done to the networks.

In an interview with a professional of the SNL of Chile, this underlines as a very important aspect that within the grant an adaptation of the work carried out by the SNL to the conditions of each country was allowed. Therefore, what was planned in an initial scheme had to be changed, because it was not going to work, or it didn't make sense to implement what was planned.

"It is very gratifying to see that regardless of the differences that sometimes frustrate, also because sometimes the progress is very slow, there is progress. So, it is gratifying to see that, for example, when learning a methodology, it is already implemented, it is already arranged in a laboratory so that this or another is incorporated to be updated." (SNL)

Likewise, a great contribution to the standardization of methods and procedures has been constituting by the technical documents prepared by the grant and the great majority of the interviewees recognize this. However, it was also noted that in some countries the manuals have not been disseminated as expected.

On the other hand, the SNL that received donation equipment saw their diagnostic capacity improve, some being especially valued, such as the servers that boosted their work at a very high level. This acquisition has also generated a reputational value before the ministries and internationally. The three countries where the SNL are located are not eligible for national grants from the Global Fund, making it more difficult for them to access these benefits.

However, not all the NRL agreed with the level of exclusive strengthening of the SNL, since they consider that, of all the countries of the Americas, they are the best found and the investment should be extended to the NRL who had more difficulties. This was initially conceived in this way, including the purchase of equipment and supplies for NRL from countries not eligible for the FM, but during the rounds of negotiation of the Concept Note, the budget was not approved in favor of the NRL. However, the analysis of the results shows that the cascade design and, therefore, the investment in the SNL paid off, although it is also true that countries with more limitations could not grow in the same dimension as those with more resources.

"Perhaps my point of view is that I would not have strengthened or purchased equipment only for supranational because they are supposed to be the best, but it is a point of view nothing more, actually most things were reached by consensus or by the majority."(NRL)

The satisfaction of the needs of the NRL has highlighted other aspects that were not properly relieved. The fact is that the training on biosafety and TAV for some countries with scarce resources has evidenced the deficiencies of the physical conditions of their laboratories (as in Guatemala, Venezuela, and Belize), which require a major investment, but there are difficulties to develop sustained advocacy actions.

"The grant has revealed the deficiencies in structural terms that some or several of the national laboratories have and that require interventions that are beyond the project; that is, direct public investment is required by the ministries."(SECOMISCA)

If we could describe the ideal course of the laboratories for its strengthening, we could summarize it in 6 main steps:

1.-Receipt of updated technical documentation and participation in the training,
2.-Realization of external quality control and reception of advice and technical assistance,
3.- Improvement of internal procedures and/or incorporation of molecular methods,
4.- Reformulation of algorithms and strengthening of its national network,
5.- The relevance of laboratories in the health system and articulation with NTP and
6.- Incidence policy in authorities to make laboratory strengthening sustainable.

However, as we discussed in the previous chapters, not all laboratories have followed these steps. The use of the benefits of the grant has been uneven because as we observed in the concept note and it was evident in the survey of Structure and operation of the networks in 2017, the conditions of the laboratories were disparate.

Some were more consolidated than others and were able to take better advantage of the opportunities opened by the grant. Other laboratories with initial difficulties have moved towards a strengthening process (such as Bolivia), but there are also several

with adverse conditions that have not been able to develop all the opportunities that the grant gave them.

Difficulties in grant implementation

➡ The difficulties encountered in implementing the grant were diverse. The principal recipient (ORAS-CONHU) and the subrecipients (SECOMISCA and PAHO), initially worked at different speeds and from different expertise. In some activities, ORAS-CONHU or SECOMISCA was in charge of the organization and PAHO of the technical. At first, it was difficult, because PAHO was used to operate autonomously, but over time they could complement and articulate.

During the implementation, many problems were linked to logistic issues, from managing the consent for training, to the transfer of strains and customs clearance. The Secretariat of ORAS-CONHU developed mechanisms that could facilitate communication between both dimensions (the management with the technique). In many cases, the obstacles could be reversed, but not in all, so some professionals were unable to attend the planned training, due to bureaucratic barriers or because the ministry administration designated a non-laboratory staff to participate in these events.

"Another of the elements that did not flow at all were the logistics processes. At the beginning of the project, it was difficult to refine the purchases, the management of permits in the ministries for the assistance of the technicians to the training." (PAHO)

In some countries, a stumbling block was the transfer of strains and their clearance. The shipment of panels that the SNL made to the NRL for diagnostic control was hindered by the requirements in the conditions that air transport entails when moving this type of material.

"Difficulties have also been seen, for example, for transfers of control panels, for example, that happened in Paraguay and I think in Venezuela, but it was a problem of the transport company, Courier. Last year after having a meeting with them, it was possible to explain

the importance of the transfer and also the importance that they can better coordinate with the countries where these control panels were going." (CARLAC)

As ORAS-CONHU carried out the negotiations and coordinated with a single supplier[18], the problem was resolved, although, in the case of Cuba, there are structuring conditions, such as the blockade that prevents companies and airlines from operating in this area, which is still making it difficult panel transport to this country.

The customs clearance was also a problem in several countries, partly because the governments were late in disbursing the corresponding counterpart, since the shipment was paid by the grant, but in some cases the national regulations oblige the country to assume the customs clearance; partly because of the characteristics of the samples that required additional procedures; and sometimes due to lack of coordination between the authorities. However, the customs clearance problems were resolved by the management of ORAS-CONHU coordination. In some cases, the latter institution had to bear these costs even though it was not their full responsibility as the grant progressed as the budget for this item originally had to decrease. But, as for the entry of the equipment, in many cases, the payment for the PR was made due to the impossibility of being assumed by the country and anticipating the increase in costs that would have implied the permanence of these materials for a long time. customs time.

We had to assume the budget of several customs, not only of the strain panels in many countries when hiring the door-to-door service where it was feasible. Also, for the teams, we had to put part of the budget to assume all that is the customs clearance of Mexico. Argentina last year sent us a letter, telling us that they were in difficulties, obviously understandable, and that they could not do the customs clearance, that they were trying and that every day that the products were left in the warehouse, the amount was rising. The grant has had to constantly adjust to overcome situations on the fly." (ORAS-CONHU)

Another difficulty observed was the lack of certification of biosafety cabins, at the beginning of the grant, it was aware of the limitations that laboratories had

[18] World Courier

for certification, so the training of engineers to provide these services to NRL was financed, however, during the implementation, the shipment of panels to those countries where the cabins were not certified was suspended. In Central, America SECOMISCA was able to articulate these needs with another project with the CDC that is in charge. Dozens of cabins were certified in Belize, El Salvador, Honduras, and the Dominican Republic. However, in many countries diverse problems were experienced for the withdrawal and entry of the certification team, as well as the availability of the necessary inputs, for example, the use of formaldehyde for disinfection.

According to various actors, a great obstacle that still persists is the little relationship or communication that exists between national programs and TB laboratories and, even, within the same laboratories with other areas. This situation, already manifested in the review made of the diagnosis of this subsidy, prevents that what has been done by the subsidy has greater reach or finally greater sustainability, and was repeatedly expressed by the actors interviewed.

"There is very little communication between programs and laboratories at times because they are different dependencies, so that does not allow coordination. In some countries, it depends more on personal communication than institutional communication. And then according to the fiefdoms in the ministries, it is said: " Ok, don't mess with me," that is an obstacle and people have complained about it, and even within the same laboratories, the tuberculosis area feels like relegated from the rest of the components of the laboratory itself." (CARLAC)

Moreover, there is a recurring idea that national programs, in general, were not appropriated the grant. As a member of CARLAC says, *"it is a loss of opportunity of the national program in some countries, when having a regional grant as head of the program you do not appropriate that grant that exists and that you could take advantage of both politically or see how some actions in the future be sustainable."*

It is even noted that a desirable objective would have been to achieve complementarity between the regional Tuberculosis grant and the Global Fund regional grants for other components, or national ones.

"If money has been put in, both from the national grant and from the regional grant, a better articulation should be seen, because there is a very large limitation, and it is the divorce that exists between the TB programs and the national laboratories, then to I have had to visit 3 countries and I see that if they were islands, over there the TB program and over there the national laboratory and they are not articulated, although a complementarity could have been carried out with the national and regional subsidies ; then that was a very important gap because, although agreements were signed from the political side, at an already operational level, it was not possible to articulate." (CARLAC)

It should also be stressed that, beyond these criticisms, there is the impression, as expressed by the majority of informants, that the relations between programs and laboratories have improved since the grant, particularly due to the existence of spaces of mutual discussions in which they have agreed. As a PAHO representative says, "This narrowing of work between national programs and the heads of laboratories has served, I think it has been a very important product of the grant." Also, from the main receiver you have this impression:

"We perceived at the beginning of the project that there were countries in which the program and the laboratory were quite distant and we have felt a positive evolution in that approach between laboratory and program, a recognition more on the part of the programs, of the right arm that it constitutes for him the laboratory and on the part of the authorities also when understanding the importance of the work that the laboratories and the programs do. We think that this project has activated all that relevance. "(ORAS CONHU)

Pending agenda for the strengthening of Laboratories

➡ It is important to note that in relation to the situation of the NRL and the RNL there is a very unequal development or very particular characteristics of each country, for example, some have a lack of personnel to fulfill all these tasks that derive from the strengthening of the laboratory, being this one of the main obstacles to enhance the learning and benefits of the grant. It may happen that what was learned during the grant is lost due to not having the possibilities to develop it, either because of the high turnover of personnel in the bases or because of the inability to implement it

without sufficient resources, or for not managing the changes politically necessary to reverse this situation.

Despite the ability to adapt the grant in each country, some structural problems remain. Thus, the problem of very poor infrastructure in some countries raises the question of how sustainable the training is if the material infrastructure of the laboratories is not improved, because biosafety conditions affect the quality of the diagnosis.

The grant stimulated concern about the issue, but low-income countries have more difficulties. Therefore, the grant could end up benefiting those with more resources more. While the government's agenda is influenced, it can be weak if changes in the leadership of the laboratory generate a blur and a new account. According to a representative of CARLAC, more strategic progress must be made by strengthening some laboratories with basic biosafety infrastructure. In general, it would have been reasonable for various types of intervention (even with different investments) to be considered in countries depending on the installed capacities or in any case manage complementary funds for laboratories in critical situations.

On the other hand, it must be affirmed that the commitment to promote molecular methods in most countries is faced with institutional barriers (centralism and low political will, infrastructure deficit), ideological (positions contrary to the dependence of transnational pharmaceutical groups), economic (cost of cartridges).

In one way or another, efforts were made to indirectly address these barriers through political influence in what constituted the technical and high-level meetings, or other activities that have involved a discussion on these issues. It should be noted that, although the NTP were incorporated into the activities, not in all countries, the political will was achieved or advocacy was done or there is an idea of the cost-effectiveness of incorporating the Xpert. The technical strength of the grant, which relied on PAHO, in most cases has managed to transcend these difficulties, accelerating the implementation of molecular methods, and in several countries, laboratories are committed to its implementation.

The political component was planned from the beginning to give sustainability to the grant, but the methodology of the grant had not been designed since there was no data "it was not possible to meet with the ministers if there was nothing to offer," said a representative of SECOMISCA. Only after the preparation of the cost-effectiveness study, in January 2018[19], it was clear what the amounts involved in supporting the core activities of the network. This data allowed discussing factual issues, processes, and budgets, in meetings with ministers and health secretaries, especially in the Central American network.

Regarding internal sustainability, several interviewees agree that the implementation of the grant made national laboratories more visible. But beyond that, the authorities became more aware of the deficiencies of the laboratories in technological aspects, which must be resolved by the national budgets of the countries, helping to think about the need to update and visualize the positive impacts that this would have on the national network and the health system in the fight against TB.

"The grant has revealed the deficiencies in structural terms that some or several of the national laboratories have and that require interventions that are beyond the project; that is, direct public investment is required by the ministries." (SECOMISCA)

Aspects not contemplated in the implementation

➡ During the grant, advocacy activities focused on recipients. However, after completion, they would have to be performed directly by the NRL. It is important to indicate that there was a consensus among several interviewees that what should be generated is the leadership of the laboratories in the fight against TB, and their demands must be met and have a more leading role among the other actors and in particular with national programs.

However, the reality gathered in various interviews is that currently not everyone is empowered in the same way. Likewise, not everyone navigates in the same scenario,

[19] The exact name of the study was: "Cost effectiveness in the diagnosis of tuberculosis" prepared by the grant.

nor in all countries, the authorities are equally sensitized. According to a PAHO representative: "many of the laboratories are not participating in the preparation of national strategic plans or the Global Fund conceptual notes, sometimes only the program does and it is not interested in the laboratory". That is why it is considered a weakness of design to have not explicitly contemplated the strengthening of advocacy among laboratory staff [20].

On the other hand, it would have been very useful to place greater emphasis on communications work. It is known that the principal recipient sustained interest in developing this area, however, the Global Fund did not include it prominently in the grant. The advisor to the issue of leadership and governance, Dr. Mario Rovere, believes that the media impact is central to any process of law in the health sector and that should provide a more communicative component in the grant.

Although some communications activities were financed, they were conceived in isolation and had no relevant weight in the overall budget of the grant. It is worth noting the role of videos and other communication materials produced with creativity to support advocacy actions. It is also important to note that the principal recipient apart from these scheduled activities regularly developed informative tools such as press releases, newsletters, rapporteurs, but these were assumed as additional work by the ORAS-CONHU staff. These communication activities were well-valued by the actors linked to the grant and can be considered of great utility and impact, demonstrating that a larger budget would have been ideal in the design of the grant for these purposes.

Otherwise, sustainability is not limited to the relationship between instances of the State, civil society must be involved. Moreover, one of the CARLAC members interviewed stressed that for there to be sustainability and political will, the presence of an external actor that presses, observes and monitors what has been developed by

[20] It should be note that another perspective regarding the legal profession is that it must also be done at a higher level than the laboratory since those who decide are higher and for a matter of configuration of the hierarchical structure of health systems, the authorities do not favor dialogue with the NRL staff.

the state authorities is necessary. Since governments operate on public pressure, for changes to be sustained over time, civil society must be encouraged as a participant in the processes.

Another member of CARLAC said that to achieve greater sustainability, the grant should have given a more active role to the Country Coordination Mechanisms (CCM) of the Global Fund. As is known, these agencies ensure links and coherence between Global Fund grants and other national health and development programs and carry out Strategic Monitoring activities.

I believe that the route would be to strengthen the CCM because the focal points that are part of the CCM have more contact and more access to the authorities of the Ministry of Health of their countries, and other Ministries. Because CCM are not only made up of the Ministry of Health but of other Ministries such as Finance. So I think it would be strengthening the focal points more, because they better understand what the project is about and that way they also make the beneficiaries have more access to their local authorities, thus seeking sustainability." (CARLAC)

According to some interviewees, a topic that the grant did not directly contemplate was the management training in general, since the profile of the professionals is generally limited to the handling of technical/scientific subjects. These tools would allow them to better plan and manage the resources provided by the grant and their own, without running the risk of underutilizing or wasting the advanced.

"I consider that the use of new technologies is quite difficult because not all countries dominate them. Everyone has to train if you leave and then the team stays there, who is going to keep it? That is not viable. That has to be assumed by each country. I believe that the components of management, administration, have to be improved, because that is the other issue, that they do not know how to administer, plan, so there we have to prepare the staff in other tools that can allow them to have a vision for the future, not a short-term thing about a project; that's what happens, they conform "(CARLAC).

Internal sustainability has a budgetary dimension that we address in point 3, but it also has a managerial dimension that is not sure how to deal with it. The grant-generated

a set of activities that achieved changes in personnel, practices and public policy of TB, but these changes were not homogeneous for all laboratories. Some postponed the implementation of "unplanned" activities towards the end of the grant for when they have more time.

"As a result of this quality control course, we have to do the entire quality management system inside the laboratory, which we had not trained since we had not done; that is, we had intuitive procedures, protocols, but now we have to put together everything in the course they taught us; that is, the manuals, the management system, and that will take time! Moreover, we said: "Well, we are going to set a goal for 2019, because if we set out to do everything we get stunned and how anxiety wins us"; then we said: "No, this year we are going to propose to do such a thing, and we have a lot of material to work, a lot." (NRL)

However, in that immediate future, there will be no visits by ORAS-CONHU or SECOMISCA, pressing to make replicas or to disseminate the results or simply to manage training. While it is true that, if TAV are financed, part of this monitoring of the continuity of benefits could be made, but these visits do not cover the entire spectrum of changes that the grant has generated.

On the other side, PAHO could assume this follow-up, but in the words of one of its representatives, the question remains: "Is there any commitment that says that this follow-up should be done? We think of goodwill and then we in the future as part of sustainability can make recommendations so that progress does not stop, like PAHO, when going to countries". Due to resource difficulties, PAHO can hardly visit all 20 countries and do so regularly, therefore, it is not clear what are the commitments, beyond the financial and technical, that laboratories would assume to deepen the benefits of grant and to monitor its compliance.

For the principal recipient and the subrecipients, it is not clear what their role will be in the future regarding regional multilateral responses to tuberculosis. The grant has meant an apprenticeship for ORAS-CONHU and SECOMISCA and in both cases, the fight against tuberculosis fits with its mandate, but the work plans are under construction. For its part, PAHO has a very precise competence, but the resources available for visits and supervision are uncertain. The laboratories also perceive

uncertainty about the role they will play in the future and how they will contribute to the functional maintenance of the Americas network. The only certainty is to guarantee the continuity of the basic activities through the relationship with the SNL, in the short term.

"The short and medium future scenario will require some challenges, first the sharing of the way to achieve the sustainability of supranational laboratories in terms of the activities they represent for national reference laboratories." (SECOMISCA)

Finally, another limitation of the grant has to do with the formalization of the commitments made with the countries. Regarding the SNL, the responsibilities that the SNL would assume after the grant was finalized were not established in writing because these are defined before and will persist after the implementation is completed. Although the relationship that SNL have concerning the network of laboratories in the Americas was marked by the technical support of PAHO, both SNL and NRL are free to terminate their commitments.

However, the level of investment that the grant made in the SNL was not intended to strengthen the SNL to perform their functions in their country but was directly aimed at ensuring that shortly their improvement would be taxed in benefits towards the NRL. office. Fortunately, two of the three SNL remain committed and have assumed their responsibilities, while one of them still does not crystallize the political will to have leadership as SNL in the entire network, in fact, two of the countries that were at their charge are now assisted by other NRL.

V. Conclusions: Lessons learned from the grant

V Conclusions: Lessons learned from the grant

➡ Next, we present the main lessons learned that we observe from analyzing the results obtained during the implementation of the grant.

• 5.1 Strengthening of the NRL

• The strengthening observed in the laboratories was due to the synergy generated by the use of various strategies (quality control, updated documentation, training and technical visits), articulated under the technical leadership of PAHO.

• The investment made in the network of laboratories directly results in the fight against TB because NRL, with good conditions, strive to strengthen national networks (updating them with documentation, training them and including them in TAV) and generating changes in procedures and the algorithms.

• The activities concentrated in a short period of time strengthened the knowledge, skills, procedures and diagnostic practices of the laboratories, generating commitments and interest in the updating and adoption of fast and molecular methods.

• The strengthening of the capacities of the NRL finds a limit in the structural conditions of the laboratories, which must be managed. The incorporation of new evidence brings new needs and also demonstrates the shortcomings that require high-level political management.

• Countries with structural deficiencies in infrastructure, biosafety, personnel, resources or disarticulation of efforts to combat TB, have more difficulties to enhance the learning and benefits developed by the grant.

• 5.2 Strengthening of the SNL and the Network

• The investment in the SNL, in equipment, training, advice, quality control and updating of documents, results in the improvement of the quality of the technical

assistance provided to the NRL, revitalizing the laboratory network, which served as a model so that the NRL redefine their role before their national network.

- The advisory and technical assistance to the SNL promoted the update, especially in rapid molecular methods for the genotypic and phenotypic diagnosis of M. tuberculosis; the improvement in biosafety, and the purchase of equipment, generating greater confidence and prominence of the personnel that participated in the activities.

- The use of a design based on "flexible activities" and "training supervisions", developed in the technical visits, had the virtue of adapting to the NRL conditions and the epidemiological characteristics of each country, respecting the "technical framework" for updating, generating mutual learning, in the SNL expert and in the NRL staff.

- Internships, technical meetings, and TAV consolidated the relationship between NRL and SNL, resulting in improvements observed in laboratories.

• 5.3 Sustainability of the TB laboratory network in the Americas

- The strengthening achieved in the NRL, together with the involvement of NTP promoted by the grant, made visible the importance of diagnosis in public policies of the fight against TB and generated collaborative processes to channel resources and political will.

- The advocacy capacity of ORAS-CONHU and SECOMISCA at the multilateral level was key to generating sustainability commitments, which in Central America resulted in an interministerial agreement and which in South America is scheduled as a focus for the second half of 2019.

- The direct political efforts developed by ORAS-CONHU and SECOMISCA and the interlocution promoted between laboratories and authorities revitalized the strategic agenda for the improvement of laboratories, but this requires more intense advocacy.

The NRL would require political and communicative management skills for which the majority is not prepared.

- Participation in technical meetings and training built a collaborative fabric between NRL which resulted in mutual support and exchange processes, revitalizing relationships within the network.

- Regardless of the relationship between SNL and NRL, staff participation in joint activities builds horizontal collaborative networks, which work for exchange and mutual advice, and could be the embryo of a different model of reciprocal cooperation and sustainability.

- The investment in the training of specialists, who provide services to laboratories, creates future conditions for sustainability, but it is necessary to develop the procedures to finance and enable the certification of cabins.

• 5.4 Grant design and management

- The results were enhanced thanks to the continuation of the previous activities of the network, while there was an antecedent of articulated work, but the grant gave them greater frequency and intensity, adding the advocacy component of the regional integration entities.

- The international and expert voice of the PAHO liaison for laboratories, the Regional Working Group and the SNL, reflected in the reports of the technical visits and documents, serves as a central resource for political management, facilitating the purchase of equipment, supplies and laboratory improvement commitments, therefore, this presence and leadership must be maintained.

- The high-level management with authorities and officials that ORAS-CONHU and SECOMISCA carried out, unblocked the bureaucratic barriers, marking the route for future efforts, although some difficulties will persist after the grant is over.

- The external and centralized management of resources facilitates the purchase, contracting of services, the participation of experts and relieves bureaucratic difficulties. Some processes were improved, but others will recede when the grant ends, such as the agility to process permits and consent.

- The combination of PAHO's technical expertise, together with the legal capacity of ORAS-CONHU and SECOMISCA, contributed significantly to improving laboratory conditions and to channeling external sustainability.

- To enable internal sustainability, it is necessary that the subsidies have a direct strengthening component of the advocacy capabilities of the laboratories, as well as resources for media and communicative advocacy activities.

VI. Challenges for the laboratory network

VI Challenges for the laboratory network

➡ We present a set of challenges that laboratories in each country should face in the face of their consolidation and growth needs, and for the management of internal sustainability. We also describe those that as a network of the Americas would have to grow and articulate. These challenges were presented to the laboratories of Central America and recipients, and contributions were received that are included in the following paragraphs.

• 6.1 Development of an own agenda, plans and advocacy strategy in each country

- Solve infrastructure problems related to biosafety.

- Support and contribute to the construction or consolidation of transverse sample transport systems for all health programs, networks, and services that respond to the needs and flows in TB.

- Integrate your discussions and areas of intervention into other health programs, areas or directions.

- Contribute to the design, implementation or improvement of information systems, based on nominal data records and for all vital and health situations, including TB.

- Provide the necessary personnel to meet the needs of their national networks, for the implementation of new methods and the improvement of diagnostic procedures.

- Prioritize investment in rapid and molecular methods, with the acquisition of equipment and its inputs, according to WHO regulations and the epidemiological characteristics of each country.

- Ensure preventive and corrective maintenance of equipment and software and the certification of biosafety cabins

- Deepen the benefits of the grant by transferring the knowledge and expertise acquired to the rest of the laboratory members and the national laboratory network.

- Fund and maintain the "training supervision" carried out by TB specialists, to the national network of laboratories, according to the attributions and responsibilities of the institution in charge of each country.

• 6.2 Routes for active management in the face of logistics and bureaucratic obstacles

- Improve the management model (purchases of equipment and supplies).

- Streamline staff authorization procedures to attend training and internships, ensuring that the right people are those who participate.

- To refine the administrative processes for the transfer of the strains and their customs clearance, through inter-sectoral political management.

- Define the modality and procedures for "hiring" technical assistance and international biosafety experts.

- Ensure the interlocution of the heads of laboratories with the national networks during the technical visits of the SNL or PAHO, to jointly analyze and improve the problems.

- Implement incentives and administrative mechanisms to stimulate or reward the updating of laboratory personnel.

• 6.3 Leadership in the political management of Laboratories, beyond its traditional technical role

- Develop operational research by TB laboratories, which broadens the meaning of their work and generates arguments for decision making towards TB control.

- Promote the updating of the algorithms and encourage the improvement of the transfer of samples, in the light of the new diagnostic methods, in dialogue with the NTP.

- Manage greater participation of laboratories in decision-making processes such as national strategic plans, negotiations with the Global Fund or budgeting.

- Position the importance and need for investment in rapid and molecular methods of TB diagnosis.

- Improve articulation with NTPs to channel existing resources towards the optimization of laboratory diagnoses and make improvements in TB-related health management.

- Develop advocacy strategies for human resources and available that are trained, trained and committed, not lost or absorbed by the private sector.

- Guarantee the purchase of supplies and materials for rapid and molecular tests, incorporating them into the budget or managing it through the country subsidies or the agreements of governments with PAHO for the acquisition of inputs with subsidized prices through the PAHO Strategic Fund.

• 6.4 Continuity at the budgetary and operational level of network operation

- Maintain the development of skills and internships for NRL and SNL members in laboratories of excellence.

- Ensure the financing of the transfer and clearance of strains for external quality control.

- Explore institutional designs to finance and enable technical visits, internships and booth certification.

- Promote the relationship with civil society and CARLAC focal points as strategic allies for the sustainability of laboratories and problem-solving.

- Promote horizontal collaborative processes among NRL to alleviate the burden of SNL and give internal sustainability to the network, promoting virtual and interactive mechanisms.

- Consider special mechanisms to finance those laboratories that are in a critical condition, exploring options such as donor tables or private contributions.

- Define mechanisms for the future to generate a constant update (preparation, translation, and updating of guides and manuals) so as not to return to the previous situation of technical delay.

- Manage with PAHO the designation of a focal point in the regional program to meet the needs of laboratories in the region.

- Define the processes for joint learning, as a network, in spaces for discussion and building trust and collaborative work.

- Expand the horizon of resource management at the inter-ministries level, to make commitments more sustainable, also having to influence the Ministries of Economy and Finance, or similar.

VII. Annex

VII Annex

Annex 1: Matrix of questions according to key informants

Objectives	Questions	Aspects to deepen	
Control data	In which grant activities did you "participate?	• Mark activities • Coordination Meetings	a.- NRL/SNL (free staff) b.- NTP
1: Has the grant strengthened the network of TB laboratories in the region?	How do you evaluate the contribution of the Technical Guides, which developed the grant?	• Quality and clarity • Unificación • Use in the Laboratory	a.- NRL/SNL f.- RP/SR
	How did the technical advice and visits implemented by the laboratory strengthening grant contribute?	• Usefulness regarding needs • Difficulties encountered	a.- NRL/SNL f.- RP/SR
	How did the development of capacities, internships and attendance at congresses contribute to the strengthening of the laboratory that promoted the grant?	• Limitations observed • What concrete positive effects	a.- NRL/SNL f.- RP/SR
	How do you evaluate the equipment (if applicable) and training in the management of the equipment developed by the grant for your laboratory?	• Limitations or inconveniences • Sufficiency • Satisfied current needs	a.- NRL/SNL f.- RP/SR
	In general, what has been the main contribution of the grant to the strengthening of your laboratory?	• Articulation and Synergy • Interministerial cooperation • Put on agenda	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR

Objectives	Questions	Aspects to deepen	
5: What have been the main critical nodes and what solutions are proposed in front of them?	In your opinion, what were the main difficulties in strengthening laboratories?	• Internal disarticulation • Lack of political will • Lack of Media Agenda • Civil Society Participation	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR
3: Do the interventions and activities proposed in the concept note respond to the current needs of the Tb laboratory network for its proper functioning?	Did the activities planned by the grant meet the needs of the laboratories?	• Identify unmet demands	a.- LRN/LSN c.- OPS f.- RP/SR
	What new needs arose in the course of the grant and are not being met?	• Identification of new demands	a.- NRL/SNL c.- PAHO f.- RP/SR
4: Have adjustments been made during implementation, based on control recommendations, supervision, technical assistance?	Can you indicate what changes or innovations in your Laboratory generated the technical assistance, through visits, controls, supervisions or recommendations?	• At the level of procedures • Logístic • Managers • Administrative and authorization • In the relationship with the NTP • In resources or consideration • Problemas políticos	a.- NRL/SNL c.- PAHO f.- RP/SR
	What were the main difficulties in implementing these technical assistance recommendations in your laboratory?	• Administrativas y de autorizaciones • En el relacionamiento con el PNTB • En los recursos o contraprestaciones • Problemas políticos	a.- NRL/SNL c.- PAHO f.- RP/SR
2: Has the issue of the role of the laboratories of Tb gained relevance during the implementation of the grant?	What were the main contributions of the grant to the fight against TB in your country?	• Reduction of the diagnostic gap • Relevance of TB in public policies • Articulation with national programs	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR

Objectives	Questions	Aspects to deepen	
	How did the grant favor the relevance of the diagnosis of TB in public health policies?	• Budget • Recognition of the role of the Laboratory • Social and political factors that favored its relevance	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR
6: What additional efforts are required for grant progress to be maintained or strengthened upon completion?	What mechanisms has your country developed to generate the sustainability of regional grant actions?	• Questions from Carmen Navarro	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR
	What problems jeopardize the sustainability of the changes and improvements that the regional grant developed?	• Political will • Uncoordination • Lack of resources • No prioritization • Administration management	a.- NRL/SNL b.- NTP c.- PAHO d.- Ministries e.- CARLAC f.- RP/SR
	On the political side, what progress has been made in your country to make the regional grant actions sustainable?	• Questions from Carmen Navarro	a.- NRL/SNL b.- NTP c.- PAHO f.- RP/SR
	In the economic / financial / budgetary aspect, what progress has been made in your country to make the regional grant actions sustainable?	• Questions from Carmen Navarro	a.- NRL/SNL b.- NTP c.- PAHO f.- RP/SR

ANEXO II: Temas de las Visitas de Asesoría Técnica de los LSN por año, a la fecha

VISITAS DE ASISTENCIA TÉCNICA DE LSN A LRN

SNL	Receiving country	of 2017	Training topic	Professional in charge	of 2018	Training topic	Professional in charge	De 2019	Training topic	Professional in charge
Argentina	Guyana	Dec 4-8 / 2017	Biosafety lab monitoring system. Management information. Preventive and corrective maintenance of equipment.	David Avendaño	Mar 25-29 / 2019 (Rescheduled)	Biosafety lab monitoring system. Management information. Preventive and corrective maintenance of equipment.	David Avendaño	Sep 02-06 / 2019	LQAS sheet panels. Diagnostic procedures: culture and DST. Preventive and corrective maintenance of equipment. Management of information. Agreements for the sustainability of the technical assistant	David Avendaño
	Paraguay	Dec 3-6 / 2017	MGIT: DST 1Ly2L. Decontamination methods Quality management: Internal and external controls	Norberto Símboli	Oct 22-26 / 2018	Biosafety BSL3 operation. Leadership in the RNL. BM Lab Planning. Algorithm and new fast methods. Cepario	Norberto Símboli	Aug 26-30 / 2019	Biosafety in BSL3 operation. MGIT: DST 1L&2L. Genotype LPA. Follow-up TAV 2018 recommendations	Norberto Símboli

	Perú	Dec 11-15 / 2017	Biosafety BSL3. Entry of samples and / or isolates. Traceability Preparation of media and reagents. Algorithms DST 1Ly2L. Culture. Cryopreservation, technology transfer. Investigation BK quality control, cultivation and DST.	Beatriz López	Oct 15-19 / 2018	Biosafety Algorithms Quality Management TAV 2017 recommendations follow-up	Roxana Paul	Aug 12-16 / 2019	Current algorithms. MGIT: DST 1L&2L. Genotype plus. Visit to the national TB lab network.	Roxana Paul
	Venezuela	Nov 27– Dec 1 / 2017	Biosafety lab monitoring system. Management information. Preventive and corrective maintenance of equipment.	David Avendaño	Nov 19-23 / 2018	Biosafety Lab records Quality management system. Follow-up TAV 2017 recommendations.	Eduardo Mazzeo	Sep 16-20 / 2019	Management of information. Quality System Management. Sample transportation and transfer. Genotype	Eduardo Mazzeo
	Bolivia*	* It belongs to SNL Chile						Aug 12-16 / 2019	Equipment maintenance and CSB Certification	Luciana Vásquez
Chile	Uruguay	Oct 17-20 / 2017	LPA and other laboratory techniques	Tamara Leiva Calderón	Apr 23-27 / 2018	Biosafety and risk assessment	Angélica Sccapaticcio	Sep 2-6 / 2019	Fluorescence and other lab techniques	Marcela Moreno

SNL	Receiving country	of 2017	Training topic	Professional in charge	of 2018	Training topic	Professional in charge	De 2019	Training topic	Professional in charge
Chile	Dominican Republic	Set 25-30 / 2017	Molecular Biology and Xpert	Tamara Leiva Calderón	Jun 4-8 / 2018	Biosafety and Risk Assessment	Angélica Sccapaticcio	Aug 12-16 / 2019	Fluorescence and LPA sample flows	Marcela Moreno
	Colombia	Dec 18-22 / 2017	Surveillance and impact of new methods	Fabiola Arias	Jun 25-29 / 2018	Molecular Techniques	Tamara Leiva Calderón	Jun 22-26 / 2019	Molecular Techniques	Tamara Leiva Calderón
	Ecuador	Dec 11-15 / 2017	Susceptibility of M tuberculosis, proportions method (MGIT)	Angélica Sccapaticcio	Aug 6-9 / 2018	Resistance Surveillance	Fabiola Arias	Apr 22-26 / 2019	Training in LPA and Xpert MTB / RIF	Tamara Leiva Calderón
	Bolivia*	Nov 27 – Dec 2 / 2017	LPA installation evaluation	Tamara Leiva Calderón	Dec 3-7 / 2018	LPA	Karla Kohan	* Assisted in 2019 by the SNL Argentina		
	Cuba**	11-15 Dic/2017	Biología Molecular	Tamara Leiva Calderón	10-14 Dic/2018	Bioseguridad en el Laboratorio de Tuberculosis.	Angélica Sccapaticcio	** Assisted in 2019 by the NRL Colombia It belongs to SNL Chile		
Colom-bia***		*** NRL that covered TAV 2019 to Cuba						Oct 21-25 / 2019	LPA (Genoty-pe) for drug resistance gene detection	Claudia Llerena Polo
Mexico	Guatemala	Sep 18 - 22 / 2017	PFS 2L and modified Petroff culture, culture yield.	José A. Martínez Guarneros	Apr 23 – 27 / 2018	Biosafety in the Tuberculosis Laboratory	Amalia Barquet Fuentes	Apr 1- 5 / 2019	LPAS	Carlos Arturo Vazquez Chacón

Mexico	Belice	Aug 20 – 26 / 2017	TB and BK Network Management	Susana Balandrano	May 14 – 18 / 2018	Biosafety in the Tuberculosis Laboratory.	Amalia Barquet Fuentes	Apr 29-May 3 / 2019	Rapid molecular tests / Xpert MTBRIF	José A. Martínez Guarneros
	Honduras	Oct 16 - 20 / 2017	LED microscopy and panel development	Carolina Flores Marroquin	May 21 – 25 / 2018	PFS 2L in proportions LJ./ or MGIT	José A. Martínez Guarneros	May 13-17	Biosafety in the Tuberculosis Laboratory.	Amalia Barquet Fuentes
	Panamá	Nov 13-17 / 2017	BK and LQAS sheet panels	Carolina Flores Marroquin	Jun 4-18 / 2018	PSD 1Ly2L en MGIT	José A. Martínez Guarneros	Mar 25-29 / 2019	LPAS	José A. Martínez Guarneros
	Costa Rica	Oct 2-6 / 2017	PFS 2L MGIT 960	José A. Martínez Guarneros	Jul 2-6 / 2018	BK and LQAS sheet panels	Carolina Flores Marroquin	Apr 29 – May 3 / 2019	Biosafety in the Tuberculosis Laboratory	Amalia Barquet Fuentes
	El Salvador	Nov 27 – Dec 1 / 2017	Development of BK performance panels in TB, LQAS sampling	Carolina Flores Marroquin	Jul 23-23 / 2018	PFS 2L in proportions LJ.	José A. Martínez Guarneros	Mar 18-22 / 2019	Biosafety in the Tuberculosis Laboratory aimed at organizing the move.	Amalia Barquet Fuentes
	Nicaragua	Sep 18-22 / 2017	Development of BK performance panels in TB, LQAS sampling	Carolina Flores Marroquin	Jan 14-18 / 2019 (Rescheduled)	DST 1Ly2L en MGIT	José A. Martínez Guarneros	Apr 1-5 / 2019	Biosafety in the Tuberculosis Laboratory.	Amalia Barquet Fuentes

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