

Final evaluation of the contribution and sustainability of the grant "Strengthening laboratory diagnosis of tuberculosis in the region of the Americas."



Systematization of successful experiences and learned lessons.

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## ACRONYMS

ВК	Sputum smear
COMISCA	Council of Ministers of Health of Central America and the Dominican Republic
BSC	Biological Safety Cabinets
GDF	Global Drug Facility
GLI	Global Laboratory Initiative
ITM Belgium	Institute of Tropical Medicine, Antwerp (Belgium)
InDRE	Institute of Diagnosis and Epidemiological Reference Mexico
NIID	National Institute of Infectious Diseases – Argentina
IPH	Institute of Public Health of Chile
LPA	Line Probe Assay for rapid detection of mutations associated with anti-tuberculosis drug resistance.
SRL	Supranational Reference Laboratory
NRL	National Reference Laboratory

CCM	Country Coordination Mechanism
RCM	Regional Coordination Mechanism
UN	United Nations
WHO	World Health Organization
РАНО	Pan American Health Organization
ORAS-CONHU	Andean Health Agency-Hipólito Unanue Agreement
NTP	National Tuberculosis Control Program
DST	Anti-tuberculosis Drug Sensitivity Test
PR	Global Fund Principal Recipient
RR	Rifampicin Resistance
SE-COMISCA:	Executive Secretariat of the Council of Ministers of Health of Central America and the Dominican Republic.
SR	Global Fund Subrecipient
TB-DR	Tuberculosis drug-resistant
TB-MDR	Tuberculosis Multi drug-resistant
XDR-TB	Extensively drug-resistant tuberculosis
TAV	Technical Assistance Visit
HIV	Human immunodeficiency virus
XPERT MTB-RIF	Ultra Rapid molecular test detecting Tuberculosis Complex and rifampicin resistance in the same study.
GeneXpert®	Equipment uses closed cartridges and simplifies the execution of the molecular method because it integrates and automates the three processes – sample preparation, DNA amplification, and detection of tuberculosis.
Genotype®	Test Based on Linear Probe Hybridization (LPH) Detects M. tuberculosis Resistance to Anti-TB Drugs.

# I. Presentation



Tuberculosis (TB) remains a public health problem in the Region of the Americas. In 2021, there were an estimated 309,000 cases of all forms of the disease. COVID-19 has reversed progress on the End TB Strategy: in 2021 the number of TB deaths increased to 32 000 and the incidence continued to rise slightly. However, progress was evidenced in the introduction and expansion of rapid molecular tests, reaching 30% of suspected cases diagnosed by these methods. 4 820 cases of rifampicin-resistant or multidrug-resistant TB (RR-TB/MDR) were detected, of which 94.8% started treatment. The proportion of RR-TB cases studied for fluoroquinolone resistance increased to 41% compared to 28% in 2020. In 2021, 59 more cases of extensively drug-resistant TB (XDR-TB) were diagnosed and reported in 14 countries of our continent, compared to the previous year (WHO. Global Tuberculosis Report, 2022).

There were an estimated 32 000 new cases of TB in people with human immunodeficiency virus (HIV) infection, as well as 32 000 deaths from TB, of which 28.1% are in people with HIV<sup>1</sup>. Seven countries account for 80% of TB/HIV cases: Brazil, Mexico, Colombia, the Dominican Republic, Haiti, Peru and the Bolivarian Republic of Venezuela. Information on cases of comorbidity with diabetes and preventive treatment remains limited; treatment outcomes show no favorable changes in their cohorts<sup>2</sup>.

Although the TB situation in the region reflects the persistence of social determinants and risk factors that most directly affect vulnerable population groups, some countries are closer to eliminating the disease as a public health problem. National program efforts need to be accelerated, most with their resources, to meet the goals of the End TB Strategy and with the international commitments made by the countries.

Since the beginning of the COVID-19 pandemic, in the first quarter of 2020, the provision of health services, in general, was altered, including those of TB, due to confinement measures, the fear of the population being infected in health services and the redirection of staff towards the attention of the pandemic. This has affected TB prevention and control interventions in all countries. In the Americas, a 16.8% decrease in TB case reporting was observed in 2020 compared to 2019. Among the 28 reporting countries, there were 239 121 reported cases from one year to the next to 197 364<sup>3</sup>.

With a sense of networking and cooperation between countries, the World Health Organization (WHO) has chosen 5 Supranational Reference Laboratories (SRL) for TB in the Americas. Three of them are in Latin America and are the ones that have assumed the greatest responsibility in the region: Argentina (National Institute of Infectious Diseases, NIID, Buenos Aires), Chile (Institute of Public Health, IPH, Santiago de Chile), and Mexico (Institute of Epidemiological Diagnosis and Reference, InDRE, Mexico City). The other two are the Center for Disease Control and Prevention (CDC) in Atlanta and the Pasteur Institute on Guadeloupe Island, France.

Since 2004, the Pan American Health Organization (PAHO) has supported the creation of the Regional TB Laboratory Working Group (RLWG-TB) to complement the work of SRL and coordinate their actions through technical assistance to the Regional TB Program and the National TB Reference Laboratories (NRL), as well as in monitoring and evaluation activities to LRNs and National Laboratory Networks, in addition to training, among other actions.

1 WHO (2022). Global Tuberculosis Report.

Washington, DC: OPS; 2022. Disponible en: https://doi.org/10.37774/9789275326497 3 Op cit

<sup>2</sup> Organización Panamericana de la Salud. Tuberculosis en las Américas. Informe regional 2021.

From 2017 to the present, the Andean Health Agency – Hipólito Unanue Agreement (ORAS-CONHU), PAHO/WHO, and the Executive Secretariat of the Council of Ministers of Health of Central America and the Dominican Republic (SE-COMISCA) have been the implementers of two consecutive grants financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, for the "Strengthening Laboratory Diagnosis of Tuberculosis in the Region of the Americas". ORAS-CONHU is the principal recipient (PR) of resources, and PAHO/WHO and SE-COMISCA are subrecipients (SR). The first phase (2017-2019) covered 20 countries in the Americas, while the second phase (2020-2023) included 17 countries. This latest grant has been complemented, in the wake of the COVID-19 pandemic, with additional C19RM funding for bidirectional detection of SARS-CoV2 and TB.

The ongoing grant, in both the TB and C19RM components, concludes on October 31st, 2023. The participating countries are Bolivia, Colombia, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Nicaragua, Paraguay, Peru, Suriname, Venezuela, and the three Latin American SRLs located in Argentina, Chile, and Mexico that function as network heads for their respective areas of assistance to LRN.

The grant aims to contribute to improving the quality of tuberculosis (TB) diagnosis in laboratory networks by strengthening the capacities installed in the region.

#### The specific objectives are:

- a. Consolidate commitments for the sustainability of SRL and NRL in the region.
- **b.** Support the adoption and operationalization of international recommendations on TB and the diagnosis of drug-resistant and multidrug-resistant TB (TB-RR/MDR) in national policies, monitor their implementation, and optimize the use of TB equipment at national and regional levels.
- c. Contribute to the development, harmonization, and implementation of information systems in national and regional networks of TB laboratories, with an inter-programmatic approach

#### The specific interventions of the C19RM regional allocation are:

- a. Facilitate the transmission of diagnostic results for COVID-19 and other diseases using real-time molecular platforms for Guatemala, El Salvador, and the Dominican Republic (connectivity).
- **b.** Implement integrated bidirectional detection of COVID-19 and TB using multiple next-generation platforms (GeneXpert 10 colors and/or Xpert<sup>®®</sup> SARS-COV-2 cartridges).
- **c.** Develop a civil society outreach campaign on the right to molecular diagnostics as an initial test in 10 countries.
- **d.** Conduct operational research by civil society on factors affecting productivity and access to rapid molecular tests in 11 countries

# **II. Executive Summary**



This study shows the results of the systematization of experiences and learned lessons from the regional grant TB.Lab20-23, to analyze the benefits achieved, and identify good practices and difficulties. It is hoped that future regional initiatives can replicate and improve interventions to strengthen laboratory diagnosis of both TB and public health surveillance in a more comprehensive sense.<sup>4</sup>

This document is based on interviews and questionnaires carried out with 91 key informants: laboratory heads; responsible for the NTP; representatives of the CCM and the RCM; participants and beneficiaries of training and advisory activities; as well as those in charge of the grant of the main recipient and sub-recipients<sup>5</sup>.

The COVID-19 epidemic meant, at the beginning of the grant, a serious difficulty because, due to the restrictions, it was not possible to carry out the activities in person. The grant implemented a virtual platform that allowed laboratory members to be trained and have advocacy meetings with authorities.

The design of the activities used a virtuous sequence that begins with the preparation of situational studies of the laboratories, such as updating the structure and operation of the laboratories of the national networks, or that which characterizes the state of the information systems, or that of monitoring the financing flows for the functions to be fulfilled by the SRL and NRL. These studies are used to make decisions and strengthen advocacy efforts to make the weaknesses and progress of the laboratories visible to directors, vice ministers, ministers, and other authorities.

Multilateral political advocacy was a highlight activity of the grant coordinated by the SE-COMISCA and ORAS-CONHU organizations. The agreements and resolutions achieved have greater strength for their implementation, making it easier for civil society and officials in charge of the fight against TB to monitor and demand compliance.

The heads of the laboratories and those responsible for the TB programs highly value national political advocacy, as it is a unique opportunity for technical managers to influence senior management. The high-level meetings managed by ORAS-CONHU and SE-COMISCA raised awareness among decision-making authorities, kept TB on the decision-making agenda, and sought to reaffirm previously signed commitments and assume new ones to strengthen laboratory diagnosis.

Bilateral advocacy has managed to overcome many logistical barriers. However, other problems persist that are not in the hands of the ministries of health but originate from national regulations or that are the responsibility of the Treasury or Economy portfolios of one country or another.

The grant developed capabilities in the laboratories of certain countries (Colombia, El Salvador, and Peru) so that their personnel were accredited in the certification of biological safety cabinets (BSC). This makes it possible to reduce costs and improve the capacity of the laboratories, while building solidarity between the countries of the region since this resource is shared at a minimum cost that covers transfers and stays of the certifier, without charging fees. This effort allowed us to add five new CSB certifiers to the two specialists from Argentina and Mexico trained by the previous grant.

<sup>4</sup> A more extensive explanation of the objectives, justification and methodology used in the study can be found in the annex 1. 5 For more details on the informants, see annex 4 and annex 5 at the end of the document

Additionally, the grant hired consultants for 18 months in six countries (Argentina, Chile, Colombia, Guatemala, Mexico, and Peru) with considerable advances in their quality management systems in the respective institutes where the SRL/NRL resides, to support the accreditation process of diagnostic methods under the ISO15189 standard (except Colombia, which would accredit with ISO 17025), which has resulted in an improvement in the capabilities of the laboratories and the quality assurance of their procedures and results.

Under the responsibility of the PAHO subrecipient, a set of workshop and training sessions were developed, among which the one on new diagnostic methods stands out, developed in Chile with very good acceptance among the participants. The workshop contributed to reinforcing the knowledge of the new staff, an improvement in laboratory processes, and even, in some countries, a programmatic change.

The consultants financed by the grant for the improvement of TB laboratory information systems developed tools in this regard. Some managers were able to implement and use these tools, such as the dashboard to manage data more efficiently, and some managers plan to implement and socialize this tool in their national network. However, the improvement of information systems faces structural difficulties, of a regulatory nature, the coordination of actors, a shortage of personnel, logistical deficiencies, and computer skills in those responsible.

The effort to increase voices that demand greater investment in laboratories and the participation of CCM representatives in advocacy stands out. It is suggested to address aspects such as comprehensive training of representatives and improve communication in future grants.

Regarding the financial sustainability of the laboratories, it is observed that the economic crisis in Latin America has affected the allocation of resources for them, which has generated concern about their longterm sustainability. Some interviewees expressed concern about changes in government and the possibility of reducing the resources assigned to laboratories. However, other interviewees believe that there is a political consensus that protects laboratories and guarantees their financing.

Finally, it is recommended that future grants consider time and space to consult in depth with each laboratory what their needs and priorities would be so that grant activities are better adapted to the specific realities of each country. This interest would contribute to sustainability.

# **III. Systematization results**



This chapter presents the results of the information obtained in the interviews, meetings, and questionnaires carried out within the framework of systematization. The results have been divided into six points that group the areas that in our opinion can show the observed changes and the synergistic consequences of the activities implemented by the grant. Three of them address the main objectives of the grant. Two, the conditions of the management and implementation of the grant, and, finally, one point focuses on the future perspectives of strengthening laboratory diagnosis.



# **3.1** About the context of the grant assumptions

The COVID-19 epidemic represented a challenge for the fight against TB in the countries of the Americas. For the grant in particular, the epidemic, especially in its initial phase, constituted a barrier to fulfilling the activities and strengthening laboratory diagnosis. Progressively, the principal recipient and subrecipients developed mechanisms

to implement training, advice, and advocacy activities with authorities virtually, achieving compliance with most of the goals.

However, the context was adverse, since at the beginning of the COVID-19 epidemic some countries had many difficulties in developing their diagnostic, care, and follow-up activities for TB patients.

For example, flight restrictions affected external quality control at NRL. In several countries, TB care at the first level was deactivated, in addition the referral of new cases was restricted and follow-up of already identified cases was weakened. On the other hand, the supply of medicines for people with TB was interrupted.

The human resources and equipment of the TB laboratories were reassigned to COVID-19 diagnostic work. The personnel working in the laboratories were also affected by the disease, reducing the diagnostic capacity of the laboratories.

""I would say that the pandemic, in a sense, did not do any good for the progress that was made in tuberculosis because many health services were neglected. There was a lack of personnel dedicated to care, sample collection, and the entire circuit that works for tuberculosis. But in other things, there was also a lack of supply of medicines and many things linked to the first level of care, where patients were left adrift" (ORAS)

There were countries in which many efforts were made to continue the diagnosis and care of people with TB, and creative solutions were sought, for example, smartphones and cameras were used (VDOT6) to give continuity to the monitoring of treatments. Virtual services were also used to train community TB leaders.

#### 6 Video-supported TB treatment

In addition, the pandemic brought with it some positive side effects, as a lot of technical information was disseminated about the importance of laboratory diagnosis, especially molecular tests, and the need to provide personal protective equipment, supplies, personnel, and equipment to national laboratories. It was also possible to position in public opinion the importance of early molecular diagnosisfor timely care, which meant an advance in the positioning of laboratory diagnosis in general that was later useful for the grant's advocacy actions.

"I believe that, in the case of the central laboratory, COVID resumed the importance of the epidemiological surveillance laboratory at the level of Guatemala. There was an assessment of what the laboratory was doing. Of course, they were actions about COVID, but in the end, we all benefited, because it was once again identified that the national laboratory existed, and we gave it support in the face of greater interest in surveillance laboratory tasks." (Guatemala)

The fight against the COVID-19 pandemic also influenced decision-makers who work outside the health sector, as it forced officials to prioritize the purchases of supplies, reagents, laboratory equipment, and maintenance tasks. Some national administrations, for their part, were forced to reduce bureaucratic processes, streamline customs clearance, and create facilities for laboratories to operate more expeditiously.

"I believe that the State, even with the current economic crisis, is assuming the health issue quite responsibly. The example is that in recent months we urgently needed to pay the medication bill and it was very agile. A couple of days after the proformas came, the resources were acquired, and the invoices were paid to have the supplies and medications. So, I think the health issue is a matter of priority." (El Salvador)

For this reason, some decision-makers from non-health sectors understood the central place that laboratory diagnosis occupies in a national epidemiological strategy. They are more aware of the resources required to have laboratories with good diagnostic capacity and the importance of strengthening the State's leadership in these processes. This facilitates dialogue with decision-makers since the COVID-19 epidemic has familiarized them with the logistical needs and administrative procedures of laboratories.

*"In terms of strengthening laboratory diagnostic capacities, the pandemic was conducive to improving tuberculosis laboratories."* (ORAS)

In some countries in the region, public, media, and electoral pressure arose to increase government investment in the health system, since the high human costs generated by the pandemic exposed the precariousness of health systems and the deficiencies of the State to ensure fulfillment of the right to health of their populations.

From the perspective of the principal recipient, "these changes facilitated the realignment of the importance of TB among decision-makers. After the COVID-19 health crisis was overcome, little by little the commitments made in the first grant were resumed." The synergy generated by the two subsidies has made decision-makers more aware that it is possible to combat TB through new methods and the strengthening of laboratory diagnosis.

The visibility of the regional and global problem helped the lobby to obtain more national funds for the expenses corresponding to the fight against Tuberculosis" (Paraguay)

In summary, COVID-19 significantly affected laboratory diagnostic activities in the countries of the Americas. However, despite all the difficulties, it is observed that many authorities have reassessed the health problem and in particular the role of laboratories for early detection, which translates, in some cases, into a greater predisposition to meet the demands for inputs and financing.

The basic assumptions for the development of the grant activities were altered by the COVID-19 epidemic. That is, the grant had as its starting point a set of advances and achievements from the previous grant. However, in the initial phase of the epidemic, some of the basic functions of the laboratories were weakened, but despite the adversities the grant was able to adapt the activities to the virtual environment, managing to develop training, meetings with authorities, and advice. In addition, capitalizes on the relevance of laboratory diagnosis driven by the epidemic.



# **3.2** About the management and implementation of activities

The beginning of the implementation of the grant coincided with the COVID-19 epidemic, therefore, it was not possible to travel to develop training, nor to send samples for external control or advocacy activities, due to mobility restrictions.

The first measure taken by the principal recipient and the sub-recipients was to reschedule the activities, waiting for

the quarantine to be lifted in a few weeks. As the restrictions persisted, it was decided to postpone some activities and change the modality of others. For example, it was decided to conduct training virtually using existing platforms (Zoom, Teams), to which the Global Fund agreed.

There was not much previous experience in the development of virtual laboratory training and there was doubt as to whether the distance modality would develop the competencies and skills expected of laboratory technicians. One of the achievements of the implementation of the grant , precisely, was to acquire the licenses and structure the use of virtual platforms to carry out these trainings.

From the perspective of some laboratory managers and participants, the virtual training allowed the call to be expanded, which they took advantage of to include a greater number of laboratory participants and on some occasions members of the national laboratory networks, making participation more inclusive training.

"One of the advantages is that these virtual sessions, in conjunction with the tuberculosis program, have now been held every month and participation is very massive. It does not mean leaving aside what is in person, which is very valuable, but I think we have acquired a new tool to be able to communicate." (Guatemala)

The virtual platforms also served to develop advocacy meetings with authorities, as well as coordination and dialogue meetings between members of the laboratory network of the Americas. Therefore, through the implementation of virtual platforms, the goals of knowledge transfer, skill development, and political advocacy were met. "The use of the digital platform was a very good option. I think it should be done periodically when criteria are required to be updated and there are new improvement methods for daily activities." (Venezuela)

On the other hand, activities that required laboratory practices or training in the manipulation of instruments were not possible to implement during the COVID-19 pandemic, therefore, they were carried out in person, when the restrictions were lifted.

Regarding the design, we found that the development of the activities was based on an interesting sequence, which begins with the preparation of studies that raise a situational state on an aspect of the laboratories. These studies are then used to make decisions, strengthen the efforts of the legal profession, and make the weaknesses and progress of the laboratory visible to directors, vice ministers, or ministers.

An example of the positive synergy generated by this sequence is the funding flow report that was used in all advocacy meetings with high-level officials since the figures of the financing gaps for each function of the SRL/NRL helped show those responsible where the critical nodes that require a financing effort are located. Additionally, these reports were used by the laboratories themselves and by the NTPs to guide their resource management or planning efforts.



"We proposed this year a budget expansion for 2024, which at this time is still in process, but one of the technical arguments we used was that report, in other words, we incorporate it into the information that we deliver to the budget area to request the budget expansion so that we are already putting it to practical use." (Chile)

It is observed that in this grant there is an important synergy between the technical development component of the laboratories and the political component, articulating the situational diagnoses of the studies with the advocacy meetings with the authorities. In general, laboratory heads and PNT managers are satisfied with the management of the grant's advocacy activities.

- "For my part, I believe that each of the gaps in the diagnosis was addressed in a very accurate and timely manner. "We would greatly like them to continue with these types of grants since they are beneficial to our country." (R. Dominicana)
- ""It was not just a laboratory grant, the truth is that it was considered the most comprehensive issue (...) It is not only a grant to strengthen the laboratory but immersed in a strategy, and I also see that as very positive, because many times the issues that happen within the laboratory occur there among the technicians and are not always related to the programmatic strategy. So that also seems like a great achievement to me." (Argentina)

Regarding management style, several people interviewed highlighted the dedication put in by the team in charge of implementing the activities. Among the most highlighted aspects were the constant transparency of the implementation through the monitoring sheets and the presentations in the dialogue meetings. Also highlighted were the monitoring of activities and the permanent information provided to laboratory heads regarding the procedures carried out with the authorities or the forwarding of documents delivered to the ministries/secretariats of health.

The heat shown by those responsible for the grant has its reason because the information flows from the ministries to the programs or laboratories are not always efficient. The documents, invitations, and memories help developed within the framework of the grant were sometimes lost along the way but were copied to

the laboratory heads and NTP for follow-up. There are hierarchies and bureaucratic procedures that cannot be ignored in international management, since they must first go through the international relations offices of the ministries and, from these to senior management



= "The administrative management and management carried out by the people who managed the grant was fundamental to finally achieve the objective of reaching implementation in Colombia since at first the country's authorities were reluctant" (Colombia)

In other words, the information flow on the management of the grant was highly valued by those responsible for the laboratories and the NTP, which was a good practice by those responsible for the grant to unblock the knots in the flow of information that has consequences on the development of activities.



#### 3.3 About sustainability for the operation of the NRL

Below, the achievements, difficulties, and successes of the set of activities related to the management of the sustainability of the changes generated by the previous and the current grant are presented. The activities are framed in the goal of the State having a greater participation in the financing and strengthening of laboratory activities.

#### Multilateral advocacy actions

One of the good practices observed was the political advocacy deployed in a coordinated manner by the multilateral organizations SE-COMISCA and ORAS-CONHU. The strategy was led by SE-COMISCA in Central America, promoting the inclusion of demands for laboratory strengthening in its multilateral meetings, which are attended by the ministers or vice-ministers of the health of the member countries, and binding compliance commitments are achieved for the signatory countries7. Two resolutions were promulgated in June 2023, one that promotes regional planning for TB control and the second that prioritizes the sustainability of national laboratories (Resolution COMISCA -02-2023 and Resolution COMISCA-03-2023<sup>8</sup>)

In the case of the countries of the Andean area, two ORAS-CONHU resolutions were issued at the Meeting of Ministers of Health of the Andean Area (REMSAA) in November 2022. Resolution REMSAA XL/557 calls for the adoption of WHO recommendations for the prevention, diagnosis, and treatment of tuberculosis within the framework of the "End TB" strategy. Resolution REMSAA XL/560 urges the National Institutes of Health or their counterparts to strengthen the quality management system of national public health and epidemiological surveillance laboratories. In addition, the Andean TB Committee was tasked with monitoring the implementation of said recommendations.

<sup>7</sup> Countries of Central America and the Dominican Republic.

<sup>8</sup> COMISCA RESOLUTION 02-2023 regarding the preparation of the Regional Strategic Plan for Tuberculosis in Central America and the Dominican Republic COMISCA RESOLUTION 03-2023 regarding the Sustainability of National Public Health Reference Laboratories of the Member States of the SICA

This strategy was implemented in the previous grant and generated an important precedent that the current grant has continued as a multilateral advocacy actions. These agreements and resolutions have greater force for their implementation and allow monitoring and enforcement of their compliance by civil society or the same officials in charge of the fight against TB. Some officials used the resolutions to support their calls for greater financial support for their activities.

It is concluded, therefore, that multilateral advocacy is a good practice that has only been possible through the "regional grant" modality thanks to the capabilities of the principal recipient and the subrecipient SE-COMISCA to handle issues of interest, joint meeting between the ministers of the subregional blocs

#### **Direct advocacy with national officials**

Regarding political advocacy, this is an activity highly valued by the heads of the laboratories and by those responsible for the TB programs, since the technical teams have few opportunities to influence senior management.

The high-level meetings held by ORAS-CONHU and SE-COMISCA raised awareness among the authorities, kept TB on the decision-making agenda, and sought to reaffirm previously signed commitments or assume new ones to strengthen laboratory diagnosis. This advocacy work constitutes a good practice of this grant that seeks to continue the efforts deployed with the previous regional grant from the Global Fund.

However, for future grants , it is necessary to consider some structural aspects that hinder the implementation of the commitments that have been observed in some countries. In some cases, the change of government generates the replacement of officials, who are not always informed of the commitments. Difficulty also occurs, for example, with new directors of national TB programs, who are not familiar with the grant's previous activities or do not receive the studies that the grant provided to their predecessors. This generates interruptions and sometimes a disconnection of officials with the political advocacy processes underway.

It would be desirable for future grants for recipients and subrecipients to concentrate all files and communications produced within the framework of the grant in cloud folders for each country. In this way, the effect of personnel change would be reduced, and it would make it easier for laboratory heads and those responsible for the NTP to recover information that is often dispersed in email that were sent.

Bilateral incidence has managed to lift many of the logistical problems that prevented, for example, the performance of external quality control of diagnostic methods. But after the pandemic, other problems arose such as inflation, greater customs obstacles, and bureaucratic delays in approving purchases or payments.

Many of these problems are not in the hands of the ministries of health but originate from national regulations that are the responsibility of the country's Treasury or Economy portfolios. In some countries the problem originates from the increase in prices for transporting samples that exceeded what was budgeted, in others it was the absence of transport companies willing to transport biological samples or the prohibition of payment to technical personnel traveling for the supervision or training of the national laboratory.

The grant was wise enough to continue the development of management instruments that had proven useful in the previous grant. The study of LRN financing flows was one of the most useful instruments, as it made clear which of the 13 functions of the LRN were financed according to the source of resources (public or external), allowing the identification of gaps in financing. Furthermore, since it was a study repeated for three years, it was possible to monitor whether the financing gap increased or decreased.

The information contained in the study of financing flows is not usually investigated by laboratories or ministries, which are aware of the needs, but hardly quantify the amounts necessary to reverse the situation. With the figures in hand, the problems are made visible and the discussion with the authorities was better focused on the advocacy meetings managed by ORAS-CONHU and/or SE-COMISCA.

Another study that was published was the update of the situation of the national laboratory network of each country, which consisted of the inventory of the equipment available, and the types of diagnostic methods performed in each of the laboratories. This study showed that there was an increase in the use of rapid molecular methods recommended by WHO and the incorporation of certified biosafety cabinets and multiple-use platforms for molecular diagnosis. This inventory became a useful instrument to identify the needs of the national network and a key input for strengthening laboratory diagnosis with a national perspective.

Advocacy meetings in 2021 were mostly virtual, but in-person meetings were held in subsequent years. In most cases, ministers, vice ministers, advisors, program directors, and laboratory heads or those responsible for epidemiological monitoring were present at these meetings, generating an important exchange between the technical criteria provided by the actors in the fight against TB and political considerations. In a few cases, the authorities did not involve the NRL or NTP in the meetings, which was the decision of the officials.

Most of the meetings became spaces where there was the opportunity to raise the needs of the program and the national laboratory, which hardly happens without an external visit. In some countries, this dialogue depends on the position of the person responsible and their ability to influence the authorities, hand in hand with the importance that the fight against TB has in national public policies. The contribution of the grant for political dialogue between the laboratory and the authorities has been more substantial when the actors in the fight against TB have weak political leadership.

As a result of the advocacy meetings, minutes (executive summaries) were prepared, which were then distributed in most cases by the authorities themselves to those responsible for the NTPs and laboratories. In any case, ORAS-CONHU informed the NRL and NTP of the agreements agreed upon in the meetings.

The production of situational studies from laboratories is not enough to generate political will in decisionmakers; it was thanks to advocacy actions that the impact of these documents was enhanced to capitalize on a government predisposition such as, for example, in the governments of Mexico and Colombia, that, despite the austerity measures, agreements were reached that served to generate greater support for the laboratories.

Regarding the beneficiary countries of the grant that do not participate in multilateral organizations, such as Argentina, Mexico, Paraguay, Haiti, Guyana, and Suriname, multilateral actions cannot be developed, for this reason, two rounds of visits were carried out to ensure greater commitment from its authorities and officials to strengthen its NRL

#### About fulfilling government commitments

One of the focuses of the political management of the main recipient and the subrecipients was compliance with the agreements made within the framework of the last grant. In general terms, these agreements consisted of commitments for

governments to include greater resources in their budgets so that the reference laboratories could fulfill their functions for optimal performance.

Some countries such as Argentina, Mexico, and Chile, which had committed to incorporating more personnel for the laboratory, managed to meet the objective, permanently incorporating personnel so that the laboratory fulfills its functions as NRL, but also as SRL.

 $\Xi$  "The sustainability difficulty for the grant was the human resources in the laboratory and that was resolved. After the first grant, it was possible to ensure the permanence of the people who were hired by the grant. Those people are still there, so that was an achievement in favor of sustainability." (Chile)

Regarding the commitment to continue external guality control, during the pandemic in many cases, it was interrupted due to the guarantine. Subsequently, the laboratories developed many efforts to comply with the commitments, managing public resources or international projects, and achieving the shipment of the strains to their countries.

"The main difficulty lies in the funds for shipping from the SRL to our laboratory (which were mostly = obtained through collaborations in projects). The Ministry of Health was insisting on supporting the funds and now after almost 5 years it is in the process of inclusion." (Paraguay)

Bureaucratic obstacles also played a role in the failure to comply with external quality control, whether due to customs problems or excessive delay in spending authorizations.

Other laboratories, however, had problems financing shipments. In some cases, the problem of inflation made it difficult to transport samples, since the prices budgeted by governments differed greatly from the updated post-pandemic costs, making it impossible to cover expenses.

- 🧧 Well, this year it was not possible to do (shipping of strains), because when the procedure was already in place, it turned out that the initial quote with which the electronic procedure began changed. When we had it, the new quote was requested, there was a difference of more than 1000 USD. At the ministry level, it can vary little, but not 1000 USD, so it could no longer be done technically" (Guatemala)
- "Funding shortfalls and difficulties in customs clearance are the biggest challenges." (Haiti)
- = "Financing deficits are the main difficulty for the continuity of quality control. Despite the financial gap, we were able to continue with quality control. This is an achievement for us" (Surinam)

Despite having financing, in other cases, the problem was due to the lack of companies willing to provide the service of transporting risky biological samples. In other cases, bureaucratic obstacles, cumbersome procedures, or regulations prevented payments or contracting transfer services on time. These difficulties exceed, as already mentioned, the decision-making scope of the laboratories, and even the ministries themselves, since they involve the deficient functioning of the market or supranational regulations.

- = "Unfortunately, we have had problems with the transfer of the panel (...) Although the country has the national budget for this activity at the administrative level, it is impossible to execute said budget or redirect the funds so that one of the people trained through the grant can come to the country and carry out the certification of the cabinets, which is a condition for receiving the strains" (Honduras)
- 🗮 "We were not lucky, like other countries, that airlines took samples to and from Mexico. We did not find any company that would take us, there were restrictions from the airlines, which were not willing to carry highly dangerous materials, such as drug-resistant strains." (El Salvador)

"There is financing. However, we lack a company that can provide this service in the country, since contracts with foreign companies are difficult either due to internal requirements or due to payment." (Bolivia)

Problems like those experienced in the transfer of samples are observed in the purchase of supplies and reagents for laboratory diagnosis. Laboratories have problems in their acquisitions due to increased costs, delays in purchasing, the fact that there is a single supplier, or the increase in transportation prices

- "Conly the purchase of supplies was made. There were difficulties in sending the customs clearance and nationalization letter through the Ministry of Foreign Affairs." (Surinam)
- "Regarding the purchase of supplies, equipment, and reagents, the main difficulty is how to provide the necessary funds to ensure universal access to diagnosis. There is great bureaucracy in the processes of placing the order, budget, approval, and payment before the period indicated in the budget expires, as well as import and customs clearance promptly, ensuring arrival with integrity to the recipient laboratory. (Paraguay)
- "The State knows that there is this inflation and, therefore, they partially compensate for it. That's why I tell you: what I request is bought, in that aspect, we have had no problem, after the entire bidding process, etc. Everything takes months. I can't say "I couldn't buy such a thing." If I have not been able to do it, it is because the supplier did not submit to the tender or because they did not have it in stock." (Argentina)
- "Perhaps to reduce costs, it takes a long time to make deliveries. Sometimes purchases that you have scheduled, local lab purchases, for example, that you schedule in January, the process is done, and you receive them in May or June. These problems have perhaps been the strongest in terms of supplies." (Guatemala)

At the request of the Global Fund, a marketing plan was included in the grant so that the SRL could develop external services and thus contribute to generating their income and boosting their sustainability. From the perspective of the supranational laboratories, this consultancy did not make sense since the nature of the national institutes is to provide a free public service to the population, therefore, developing services for third parties is distorting existing standards and diverting the few available personnel from their priority tasks.

In short, the marketing consultancy for laboratories to develop their income, proposed by the Global Fund, was not of interest to the laboratories. The regulations of some countries made the possibility of offering services to third parties unfeasible, in addition to the fact that the laboratories themselves considered the sale of services as contradictory to the reason for being of their institution.

- "We are reference laboratories, and Argentina said the same thing and Mexico said the same thing. We cannot sell service because we are part of the laws, surveillance of tuberculosis resistance is part of this, of the supreme decree of surveillance of communicable diseases. Therefore, we must do it and no one is charged." (Chile)
- "We are not an independent laboratory; we are a laboratory that is within an institution. Therefore, we cannot offer services when the Institute here is going to tell us that this cannot be done. By law, it cannot be done. They don't even let us receive suppliers. (...) So, it is not about arriving and saying I am going to sell this in a country, marketing. No, no, you can't, and we never understood that, ever. We were never able to make ourselves understood between the 3 SNL with the consultant." (Chile)



# **3.4 About the incorporation of international recommendations**

The grant developed a set of activities aimed at improving technical and managerial capabilities that were carried out or had close advice from the PAHO subrecipient. The activities consisted of technical meetings, visits, and supervisions to the laboratories, publications of documents, training on diagnostic tools, accreditation of laboratory tests, improvement of

maintenance processes, and certification of the BSC of the laboratories.

In recent years, and with the relevance that COVID-19 gave to laboratory diagnosis, countries acquired equipment to improve the quality of tests. However, there was a weakness in equipment maintenance and BSC certification, a service that involves an outlay each year but which, after the equipment has been purchased, has not necessarily been budgeted for.

The pandemic stimulated the development in a short time of equipment with better performance for the simultaneous diagnosis of samples and with greater versatility for diagnoses of different diseases. New procedures and supplies were also approved, which highlighted the need to update laboratory personnel.

It is within this framework that the grant activities are presented as a necessity to improve the technical capabilities of the laboratories.

#### About equipment and technological strengthening of laboratories

This grant sought to develop capabilities in the laboratories of three countries so that their personnel could be accredited in BSC certification, which would reduce costs and improve laboratory capacity. Instead of sending staff to the United States for training, NSF International was contracted and the workshop was held in Lima in August 2022. A profile of the participant was created <sup>9</sup> and they were selected in coordination with the laboratories to occupy the 7 places available in the course, which would initially be occupied by two participants from El Salvador, two from Colombia, and three from Peru. Colombia designated a single person and Bolivia requested to train a specialist to take advantage of that position and committed to acquiring, with the national budget, the equipment to carry out its work if it were authorized to provide the service.

Of the seven trained, five passed the established exams. The grant purchased a set of equipment to certify BSC in each country (El Salvador, Colombia, and Peru) and additionally performed the calibration of the equipment acquired in the previous grant (from Mexico and Argentina). There are currently seven BSC certifiers trained by the regional grant in five countries, with the capacity to provide the service throughout the Americas region.

Those professionals who managed to become accredited are positively reversing the investment in their respective countries and others in the region. The accredited personnel of the LRN of Lima certify the

<sup>9</sup> The participant should be a laboratory staff with specialties of biomedical engineers or biotechnologists or similar, be fluent in English, be familiar with cabins and sign a commitment to remain in public service for 5 years.

cabinets of their laboratory, but also for the other laboratories of the institute to which it belongs, for its national network, and even for countries such as Ecuador and Venezuela. In Colombia, the accredited person supervises the quality of the certification carried out by the suppliers. The specialist from El Salvador also made the diagnosis of BSC in his country. In Mexico, the accredited person has certified nearly 100 InDRE cabinets, is doing the same with the national network laboratories, and has certified BSC in the Dominican Republic. This professional, as well as the one from Argentina, both trained in the previous grant, had their NSF accreditation licenses renewed. The Argentine specialist, in addition to the service provided to its entire national network, has provided the certification service to the laboratories of Paraguay and Bolivia.

- "The training received in BSC certification marked a before and after, a milestone in the biosafety of tuberculosis diagnosis, a transcendentally positive intervention for Paraguay." (Paraguay)
- "This person who was trained with the grant and who passed his course and everything, is currently verifying the institute's cabinets. Because as a supplier comes and offers us the service, they are verifying that the service is good, with the equipment that the grant gave us." (Colombia)

The accreditation of own personnel for cabinet certification therefore had a significant impact on reducing costs for laboratories. This activity has had a very important cascading potential, although it was not within the reach of all countries due to budgetary limitations or in certain countries no plant personnel met the requirements to participate.

"Something that we have been very strengthened and that I am very grateful for is that we have personnel trained in BSC certification, which is very important for the country. It was formed by the grant. That is an achievement that is applauded because to date he, our technician, has performed many certification services all of the institute's cabinets are certified. All of them, and there are more than 100." (México)

"In fact, (costs) have been reduced, apart from the fact that it is not a company. With the company, everything can be wrong, and they still charge you, rate it according to them, and give you their report. On the other hand, not here, they make sure everything is fine." (Perú)

"Thanks to the grant, Bolivia has certified cabinets in two departments of the three visited, which previously did not have one. Unfortunately, the professional who went to train for cabinet certification did not have the necessary knowledge to be able to perform as established." (Bolivia)

It must be emphasized that BSC certification is not a problem in all countries, since some laboratories such as those in Colombia, Guatemala, or Chile have funds to hire private companies or the institute has engineers who carry out these tasks.

"This group has some engineers who oversee maintaining easy equipment such as agitators, and material heating plates. And if you do not have personnel for sophisticated equipment, a service provision contract is made. (...) The annual programming that the Institute makes of all its equipment is called the Annual Metrology Plan." (Colombia)

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*"We hire services here, here there are private companies that do certifications or parameter verifications. It is within the verification process of the annual equipment maintenance plan."* (Chile).

"The central laboratory, for many years, has included the maintenance part. Fortunately for us, there is a provider that sells the services, which is certified in cabinets, so we have the facility to be able to hire this service." (Guatemala) For possible future grants, solutions should be considered for laboratories in countries that do not have funding to pay for BSC certification, nor companies that provide this service, or whose prices are very high. In other cases, even if funds are available, there are bureaucratic obstacles to bringing in experts to certify the cabins. As a solution, some countries use cooperation funds for the maintenance and certification of the cabinets, but in the perspective of reduction of international funds and the absorption of these tasks with state resources, it is not certain that this recommendation can be met. of the WHO.

- "The certification of the cabinets has also been a problem for this year 2023. Although the country has the national budget for this activity, at the administrative level it is being impossible to execute said budget or redirect the funds so that one of the people trained through the grant can come to the country and carry out the certification." (Honduras)
- \*The maintenance part for the laboratory network is poor, it is very poor, even though the people who provide maintenance have been trained in the importance of why to certify cabinets. So, it was possible to certify the cabinets of the tuberculosis laboratory network but with external financing." (Guatemala)

Other activities focused on the accreditation of diagnostic methods in laboratories in Argentina, Chile, Colombia<sup>10</sup>, Guatemala, México and Perú. Consultants were hired for a year and a half in each country to support the accreditation process under the ISO15189 standard, creating documentation and the quality management system.

In some countries, such as Peru and Guatemala, the grant's hiring of the support professional for accreditation was extremely important to be able to move forward with the process, because documentation was not available, nor was the management of the accreditation organized. quality. On the other hand, in other countries such as Chile and Argentina, the laboratory already had the procedures and systems refined and the contribution of the consultant was limited, but equally key, without which accreditation would not have been achieved.

- "We are very grateful that we have been included in some interventions that were only initially for supranational. We have been included and that has allowed us to have strengths and capabilities. Now, today, perhaps we would not have had them if we had not had the support of ORAS. Above all, it is the issue of accreditation. Last week we passed the accreditation process for the last two methods that we were missing" (Perú)
- "Yes, it was supported by this grant, which is why I tell you, if we had not had this support, I believe we would not have embarked on the accreditation process. We already had a quality management system in place, but we did not know the requirements of standard 15189. Therefore, if it had not been for the grant, we surely would not have started the accreditation process." (Argentina)
- We didn't need to do an implementation, we didn't need to have the work, it was much less than what other countries had to do, so, that person who was hired was like a little extra support in some specific activities, but not to build a system or to put together a system. The system has been ready at the Institute for years." (Chile)

<sup>10</sup> The Colombian laboratory participated in the process and a consulting firm was financed to facilitate accreditation, but the National Health Institute works under the ISO17025 standard.

For directors, having obtained international testing accreditation is extremely important as it is an achievement of their management and an indicator of the quality of their laboratory, which results in their better positioning within their respective institutes and internationally, it certainly qualifies them. to obtain a better category as a laboratory. This condition generates confidence in the quality assurance of laboratory diagnosis.

In countries like Mexico or Chile, accreditation has developed without obstacles, since in their institutes there is a mechanism for financing the accreditation and reaccreditation of laboratory tests, in other countries they have difficulties in financing these processes. In future subsidies, progress can be made in the management of this disbursement, which the laboratories do not have budgeted for.

- Ξ "That is part of the institute's budget, a purse. Here there is an institutional quality management unit. It is the one that generates the resources or takes resources from the institute's budget so that these accreditation and reaccreditation processes are carried out annually. So that is why on that side it is within the same functions of the institute." (Chile)
- 😑 "I am a little worried about maintaining the accreditation if we achieve it, which I am convinced that we are going to do. Economically tough years are coming for Argentina, according to what appears in the media. But I think that if we achieve it, it will not impede maintaining it." (Argentina)

#### About technical-managerial capacity development activities

In the interviews carried out, there was a consensus regarding the positive assessment of the training received as part of the grant through PAHO and the hired consultants. The update on diagnostic methods is highly valued because the changes and innovations in this field COVID-19 pandemic, since in a short time there was a greater development of technical innovations, reagents, medications, platforms, and methods.

The problem is not access to information since PAHO/WHO publishes regularly - although in English most of the time - on the technical updates of all the procedures it recommends. The problem is that the pace of work in the laboratories does not leave time for self-training, which is why these activities promoted by the grant are highly valued by the laboratory staff.

- = "I think that the main contribution, beyond the equipment that was purchased from GeneXpert and tests, which whether we like it or not, is this development of human resources that has been crucial to continue moving forward in the fight against tuberculosis." (El Salvador)
- = "That for us is the most important thing because we know that in the institution we must compete with the entire Institute. And the resources are scarce, so getting training or having someone come here annually as the grant does, brings them, is super." (Chile)

Of the set of trainings and workshops promoted by the grant, the one that stood out the most was the "new diagnostic methods" workshop, developed in Chile with very good acceptance among the directors and the participants. In addition to improving skills and abilities, this activity also constitutes a space for meetings and exchanges between participants.



🧧 "My work is towards the network of laboratories as a whole, the knowledge acquired helped me guide and focus my strategies" (Participant from Guatemala)

= "The course enabled us to be updated and learn about new diagnostic tools." (Participant from Suriname)

The important thing is that this training was not restricted to the development of individual competencies and skills of the participants, but rather in the interviews it was clear that the training resulted in the renewal of ideas and provided inputs to rethink diagnostic procedures and in some cases the hand with the national TB program.

- The course facilitated changes in the sample processing work algorithm, implementation of the Xpert®
  - MTB/XDR test to accelerate second-line DSTs, implementation of linezolid, bedaquiline, and delamanid DSTs." (Participant from Paraguay)
- "We learned about the implementation of DST for delamanid, linezolid, bedaquiline, change of algorithm for DST by Xpert<sup>®</sup> MTB/XDR, sustainability for the implementation of the universal access rapid molecular test for each presumptive case for another year." (Participant from Ecuador)
- = "New techniques approved by PAHO/WHO are being verified for a diagnosis more in line with our reality (implementation of Truenat, LAM)." (Bolivia)

As of the date of preparation of this systematization, not all the PAHO technical visits planned for the 17 countries within the framework of the grant had been completed, since those scheduled for previous years were postponed due to the pandemic. However, the interviewees valued the technical visits carried out, since they are not only limited to identifying problems, but they are also training and helping to improve procedures, providing solutions and criteria that are often not recorded in technical manuals.

In addition, the visit reports are used by the laboratories to carry out procedures at the institutes or with the ministries. When it comes to positive evaluations, they are used to position the quality of your technical work. When it comes to negative evaluations, the reports are used to manage further support.

- "I think there is a good vision regarding the PAHO staff, which is Dr. Montoro. He is always open to coming here whenever he wants and checking our laboratory. In that sense, we always feel strengthened by him, that he looks towards our laboratory." (Peru)
- "They help us by providing a different vision to what we perceive, in addition to giving recommendations from experiences they have seen in other countries." (Venezuela)

"These visits generate a greater commitment in the authorities since they see that the processes are closely monitored. Also in these visits, agreements are generated that allow us to advance or streamline processes within the country." (Honduras)

Regarding the production of materials and manuals, the publications focused on the maintenance of equipment and the translation of WHO technical documents into Spanish. Compared to the previous grant, fewer new documents were prepared, because a good part of the updating needs that were more pressing in 2017 had already been covered.

Laboratories use publications for various purposes, in some cases to improve their diagnostic procedures and in other cases, they use them to develop training in their national networks and include them in training programs. In other laboratories, the use of publications is discretionary.

"The documents support us as a tool for training laboratory network personnel, they also serve as a guide for updating regulatory documents and to accelerate the process of implementing new laboratory processes. For example, the translation of the manual for the processing of feces, or the manual for equipment maintenance, biosafety, and the rest of the technical manuals has helped us." (Honduras)

"The TB program has held diploma courses, and where we have part of the laboratory component since they (the documents) serve as a reference for training." (México)

It should be noted that the training and technical information distributed by the grant has meant a change in the quality of the diagnosis but has also impacted the procedures and organization of work. It is also necessary to highlight that at an individual level, the training activities have generated professional growth in the laboratory staff.



*"It has allowed me to have a better vision when collecting the necessary data and its subsequent analysis for the preparation of studies and possible publications."* (Peru)

"It has been useful to receive technical training and the possibility of learning about visions and solutions applied in different countries, with different levels of complexity and resources." (Chile)



#### 3.5 About information systems

Information systems were a recurring concern in the management of national laboratories; in fact, several national grants included resources for their improvement or enhancement, and governments made efforts to create, improve, or enhance their systems.

This grant proposed the optimization of laboratory information systems as one of the central objectives. In 2022, a diagnosis was prepared about information management in national

networks. The diagnosis placed each country in one of four quadrants according to the level of development of its information systems. The purpose of this instrument was to identify the shortcomings of their systems and be able to manage resources.

Additionally, three instruments were developed. One of them was a tool that allowed evaluation of the quality of the data that is captured by the information systems at the different levels of the national laboratory network. The second instrument was a dashboard or data command that graphically displays the laboratory indicators and allows a more complete visualization of the information. The third instrument was designed for the triangulation of information handled by different sources such as the NRL, the NTP, and the public health surveillance directorate or its national equivalent. Additionally, virtual technical assistance was provided to each country and there was in-person advice to 7 countries; the 3 SRL and 4 NRLs (El Salvador, Guatemala, Honduras, and Paraguay)

One of the three objectives of the project, related to the information system, has required a set of conditions to be carried out, since the countries have shown great inequality in the conditions necessary to incorporate the informatic tools produced by the consultancy. The grant faced the fact that countries have very heterogeneous information developments. The consultancy contributed a lot to countries that are in the process of developing their systems or have gone through several trial-and-error experiences with informatic solutions that did not work. The grant allowed them to identify the informational nodes and reissue the need to undertake the development of the system, it also served to position the importance of making improvements in the programs and adjusting current procedures.

For their part, some laboratory managers were able to understand the contribution and usefulness of the tools produced by the grant, such as the dashboard, which synthesizes statistics for epidemiological analysis. They currently use it to monitor the evolution of WHO indicators and to prepare reports for decision-making and planning.

"I am also implementing this tool precisely in the national plan, in the national strategy for the analysis of information. It will be my evaluation indicator, which will be the recommended productivity through the Power BI tool<sup>11</sup> that the consultant Juan José Victoria gave us, that I have been using." (Mexico)

In the cases of countries with advanced information systems such as Paraguay, Argentina, or El Salvador, their systems articulate epidemiological, primary care, and laboratory information. Therefore, its information systems function adequately, and the consultancy contributed with small improvements to the processes already in place.

- "Argentina is very advanced on this issue, it has all that, and it is managed by the CONI Institute in Santa Fe. Argentina has an online system, where all TB cases are registered, not only in the clinical part but also in the laboratory. (...) As it is a PAHO/WHO collaborating center, they also already know what indicators this country should have. So, those indicators come out of this online system that I am telling you about. This was discussed with Juan José Victoria, that all that dashboard and everything they have done to us is not very useful to us because we already have it in another system." (Argentina)
- "Here in recent years, there has been a digital transformation, a very good development in spectacular information systems, local information systems in every sense. The health information systems that are unique and that group the different modules, both for tuberculosis and HIV and for all diseases, are on the same platform, in the same system." (El Salvador).

However, various structural obstacles are observed that limit the development of information systems. One of them is the difficulty in having updated data, since some laboratories record the information in spreadsheets and even by hand, partly because there is a fear that the information will be lost from the servers and there is distrust in storage resources. To have updated data, human resources are required, which are usually very busy in diagnostic work.

- "Indirectly there would also be a human resources gap, because to the extent that you have an information system that requires a lot of manual intervention, because it is not well automated, that is not loading information from other systems automatically, a lot of work is generated. manual and human hours dedicated to that." (Chile).
- "Why is the information not captured yet? It is until March 22, why is that like this? I told Juan José, something in which we also had problems and that we identified in the last meeting of the financing flow consultancy and the current one, is the personnel. I have few staff." (Mexico)

<sup>11</sup> The dashboard developed within the framework of the grant is an application based on the Microsoft System called Power BI, which is an interactive solution for data visualization

Another problem reported by those interviewed is the difficulty in influencing computer systems. This is because some systems are administered by the institutes to which the SNL/NRL belong or are managed by specialized institutions within the state apparatus, but which are not related to the health sector. Therefore, achieving change will require more time and advocacy at a higher level.

The interviewees also reported that when they promoted improvements in information systems, they had problems making connectivity compatible between equipment on different platforms. On other occasions, the regulations for data management did not allow the use of software that is not audited by the country's public institutions, or the regulation restricts the use of servers located abroad, all of which makes the use of solutions difficult. external IT proposals.



On the other hand, operating an integrated information system requires good coordination between the laboratory, program, and primary care system, but these articulations do not always flow virtuously in all countries. For example, in Peru, meetings were held with the experts who oversee the computer system, but they did not understand the perspective that was intended to be given to the system from a laboratory point of view.

"The engineer was also there, involved in these meetings that took place with this consultant. But it seems that they did not understand very well what was wanted. I think he was left in limbo with him because they could have worked a lot there, but not because he focused on the laboratory and the SIGTB,<sup>12</sup> he said that they didn't see the laboratory. It's like why am I here, they said." (Peru)

In other cases, the difficulty lies in the fact that the health system in certain countries does not use the identity document as a unique identifier for procedures, consultations, or diagnoses. Therefore, the same patient has one number for their medical history a different number for their hospitalization, and another for the results of their diagnosis, generating enormous difficulties in interrelating the databases to which the same patient belongs and being able to carry out traceability.

Another obstacle to improving computer systems consisted of the skills and abilities of those responsible. In some cases, the applications were installed, and the data was used for laboratory analysis and planning. In other cases, those responsible could not familiarize themselves with the instruments or, despite the instructions provided by the consultant, they could not take advantage of the instruments.

- "He offered us a dashboard that in my brain I still don't know what that is, so he offered us that based on the indicators that the WHO had, but I think that, in the end, because we only have matrices in Excel It was not so applicable to the system." (Colombia)
- "I'm going to be super honest: when you see him work, it looks easy, but when you later want to use it, it costs a lot! I do not have the same ability, we do not have the same ability as Juan José and it is very difficult for us to use it, we do not understand or do not know how to paste the data well. And no, the truth is that we stayed that far, because when we are with him everything is fine, but when we are alone, no, no, it is not so easy to use it." (Chile).

<sup>12</sup> Tuberculosis Management Information System run by the NTP.

The institutional and regulatory limitations of each country generated difficulties in managing this objective. However, the diagnosis and the meetings held with the consultant generated in some countries the reactivation of work aimed at improving their information systems.

As a result of the consultancy, in Colombia and Chile, which have been implementing improvements to their systems and are in a testing phase, the presence of the consultant allowed the discussion on the information systems and, although it was not, they made substantive changes, opened coordination between officials from different agencies and an agenda for improvements.

- "Yes, that diagnosis helped us to accelerate the new computer system of the reference laboratory that we are now launching in May, (...) So yes, Juan José's visit served to give that boost that we had to this grant that had been there for a long time, and we were able to get it out and it has been in operation since May." (Chile)
- "Beyond some technical issues that it contributed; it seems to me that it was also a unifying factor in that different actors could sit down. It seems silly, but it is an achievement that the people who make the system could take a week and sit down with the laboratory. Within the framework of what this very qualified consultant contributed, they were able to sit down and rethink how to improve that. "I think the important thing was the opportunity to meet." (Argentina)

Despite the structural difficulties, the consultancy funded by the grant was wise enough to develop tools to improve information management in laboratories that some managers were able to implement and use in their work. In Mexico, for its part, it is planned to implement the dashboard developed by the consultant in many laboratories in the national network to manage data in a faster and more efficient way.

- "It did help us, and I appreciate Juan José's assistance to this laboratory, he left me two tools for analyzing data from this laboratory. They are a database that allows me to automatically extract multi-resistant, extensively resistant, or XDR cases. And another tool that allows me to analyze the Xpert results." (Argentina)
- "I am going to socialize this dashboard throughout the country, to the regional or state laboratories, so that they can also do their analysis. That was like something that Juan José Victoria left me. So right now, I am in that process, precisely for that reason the meeting of the General Directorate of Epidemiology with the Program and with us was very important to be able to generate this, to legalize it" (Mexico)



# **3.6 About sustainability and future perspectives**

Below are the opinions and reflections of the informants consulted regarding how they perceive the future sustainability of the laboratory strengthening processes that the grant has launched. Likewise, suggestions and proposals for actions that enhance the progress achieved to date are collected.

#### About the incorporation of civil society in the legal profession

One of the lessons learned from the first grant was the need to increase voices demanding greater investment in laboratories, which can convince decision-makers to allocate greater resources to strengthen laboratory diagnosis.

Under this premise, the current grant sought to involve representatives of the Global Fund CCM and the RCM. They participated in regional dialogues, accompanied some visits, and participated in the strategic monitoring of compliance with grant activities.

The balance is positive because before the grant the CCM and the RCM were weakly related to the fight against TB. The information provided and their participation in the dialogue meetings contributed to the representatives' understanding of the importance of the laboratory as a central axis in the programmatic commitment to reduce TB at the regional level. Therefore, the grant has raised awareness among representatives and has encouraged them to advocate in the future for more resources in government dialogue spaces.

In future grants, it should be considered that the participation of CCM representatives requires comprehensive intervention so that they can more effectively exercise their advocacy role in favor of strengthening the laboratories. To do this, the following aspects should be considered:

- All countries with national GF subvention in any of their components have CCM formed. Sometimes those
  who participate in these meetings are those responsible for the NTP, who are the ones who are assuming
  the presidency at that time, which makes it impossible for these citizen participation mechanisms to put
  pressure on the decision-makers.
- In countries where there are representatives of civil society, groups or people affected by TB do not participate with much weight. Most CCMs come from institutions and organizations related to HIV-AIDS. This implies that they are not familiar with the problems and conditions of TB, which makes it difficult for these delegates to advocate for this health problem, even more so if they are unaware of it.
- In countries with representatives of TB organizations in the CCM, a weakness of TB organizations is observed, which is reflected in their high turnover or intermittent participation in grant activities.

 There is an imbalance in the influencing capacities and their knowledge about TB. Some representatives have a more experiential knowledge of TB and provide knowledge of living conditions and implementation issues from the patient's perspective, but they find it difficult to understand the complexity of laboratory procedures and public policy that is the norm. However, in some countries such as Colombia or Ecuador, for example, the representatives have good technical management of the problem and are also familiar with the public policies to combat TB in their country.

In the interviews, in general, it is observed that the representatives recognize the main message of the grant, that is, the importance of laboratory diagnosis of TB and the need to invest more in them.

In a future grant, involving the representatives of the CCM to position the strengthening of laboratories in public policy, the prior task will be to qualify them in the management of basic technical aspects and the knowledge of TB public policies. Likewise, in addition to considering the possibility of training them in political advocacy actions, synergies should be made with grants that work on the issue of TB with civil society or CCM at that time.

#### About the financial sustainability of the laboratories

According to Ernesto Montoro, the budget gaps are still very large to cover the needs of laboratories in the framework of TB, since "there is still a need for political will to put TB at the center of national public policies and allocate resources necessary to close the gaps identified in the grant studies."

The development of laboratories should be promoted from a more comprehensive health perspective since TB is a multidimensional epidemic related to vulnerable groups, situations of poverty, populations deprived of liberty, etc., which goes beyond the effort that ministries can develop. the health of the countries. Therefore, we must support the efforts that are being promoted by multilateral organizations such as the UUNN, since international agreements generate commitments in States and promote multilateral processes that can lead governments to include TB among their main health priorities. public politics.

"From the high-level meeting that will be held at the United Nations, which is the second meeting after 2018, the authorities will participate, some ministers, presidents, and they must assume this commitment for the next goals. And we do see that some countries are prioritizing or considering the role of placing tuberculosis as a priority, even thinking about the elimination of the disease." (PAHO)

However, a recurring concern about sustainability is the economic crisis that Latin America is going through, since due to inflation the committed budgets are not enough to cover the needs for the operation of the laboratories. Some countries have mechanisms to compensate for differences between budgeted and actual costs, but others cannot cover these shortfalls and consequently, the amount of financing is reduced. There is also pressure to reduce expenses in the State, especially in personnel, since it is difficult to replace personnel who have resigned and even less so to create new positions.

Regarding the political sustainability of the advances and achievements of strengthening the laboratories, different perspectives are observed. Some countries, such as Peru, Chile, Argentina, or Mexico, consider that there is a political consensus that shields laboratories from political swings. In such a way that government changes will not affect the allocation of resources for laboratories, even though most of the resources come from the public treasury. Furthermore, some interviewees maintained that governments that have greater concern for the well-being of the population are more willing to invest in health issues and this is reflected in greater financing for laboratories.

- "I think that we are going to be able to maintain, with a lot of effort, the activities, and it will be difficult for what has been achieved to be lost. We can continue moving forward or take one more step. What has been achieved will not be lost because it is already an achievement and that will be maintained. (Argentina).
- "The strength of our work comes from good coordination with the program. If there wasn't one, maybe they wouldn't pay as much attention to us and we wouldn't succeed. But they are very attentive to what we need, they don't give us everything, but they do give us a large part." (Peru)
- "It is political propaganda from my point of view because we have had right-wing governments, we have had alternation in the country. That situation will not happen because in the end what always happens in the country, is that every time a government arrives, all its people enter the system. We the technical people continue to stay here because the good thing this country does have is that the advisors and directors of the institutions can move around a lot, but the technical part remains." (Chile)
- \*There was something important that occurred this year with this change of government, which was that the resources issued by the nation to territorial entities were increased. That increase was 64%. Something very important for the country and the issue of strengthening diagnosis is also included there. "These benefits everything that has to do with operational research, but also with active search, detection and so on." (Colombia)

On the other hand, other interviewees have the opposite opinion. From their perspective, a change in government can affect the allocation of resources and put at risk the continuity of support for laboratory diagnosis, restricting the assigned budget or failing to fulfill the commitments to assume with the public budget the financing of supplies, equipment, or personnel of the laboratories, and thus affect the functions of this.

- "With the change of government, I don't know how that will be because one of the points is that many of the agreements remain at a high level so that they can be fulfilled. Sometimes they just stay there, really in the word part. Yes, it does make me a little sad. Right now, perhaps the part of the 50% that we still have subsidized, we would have to see how to leave the commitment that it will be absorbed regardless of whoever is there." (Guatemala)
- (Maybe yes, we don't know how it will behave or if the situation is going to be generalized or how each country can deal with it. Although advocacy efforts are made and commitments are made later, in practice it would be necessary to see if they can be fulfilled." (PAHO)

#### **Recommendations and bets for the future**

In general, it is observed that those responsible for laboratories and TB programs have a positive assessment of the contributions of the grant to strengthening laboratory diagnosis. However, there are certain grant mechanisms that from their perspective require adjustments. A problem frequently mentioned in the interviews was the need for the design of the grant activities to be carried out in a consultative manner, including the opinions and needs of the laboratory heads.

The demand is that some activities are designed based on regional indicators that are very well adapted to meet the needs of a group of countries but do not fit the specific demands of others. For example, the laboratory has a higher technical level than that taught in the training and does not provide a substantive

contribution. It can also happen that the reverse process occurs, some laboratories need more basic solutions - as is the case of information systems - that require prior training levels to be able to implement them.

- "I feel that there are some systems that can be generalized to everyone, but there are others that must be very specialized to each of the regions and place. When something is already brought as a standard, sometimes it can be applied and be useful to the place or it could not be, and I feel that with this information systems consultancy something like that happened to us." (Guatemala)
- "I believe that regional proposals must take a closer look at the conditions and characteristics of the countries, to make differentiated interventions and not so regional, not generalized as was the case in this one. Of course, they put regional indicators, and not country indicators, but that could be negotiated or adjusted a little more. I think that was missing a little bit from this grant." (El Salvador)
- "We do not participate as national reference laboratories in the preparation of proposals. I believe that it is also important that we intervene because all countries may have different needs." (Colombia)

Another challenge has to do with the scope of the regional multi-country subventions, since in the last two grants this focused on the SRL and NRL laboratories, but the interviewees observe that the situation of the national laboratory networks requires a great effort to improve its diagnostic capacity. The realities of the laboratories of each country are different, in geography facilitates integration, in others distance or inaccessibility or even the administrative structure constitutes a barrier to improving their capabilities, and if the national network of laboratories does not function properly, the commitment to eliminating TB will be remote.

"Already in the second grant we also raised this need that it seemed perfect to us that the supranational laboratory trained other countries and everything, but we also needed to strengthen our network." (Argentina)

On the other hand, it is argued that to generate political will, regional grants must expand their scope. Although it is understood that the place occupied by laboratory diagnosis is central to tuberculosis, the dominant perception of the authorities continues to focus on the care of cases. Grant efforts focused only on laboratory diagnostics do not attract the same attention as if they were accompanied by other more attractive components in the eyes of politicians.

It is suggested that regional grants could articulate primary care components, which would facilitate greater involvement of other actors in the fight against TB. This link would have the virtue of being more valued by political decision-makers since direct impacts on the population tend to tip the balance of resources in decision-makers.

From an efficiency perspective, the strengthening of laboratories must go hand in hand with early identification because if the sample is collected late when the patient has been affected for months and infecting those around him, molecular diagnosis contributes little to reducing the risk. epidemic.

- "It must be very strategic in joining TB with other components, for example, care, prevention, and that it goes hand in hand with national programs, because many times in the administrative structure laboratories, especially national ones, are considered support services" (RCM).
- "I think it could be useful for a new grant to incorporate programmatic themes now more strongly and for the emphasis to not be so exclusively on the laboratory area. I understand that the grants have had an emphasis on laboratory networks and in fact that is the name of the grants, it says so, but perhaps it would help us to do more advocacy if we could show the authorities the issues related more to the assistance network, with direct attention to people; That generates much more interest from the

authorities. I believe that the laboratory issue itself, which is perceived as something very technical, is a little more distant from the political sphere." (Chile)

From another perspective, those interviewed maintained that the parliamentary route is also valid for generating comprehensive changes in the health sector since it results in greater support for laboratories. The experiences of new laws in Argentina, Chile, and Colombia with comprehe to health, and with a more current approach to the epidemic, may provide clues about the route to follow in future advocacy interventions.

- "It would be interesting to be able to strengthen the parliamentary front as well. The other thing that is also important is the law because this comprehensive care that could be achieved has a very interesting framework from the approach. So maybe on that side, it gives us a certain protection." (Argentina)
- Tuberculosis has also targeted vulnerable groups. There are no longer some who are not going to go to the health systems to receive regular care, we must go out and look for them and that is where the new norm made a complete change in focus of active search for cases. "It is different from the concept that was previously had in the other regulations." (Chile)

The development of skills has been one of the activities most valued by those responsible and participants, consequently, it is also demanded that it continue, even beyond the "regional grant" format. It is suggested that a "continuing education" service could be developed for laboratories and their national networks, since staff turnover is becoming more frequent and, therefore, new laboratory members need to be retrained. More differentiated training is also suggested, because there is an expectation of growth of some laboratories that aspire to be leaders in the region, becoming supranational or improving their capabilities to perform complex diagnostic processes.

- "Part of that sustainability is a strategy of continuous training at different levels. Sometimes the mistake is that everything is centralized, that if they are training, they only go to the central level part, and in the hospital networks people are not included, who are perhaps more stable than those at the central level. So, I think it is important when these types of grants occur in which there is capacity development, these continuous training programs guarantee that there is this generational change of knowledge transfer." (RCM)
- "We need to maintain continuous training at the NLR, technical and management, due to the incipient generational change of the tuberculosis diagnosis referents at the NRL". (Paraguay)
- "If you told me that there is another new fund, what should we consider, one of the issues could be improving the issue of personnel competencies, which is something important. And not the same ones but differentiated competencies that a national or supranational must have. (Peru).
- (In-person training is and must continue to be part of the Agency's strategy since it allows for the generation of an exchange of experiences between the countries that attend, as well as an update on new methodologies or international recommendations." (Honduras)

Another demand is to continue with the equipment since some laboratories find it difficult to incorporate modern equipment or have obsolete equipment that has already reached its life cycle, and the grant allows them to improve their capabilities and, in some cases, to receive the latest equipment. the generation that allows them to enhance their capabilities.

However, it is requested that the equipment be adapted to the needs of the laboratories, since in some countries the equipment deficit is concentrated in isolated areas, therefore, mobile diagnostic equipment is required. On the other hand, other laboratories require equipment that enhances their diagnostic capabilities to another level.

- There is the purchase of equipment that we know would be much more difficult for our institutions to obtain. We had asked for a sequencer, that was our goal as a reference laboratory, but it was not approved by the Global Fund and in the end, we had to accept the 10-color GeneXpert." (Peru)
- "Today I would ask for portable equipment for indigenous areas, for remote areas. If today, they say to me "What do you want?" I would answer "15 teams or 10." (...) ORAS gave us one that is arriving, which is a little delayed due to our different situations." (Colombia)

# IV. Lessons learned and good practices



- During the COVID-19 pandemic, a success of the grant was the implementation of virtual platforms that served to develop training, advisory, and advocacy actions. Other training activities that required inperson training and laboratory procedures were postponed to be carried out in person.
- Despite the adversity that COVID-19 meant by absorbing the resources and attention of the health sector, the grant was able to capitalize on the relevance of laboratory diagnosis to reposition TB laboratories in the advocacy efforts developed with authorities and officials.
- The multilateral advocacy strategy is one of the strengths of the principal recipient and sub-recipient SE-COMISCA, which showed positive results through the production of resolutions, creating conditions for officials and managers to promote measures to strengthen their laboratories. In addition, it fostered the intergovernmental legal framework that is used by actors in the fight against TB to manage resources or appeal for greater prioritization.
- The national advocacy strategy was highly valued by those responsible for laboratories and NTP, as it allowed them access to senior management, but also gave visibility to the laboratories. In most cases, it was possible to highlight the need to strengthen and finance laboratory diagnosis in the decision-making agenda.
- The development of studies repeated over time generated a virtuous circle of impacts, as they
  facilitated the visibility of achievements and problems for the management of programmatic impact. It
  helped those responsible for the laboratory or the PNT to plan and dialogue with their superiors. The
  studies achieved a synergistic articulation between the technical and political dimensions.
- In particular, the study of financing flows was a multimodal instrument that served to identify the financing gaps of the laboratories, but at the same time, it was extremely useful to argue and convince the authorities and officials to allocate greater resources for the laboratories. of TB.
- Those interviewed agree in positively valuing the support received by the grant for the accreditation
  of diagnostic tests of their laboratories in 6 countries. In addition to improving procedures, it has
  repositioned the image of the laboratories before their institutes and before the authorities of the
  sector.
- The training of cabinets certifiers has been a practice that has generated synergistic impacts, as it has allowed laboratories to save resources, has facilitated service to other countries in the Americas, and has resulted in a greater appreciation of the authorities by providing the service to other laboratories of its institutes and networks.
- Training laboratory personnel in updating new diagnostic tools was one of the activities most valued by participants. Its benefits can be observed at the individual level but also in the redesign of procedures and at the programmatic level.
- The incorporation of other voices from civil society to influence governments in favor of strengthening TB laboratories was successful. The representatives of the CCMs became familiar with the needs of the laboratories and understood the importance of strengthening laboratory diagnosis before decision-makers.



- The achievements observed in the current grant must be analyzed as a synergistic process linked to the previous Global Fund grant since it was wise to continue with analysis activities that were very effective for the legal profession. Furthermore, this continuity has accumulated information that allows us to have a perspective of the initial situation of the laboratory network of the Americas and the progress currently obtained.
- This is a limited grant, which sought to reinforce the boost that the previous grant gave to the network of laboratories in the Americas. The grant addressed processes that are usually difficult to make viable, such as the absorption of laboratory expenses with public treasury and the development of information systems.
- Despite the efforts, structural barriers persist in some governments, such as limited personnel, bureaucratic obstacles, and austerity plans, which limit the continuity of the strengthening of laboratories.
- Multilateral advocacy has generated a regional regulatory framework in the countries of Central America and those of the Andean group that improves the conditions for the demands of civil society and for the political management of the actors in the fight against TB. In addition, it has repositioned the importance of laboratory strengthening in the managing institutions SE-COMISCA and ORAS-CONHU.
- National advocacy actions with ministers and vice ministers were crucial to making visible the financing gaps of laboratories, bureaucratic procedures, equipment needs, and human resource demands. In several countries, advocacy made it possible to obtain more resources and commitments or it was possible to put these needs on the decision agenda, although some obstacles depend on other ministries or entities that are outside the reach of the ministries of health.
- The articulation between technical intervention, especially the production of situational studies, and advocacy intervention has demonstrated a synergistic impact between these two strategies. In addition to strengthening the laboratories, it allowed the actors to dialogue with the authorities based on objective data. This design of activities deserves to be continued.
- Laboratories take into account their nature as a public service and their leading role in laboratory diagnosis, therefore, the proposal to generate their income through services to third parties was not of interest to the SRL, furthermore, in some countries, It was not feasible due to national regulations.
- Despite the progress observed in some countries in identifying deficiencies and implementing improvements in their information systems, a more comprehensive intervention must be considered for future grants. It is recommended that barriers such as weak coordination between laboratory, program, and surveillance be addressed; the absence of a unique identifier for affected individuals; the integration of information managers; and programmatic management for the articulation of digital environments.
- It would be desirable for future grants to develop virtual repositories that house the documents, studies, communications, and minutes of each country. The purpose of this system would be to make it easier for TB officials to retrieve information, but it will also allow for continuity in the event of changes in those responsible.
- A tension is observed between laboratory strengthening measures based on regional trends and the needs of each laboratory. It is desirable to achieve a balance between both prioritization approaches. This is possible if more time and effort is spent in direct consultations with laboratory heads and those responsible for TB programs, to agree on priorities in the stage before the design of the grant.

- The legal profession needs to be expanded and the strategy of incorporating other voices that demand greater investment in laboratories and convincing decision-makers to allocate greater resources to strengthen laboratory diagnosis is a wise one. However, there are difficulties in involving CCM representatives in advocacy, which will require greater investment in activities for their empowerment.
- There are various routes to continue strengthening the laboratories. Among them are the impact on national standards; the management of commitments in multilateral instances; and the development of interventions that articulate preventive and primary care with laboratory diagnosis.
- The question about the sustainability of the achievements achieved by both subsidies is influenced by the concern about the viability of populist discourses of privatization, reduction of the State, or state takeover. Some opinions maintain that there is a real danger of a setback in the progress made in strengthening laboratories due to changes in government. Other opinions emphasize that technical personnel are essential for the functioning of the State and that there are national policies that cannot be dismantled.

OPS Organismo andi Convenio Hipóli	
	2017
	<ul> <li>SNL/NRL and the NTP had little visibility and access to political decisions</li> <li>Lack of knowledge of financing flows for SNL/NRL</li> <li>Shortage of CSB certifiers</li> <li>High need for equipment and supplies</li> <li>Potential for quality improvement, but there was not the necessary support</li> <li>Need for HR updating</li> <li>Structure and functioning of national TB lab networks outdated.</li> <li>Weaknesses in information systems</li> <li>TB commitments that did not emphasize laboratory diagnosis</li> <li>Little articulation of actions between the components of the GF in the countries and little prioritization of TB</li> </ul>
2023 SNL/NRL and NTP with access to the authorities, and their	
needs transferred to the MCPs for synergies Estimated operating costs of the SNL/NRL, resources origien and gaps, were key to planning 7 CSB certifiers at the service of the laboratory network	
and other countries	
6 laboratories with strengthened quality management, 4 laboratories with 2 new accredited TB methods and 2 laboratory with advanced processes	
Laboratory personnel trained with protocols for operational	
Published the structure and operation of the national TB lab networks updated to 2021.	
Tools to improve the quality of information available, and 7 countries with technical assistance.	
Ministerial resolutions committing to strengthen TB lab diagnosis	END
Greater involvement of CCM in TB issues and synergies for strengthening all components of the GF	

## Annexes



#### **ANNEX 1: OBJECTIVES AND DESIGN OF THE STUDY**

The TB.Lab20-23 regional grant has a performance framework and a monitoring and evaluation plan, where the indicators, goals, and milestones are defined by which the degree of programmatic progress is periodically evaluated. However, the systematization of experiences and lessons learned, as well as the evaluation of the sustainability of the progress achieved, is considered a key tool to measure benefits and estimate the potential for synergies with other efforts, to make timely decisions towards a better taking advantage of the resources available in other subsidies or through public policies.

#### **Justification**

The central idea of the grant is to promote the self-sustainability of national and supranational tuberculosis laboratories so that they fulfill all their functions and terms of reference for which they were created. In each of the 20 countries that benefited in the first stage (2017-2019), it is of utmost importance that the commitments acquired by governments and authorities to improve equipment, the availability of human resources, and the development of laboratories have continuity.

These are complex processes since the activities involve the consolidation of the laboratory network, weaving bridges, and ties between those responsible and the participants of the activities. In addition, the grant involved the implementation of advocacy and management strategies with decision-makers and authorities.

This last component is key to guarantee the sustainability of the effort developed in the past and present grant. Therefore, it is important to identify which strategies and activities worked and allowed the continuity of political and budgetary support to the SRL and NRL of TB.

The set of strategies and activities developed constitute valuable information to document the experience of building laboratory networks and, in general, regional coordination around health problems.

The lessons learned, as well as the difficulties observed, will serve to optimize future processes to strengthen the laboratory network in the Americas. In addition, they will also be useful for strengthening other laboratories or national health programs.

#### **Objectives of systematization**

- **a.** Analyze how global, regional, and institutional contexts positively and negatively influenced the implementation of grant activities.
- **b.** Identify the successes and limitations of grant management to obtain lessons learned that serve for future interventions.
- **c.** Know the achievements and limitations experienced with the activities to strengthen laboratory diagnosis and its information systems.
- **d.** Evaluate the level of consolidation of the sustainability of the laboratories that the grant promoted through its advocacy and positioning activities.

#### Instruments and investigative processes

The methodology used includes collecting information from the main actors who have participated in the implementation of the project, from the participants in the activities developed, and from the authorities involved in the sustainability of the actions to strengthen the diagnosis of tuberculosis.

To this end, a set of research actions was implemented with primary sources and secondary sources to gather a plurality of points of view on the results of the implementation and the perspective of self-sustainability.

Below, we present a set of actions and methodological instruments that were developed to meet the stated objectives:

- Coordination meetings and receipt of orientation with the principal recipient and sub-recipients in charge of grant implementation.
- Review of the documentation, materials, technical guides, and communicative products developed within the framework of the grant, and the development of qualitative indicators to measure the potential of sustainability.
- Semi-structured interviews with key actors from national TB programs (NTP), SRL directors, and NRL directors.
- Semi-structured in-person and/or online questionnaires for key actors who participated in the activities implemented by the project.
- Interviews with members of the CCM (Country Coordination Mechanism) of the Global Fund.
- Interview with the person in charge of the Regional Coordination Mechanism (RCM)
- Analysis and triangulation of information obtained from the different perspectives of key actors and project participants.
- Presentation of preliminary findings to the coordination team and project partners.

#### **Study components**

#### a. Grant management analysis

The characteristics of the global context that influenced the achievements and limitations experienced in the grant were investigated. It was also analyzed whether global and regional conditions (especially the COVID-19 pandemic) implied a modification of the objectives and activities and what were the solutions developed by the main recipient and the sub-recipients.

The heads of the PR were interviewed: ORAS-CONHU, the sub-recipients: SE-COMISCA and PAHO, and the head of the RCM.

#### b. Influence of institutional and political conditions on the implementation of the grant

The institutional conditions of the SRL/NRL, the NTP, and the Ministries of Health of each country that influenced the development or delay of the experience were analyzed. Likewise, the political conditions (changes in government, changes in public health policies) that could affect the commitments made to strengthen the laboratories were analyzed. Information was obtained from:

- Heads of the PR: ORAS-CONHU, and for the sub-recipients: SE-COMISCA and PAHO
- Directors of the NRL
- Directors of the SRL
- Heads for the NTP

#### c. Difficulties and opportunities arising during the implementation of the grant

The tensions and contradictions that appeared during the development of the grant were investigated. Key elements that enhanced or weakened the interventions were also identified. Information was obtained from:

- Heads of the PR: ORAS-CONHU, and for the sub-recipients: SE-COMISCA and PAHO
- Directors of the NRL
- Directors of the SRL
- Heads for the NTP

#### d. Factors that influenced the achievements obtained by the grant

- The activities that, during the implementation of the grant, made a substantive contribution to achieving the objectives were identified.
- Special emphasis was placed on analyzing the factors that positively and negatively influenced the different components of the project.
- The thematic concept that the grant has been able to mainstream among the members of the laboratory network was identified.
- The level of sustainability of the laboratory network developed through the grant was analyzed

#### Information was obtained from:

- Heads of the PR: ORAS-CONHU, and for the sub-recipients: SE-COMISCA and PAHO
- Directors of the NRL
- Directors of the SNL
- Heads for the NTP
- Members of the CCM

#### Key activities that were evaluated

- a. Monitoring activities for commitments and financing gaps
- Consulting for monitoring sustainability commitments and financing flows for the SRL and NRL
- Study on structure and functioning of national TB laboratory networks.
- Civil society operational research on the use and access to rapid methods for initial diagnosis of TB
- b. Advocacy and positioning activities
- Political advocacy meetings for the gradual increase in the absorption of activities with the country's budget
- Regional communication strategy and SRL positioning plan
- Dissemination campaigns with civil society to demand the right to timely diagnosis through rapid tests.
- Regional dialogues with the CCM, NTP, and RCM
- c. **Production of materials and manuals**
- Translation and dissemination of 9 technical documents published by WHO on laboratory diagnosis of TB
- Teaching materials on preventive maintenance of TB laboratory equipment
- d. Supervision and advisory activities for SRL/NRL
- Visit of the WHO Supranational TB Network to the 3 SRL
- Training technical supervision of the PAHO group of experts in 17 countries
- SRL attendance at GLI annual meetings

#### e. Technical-managerial capacity development activities

- Workshop on new diagnostic tools
- Workshop on the accreditation process of TB laboratories under the ISO 15189/17025 standard
- Virtual laboratory management course for SRL/NRL personnel
- Virtual operational research course
- f. Equipment and technological strengthening of laboratories
- Purchase and calibration of equipment for BSC certification
- Purchase of reagents for the new 2L oral drugs for DST recommended by the WHO
- BSC certifier training course
- Compra de equipos e insumos para detección bidireccional de COVID-19 y TB
- TB laboratory accreditation
- g. Strengthening data management and information articulation
- An instrument for monitoring data quality, a dashboard for monitoring TB indicators, and a tool for triangulation of information from different sources
- Technical assistance in information systems to 7 countries
- Update on the status of information systems in the national TB laboratory networks in the 17 countries
- Multi-platform connectivity management

#### **Procedures for data collection**

With the collaboration of the Principal Recipient, a directory was prepared with the names, emails, and cell phones of the participants and beneficiaries of the grant activities.

With the support of ORAS-CONHU, a letter introducing the systematization consultancy was sent to the 17 heads of laboratories, the 17 responsible for NTP, members of the CCM, and the RCM, explaining the objectives and procedures to be followed and requesting their support. collaboration.

To develop the systematization, information was collected from different beneficiaries of the project, partners, and allies:

a. Laboratory heads were invited to participate, giving them the option of answering an online questionnaire or being interviewed through an online platform such as ZOOM or Google Meet. During country visits, face-to-face interviews were prioritized with the three SRLs (Argentina, Chile, Mexico) and three NRLs (El Salvador, Guatemala, Peru).

- **b.** The main people responsible for the NTPs were also contacted, with whom the same procedure was followed: online surveys, and online interviews, and 4 of them were interviewed in person.
- **c.** Information was obtained from members of laboratories that participated in project activities to collect the beneficiaries' opinions on strengthening the laboratory network. This was done through semi-structured questionnaires.
- d. Members of the Global Fund CCMs were interviewed at the meeting that took place in El Salvador on May 30 and 31, 2023. In coordination with the principal recipient, representatives of the countries that were most involved in specific activities were prioritized. of the grant such as monitoring visits, BSC certification, technical assistance in information systems, or accreditation: Colombia, Ecuador, Guatemala, Honduras, Nicaragua, Dominican Republic, and Paraguay.

### Annex 2: Matrix of questions according to key informants

Objectives	Questions	LSN	LRN	PNT	Participants	CCM/ RCM
Control data	What grant activities did you participate in?			х	х	х
Analyze how global, regional, and institutional contexts influenced the	How did the regional or global context influence the implementation of the activities or improvements promoted by the grant?	x	x			
implementation of grant activities creating adverse conditions and opportunities	How did your country>s institutional or governance context influence the implementation of grant activities?	х	x	х		
	What were the successes and limitations in the way the sub-recipients implemented the activities in which they participated?		x		x	x
	How do you evaluate the contribution of the grant to strengthening TB diagnosis in your country?		х	х		х
Identify the strengths and weaknesses of grant management to obtain lessons learned for future interventions	How did the grant contribute to improving the technical assistance of supranational laboratories to national reference laboratories?	x				
	What has been the main contribution of the grant to the strengthening of laboratories?	x		x	х	
	What were the exchanges, and collaborations that because you participated in activities like these you developed with colleagues			x	x	x
	How did the training promoted by the grant contribute to the strengthening of your laboratory?		х			
Know what the achievements and	How did the consultancies and technical visits (of SRL and PAHO) of the grant contribute to the strengthening of the laboratory?		х			
with the activities for the strengthening of laboratory diagnosis and its	How did the training promoted by the grant contribute to strengthening the laboratory?		х			
information systems	How do you evaluate the technical assistance/supervision to your Laboratory developed by PAHO, WHO, and the experts hired by the grant?	х				

Objetivos	Preguntas	LSN	LRN	PNT	Participantes	MCP/ MCR
	How do you evaluate grant-driven activities to build preventive equipment maintenance capabilities, perform BSC certification, <sup>13</sup> and improve quality toward accreditation of your laboratory?		x			
	How do you evaluate the contribution of advocacy and positioning activities (communication strategy, timely diagnosis campaign) to the diagnosis of TB?		x			
	How did the TB laboratory information tools developed by the grant contribute to the Laboratory's information system?		x			
	What has been the contribution of the diagnostic activities implemented by the grant to design the strategy to strengthen the laboratories?	x				
Know what the achievements and limitations are experienced	How do you evaluate the contribution of advocacy and visibility activities to survey TB diagnosis in your country?	x	х			
with the activities for the strengthening of laboratory diagnosis and its information systems	How do you evaluate the activities for bidirectional detection of COVID-19 and TB, implemented by the grant?	x	х			
	What was the main benefit of your participation in grant activities?			x	x	
	Can you indicate what changes or innovations these activities generated in the daily practice of your Laboratory				х	
	What were the main difficulties in implementing in your laboratory the changes promoted by these activities developed by the grant?				x	
	What has been your country's level of compliance with the commitments to support the TB laboratory under the previous grant?	x	x			
Evaluate the level of	How did your country>s commitments to continue with the quality control of your laboratory continue?		х			
consolidation of the sustainability of the aboratories that the grant promoted through its advocacy and positioning activities	What were the main difficulties in complying with institutional agreements (inputs, personnel, equipment, resources, political support, etc.)? for strengthening your laboratory?	x	x			
	How do you see the sustainability of grant- driven changes in your lab?	x		x		x
	In the future, what would be the main difficulties in sustaining the strengthening of laboratories in the countries under your charge?	×				

### Anex 3: Key informants

	Institution	Country	Name	Interview	Questonnaire	Did not respond
1	ORAS-CONHU	Receptor Principal	Lourdes Kusunoki	х		
2	ORAS-CONHU	Receptor Principal	Patricia Jiménez	х		
3	SE-COMISCA	Subreceptor	Alejandra Acuña	х		
4	SE-COMISCA	Subreceptor	Rosibel Cruz	х		
5	SE-COMISCA	Subreceptor	María de los Ángeles Campos	х		
6	RCM		Patricia Mira	х		
7	РАНО	Subreceptor	Ernesto Montoro	х		
11	SRL	Argentina	Norberto Símboli	х		
12	SRL	Chile	Fabiola Arias	х		
13	SRL	Bolivia	Helga Laura Alvarado		×	
14	NRL	Colombia	Claudia Llerena	х		
15	NRL	Perú	Zully Puyén	х		
16	NRL	Ecuador	Greta Franco		х	
17	NRL	Paraguay	Pilar Ilka Muñoz			x
18	NRL	Venezuela	Luis Raúl Rojas		×	
19	SRL	México	Armando Martínez	х		
20	NRL	Guatemala	Nancy Ayala	х		
21	NRL	El Salvador	Yanira Meléndez		х	
22	NRL	Honduras	Cesar Zelaya		х	
23	NRL	Nicaragua	Zoila Argeñal		x	

24	NRL	Dominican R.	Orquídea Moreno		x	
25	NRL	Haití	Jacques Boncy		x	
26	NRL	Surinam	Shalinie Baldi		×	
27	NRL	Guyana	Joyce Whyte-Chin			x
28	NTP	Argentina	Marcela Natiello	х		
29	NTP	Chile	Nadia Escobar	х		
30	NTP	Bolivia	Carlos De la Rocha			х
31	NTP	Colombia	Dr. Julian Trujillo	х		
32	NTP	Perú	Julia Ríos			х
33	NTP	Ecuador	Vladimir Díaz			x
34	NTP	Paraguay	Sarita Aguirre	х		
35	NTP	Venezuela	Mercedes España		x	
36	NTP	México	Fátima Luna	х		
37	NTP	Guatemala	Sandy Cano Lemus	х		
38	NTP	El Salvador	Julio Garay	х		
39	NTP	Honduras	Norma Leticia Artiles		x	
40	NTP	Nicaragua	Arelisabel Ruiz			х
41	NTP	R. Dominicana	Clara de la Cruz	x		
42	NTP	Haití	Willy Morose			x
43	NTP	Surinam	Eric Commiesie		x	
44	NTP	Guyana	Jeetendra Mohanlall			x
45	ССМ	Guatemala	Ana Piedad López	х		

46	ССМ	Honduras	Yolanda Vélez Ventura	x	
47	ССМ	Nicaragua	Bruce Menzie Offer	x	
48	ССМ	Colombia	Deccy González Ruge	x	
49	ССМ	Perú	Fabiola Rojas		х
50	ССМ	Bolivia	Paola Pinto		x
51	ССМ	Ecuador	Susana Aguilar	×	

### Annex 4: Participants in activities

	Country	Institution	Name	Position
1	Perú	National Institute of Health	Belisa Asto Ruiz	Biologist
2	República Dominicana	Ministry of Public Health and Social Assistance	Elizabeth Cepeda Rosario	DST specialist
3	Guatemala	Ministry of Public Health and Social Assistance	Gilda Martínez	Laboratory Network Facilitator
4	El Salvador	National Public Health Laboratory	Johanna Acuña	Clinical Laboratory Professional
5	El Salvador	Ministry of Health	René Guevara Hernández	Clinic laboratory Coordinator UPCTYER
6	México	Management and Analytical Quality Specialized Consulting	Maribel Espinosa Pulido	General Director
7	Guatemala	Directorate of the National Health Laboratory	Luz Elena Vásquez	Facilitator, Laboratory Network Section
8	República Dominicana	National Health Service, Hosp. Luis Morillo King	Esther Carolina Espinal	Bioanalyst in charge of Tuberculosis Laboratory Services
9	Venezuela	Regional Respiratory Health Coordination, Zulia	Mariana Semprún	Bioanalist
10	El Salvador	National Public Health Laboratory	Johanna Acuña	Clinical Laboratory Professional
11	Ecuador	National Public Health Research Institute INSPI	Sandra Uruchima	Analist
12	Chile	Institute of Public Health	lkela Muñoz Espinoza	Medical Technologist at Mycobacteria section
13	Paraguay	Central Public Health Laboratory	Pilar Ilka Muñoz Villanueva	Head of the Tuberculosis Department
14	Chile	Institute of Public Health	Javier Figueroa	Medical Technologist
15	Colombia	National Institute of Health	Yanely Angélica Valbuena Arias	Consultant - implementation of standard 17025
16	Paraguay	Central Public Health Laboratory	Daniel Vázquez	Biochemist professional
17	Honduras	National Surveillance Laboratory	Yerlin Irina Ordóñez	Laboratory Head
18	Guatemala	Tuberculosis Program	Wendy Meléndez	Laboratory Technical Assistance Manager
19	Paraguay	Central Public Health Laboratory	Dorothea Bergen	Biochemist professional
20	México	National Institute of Epidemiological Diagnosis and Reference InDRE	David Vázquez González	Chemist Analyst
21	Chile	Institute of Public Health	Álvaro Diaz Briceño	TB Reference Laboratory Professional
22	Chile	Institute of Public Health	Karla Kohan	TB Reference Laboratory Professional
23	Chile	Institute of Public Health	Angélica Scappaticcio	TB Reference Laboratory Professional
24	Nicaragua	National Center for Diagnosis and Reference	William Antonio Ruiz Rodríguez	Health laboratory specialist
25	Argentina	National Institute of Infectious Diseases INEI ANLIS "Carlos G. Malbrán"	David Avendaño	Biochemist professional
26	Perú	National Institute of Health	Miriam Judith Alarcón León	Biologist
27	Argentina	INER Dr. Emilio Coni - ANLIS	Mailen Ribero	Biochemist professional
28	México	National Institute of Epidemiological Diagnosis and Reference InDRE	Belem Torres Longoria	Project Coordinator in the Diagnostic and Reference Directorate

29	El Salvador	National Public Health Laboratory	Yanira Emperatriz Meléndez Cortez,	Mycobacteria Section Manager
30	Colombia	National Institute of Health	Claudia Llerena Polo	NRL Coordinator
31	Paraguay	Central Public Health Laboratory	Gerónimo Ortellado	Biochemist responsible for the diagnostic section of the NRL
32	Ecuador	National Public Health Research Institute INSPI Quito	Paulina Marisol Correa Fernández	Mycobacteria technical analyst
33	Dominican Republic	National Public Health Reference Laboratory Dr Defillo (LCTB)	Sisy Espinosa	TB bioanalyst
34	Argentina	National Institute of Infectious Diseases INEI ANLIS "Carlos G. Malbrán	Eduardo Mazzeo Francisco	Biochemist professional
35	Chile	Institute of Public Health	Marcela Moreno	Medical Technologist
36	Chile	Institute of Public Health	Andrea Clunes Glavinovic	External consultant
37	Argentina	National Institute of Infectious Diseases INEI ANLIS "Carlos G. Malbrán"	Ezequiel Zubillaga	Advisor
38	Ecuador	National Strategy for the Prevention and Control of Tuberculosis and Leprosy - Ministry of Public Health of Ecuador	Adriana Chacón	Analyst - responsible for the laboratory and drug-resistant tuberculosis component
39	El Salvador	Ministry of Health	Argueta Lidia	Microbiology Coordinator
40	Ecuador	Instituto Nacional De Investigación Pública National Public Health Research Institute INSPI	Heidy Buenaño	Technical Analyst
41	República Dominicana	Ministry of Public Health and Social Assistance	Leonarda Reyes	National Manager of the Laboratory Network of the National TB Program
42	México	DGE/ National Institute of Epidemiological Diagnosis and Reference InDRE	Amalia Barquet	Chemist Analyst
43	Perú	Ministry of Health	José Luis Tataje Córdova	Biologist - Technical team Tuberculosis Directorate
44	México	National Institute of Epidemiological Diagnosis and Reference InDRE	Armando Martínez Guarneros	Head of the Supranational TB Laboratory
45	Honduras	Health Secretary	Mitzi Castro Paz	Head of the National Surveillance Laboratory
46	El Salvador	Ministry of Health	Celina Herrera	Coordinator of the National Network of Clinical Laboratories
47	Perú	National Institute of Health	Eddy Valencia Torres	Head of the Quality Management Team
48	México	National Institute of Epidemiological Diagnosis and Reference InDRE	Juan Antonio Tapia García	Consultant
49	Perú	National Institute of Health	Janett Soledad Portilla Romero	Consultant QMS ISO 15189- ORAS- CONHU
50	República Dominicana	National Health Service	Yoany Arias	Laboratory and Images Director