

# **Baseline Assessment of Sample Referral Networks in Vertically Managed Disease Control Programs for HIV and TB in the Dominican Republic**

**March 2015**



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Systems for Improved Access  
to Pharmaceuticals and Services



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**SIAPS** The SIAPS logo, which consists of the word "SIAPS" in a green serif font next to a blue stylized human figure icon.

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The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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## **Key Words**

transportation, laboratory, samples, HIV, AIDS, tuberculosis

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## ACRONYMS AND ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
CD4	cluster of differentiation 4
CONAVIHSIDA	Consejo Nacional para el VIH y el SIDA (National Counsel for HIV and AIDS)
DIGECITSS	Dirección General de Control de las Infecciones de Transmisión Sexual y SIDA (General Directorate for Control of Sexually Transmitted Diseases and AIDS)
DPS	Dirección Provincial de Salud (Provincial Health Directorate)
DR	Dominican Republic
EID	early infant diagnosis
LNSPDD	Laboratorio Nacional de Salud Pública Dr. Defilló (national reference laboratory)
MoH	Ministry of Health
HIV	human immunodeficiency virus
NGO	nongovernmental organization
PNCT	Programa Nacional contra la Tuberculosis (National TB Control Program)
SAI	Servicio de atención integral (Integrated Health Service)
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedures
SRS	Servicios regionales de salud (Regional health services)
TAT	turnaround time
TB	tuberculosis

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## **EXECUTIVE SUMMARY**

At the end of 2013, the Ministry of Health (MoH) in the Dominican Republic (DR) deemed of paramount importance evaluation and development of the supply chains within the referral networks for HIV and tuberculosis (TB) laboratory samples, in an effort to advance its efforts to control the spread of both diseases.

The results presented in this technical report have been adapted from a pioneering, evidence-based assessment that took place in the DR in 2014, which collected data around the country, at all levels of public health laboratories, regarding the performance of the referral networks of vertically managed disease control programs for HIV and TB. Data were collected during two weeks of surveys that consisted of a series of quantitative and qualitative questions and register reviews.

These results strongly indicate a profound need for systems strengthening through integration and pooling of resources of vertically managed disease control programs, standardization of procedures, and extensive supply chain-related capacity building.

## BACKGROUND

In recent years, the Dominican Republic (DR) introduced new technology and methods for the diagnosis of tuberculosis (TB) and human immunodeficiency virus (HIV) aiming to improve diagnostic services and delivery. Subsequently, national disease control programs, including the National TB Control Program (Programa Nacional contra la Tuberculosis; PNCT), the General Directorate for the Control of Sexually Transmitted Diseases and AIDS (Dirección General de Control de las Infecciones de Transmisión Sexual y SIDA; DIGECITSS), and the National Counsel for HIV and AIDS (Consejo Nacional para el VIH y el SIDA; CONAVIHSIDA) have facilitated universal access for sputum smears, cultures, drug susceptibility tests, cluster of differentiation 4 (CD4) counts, viral load tests, and Proviral DNA testing for early infant diagnosis (EID) for HIV.

Currently in the DR the most technologically advanced HIV and TB laboratory resources are concentrated in 13 regional reference laboratories, the Dr. Defilló National Public Health Laboratory (Laboratorio Nacional de Salud Pública Dr. Defilló; LNSPDD), and the nongovernmental organization (NGO) Profamilia. The Dominican Public Health Sector Reform of 2003<sup>1</sup> and the Model Guide for the Development of the Regional Health Services<sup>2</sup> name the Regional Health Service (Servicio regional de salud; SRS) offices as responsible for providing oversight and all supply chain-related services. Currently there are nine autonomous SRSs, though the autonomous regional management model has shown marked shortcomings in the referral networks for TB and HIV laboratory samples and the turnaround of test results, according to previous technical reports<sup>3</sup> and mainly of anecdotal evidence on service-level performance.<sup>4</sup>

In an effort to strengthen its service delivery, the DR Ministry of Health (MoH) requested technical assistance for a baseline assessment<sup>5</sup> from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, a project funded by the US Agency for International Development for strengthening health systems. This assessment is the principal source of information adapted for this technical report and had the following main objectives:

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<sup>1</sup> Comité Ejecutivo para la Reforma del Sector Salud (CERSS). Decreto Presidencial #635-03 – Reglamento de Rectoría y Separación de Funciones Básicas del Sistema nacional de Salud; 2003.

<sup>2</sup> Secretaría de Estado de Salud Pública y Asistencia Social (SESPAS). *Modelo de Red de los Servicios Regionales de Salud: Una guía para el desarrollo de los servicios de salud para la atención a las personas*. Disposición 00024; Santo Domingo, República Dominicana: SESPAS; 2005.

<http://salud.gob.do/download/docs/Disposiciones/Disp00024ModelodeRedSRS.pdf>.

<sup>3</sup> Consejo Nacional del VIH y del SIDA (CONAVIHSIDA). Consultoría para la Red de Transporte de Muestras. 2012.

<sup>4</sup> Umaru FA, Vallederes, J. *Assessment of HIV and Tuberculosis Services in the Dominican Republic: Informing Decision Making for Program Integration and Scale Up*. Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS). Arlington VA; 2013.

<sup>5</sup> Moquete E, Tavárez Y, Montoro E, George A, Herrera M, Valdez C, Barillas E. *Evaluation of the Logistics System for Transporting Tuberculosis and HIV Samples and Delivering Test Results in the Dominican Republic's Public Health Referral Network*. Ministerio de Salud Pública de la República Dominicana; SIAPS. Submitted to the US Agency for International Development by Systems for Improved Access to Pharmaceuticals and Services (SIAPS). Arlington, VA: Management Sciences for Health; 2014.

- Collect critical data necessary for mapping the current transportation system for HIV and TB samples
- Identify the bottlenecks hampering its operation
- Support the creation of a unified samples referral network based on the evidence found

Publications on studies regarding supply chains for laboratory samples are limited. One peer-reviewed article on the restructuring of Uganda's referral network<sup>6</sup> that specifically focused on transportation of dried blood-spot samples used in EID tests of HIV was published in 2013. The intervention methodically restructured an ad hoc transportation system for samples, which resulted in improved access to treatment for the most vulnerable of populations.

After searching on PubMed and EBSCOhost databases, no evidence was found of similar investigations conducted on the implementation of a systematic assessment to address issues in the supply chain of HIV and TB biological samples and test results in the Latin America and Caribbean region.

The results described in this technical report, from the analysis of the sample delivery system to the complete turnaround of results, could be translated into tangible programming measures and potentially lay the groundwork for comparable situations elsewhere in the region or developing world.

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<sup>6</sup> Kiyaga C, Sendagire H, Joseph E, et al. Uganda's new national laboratory sample transport system: a successful model for improving access to diagnostic services for early infant HIV diagnosis and other programs. *PLoS ONE* 2013;8(11):e78609. doi:10.1371/journal.pone.0078609.

## METHOD

Local public health stakeholders were involved from the beginning of the process. A technical working group was formed to assist with the design of an in-depth baseline assessment of the sample referral network.

This assessment was executed in several stages, starting with the collection of information, through in-person interviews with national HIV and TB program leaders and compilation of central-level data from the MoH, including information regarding productivity, number of sample-collection establishments, and number of laboratories by tier.

Furthermore, three distinct quantitative-qualitative data collection tools were designed and structured to compile empirical data in four major areas:

- Delivery of samples, including preparation for delivery, packing, means of transportation, and biosafety. To determine biosafety compliance, the surveys used the World Health Organization's (WHO) Guidance on regulations for the Transport of Infectious Substances 2013–2014<sup>7</sup> as a standard, taking five of its criteria for comparison. The criteria evaluated are as follows:
  - Use of a triple-packaging system, appropriate to the United Nations category of each substance transported
  - Use of leak-proof containers
  - Use of absorbent material, in case of emergency leaks
  - Use of appropriate labeling and marks, such as biological risk labels, and orientation labels to indicate position of closures on the primary receptacles
  - Use of gloves for handling samples
- Delivery and reception of test results (turnaround, turnaround time)
- Productivity or quantity of samples processed at the central, regional and local levels
- System costs and expenditure

More than 50 local health workers were trained to use the data collection tools, conduct surveying, and collect data regarding sample quality, turnaround times (TATs), means of transportation, and biosafety.

The data collection process comprised 125 establishments (8.2% of the total) in all of the nine SRSs established by the Dominican MoH throughout the country. The selection criteria included the following:

- All four tiers of facilities by level of specialization: 59 first-tier facilities, at the community level, which have capability only for collecting samples, but not for

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<sup>7</sup> World Health Organization (WHO). *Guidance on Regulations for the Transport of Infectious Substances 2013–2014*. WHO/HSE/GCR/2012.12. Geneva: WHO; 2012.  
[http://apps.who.int/iris/bitstream/10665/78075/1/WHO\\_HSE\\_GCR\\_2012.12\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/78075/1/WHO_HSE_GCR_2012.12_eng.pdf).

processing, including two prisons and six NGOs; 35 second-tier facilities, at the municipal and provincial levels, which collect samples and have capability to process sputum smears; 9 third-tier facilities, at the regional level, which collect samples and have the capacity to process more specialized tests, such as sputum culturing; the fourth-tier facility, the LNSPDD, where drug sensitivity tests for TB patients and 80% of HIV (CD4, viral load, Proviral DNA) tests are processed. Furthermore, the selection included the nine regional SRS administrative offices, as well as 12 provincial health directorates Provincial Health Directorates (Dirección Provincial de Salud; DPS).

- The number of samples sent or processed by facilities. Facilities with low, medium, and high rates of samples sent and/or processed were considered. A high rate was considered to be 40 or more samples sent and/or processed per month.
- Facilities in both rural and urban settings.

The quality of collected data was verified for consistency on site by the survey teams' supervisors after each day of data collection; the SIAPS consultants performed a second verification at the end of each week for two weeks during survey collection. At the same time, databases were created using Microsoft Excel to house and recheck the data collected.

After collection, verification, cleaning, and input into databases, SIAPS consultants analyzed data provided by the surveys and prepared the final report.

After presenting results to local stakeholders and agreeing on a course of action, new standard operating procedures were designed and validated following a participative workshop with SIAPS consultants, regional and provincial administrators of health services, and laboratory technicians and bioanalysts from around the country.

## RESULTS

At this time in the DR, each disease control program is vertically managed and funded, thereby resulting in vertically operated referral networks and multiple modes of transportation of laboratory samples.

The data obtained are specific to HIV and TB disease control programs, thus the results from the assessment are presented as such.

### HIV

The Caribbean is the region with the second-highest HIV prevalence rate in the world (1%), after sub-Saharan Africa. Within the Caribbean region, Haiti (120,000) and the DR (44,000) are the countries with the most registered cases of people living with HIV.<sup>8</sup>

#### ***Delivery of Samples***

The DR has 77 health establishments that provide Integrated Health Care Services for HIV (Servicio de atención integral; SAI), of which the baseline study included 39 (50.6%). The SAIs provide counseling services to people living with HIV and AIDS, and collect the blood samples to be sent to an establishment capable of processing CD4, viral load, and Proviral DNA tests. Nearly 40% of the SAIs (29) are located in the capital region (SRS 0), but no samples are transported. Instead, patients are referred to go personally to the LNSPDD and have the blood samples taken there. The remaining eight regions use distribution hubs where the samples are received from all the provinces and are sent to the LNSPDD as a single delivery. These hubs are sometimes but not always located in the same establishments where SAIs are located.

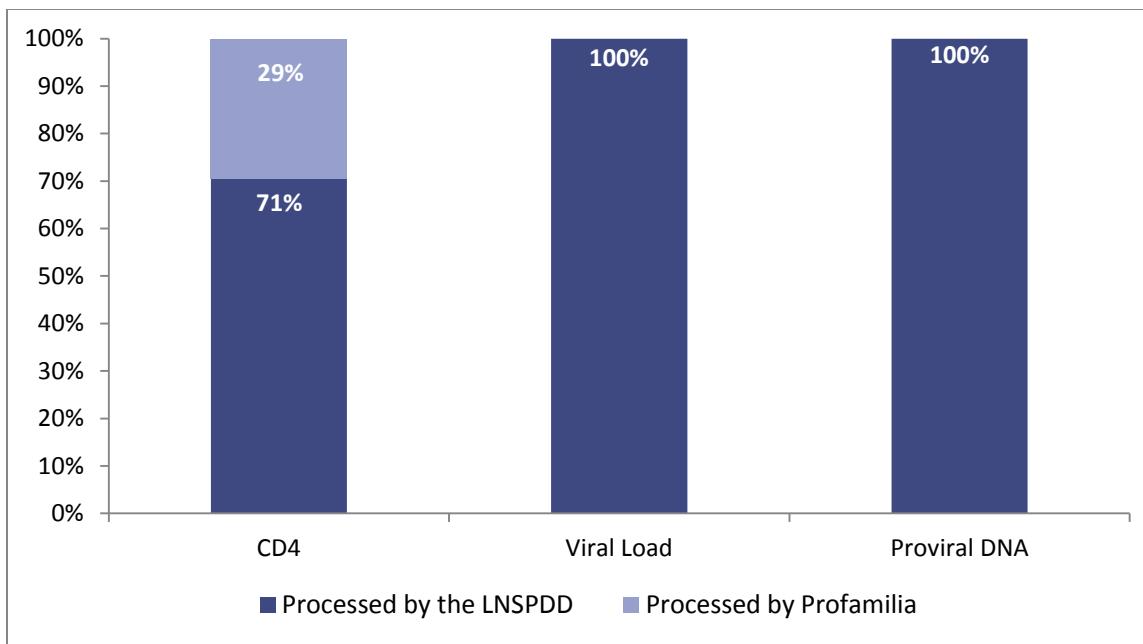
In each region, blood extraction, pickup, and delivery of HIV laboratory samples for CD4 counts and viral load is done one day per week, most commonly Tuesdays or Wednesdays, or sometimes Mondays. There is no schedule for Proviral DNA samples; they are picked up and delivered on the same days as the other samples.

#### ***Testing Concentration***

Eighty percent of all HIV sample testing is concentrated in the LNSPDD. Figure 1 shows the current percentages of samples processed, by sample type and processing site.

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<sup>8</sup> Joint United Nations Programme on HIV/AIDS (UNAIDS). *Global Report: UNAIDS Report on the Global AIDS Epidemic 2012*. Geneva: UNAIDS; 2012.  
[http://www.unaids.org/sites/default/files/en/media/unaiids/contentassets/documents/epidemiology/2012/gr2012/2012\\_1120\\_UNAIDS\\_Global\\_Report\\_2012\\_with\\_annexes\\_en.pdf](http://www.unaids.org/sites/default/files/en/media/unaiids/contentassets/documents/epidemiology/2012/gr2012/2012_1120_UNAIDS_Global_Report_2012_with_annexes_en.pdf).

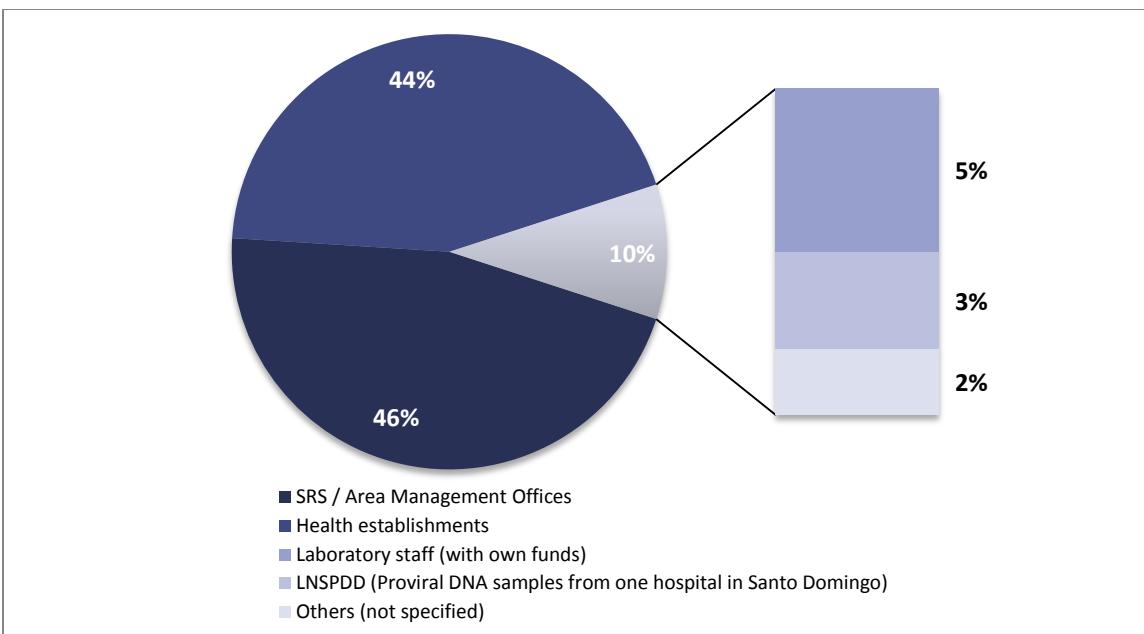


**Figure 1. Processing concentration of HIV laboratory samples in 2013**

A service agreement is in place until the end of 2014 between the Dominican MoH and the NGO Profamilia for processing all CD4 counts—29% of the country’s total in 2013—from the four northern health regions (SRS 2, 3, 7, and 8). When the agreement’s lifespan comes to an end, all HIV samples will be processed by the LNSPDD, concentrating 100% of HIV tests in a single laboratory. Currently there are no plans for changes in the installed capacity or human resources to adapt to this change in workload.

#### *Transportation Providers of Laboratory Samples*

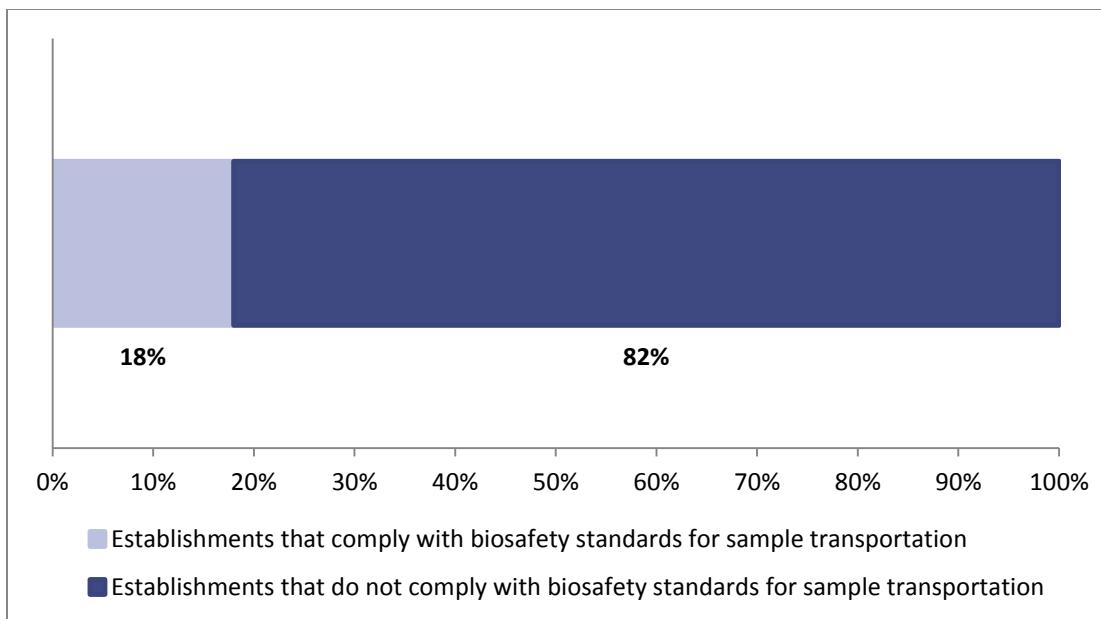
The baseline study identified several transport flows within the same disease control programs. The DR Health Sector Reform Act of 2003 states that all services must be provided by the SRSs. Evidence indicates that in the case of HIV samples, the SRSs provide transportation services in less than half (46%) of the 39 establishments surveyed. Furthermore, 44% of surveyed establishments reported transporting the samples with their own resources, as shown in figure 2.



**Figure 2. Transportation providers: HIV laboratory samples**

### *Biosafety*

The aim was not only to assess the current general biosafety conditions but also to compare them with international guidelines. Compliance was assessed against the selected criteria from the *WHO Guidance on Regulations for the Transport of Infectious Substances*. Figure 3 shows that 18% of the 39 surveyed establishments currently send HIV laboratory samples in compliance with the measured WHO criteria.



**Figure 3. Compliance with biosafety standards for HIV laboratory samples transportation**

There is an evident weakness of resources and general safety equipment. The laboratory samples are transported using a sort of triple-packing system, as stated by the WHO, but not up to its exact requirements.

Standard test tubes are the primary receptacles used. The secondary packaging, instead of being a “durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s),” according to the WHO guidance, polystyrene tube racks are used. Small commercial beach coolers are currently used as outer packaging.

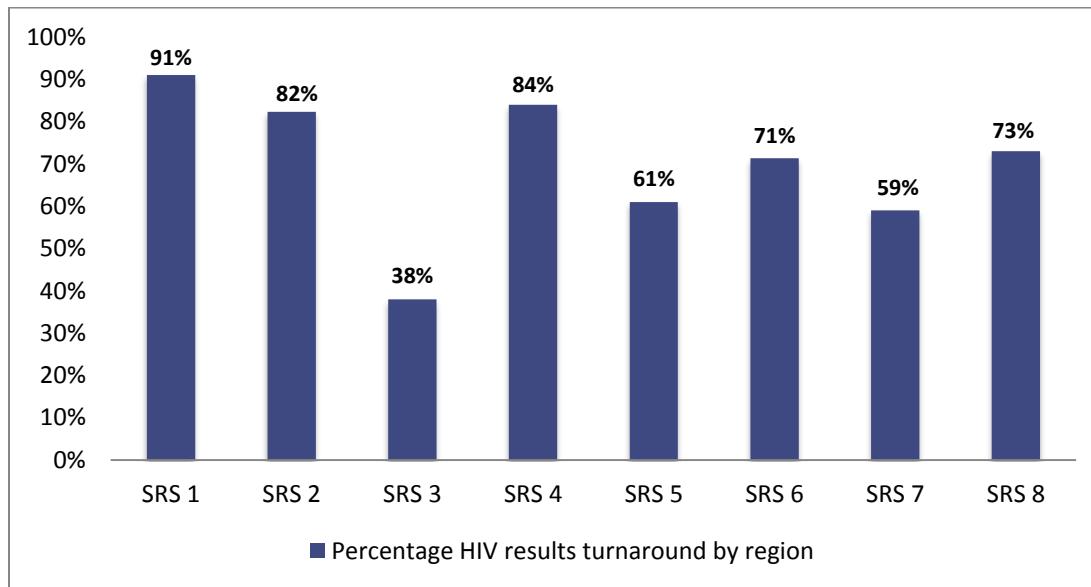
### ***Delivery and Reception of Test Results***

#### *Turnaround of Test Results*

Periodic regional supervisory visits by the MoH and other nonsystematic information indicate that test results in many cases were not returned to the establishment of origin.

Within the geographical limits of the capital region (SRS 0), 13,839 patients are undergoing either clinical follow-ups or antiretroviral treatment for HIV/AIDS (43% of the total patients registered in the DR), all of whom are referred to the LNSPDD for blood extraction. The same patients are called back to pick up their test results at the LNSPDD. Given that in this region no transportation is used for laboratory samples or results, the study did not review the data on the turnaround rate. It is expected that 100% of the patients return to obtain their results.

For the remaining eight SRSs, the baseline study revealed that 70% of all HIV samples sent for testing obtain a corresponding result. The most northeastern region in the country, SRS 3, has the lowest turnaround rate (38%), as shown in figure 4.



**Figure 4. HIV result turnaround by SRS**

That each region has different responsible entities for receiving and forwarding results downstream is a factor contributing to the varying turnaround rates and test results lost. For example, the LNSPDD processes most of the laboratory samples received and prints the results. However, the printed results are delivered back to the regions on public transportation, on occasion to the regional distribution hubs, in some cases to the SRS administrative offices, and in others to regional laboratories. Laboratory staff across the country also reported anecdotally that the LNSPDD mistakenly sends results to incorrect regions.

### *Turnaround Time*

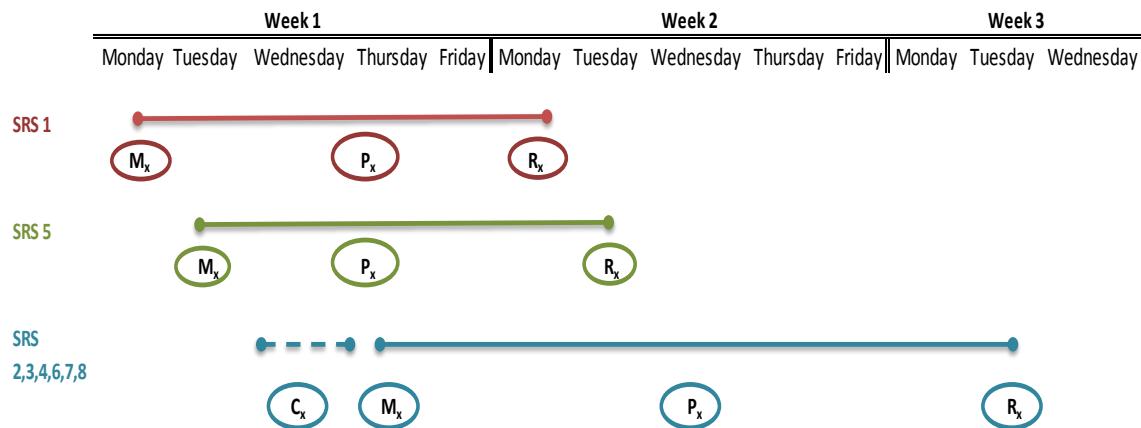
The lengthy time taken for results to return to the region of origin was captured empirically. A detailed inspection of laboratory logbooks indicated that TAT is not registered in a consistent or uniform fashion across establishments. Data were retrieved directly in some cases, and where it was not reported, triangulation was applied with the establishments where testing was done to assess the actual TATs more accurately.

The baseline assessment found that test results for CD4, viral load, and Proviral DNA take longer to return than the LNSPDD's theoretical TAT for laboratory samples. Test results are sent back to each region once a week by the LNSPDD together with the empty refrigerators originally used to transport the samples.

For example, SRS 1 delivers HIV laboratory samples on Mondays using its own vehicle door-to-door from the regional hub to the LNSPDD. According to protocol, test results from the previous week's samples are picked up when new samples are delivered. In the case of SRS 5, public transportation buses deliver the HIV samples every Tuesday, and the LNSPDD returns the results and empty refrigerators the following week on the same public buses.

For the remaining SRSs (2, 3, 4, 6, 7, and 8), laboratory samples are collected on Wednesdays, received on Thursdays at the LNSPDD, and the empty refrigerators and test results are theoretically sent back one week from the following Tuesday.

Figure 5 depicts the theoretical TAT for SRSs 1 through 8, where  $C_x$  is the process of sample collection;  $M_x$  is the arrival of HIV samples to the LNSPDD;  $P_x$  is the time for processing the tests in the laboratory, printing results, preparing envelopes for delivery of the results, and other administrative actions; and  $R_x$  are the results sent out from the LNSPDD. The figure shows that the shortest TAT belongs to samples from SRSs 1 and 5, at five business days. TAT for regions 2, 3, 4, 6, 7, and 8 should in theory be 10 business days, according to the LNSPDD schedule.



**Figure 5. Shortest theoretical turnaround time from LSNDPDD to health regions**

In reality, the baseline study found that the average TAT for HIV samples going to the LNSPDD is 20.1 days for CD4 counts, 36.4 days for viral loads, and 38.7 days for Proviral DNA. Table 1 shows a detailed account of the average TAT for HIV samples that were sent from the different health regions in the DR to the LNSPDD in 2013. Note that SRSs 2, 3, 7, and 8 do not send blood samples for CD4 counts to the LNSPDD. Instead, the samples are sent to Profamilia for processing. All CD4, viral load, and Proviral DNA testing will take place only in the LNSPDD starting in 2015.

**Table 1. Average TAT in to Receive Results for HIV Samples Sent to LNSPDD in 2013**

Region of origin	CD4 counts	Viral load	Proviral DNA
SRS 1	19.8	54	15
SRS 2	n/a	48	25
SRS 3	n/a	41.3	95
SRS 4	30	30	30
SRS 5	13.1	46.8	31.2
SRS 6	17.3	33.8	56.3
SRS 7	n/a	22.3	42.3
SRS 8	n/a	15	15
<b>Total average</b>	<b>20.1</b>	<b>36.4</b>	<b>38.7</b>

Profamilia received 29% of the country's HIV samples requiring a CD4 count in 2013. Table 2 shows that, at 10.9 days, the average TAT for samples sent from SRSs 2, 3, 7, and 8 to Profamilia was considerably shorter than that for the samples sent to the LNSPDD from SRSs 1, 4, 5, and 6.

**Table 2. Average TAT in days to Receive Results for HIV Samples Sent to Profamilia in 2013**

Region of origin	CD4 counts	Viral load	Proviral DNA
SRS 2	9.6	n/a	n/a
SRS 3	9	n/a	n/a
SRS 7	7.5	n/a	n/a
SRS 8	17.5	n/a	n/a
<b>Total average</b>	<b>10.9</b>	<b>n/a</b>	<b>n/a</b>

**Costs**

Results from the baseline assessment indicate health establishments and its personnel often pay for the costs of transporting HIV samples.

As shown in figure 2, nearly 50% of the establishments surveyed reported that the SRS does not pick up the laboratory samples, and instead the establishments (44%) or the laboratory personnel (5%) take them directly to the centers where tests are carried out. This creates additional financial burden on the establishments' already strained budgets and on health personnel.

**Tuberculosis**

Despite considerable improvements in the past 24 years, TB prevalence in the DR stands at 74 per 100,000 inhabitants (including HIV+TB), according to the WHO's 2014 TB country profile of the DR.<sup>9</sup>

***Delivery of Samples***

The PNCT has a local referral network for sputum smears, which intends to process samples within the province of origin. Each region in the DR has at least 10 establishments with the capacity to perform sputum smears through Ziehl-Neelsen staining technique and microscopy.

The referral network for processing sputum cultures takes place on a regional level, because the equipment is available only in the regional reference laboratories; however, only eight of the nine health regions are equipped to process cultures.

The referral network for drug susceptibility tests is at the national/central level. Currently, only the LNSPDD in Santo Domingo is capable of processing these tests, though trials in one of the regional reference laboratories are ongoing, to build capacity and somewhat decentralize these tests.

There is no schedule for collection, pickup, and delivery of sputum samples. The lack of a schedule and the relative longer lifespan of sputum (about five days in ideal conditions) mean that samples are sometimes collected and kept at the establishment until transport becomes available.

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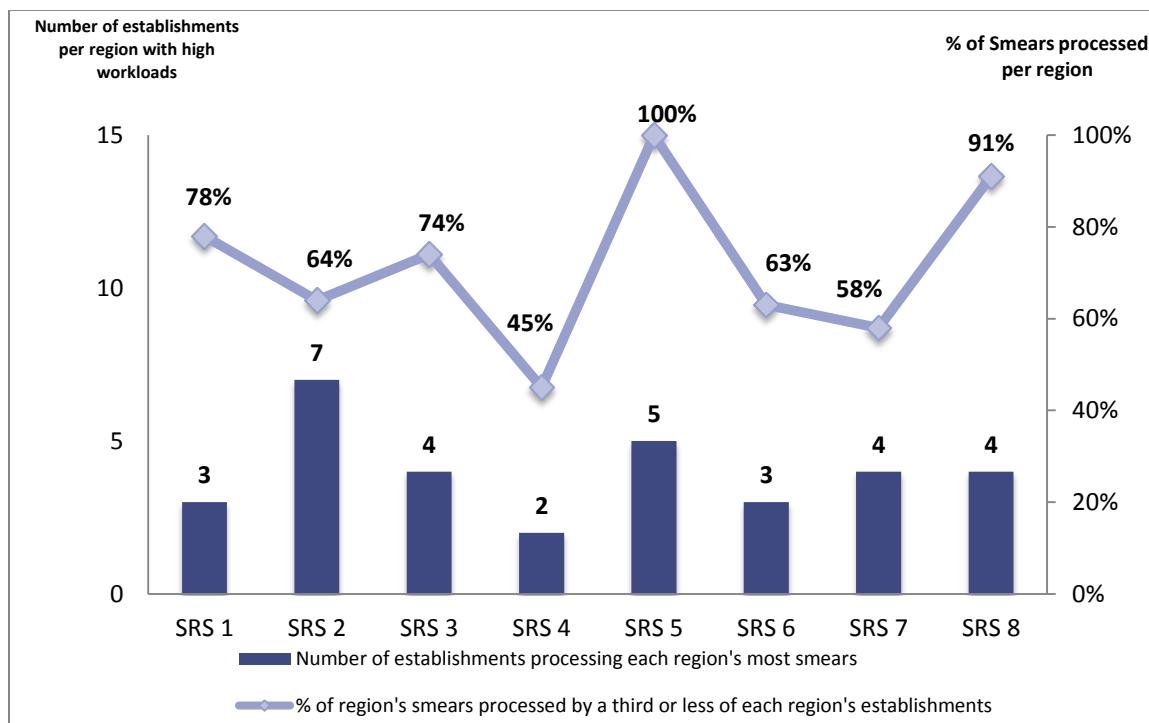
<sup>9</sup> World Health Organization. Tuberculosis country profiles. <http://www.who.int/tb/country/data/profiles/en/>.

### *Testing Concentration*

The referral network for TB samples consists of 1,269 establishments where sputum samples are taken. Of those, 146 establishments have the capacity to perform sputum smear tests, 13 establishments are equipped to process sputum culture tests, while only one (officially) is capable of performing drug susceptibility tests.

Outside the capital region, 125 establishments are capable of performing sputum smear tests. However, the study showed that on average 72% of all smears performed in the regions not including the capital in 2013 were processed in just 26% of capable establishments (32), thus exposing a worrying level of processing concentration.

Figure 6 depicts the percentage of each region's sputum smears being systematically processed by a very small number—less than a third—of capable laboratories, with numbers ranging from two to seven laboratories supporting the heaviest workloads in each SRS. With 10 laboratories, SRS 6 has the lowest installed capacity of all SRSs for processing sputum smears. However, just 3 of the 10 capable laboratories are processing 63% of all smears, while the remaining 7 process the other 37%.



**Figure 6. Processing concentration of sputum smears in 2013**

The PNCT has its network for sputum smears organized by geographic proximity, and all establishments are responsible for the samples within their catchment area.

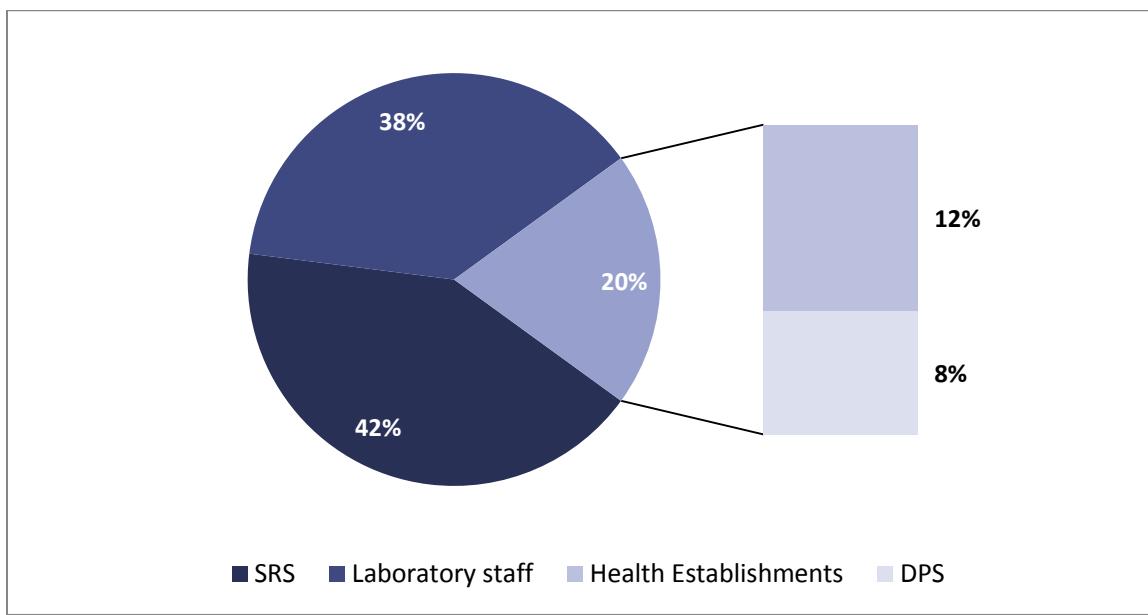
However, the evidence shows that this organization is not being enforced, and health centers send samples to processing establishments outside their geographic area. An additional short survey was conducted by SIAPS consultants together with MoH staff in three regional health establishments, as a means of verifying initial data received by the original surveys and empirically validating anecdotal information. This survey showed that in all three revisited regional health establishments, sputum samples for smear testing are being received from outside the local network.

The root causes found for this anomaly range from the systemic organizational deficiency and absence of guideline enforcement, to the idiosyncrasies of health workers who do not trust the current transportation system, or their peers.

The trust issues become programmatic when health workers do not trust their assigned reference laboratory and choose to send the samples elsewhere. Anecdotal information revealed that laboratory technicians do not trust results will return from a local laboratory; therefore, samples are sent to a regional health establishment, even though it is farther away.

#### *Transportation Providers for Laboratory Samples*

Several different transport flows exist for TB laboratory samples (figure 7). Transportation services are provided by the SRS in 42% (34) of establishments included in the assessment. In 38% of the surveyed establishments, laboratory staff with their own out-of-pocket resources take the samples to the corresponding laboratory for testing. Of surveyed establishments, 12% use their own vehicles and economic resources, and in the remaining 8%, another administrative body of the MoH, the DPS, handles sample transportation.

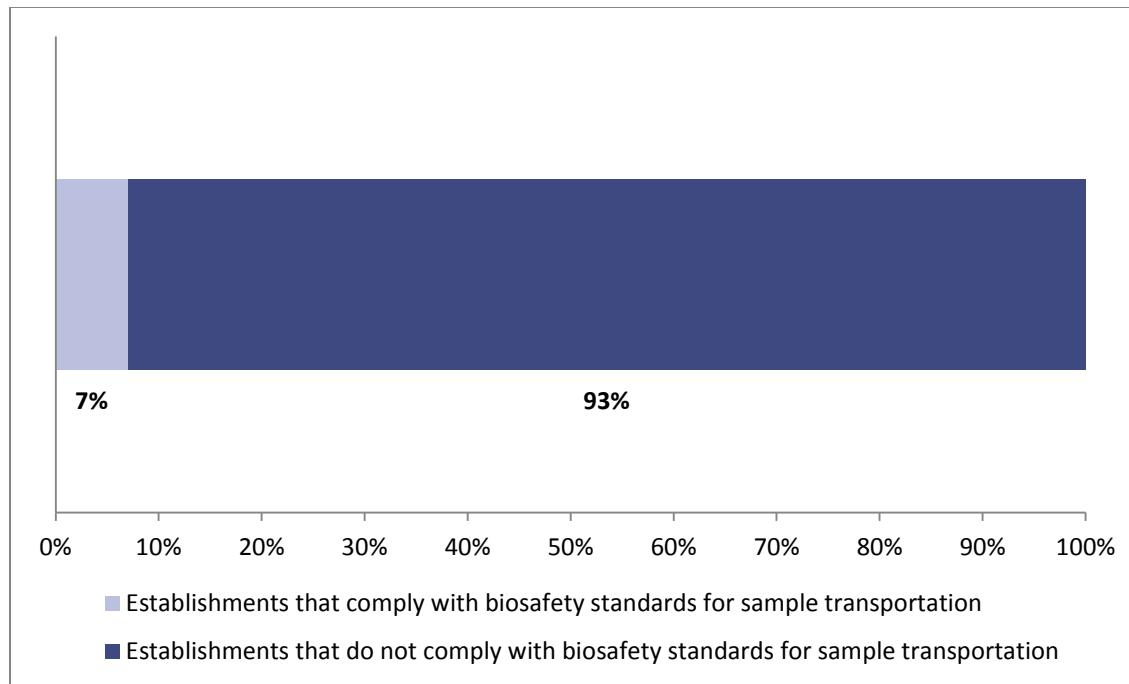


**Figure 7. Transportation providers: TB laboratory samples**

### **Biosafety**

Biosafety not only ensures that the samples arrive at their destination in ideal condition for testing, but also that the people transporting them, and the environment, are protected from harm in the event of an emergency.

Figure 8 shows that 93% of the 81 TB establishments surveyed did not comply with the five criteria taken from the *WHO Guidance on Regulations for the Transport of Infectious Substances*.



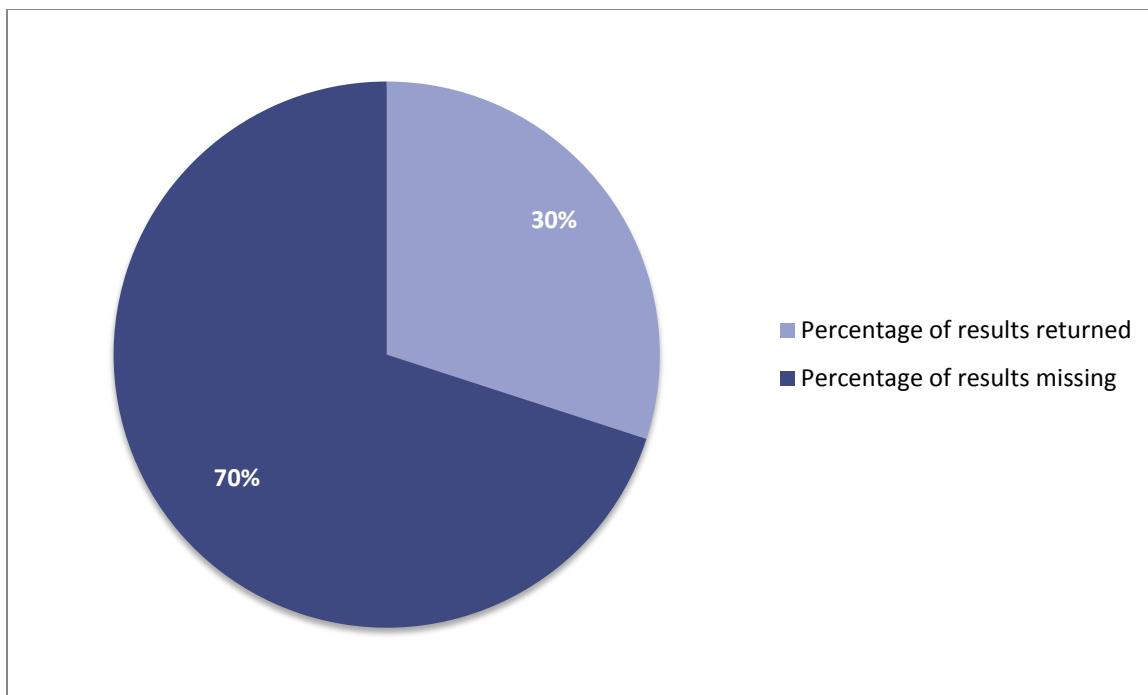
**Figure 8. Compliance with biosafety standards for TB laboratory sample transportation**

Factors contributing to low compliance include lack of enforcement of national biosafety guidelines by the MoH and the PNCT. Laboratory staff stated during the surveys that they had knowledge of the national guidelines; however, these guidelines emphasize internal laboratory operations.

### ***Delivery and Reception of Test Results***

#### ***Turnaround of Test Results***

The original establishment selection of 125 included 54 facilities where sputum is collected and sent to another establishment for smear tests. In 2013, a total of 29,525 sputum samples were sent from these 54 sputum-collecting establishments to other establishments for testing. However, when data were collected, the laboratory registry books revealed 8,760 (30%) results received back, as shown in figure 9.

**Figure 9. Sputum smear results turnaround**

#### *Turnaround Time*

The results of the baseline assessment indicate gaps among the existing TB referral networks, particularly regarding the TAT for sputum smears and cultures. The minimum average elapsed time to produce a sputum culture result is 4 weeks.<sup>10</sup> Table 3 shows results in the DR are currently taking more than three times the standard, with an average TAT of 13.85 weeks (96.7 days).

**Table 3. Average TATs in Days for TB Laboratory Samples, by SRS**

Region of origin	Sputum smears	Sputum cultures
SRS 0	1.5	76.9
SRS 1	3.4	95
SRS 2	4.3	50
SRS 3	6.5	71.3
SRS 4	3.9	68.7
SRS 5	4.1	82.5
SRS 6	12.3	n/a
SRS 7	4	102
SRS 8	2.7	227.5
<b>Total average</b>	<b>4.7</b>	<b>96.7</b>

<sup>10</sup> TB Facts.org, TB tests: Skin test, sputum & other types of TB test, <http://www.tbfacts.org/tb-tests.html>.

## **Costs**

As shown in figure 7, 50% of the establishments reported that the SRSs do not pick up the samples, but instead the laboratory personnel (38%) and the health establishments (12%) take the samples directly to the centers where tests are carried out. Laboratory technicians and other health personnel use their own financial resources to deliver TB samples from the respective health center to the laboratories.

Contributing factors that hinder or prevent the SRSs from providing services to their establishments as indicated in the Dominican Public Health Sector Reform of 2003 and the Model Guide for the Development of the Regional Health Services include insufficient follow-up and enforcement, lack of organization and human resources, and lack of funds.

## **DISCUSSION AND CONCLUSION**

The results of the baseline assessment indicate that a number of factors presently contribute to the overall delayed turnaround of results including the following:

- High concentration of laboratory samples being processed in a few testing laboratories, thus creating an overload of equipment and human resource capacity and ultimately negatively affecting TATs of test results: Concentration of sample processing is evident in both vertical disease control programs—as a strategic choice for the HIV program and resulting from lack of organization for the TB program.

It is of paramount importance to balance the workload and systemize the transportation of samples to guarantee shorter TATs because the number of laboratories is sufficient to process the amount of TB samples. Ideally, the PNCT should assess the human resource and equipment capacity in all the laboratories to decide which need to be operational, which could serve as referral hubs, and which could potentially be shut down.

In the case of HIV, when the service agreement with Profamilia is over, the LNSPDD would become the only laboratory capable of processing CD4 counts, viral load tests, and Proviral DNA for EID, putting a considerable strain on the sustainability of the system. The MoH should consider changing from a centralized processing strategy to a regional processing strategy, with designated hubs providing services to the closest provinces, to shorten distances traveled and times.

- A lack of scheduling: Although pickup of HIV samples is scheduled, the same does not apply to TB samples; thus, resources between the two disease control programs are not coordinated, even when most SAIs are located where TB samples are also collected. This results in poor use of funds and duplication of efforts.
- Failure to comply with biosafety protocols for transporting laboratory samples: This presents a major factor in the DR's issues with obtaining a result for 100% of the samples sent for testing, because optimal conditions are seldom maintained, and numerous samples arrive damaged, although laboratories seldom report such cases, evidencing a need to sensitize laboratory staff on the importance of reporting.

Having vertical disease control programs creates too many different responsible entities in the process of laboratory sample referral, leading to lack of specialization. In an integrated model, resources could be shared, and certain staff could be dedicated to the oversight of optimal biosafety standards for both HIV and TB.

- An array of different and disorganized transport flows and responsible entities:
  - The SRSs execute their responsibility to provide the service in roughly 50% of all establishments surveyed by the baseline assessment.

- The establishments make use of their vehicles and financial resources to deliver the laboratory samples.
- Laboratory staff delivers the samples, using out-of-pocket resources, in cases when neither the SRS nor the establishments provide transportation services.
- In the case of HIV, the regional hubs are sometimes but not always responsible for receiving the results from the LNSPDD. In other cases, it is the regional administrative offices of the SRS.

The ad hoc nature of the transportation flows harms the referral network's general accountability and contributes to samples arriving in bad shape, delayed TATs, and lost results.

An agile and organized transportation system is essential to prevent further spread of TB and HIV. To this end, the design and implementation of an integrated and standardized transportation system will improve the overall performance of the referral network, helping infected individuals receive appropriate and timely treatment.

The analysis derived from the baseline assessment identified a marked need for a general restructuring of the referral networks of HIV and TB laboratory samples that ranges from basic reporting practices to sample pickup planning and scheduling.

## **Proposed Interventions**

In an effort to provide structure to the transportation system, the team formed by the technical working group and SIAPS consultants designed the first-ever model guidelines and standard operating procedures (SOPs) for an integrated referral network of HIV and TB in the Dominican Republic.

Because DR laboratory staff have scarce knowledge on supply chain management, the new SOPs have been designed as a continuous flow, depicting all processes from the collection of laboratory samples, reception at processing facilities, manual and electronic information flows, communication, scheduling, results reporting, and people responsible for day-to-day operations. The inclusion of local public laboratory staff in the design and validation process should help in the transition and long-term sustainability of the proposed procedures.

The SOPs addressed seven key challenges found by the baseline assessment:

1. Assignment of establishments for sample referral: The SRSs would be responsible for coordinating with their region's establishments to clearly and visibly establish where each establishment within the network will send each type of laboratory sample, without exception. The aim is to eliminate existing and unofficial options for TB laboratory staff to decide, or instruct drivers, where to send the samples. This would help balance the workloads in TB laboratories once this measure is put in practice, except for the design of

the laboratory network not being correct or up to date to account for present and future patient needs.

2. Definition of responsibilities across the supply chain, from the laboratory technicians and truck drivers to the administrative and operative offices of the Dominican MoH: A clear definition of roles would help create accountability throughout the referral network, something that at the moment is deficient because of the ad hoc nature of the current system. In this new model, the SRS administrative offices would be responsible for 100% of the sample transportation in the country, as opposed to the current 50%, thereby eliminating unnecessary staff expenses.
3. Schedules for pickup and delivery of laboratory samples: The creation of a schedule to standardize transportation flows and to pool vehicle use and economic resources is necessary to create a more sustainable system. This schedule would determine the days and hours for sample collection, preparation, and pickup. It should also clarify the parties responsible for transportation.
4. Information systems: The addition of an electronic results management information system to link the processing facilities to the sample collection facilities and regional hubs would reduce TATs, avoid the loss of results, and drastically improve the current turnaround rates of HIV and TB test results. The proposed roadmap for implementation is to start with the LNSPDD, the 13 regional facilities, and eight regional hubs. A second phase would include provincial and municipal-level facilities. Also in terms of information systems, along with the SOPs, three different paper forms were designed to be the preferred documentation for the transportation of laboratory samples and results. The information contained in these three forms, if properly used, would be enough to periodically monitor the performance of the new system.
5. Monitoring and evaluation: Currently, monitoring and evaluation is mostly done with anecdotal information collected during supervisory visits. A monitoring and evaluation procedure and plan were developed to help obtain hard evidence to assess the performance of the system after implementation and scale-up. The three forms, plus a handful of well-defined indicators to be measured, such as TAT and percentage of results received per samples sent, should diminish the dependence on nonsystemic information.
6. Means of transportation: This is another critical subject that is addressed in the SOPs, which requires further consideration for viability of implementation. The DR's inter-regional transportation system for laboratory samples relies heavily on the use of public transportation. While this is in no case a good practice, the current resources available (public or private) dictate further use of public transportation until the MoH can procure other means. A contracted agreement must be reached between the transportation companies and the MoH to guarantee highest quality of service until other options become available.
7. Biosafety: A complete procedure was attached to the SOPs regarding biosafety measures to cover all processes from the preparation and packing of laboratory samples to the

transportation conditions, and the reception. The procedure includes the recommended materials and equipment needed throughout in accordance with the *WHO Guidance on Regulations for the Transport of Infectious Substances 2013–2014*. A considerable effort would be needed to correct biosafety measures to minimize the loss of laboratory samples in transit.

Next steps include a training of trainers on implementation of the SOPs, through a comprehensive and participative workshop to prepare local stakeholders for the challenges of managing the changes to the established system. During this workshop, all nine SRSs would prepare the implementation plans together with the aid of SIAPS consultants.

Also, the results management information system needs to be designed and developed by local MoH employees, with subsequent user training. This system should help shorten TATs at the central and regional-level facilities.

Upon scale-up, continued monitoring should be scheduled for a period of six months to one year, to have sufficient data to appraise performance of the new system. At the end of that period, a new collection of relevant data through the monitoring and evaluation indicators would be necessary to assess whether any improvements are evident.

The intervention that took place in Uganda in 2013 demonstrates that applying a systematic supply chain approach to standardize the referral network for one specific type of laboratory sample can improve dramatically the network's performance, reduce costs, and ultimately improve diagnosis and treatment. By integrating the TB and HIV referral networks, the aim in the DR is to achieve similar results, but for an array of laboratory samples and a larger population. Ultimately, the desired health outcomes are to improve the agility of diagnosis and treatment for HIV-positive and TB patients and to help prevent the spread of these diseases.