

## **Annex 3– Master Plan (courtesy English translation)**

**Disclaimer:** This document contains an unofficial and courtesy English translation of the *Plan Maestro para el fortalecimiento de la respuesta al VIH, la tuberculosis y la malaria en la República Bolivariana de Venezuela desde una perspectiva de salud pública* set forth in Annex 2. In the event of inconsistency, the version set forth in Annex 2 will prevail.

### **Master plan for strengthening the HIV, tuberculosis and malaria response in the Bolivarian Republic of Venezuela from a public health perspective**

**July 2018**

## Summary

This master plan was developed as a result of a joint technical mission in Caracas, Venezuela, on 18-22 June 2018. Its aim is to define priorities and coordinate support for international technical cooperation with the actors involved in the HIV, tuberculosis (TB) and malaria response in Venezuela (including government, civil society, health care providers and scientific societies) to ensure continued access to comprehensive and effective health services, drugs and adequate laboratory monitoring, minimize the risk of the emergence and transmission of resistance and ensure sustainability in the provision of essential services from a public health perspective.

### Epidemiological situation

Based on the latest estimates available, in 2016 Venezuela had an estimated 120,000 people living with HIV (PLHIV), 6,500 new infections and 2,500 AIDS-related deaths. The HIV epidemic is concentrated among key populations such as men who have sex with men (MSM) and sex workers (SWs), although there are no specific and recent data on prevalence. High HIV prevalence has also been detected in some indigenous communities (Warao). The mortality data available show an upward trend in AIDS-related mortality (latest data from 2015) and a reduction in the HIV detection rate (latest data from 2016), although the scarcity of reagents for HIV testing may have had an impact on the ability to detect new cases.

According to preliminary data, there were 10,185 TB cases in 2017 – an increase of 41 percent compared with 2014 (6,063 cases). This increase was concentrated among men aged between 15 and 34 in the economically active population. Almost 25 percent of all cases are concentrated among two vulnerable groups: prisoners (15.7 percent) and indigenous populations (6.8 percent). During the 2014-2017 period, the number of drug-resistant tuberculosis (DR-TB) cases almost doubled, rising from 39 to 79 cases. In 2017, the TB/HIV co-infection rate was 4.8 percent and the combined TB and diabetes rate was 5 percent, exhibiting an upward trend. TB mortality, which had been declining in previous years, has remained around 2.2 per 100,000 population since 2009. Unless urgent and effective measures are taken to reverse the current trend, these figures will make it difficult for the country to achieve the milestones and targets set out in the End TB Strategy.

There is a malaria epidemic in nine states (Bolívar, Amazonas, Sucre, Monagas, Delta Amacuro, Anzoátegui, Nueva Esparta, Miranda and Zulia), with an increase in the spread of malaria to new municipalities and parishes within municipalities already affected. Bolívar state continues to record the largest number of cases and influence the spread of malaria to other parts of the country. Amazonas state saw a huge increase in transmission in 2017. Despite a 20 percent reduction in the total number of cases reported by week 23 of 2018, there was a high dispersal of transmission in multiple locations within municipalities and new instances of transmission in historically non-malarial areas. Sucre state recorded an increase of 14 percent in week 17 of 2018 compared with the same period in 2017, when the state experienced a massive increase in epidemic behavior in several municipalities. The existence of a large, historically susceptible territory has resulted in unique transmission behavior in multiple outbreak locations. There is a

marked prevalence of malaria caused by *Plasmodium vivax* and a concentrated area of transmission by *Plasmodium falciparum*. The number of recorded deaths is low, but there are cases of severe malaria from *P. vivax* due to delays in starting treatment.

### **Health system and services**

In Venezuela's National Public Health System (SPNS), the integrated community health areas (ASIC) are considered the basic integration units within the network. They serve as geopolitical and operational areas that coordinate communities to provide a comprehensive, universal, equitable and free response with a family- and community-based approach. Currently, the HIV and AIDS, TB and malaria programs are essentially supported by the Ministry of Health (MPPS) establishments. However, there is significant potential for improvement, were the capacity of the three public sector networks to provide services and epidemiological analysis to be integrated.

The National Training Program for Comprehensive Community Medicine (PNFMIC) was established in 2005 to address shortfalls in staff numbers, with training focused on primary and community care. Actions were undertaken jointly by the Ministry of Higher Education (MPPES) and the educational program *Misión Sucre*, with the Ministry of Health coordinating the *Barrio Adentro* social program. These actions are geared toward training new health professionals, with support provided by the *Misión Médica Cubana* (Cuban Medical Mission) and Venezuelan universities. Comprehensive community doctors (MICs) trained on this program are incorporated into the SPNS to meet primary care needs at the national level; however, one of the main challenges facing the health system is the migration of health professionals and workers.

### **HIV services**

Although HIV testing services are available in 127 public centers, public health laboratories or blood banks, the voluntary counseling and testing model has not yet been implemented and progress is yet to be made in decentralizing access to rapid testing at the primary care level and on community screening strategies or testing by trained peers. The capacity to confirm HIV diagnosis is currently limited by the lack of 4th generation ELISA and Western Blot (WB) reagents, which has had a significant impact on HIV detection. Moreover, there are currently no supplies available to assess blood quality in blood banks and condoms and lubricants are not being distributed within comprehensive health services to PLHIV, nor within the primary care network.

The Ministry of Health has been providing free antiretroviral therapy (ART) to PLHIV since 1999 and in 2016 adopted a policy of providing ART to all PLHIV, regardless of their CD4 count. Of the estimated total of 120,000 PLHIV in 2016, 59 percent had access to ART (71,210 people undergoing treatment) and approximately 7 percent had a suppressed viral load. Comprehensive care and ART are currently provided in 91 specialist clinics in level III or IV hospitals in the public sector and clinical follow-up is generally carried out by specialist physicians. Antiretrovirals (ARVs) are dispensed in 51 pharmacies located near the HIV clinics. The country has laboratory capacity for viral load, CD4 and genotypic resistance tests.

Since 2017, the economic crisis has led to difficulties in the supply of ARVs, such that there have not been enough to cover all patients' ART regimens. These supply issues have also affected drugs

for prophylaxis and treatment of opportunistic infections, and reagents for CD4, viral load and resistance tests, thus compromising continued access to ART and adequate laboratory monitoring. Since April 2018, approximately 58,000 PLHIV have been affected by the drugs shortage. The Venezuelan Network of People Living with HIV (RVG+) is monitoring the supply situation in ARV dispensing centers through monitors in all the country's states. Amid ARV shortages, there have been reports of irrational use of the drugs. This poses a considerable risk of creating drug resistance and compromising treatment effectiveness, in addition to the risk that resistance will be transmitted and spread to the population.

### **TB services**

In Venezuela, 3,858 health services at various levels are providing TB services. There is potential to expand these services by integrating the entire community care network of the *Misión Barrio Adentro*. The network of services is organized by level with defined roles, and presided over by the Ministry of Health through the national TB program (NTCP). While there are established rules and guidelines, there are currently difficulties in providing services due to the situation in the country and staffing constraints. Moreover, these guidelines require updating in line with current international recommendations. Referrals and counter-referrals of patients, laboratory samples and test results between levels in the system largely fall to patients and their families, which means they incur additional financial costs. This also affects TB case detection, contact control, timely diagnosis and follow-up to treatment. In 2017, only 33 percent of anticipated respiratory symptoms were identified. Although the cure rate was 82 percent, around 105 patients were lost to follow-up. The TB information system is paper-based.

The national TB reference laboratory (TB NRL) is directly attached to the NTCP and does not report to the National Institute of Hygiene (INH), which is head of most laboratory networks. Despite this, it manages the TB diagnostic network, with 160 public sector laboratories that perform bacilloscopy and eight that also perform cultures. As none of the comprehensive diagnosis centers (CDIs) diagnose TB, they are not integrated into this network. The national reference laboratory has a GeneXpert<sup>®</sup> machine, as does the Maracaibo laboratory; however, since May 2018, neither have been operational due to a lack of cartridges. The machine is mainly used to investigate rifampicin resistance, rather than to diagnose TB. The system for transporting samples does not work. Quality control has been maintained.

### **Malaria services**

Currently, the HIV and AIDS, TB and malaria programs are essentially supported by the Ministry of Health (MPPS) establishments. However, there is significant potential for improvement, were the capacity of the three public sector networks to provide services and epidemiological analysis to be integrated. The formally approved integration structure is the ASIC, which will require significant consolidation efforts over the coming months. This integration process should involve updating the classification and functions of facilities such as the current health districts within the new ASIC-based structure.

As a medium-term strategy, comprehensive care provided within the health network, with an emphasis on prioritized programs, will be coordinated by ASICs within their area of influence.

Incorporating the Venezuelan Institute of Social Security (IVSS) and the Ministry of Education Staff Pensions and Welfare Institute (IPASME) into the health services network will increase the response capacity in urban areas across the public sector.

The microscopy network is currently running at hugely reduced capacity due to a lack of diagnostic supplies. The poor state of microscopes and staff limitations have also reduced the diagnostic network's coverage, and the quality management system for malaria diagnosis is not operational.

Late and inappropriate treatment perpetuates transmission and the risk of malaria-related complications and mortality. Treatment is subject to a data audit, with ongoing stock-outs at the local level, late initiation of treatment and an absence of treatment for cases not approved in the audit.

### **Supply management**

The provision of drugs and strategic supplies for public health programs is one of the country's biggest challenges. There is a critical stock-out of essential drugs for HIV/sexually transmitted infections (STIs), opportunistic infections, preventing congenital syphilis and malaria treatment. There are also no diagnostic and monitoring tests, insufficient reagents and supplies for laboratories and blood banks and insufficient vector control supplies (nets, insecticides and supporting equipment). This is due to a number of factors, including: lack of funding, fragmented supply management, lack of domestic pharmaceutical suppliers, insufficient internal controls in managing the distribution of certain drugs, and the illegal drug market, which has exacerbated stock-outs.

For HIV treatment, the Ministry of Health is procuring approximately 4 percent of the real ARV needs through government funds, the Pan American Health Organization (PAHO) Strategic Fund and direct international procurement. However, this is insufficient to meet national demand and some comprehensive treatment regimens only have supplies to cover a period of two months. For TB, the situation has been less critical as drugs are available from previous procurement activities and donations have been managed to avoid stock-outs. The procurement process is under way for the drugs needed for 2018.

Supply management for drugs and supplies for malaria diagnosis, vector control and treatment has been irregular. In 2017, a reduced stock of antimalarials was procured through the Strategic Fund using Ministry of Health funding and through direct international procurement, but demand has exceeded available stocks. Information on current stock levels is not available at the national level.

Some HIV, malaria and TB drugs and supplies and reagents for diagnosis are being provided through donations managed by United Nations organizations such as PAHO/World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the United Nations Children's Fund (UNICEF), as well as by some NGOs and donor countries.

In this regard, governmental and donor funding sources should be identified to achieve the following in the short to medium term: regularization of drugs and supplies availability; reorganization of supply management to ensure an efficiently managed procurement process

and coordinated distribution with public health programs and those involved in the drugs and supplies logistics chain; implementation of a logistics information system that enables stock to be controlled and monitored at the national level; and timely dispensation and delivery of drugs and supplies to the affected population.

As a technical cooperation mechanism of PAHO, the Strategic Fund has been supporting the Ministry of Health in procuring drugs and supplies as part of an agreement signed in 2010. It is on hand to support the drugs and supplies planning and procurement process, ensuring the quality of these items and at affordable prices, as well as providing technical support to improve supply management.

### **Agreed recommendations**

It is recommended that an interprogrammatic commission formed of members of the joint mission and other relevant actors be set up to monitor the implementation of these recommendations and the activities of the master plan.

### **HIV component**

- **Continued access to comprehensive care and ART.** Formalize the review of the ART guidelines agreed during the mission and the registration of new ARVs. Adapt ARV procurement plans to the new guidelines so that they are sufficient to meet the needs of the cohort, with a treatment re-initiation plan and a communications strategy, as well as a civil society support strategy to help recapture patients. The procurement plan will also include drugs for prophylaxis and treatment of opportunistic co-infections and infections and other drugs and supplies for comprehensive care (micronutrients, milk substitutes, penicillin). The PAHO Strategic Fund is the main procurement mechanism, while civil society plays a key role in the monitoring of and follow-up on drug distribution and in referring/guiding people to services.
- **Capacity building and continued access to laboratory monitoring.** Adapt the procurement plan for reagents to factor in viral load, CD4, resistance tests, and screening and diagnosis of opportunistic co-infections and infections in order to meet needs. Expand laboratory capacity for testing viral load, including by introducing GeneXpert as a comprehensive platform for HIV (viral load and DNA polymerase chain reaction (PCR)) and TB; decentralize DNA PCR testing (using GeneXpert and, if possible, by sending filter paper samples); participate in external quality control programs.
- **Broader access to HIV prevention, screening tests and diagnosis.** Design and implement a staff training plan for services so that rapid testing can be carried out, and to ensure compliance with the diagnostic algorithm, reduced stigma and discrimination, and rapid initiation of treatment. Planning and procurement for and distribution of ELISA tests and rapid tests for HIV and syphilis, condoms and educational materials are also required.
- **Improve HIV strategic monitoring and information.** Train health workers and epidemiologists at the various levels on the HIV epidemiological surveillance system and review and incorporate variables that respond to the need to characterize the epidemic and the national response. Conduct national HIV-resistance monitoring (pre-treatment).

### **TB component**

- **Improve TB case detection and diagnosis.** Strengthen TB diagnostic capacity by procuring GeneXpert equipment and cartridges, with a view to replacing bacilloscopy as the initial means of diagnosing TB and using it for other diseases (e.g. HIV monitoring with viral load). Establish and implement a crosscutting sample transportation system for multiple diseases including TB to ensure rapid diagnosis. Use portable digital X-ray equipment to strengthen TB diagnosis among at-risk populations, particularly the prison population.
- **Prevention, treatment and people-centered care.** Develop refresher/training workshops for health workers at the primary care level to strengthen the response capacity for TB prevention and control, including a coordinated workplan among the various actors and services that favors patient-centered care. Consider introducing the shortened treatment regimen for DR-TB in the country and including rifapentine in the preventive treatment of latent TB infection. Strengthen nutritional support for hospitalized TB patients and coordinate the support provided in this regard by NGOs and faith-based organizations. Include current and future TB patients in the various government missions that provide social protection and promote the participation of groups of current and former patients as principal actors in NTCP activities.
- **Access to information and TB monitoring at the national level.** Carry out an epidemiological evaluation (Epi review) of the TB situation with the aim of analyzing the available information to better understand the epidemic in the country, identify gaps and establish concrete recommendations for strengthening TB surveillance and control. Migrate to an electronic nominal information system as part of the health information system. Strengthen connectivity to enable adequate information flow, thus ensuring timely data availability and epidemiological surveillance. Strengthen monitoring mechanisms at all levels and establish active pharmacovigilance of DR-TB.
- **Improve management of the NTCP.** Update the National Strategic Plan for TB following the latest guidelines for implementing the End TB Strategy and update the inventory of maintenance, supplies and human resources needs for TB. Update guides and manuals in line with existing PAHO/WHO TB recommendations to adjust diagnostic algorithms and treatment regimens and times. Incorporate TB within the remit of ASICs, capitalize on the potential of the entire community care network to expand prevention, detection, diagnosis and comprehensive TB treatment, and strengthen primary care through broad community participation. Consider using the ENGAGE-TB approach. Strengthen TB/HIV collaborative activities, with an emphasis on integrating services at the primary care level. Ensure that the Ministry of Health provides a system whereby states can send biological material and TB reports to the national reference laboratory and the NTCP. Facilitate the management of NTCP drugs and supplies by sharing inventory information from the ministerial body responsible for storing and distributing pharmaceuticals, SEFAR. Consider making the TB NRL report to the INH to harness the resources and technical capabilities of all the national reference laboratories. Drive operational research on TB, with academia and scientific societies supporting NTCP interventions.

## **Malaria component**

- **Organize the management model to coordinate the malaria response.** Organize the following two aspects of coordination: (i) coordinating the malaria response between the national and state levels; and (ii) promoting local coordinated management structured under ASICs, so that efforts by the various state bodies (environmental health, governance, municipality and other local actors) are integrated at the local level.
- **Make immediate treatment based on early diagnosis the main malaria intervention** (to reduce the malaria reservoir and avoid complications and death). It is recommended to reorient the current data audit, making it an activity to clean the data in the analysis rather than a condition for drug delivery. The general reactivation of the microscopy network throughout the country, involving the provision of supplies, microscopes and spare parts (purchases), should be a priority, as should managing the network's quality. Continue implementing the use of rapid diagnostic tests with the aid of a technical framework and training, monitoring and supervision plans. Strategically position the concept of universal, free and immediate supply as the main premise, with improvements in the field that discourage drug commercialization. Focus the greatest efforts on setting up a local model that ensures access to diagnosis and the initiation of treatment upon diagnosis.
- **Strategically address the problem of malaria mortality by identifying and correcting failings in care delivery and malaria case management during pregnancy.** Develop and implement a methodology for mortality analysis. Organize care referral routes and management for severe malaria in specific municipalities (Bolívar and Anzoátegui are priorities), and continue to provide training in the clinical management of severe malaria. Procure drugs for severe malaria, comorbidities and medical supplies. Develop strategies for detecting, diagnosing, preventing and managing malaria during prenatal checkups and delivery care (malaria during pregnancy and congenital malaria). Develop and implement a risk-communication strategy to address the malaria epidemic.
- **Unify malaria information management and promote information and surveillance processes that prioritize local decision-making.** Unify the three information sources (epidemiology, national environmental health and states). Provide training in information management, analysis and micro-stratification at the local level (ASIC) to facilitate decision-making related to malaria and the organization of the screening-diagnosis-treatment process. Consolidate computer processes for database management (cases, slides examined) and supply facilities at the local level (ASIC) with equipment and software (computers, software, GPS) to record and manage data.
- **Implement the recommended measures for malaria vector control (long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS)) within established coverage and quality parameters.** Develop a technical framework for implementing LLINs with a programmatic focus (prioritization, distribution, promotion of their use, monitoring) and procuring LLINs. Activities to install, follow-up on and monitor the use of LLINs. IRS operations (logistics, transport) and procurement of necessary supplies. Stratification and profiling of malaria outbreaks as required by health engineering measures. Entomological and surveillance studies of resistance to insecticides.
- **Develop a policy, strategic and operational framework to address urgent public health issues related to mining** (in Bolívar and Amazonas states). Organize local networks to

facilitate early detection and immediate treatment of malaria and appropriate coverage with LLINs, and interact effectively with local actors and the community.

**Health systems strengthening.** The integration of priority public health programs with the ASIC strategy, which groups health care facilities into a network based on geographical location, is a medium-term strategy. In this regard, the following recommendations are made:

- **Create 24 pilot ASICs that integrate all programs.** A project to strengthen the formation of ASICs has been developed to improve structure, equipment, the flow of drugs and the integration of health priorities that cover mother-to-child health, the Expanded Program on Immunization (EPI), malaria, TB and HIV.
- **Create program-specific measures in conjunction with *Barrio Adentro*:** location of rapid testing equipment; malaria detection, diagnosis and treatment actions; training actions; community activation actions; availability of TB treatment (directly observed treatment – DOT); TB chemoprophylaxis and contact tracing; coordination with social protection missions for patients.
- **Create a functional coordination strategy across the country that includes proposals for structural redefinition.** This proposal should consider one phase that includes the ministerial network and a second phase that considers IVSS and IPASME.

**Supply management.** Initiate drug and supply procurement processes to ensure adequate national supplies and improve access to and availability of essential drugs. In this regard, the following recommendations are made:

- **Review and update the regulatory framework for drug supply management** (selection, planning for needs, procurement, storage, distribution, dispensation and monitoring) with all stakeholders involved.
- **Staff training on supply management processes** to ensure adequate and timely management at the state and local levels.
- **Review of the logistics management information system and its use** by all stakeholders to manage demand and stock control (local and central).
- **Develop the National Integrated Procurement Plan** to help guide procurement arrangements (direct procurement, procurement through Strategic Fund or donations).
- **Develop the drug and supplies distribution plan in conjunction with the programs and SEFAR.**

**Activities plan.** This plan details the actions needed to ensure continued access to essential, comprehensive and effective health services, drugs and adequate laboratory monitoring from a public health perspective. The plan does not include the costs of actions to maintain the structural capacities of the health system in terms of service provision.

**Overview of the master plan**

COMPONENTE	Año1 (valor estimado en US\$)	Año2 (valor estimado en US\$)	Año 3 (valor estimado en US\$)
<b>HIV</b>			
Medicamentos	\$23,208,704.79	\$20,073,762.66	\$20,374,556.94
Laboratorio	\$4,845,778.60	\$7,567,631.72	\$7,779,574.72
Prevención	\$5,479,200.00	\$5,479,200.00	\$5,479,200.00
Fortalecimiento servicios de salud	\$208,650.00	\$173,700.00	\$158,700.00
Vigilancia	\$50,000.00	\$10,000.00	\$10,000.00
<b>TOTAL VIH</b>	<b>\$33,792,333.39</b>	<b>\$33,304,294.38</b>	<b>\$33,802,031.66</b>
<b>TB</b>			
Medicamentos	\$0.00	\$504,914.00	\$673,948.00
Laboratorio	\$1,007,788.00	\$885,088.00	\$885,088.00
Prevención	\$4,800.00	\$7,800.00	\$4,800.00
Fortalecimiento servicios de salud	\$1,005,580.00	\$45,900.00	\$45,900.00
Vigilancia	\$26,200.00	\$15,000.00	\$10,000.00
<b>TOTAL TB</b>	<b>\$2,044,368.00</b>	<b>\$1,458,702.00</b>	<b>\$1,619,736.00</b>
<b>Malaria</b>			
Medicamentos	\$689,007.49	\$982,035.75	\$0.00
Laboratorio	\$2,031,075.26	\$1,364,044.21	\$849,626.53
Prevención	\$4,117,152.50	\$2,438,000.00	\$1,195,000.00
Fortalecimiento servicios de salud	\$1,736,720.00	\$188,000.00	\$163,000.00
Vigilancia	\$140,000.00	\$115,000.00	\$34,000.00
<b>TOTAL MALARIA</b>	<b>\$8,713,955.25</b>	<b>\$5,087,079.96</b>	<b>\$2,241,626.53</b>
<b>TOTAL GENERAL</b>			
TOTAL Medicamentos	23,897,712.28	21,560,712.41	21,048,504.94
TOTAL Laboratorio	7,884,641.86	9,816,763.93	9,514,289.25
TOTAL Prevención	9,601,152.50	7,925,000.00	6,679,000.00
TOTAL Fortalecimiento servicios de salud	256,000.00	185,000.00	160,000.00
TOTAL Vigilancia	890,900.00	830,900.00	506,700.00
<b>TOTAL GENERAL</b>	<b>\$44,550,656.64</b>	<b>\$39,850,076.34</b>	<b>\$37,663,394.19</b>
TOTAL VIH	\$100,898,659.43		
TOTAL TB	\$5,122,806.00		
TOTAL Malaria	\$16,042,661.74		
<b>TOTAL GENERAL PLAN (3 años)</b>	<b>\$122,064,127.17</b>		

## 1. Introduction and objective of the master plan

This master plan was developed as a result of a joint technical mission to strengthen the response to HIV, TB and malaria in the Bolivarian Republic of Venezuela from a public health perspective. The mission was undertaken in Caracas, Venezuela, on 18-22 June 2018 (see Terms of Reference in **Annex 1**).

The plan aims to define priorities and coordinate the support from international technical cooperation with actors involved in the response to HIV, TB and malaria in Venezuela (including government representatives, civil society, health care providers and scientific societies) to ensure continued access to comprehensive and effective health services, drugs and adequate laboratory monitoring. It will serve to optimize the effectiveness of the prevention and control programs for HIV, TB and malaria, minimize the risk of the emergence and transmission of resistance and ensure the sustainable provision of essential services from a public health perspective.

The situational analysis and recommendations included in this plan were discussed and agreed upon in three working groups (one for each disease) and combined at the end of the working week to promote an approach favoring synergy and efficiency:

- The HIV group comprised representatives of the Ministry of Health's National AIDS Control Program (NACP), representatives of civil society (RVG+ and *Acción Solidaria*) and the Venezuelan Society of Infectology, and advisers from PAHO and UNAIDS.
- The TB group comprised representatives of the Ministry of Health's National Respiratory Health Program, representatives of civil society (*Asociación Pro Salud Respiratoria*) and the Venezuelan Society of Pneumology and Thoracic Surgery (SOVETORAX) and advisers from PAHO.
- The malaria group comprised officials from the National Environmental Health Directorate of the Ministry of Health and officials from the Environmental Health Directorates of the Bolívar, Sucre and Anzoátegui states and from the center for research and control of tropical diseases, SACAICET, in Amazonas state, as well as malaria advisers from the PAHO country office and the regional malaria adviser.

## 2. Epidemiological situation

### 2.1 HIV and AIDS situation

Based on the latest available estimates, in 2016 the Bolivarian Republic of Venezuela recorded 6,500 (5,800–7,100) new HIV infections and 2,500 (2,100–2,900) AIDS-related deaths. In the same year, there were an estimated 120,000 (110,000–130,000) PLHIV.<sup>1</sup> From 2010 to 2016, there was a 24 percent increase in new HIV infections and an 8 percent decrease in AIDS-related deaths. Estimates for 2017 are currently being validated and, as such, are currently unavailable.

The HIV and AIDS epidemic began in Venezuela in 1982, when the first case was diagnosed. The past 35 years have seen the epidemic evolve in terms of both its size and structure. Notified cases of HIV infection have increased progressively, reaching a total of 154,046 diagnosed cases by 31 December 2016. Men are the most affected and account for approximately 75 percent of cumulative cases (**Table 1**). More recent data on the number of diagnosed and notified infections in 2017/2018 are not yet available.

**Table 1. Morbidity: HIV and AIDS cases by sex based on triennial intervals, Venezuela (1982–2016)**

Intervals	Cases			Percentage		
	Men	Women	Total	Men	Women	Total
1982–1984	20	3	23	86.96	13.04	100
1985–1987	268	14	282	95.04	4.96	100
1988–1990	1,343	115	1,458	92.11	7.89	100
1991–1993	2,367	248	2,615	90.52	9.48	100
1994–1996	2,556	364	2,920	87.53	12.47	100
1997–1999	640	109	749	85.45	14.55	100
2000–2001*	24,587	10,430	35,017	70.21	29.79	100
2002–2004	9,704	4,159	13,863	70.00	30.00	100
2005–2007	17,822	3,897	21,719	82.06	17.94	100
2008–2010	23,433	6,763	30,196	77.60	22.40	100
2011–2013	20,591	5,899	26,490	77.73	22.27	100
2014–2016	12,599	6,115	18,714	67.32	32.68	100
<b>Total</b>	<b>115,930</b>	<b>38,116</b>	<b>154,046</b>	<b>75.26</b>	<b>24.74</b>	<b>100</b>

Source: NACP

\*During this period, the program's regional coordinating bodies carried out direct case detection.

**Table 2** presents a more recent view of the epidemic, showing the 82,469 new cases diagnosed in the last ten years, disaggregated by sex. There is evidence of a significant increase in the percentage of cases among women compared with previous trends. By 2015, the annual percentage of cases had increased from 20 percent to 38.28 percent.

<sup>1</sup> Source – UNAIDS <http://www.unaids.org/en/regionscountries/countries/venezuela>

**Table 2. Morbidity: HIV and AIDS cases by sex and year, Venezuela (2007–2016)**

Years	Men		Women		Total	
	Number	%	Number	%	Number	Rate*
2007	4,869	80.00	1,217	20.00	6,086	22.14
2008	5,482	74.94	1,833	25.06	7,315	26.19
2009	8,725	77.82	2,487	22.18	11,212	39.50
2010	9,226	79.06	2,443	20.94	11,669	40.47
2011	8,976	78.13	2,513	21.87	11,489	42.20
2012	8,945	80.00	2,236	20.00	11,181	38.08
2013	2,670	69.90	1,150	30.10	3,820	12.82
2014	4,037	65.85	2,094	34.15	6,131	20.30
2015	3,508	61.72	2,176	38.28	5,684	18.56
2016	5,911	74.99	1,971	25.01	7,882	25.74
<b>Total</b>	<b>62,349</b>	<b>75.60</b>	<b>20,062</b>	<b>24.33</b>	<b>82,469</b>	<b>-</b>

Source: NACP. \*Rate per 100,000 population.

**Note.** In the 2013–2016 period, the number of cases is lower than in previous years, which could be explained by the coinciding changes made to the system that the regional coordinating bodies use to register and notify cases – these changes are still being rolled out.

Another aspect of the epidemic’s structure is the fact that it affects key populations. In this regard, as in most countries on the continent, it is estimated that the HIV epidemic in Venezuela is concentrated and remains contained within groups that are deemed to be the most epidemiologically exposed, namely MSM and SWs. The prevalence among the general population is estimated at 0.56 percent, and above 5 percent among key population groups; however, there is no specific and recent information available. To date, it has not been possible to conduct integrated bio-behavioral research to determine the actual size of key populations, HIV prevalence and HIV-related knowledge and behaviors. A bio-behavioral study among MSM and an estimation of population size are currently being planned with the support of PAHO and UNAIDS.

Indigenous population groups are also among the key populations most affected. A study published in 2013 documented a significant concentration of the HIV epidemic among Warao indigenous communities, where HIV prevalence of 9.5 percent was reported;<sup>2</sup> however, epidemiological data from the surveillance system disaggregated by ethnic groups are not available.

Data on mother-to-child transmission of HIV and congenital syphilis are limited. For 2015, the country reported a 23 percent coverage of HIV testing among pregnant women attending prenatal care.<sup>3</sup> In the same year, the prevalence rate among the 27 percent of pregnant women

<sup>2</sup> Villalba JA *et al.* HIV-1 epidemic in Warao Amerindians from Venezuela: spatial phylodynamics and epidemiological patterns. *AIDS*. 2013; 27(11):1783-1791. doi:10.1097/QAD.0b013e3283601bdb.

<sup>3</sup> Bolivarian Government of Venezuela. Ministry of Health. National follow-up report on the 2011 Political Declaration on HIV/AIDS. 2016

who were tested for syphilis while attending prenatal care was 2.8 percent.<sup>4</sup> In the absence of up-to-date data on the rate of mother-to-child transmission of HIV and congenital syphilis, the only available information comes from the results of early diagnostic tests on children exposed to HIV (DNA PCR) conducted centrally at the Rafael Rangel National Institute of Hygiene (INH) (Table 3).

**Table 3. HIV diagnosis in children exposed to proviral DNA, Venezuela (2011–2018)**

YEAR	PROCESSED	POSITIVE SAMPLES	POSITIVE PATIENTS
2011	510	23	17
2012	502	33	20
2013	567	43	28
2014	510	28	19
2015	522	32	21
2016	283	27	19
2017	282	15	11
2018*	126	12	8

Source: INH (Data reported during the technical mission. 2018)

Between 1983, when the first AIDS-related death occurred in Venezuela, and December 2015, 35,400 HIV and AIDS-related deaths have been registered in the country. Table 4 shows HIV and AIDS mortality in a ten-year period (2006–2015), during which 19,047 deaths occurred. The table shows how the cause-specific mortality rate for HIV and AIDS per 100,000 population increased from 5.80 to 8.03, among both sexes.

In terms of its significance as a cause of death, in 1998 HIV and AIDS ranked 16th out of the 25 main causes of mortality, while in 2012 it had moved up to 13th place. Mortality figures are much more accurate than morbidity figures because in Venezuela, all death certificates are subject to a comprehensive review process. This significantly reduces the percentage of causes of death that are inadequately registered, whether because the real cause of death is unknown or for fear of stigma.

**Table 4. Mortality: HIV and AIDS deaths by year and sex, Venezuela (2006–2015)**

Year	Men	Rate*	Women	Rate*	Total	Rate*
2006	1,187	8.75	380	2.82	1,567	5.80
2007	1,288	9.34	382	2.79	1,670	6.08
2008	1,223	8.73	409	2.94	1,632	5.84
2009	1,327	9.32	408	2.88	1,735	6.11

<sup>4</sup> Pan American Health Organization. Elimination of mother-to-child transmission of HIV and syphilis in the Americas. Update 2016. Washington DC, 2016. <http://iris.paho.org/xmlui/handle/123456789/34072?locale-attribute=en>

2010	1,380	9.55	450	3.13	1,830	6.35
2011	1,612	10.99	554	3.79	2,166	7.40
2012	1,603	10.89	558	3.81	2,161	7.36
2013	1,536	10.28	518	3.49	2,054	6.90
2014**	1,340	8.85	455	2.96	1,795	5.89
2015**	1,925	12.78	512	3.35	2,437	8.03
<b>Total</b>	<b>14,421</b>	-	<b>4,626</b>	-	<b>19,047</b>	-

Source: Directorate-General of Epidemiology. \*Rate per 100,000 population.

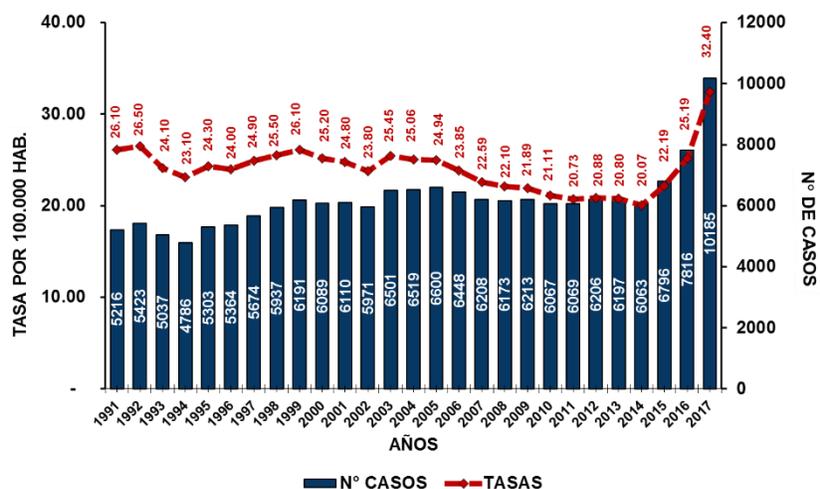
\*\*These figures are preliminary since they are still undergoing validation.

HIV and AIDS mortality data for 2016–2017 are not yet available. However, based on interviews carried out during the technical mission with key informants from health care providers and civil society representatives, there has been a recent increase in hospitalizations among PLHIV and in AIDS and HIV-related deaths (up to 20–30 per day), mostly due to disruptions in ART and a shortage of drugs for treating opportunistic infections.

## 2.2 Tuberculosis situation

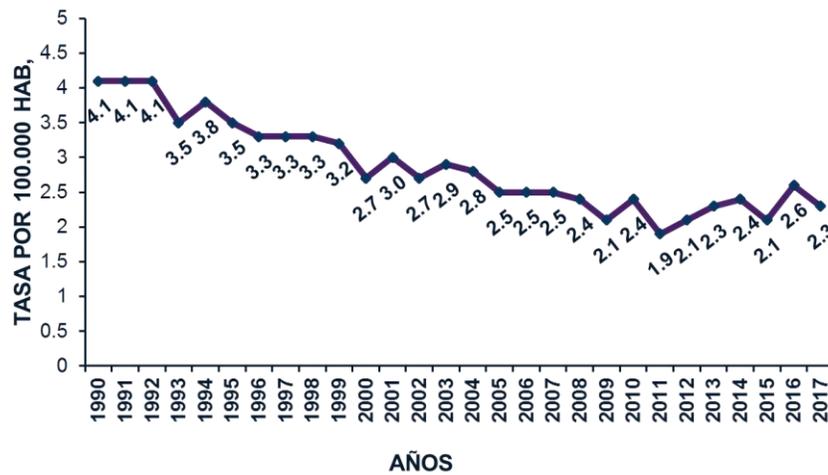
In the Bolivarian Republic of Venezuela, the number of TB cases increased by 41 percent between 2014 (6,063 cases) and 2017 (10,185 cases based on preliminary data), with an incidence rate of 32.4 per 100,000 population, the highest in more than 40 years (**Figure 1**). Half of the cases are within Distrito Capital, plus four other states: Zulia, Miranda, Carabobo and Anzoátegui. In 2017, the increase in cases was concentrated among men aged 15–34 in the economically active population.

**Figure 1. Notified incidence of tuberculosis, Venezuela, 1990–2017**



The downward trend in mortality ended in 2009, after which the rate hovered around 2.2 per 100,000 population until 2015. For 2016, the provisional notified mortality rate was 2.6 per 100,000 population, while the estimated rate was 3 per 100,000 population (**Figure 2**).

**Figure 2. Tuberculosis mortality, Venezuela, 1990–2017**



In 2017, about 25 percent of all TB cases were among two vulnerable groups: prisoners (15.7 percent) and indigenous populations (6.8 percent). Additionally, some comorbidities accounted for almost 10 percent of cases (4.8 percent TB/HIV and 5 percent TB/diabetes). The latter has been on the increase in recent years (**Table 5**).

**Table 5. New cases of tuberculosis among vulnerable populations, Venezuela, 2017**

GRUPOS	TODAS FORMAS		BK (+)	
	N°	%	N°	%
Casos TB en PVVIH	493	(4,8%)	192	(2,8%)
Casos TB en Diabéticos	506	(5,0%)	361	(5,30%)
Casos TB en privados de libertad	1598	(15,69%)	1427	(20,94%)
Casos TB en personal de salud	184	(1,8%)	87	(1,28%)
Casos TB en inmigrantes con menos de 2 años en el país	96	(0,94%)	72	(1,05%)
Casos TB contactos de TB RR/MDR/XDR	14	(0,14%)	9	(0,13%)
Casos TB en Población Indígena	698	(6,8%)	489	(7,2%)

The proportion of cases of respiratory symptoms with a positive bacilloscopy indicates a significant delay in diagnosis. The average for the country is 11 percent; however, this value is exceeded in 12 states, with the highest value close to 25 percent.

In 2018, TB treatment coverage (notified cases/estimated incidence) was 80 percent, failing to reach the 2016 target of 85 percent. In the 2014–2017 period, DR-TB cases almost doubled, from 39 to 79 cases. HIV testing coverage in TB patients showed an upward trend until 2014, when it reached 80 percent; since then it has progressively decreased, dropping to 60 percent in 2017.

Unless urgent and effective measures are taken to reverse the current trend, these figures will make it difficult for Venezuela to achieve the milestones and targets set out in the End TB Strategy (Table 6).

**Table 6. Progress and shortcomings in achieving key TB prevention and control targets**

	Progress			2020 milestone	2030 target
	2015	2016	2017		
Reduction in the number of TB deaths*	634	801	737	↓35%** 441	↓90%** 74
Reduction in TB incidence rate*	22.2	25.2	32.4	↓20%** 17.8	↓89%** 2.5
Percentage of families affected by TB facing catastrophic costs	No data	No data	No data	0%	0%

\*Provisional data \*\*for 2015

### 2.3 Malaria situation

There is an epidemic in nine states (Bolívar, Amazonas, Sucre, Monagas, Delta Amacuro, Anzoátegui, Nueva Esparta, Miranda and Zulia), with an increase in the spread of malaria to new municipalities and parishes within municipalities already affected.

Bolívar state continues to record the largest number of cases and influence the spread of malaria to other parts of the country. Compared with 2017, in 2018 there has been an increase in the number of cases and an increase in the spread of the disease (new municipalities and localities). Mass migration due to mining activities remains the main factor behind transmission and the spread of malaria, both in Bolívar state and the country. By week 22 of 2018, there had been 97 deaths from malaria (compared with 214 in 2017). Urbanization of malaria transmission is continuing in some municipalities (Caroní, El Callao and Heres) and relapses have been on the increase.

Amazonas state saw a huge increase in transmission in 2017. Despite a 20 percent reduction in the total number of cases reported by week 23 of 2018, there was a high dispersal of transmission

in multiple locations within municipalities and new instances of transmission in historically non-malarial areas. The transmission dynamic in the state is linked to an increase in mining activity and the expansion of mining areas in some of the state's municipalities, which is influencing population movement within the state and in Bolívar's mining areas. In turn, the movement of infected populations turns susceptible localities into active outbreak locations. The city of Puerto Ayacucho has the highest disease burden, which means it has a greater potential for epidemic and the spread of the disease to other parts of the state. Reported malaria mortality is low (six deaths in 2018), but there is thought to be under-reporting of registered deaths in the system in remote locations.

Sucre state recorded an increase of 14 percent in week 17 of 2018 compared with the same period in 2017, when the state experienced a massive increase in epidemic behavior in several municipalities. The state is seeing an increase in the number of municipalities and localities with malaria transmission (greater dispersion) and a transmission dynamic related to population movements from several municipalities to the mining area in Bolívar. The existence of a large, historically susceptible territory has resulted in unique transmission behavior in multiple outbreak locations. There is a marked prevalence of malaria caused by *P. vivax* and a concentrated area of transmission by *P. falciparum* (aim to eliminate the latter). The number of recorded deaths is low, but there are cases of severe malaria caused by *P. vivax* due to delays in starting treatment.

Malaria has been reintroduced into susceptible areas, creating new transmission outbreak locations with their own dynamics. This is the case in Anzoátegui, where between 2016 and 2017, the number of malaria cases rose by 1,341 percent. Malaria transmission initially affected a single parish in 2015, and spread to affect 18 parishes in 11 municipalities in 2017. By week 23 of 2018, more cases had been recorded than in the whole of 2017, when the disease exhibited epidemic behavior. The following points should be noted: (i) transmission dynamic is influenced by population movement to Bolívar state and the transit of people from Sucre seeking out mining activities in Bolívar; (ii) significant reports of cases imported from Bolívar and Sucre, although predominantly autochthonous cases; (iii) active outbreak locations have emerged, displaying their own transmission dynamics; (iv) predominance of urban transmission outbreak locations (city of Barcelona, which is highly susceptible and vulnerable to the disease); (v) high mortality rate (from malaria) in relation to the number of cases (41 deaths in 2018, i.e. 1 percent versus 0.5 percent for the whole of 2017); (vi) high relapse rate.

### 3. Health systems situation

#### 3.1 Health system and services

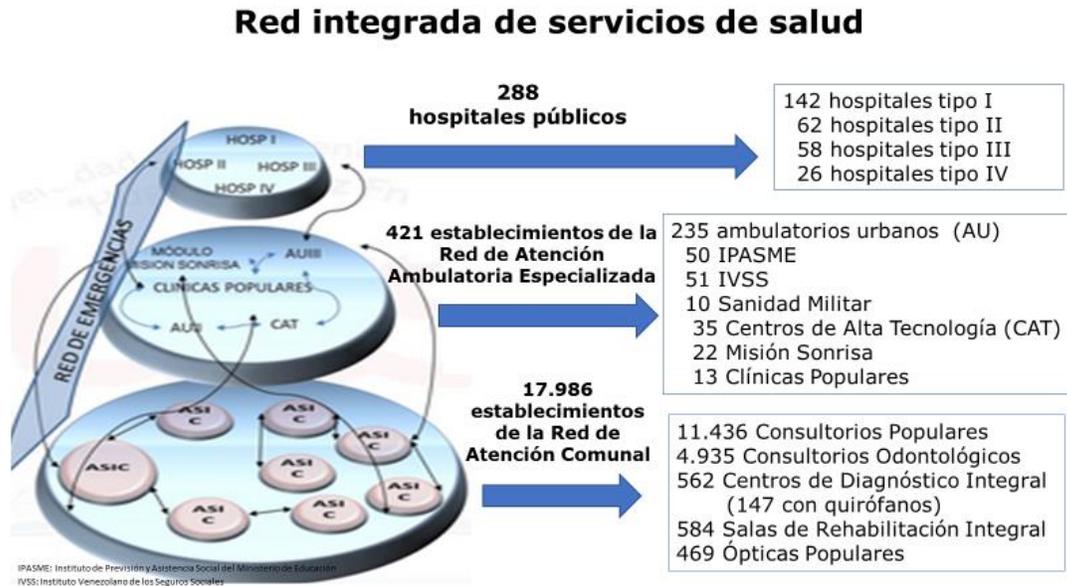
In Venezuela's National Public Health System (SPNS), the integrated community health areas (ASIC) are considered the basic integration units within the network. They serve as geopolitical and operational areas that coordinate communities to provide a comprehensive, universal, equitable and free response with a family- and community-based approach (**Figure 3**). The *Barrio Adentro* strategy prioritizes health promotion and disease prevention, without neglecting recovery and rehabilitation actions.

**Figure 3. Distribution of the integrated community health areas (ASICs) at the national level**



Health service networks are made up of a community health care network; a specialist outpatient care network and a hospital network (**Figure 4**).

Figure 4. Integrated health services network



The community health care network corresponds to all intersectoral community-based institutions, services and actions within the SPNS, and is based on a comprehensive care model and management model, which are adapted to the circumstances of each area. It adopts an inter-institutional and intersectoral approach with active community participation. The network is organized through the ASICs, which include: comprehensive diagnosis centers (CDIs), comprehensive rehabilitation services and people’s clinics, including dental clinics and opticians (Figure 5).

Figure 5. Institutions in the community health care network

### Establecimientos de la Red de Atención Comunal de Salud

#### Consultorios Populares tipo 1

- 200 familias o 1000 personas
- Lo atiende un promotor de salud supervisado por médico

#### Consultorios Populares tipo 2

- 200-500 familias o 1000-2500 personas
- Cuenta con un equipo básico de salud (médico, enfermero y promotor)

#### Consultorios Populares tipo 3

- Más de 500 familias o 2500 personas
- Cuenta con uno a tres equipos básicos de salud

#### Consultorios Odontológicos Populares

- Atienden entre 3 y 8 consultorios populares
- Cuenta con un equipo básico de salud bucal (odontólogo y técnico)

#### Ópticas Populares

- Atienden un mínimo de 5 ASIC
- Cuenta con un equipo básico de salud visual (optometrista y técnico)

#### Centros de Diagnóstico Integral

- Atienden la población de un ASIC, 24 horas
- Cuentan con un equipo multidisciplinario de salud (médicos, especialistas, enfermeras, oftalmólogo, técnicos, farmacéutico, personal de apoyo gerencial y de mantenimiento).

#### Salas de Rehabilitación Integral

- Atienden la población de un ASIC
- Cuentan con un grupo multidisciplinario de salud del área de rehabilitación integral (fisiatra, fonoiatra, técnicos en terapia física, terapia ocupacional, terapia del lenguaje, psicología, trabajo social y podología).

**Su organización geográfica y poblacional está referenciada por las Áreas de Salud Integral Comunitaria (ASIC).**

The CDIs offer the following:

- **Care services for the population:** accident and emergency, observation room, intensive and intermediate care unit, general surgery (not in all CDIs), orthopedics and traumatology, minor outpatient surgery, delivery rooms (only those that are authorized), neonatal care and pediatric units.
- **Diagnostic services:** including clinical laboratory, ultrasonography, X-ray, endoscopy, Ultra Micro-analysis System (SUMA) laboratory (only those that are authorized) and electrocardiography.
- **Medical clinics:** ophthalmology, general surgery, orthopedic trauma, gynecology and pediatrics (not in all).
- **Care support services:** coordination office, reception and waiting room, pharmacy and supplies repository, sterilization area and statistics department.

The specialist outpatient care network incorporates comprehensive dental care centers, advanced technology centers (CATs) and surgical and specialist clinics. The hospital network has 288 public hospitals with care complexity levels ranging from level I to IV.

Currently, the HIV and AIDS, TB and malaria programs are essentially supported by the Ministry of Health (MPPS) establishments. However, there is significant potential for improvement, were the capacity of the three public sector networks to provide services and epidemiological analysis to be integrated. The formally approved integration structure is the ASIC, which will require significant consolidation efforts over the coming months. This integration process should involve updating the classification and functions of facilities such as the current health districts within the new ASIC-based structure.

As a medium-term strategy, comprehensive care provided within the health network, with an emphasis on prioritized programs, will be coordinated by ASICs within their area of influence.

Incorporating the Venezuelan Institute of Social Security (IVSS) and the Ministry of Education Staff Pensions and Welfare Institute (IPASME) into the health services network will increase the response capacity in urban areas across the public sector.

### **3.2 Human resources**

The National Training Program for Comprehensive Community Medicine (PNFMIC) was established in 2005 to address shortfalls in staff, with training focused on primary and community care. Actions were undertaken jointly by the Ministry of Higher Education (MPPES) and the educational program *Misión Sucre*, with the Ministry of Health coordinating the *Barrio Adentro* social program. These actions are geared toward training new health professionals, with support provided by the *Misión Médica Cubana* (Cuban Medical Mission) and Venezuelan universities. Comprehensive community doctors (MICs) trained on this program are incorporated into the SPNS to meet primary care needs at the national level. To date, 23,990 comprehensive community doctors have graduated in seven cohorts, 12,269 of whom specialized as comprehensive general practitioners (MGIs).

One of the challenges facing Venezuela is the migration of health professionals and workers. According to the country's Doctors' Federation, it is estimated that of the 66,138 doctors registered in the country in 2014, 22,000 migrated. It is also estimated that 6,000 laboratory workers and between 3,000 and 5,000 nurses migrated.

### 3.3 Access to HIV prevention, diagnosis, comprehensive care and treatment services

#### HIV testing services

Up until 2015, there were 127 public health centers, public health laboratories or blood banks operating in the country, distributed across all federal entities, working to detect HIV antibodies. Currently, 57 laboratories have the capacity to run ELISA tests and 42 can perform Western Blot tests (Table 7).

**Table 7. Public institutions carrying out HIV testing (2015) and with laboratory capacity to perform HIV screening and confirmation tests (2018), by federal entity**

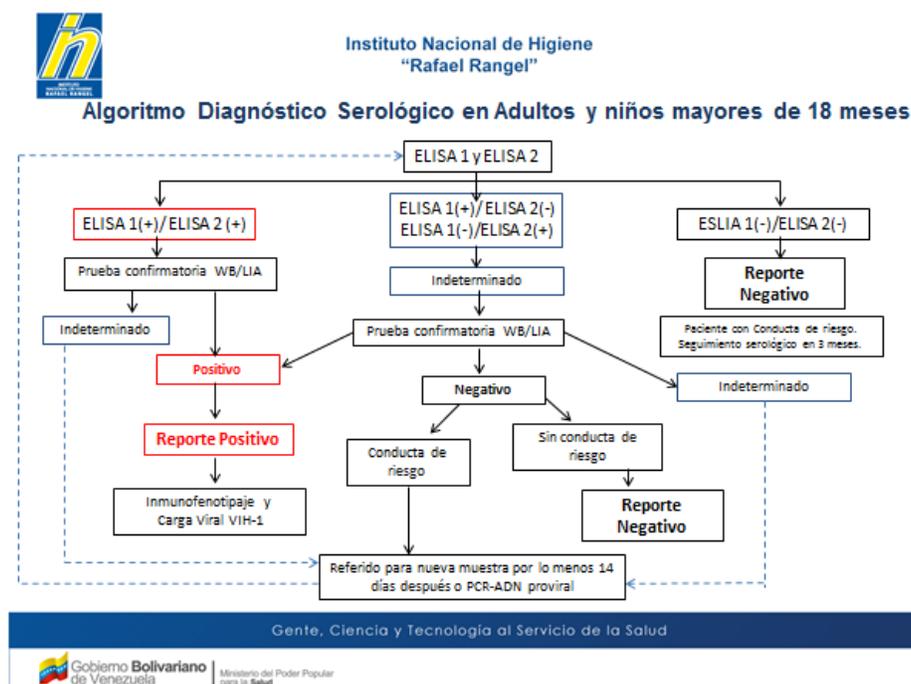
Federal entity	No. of institutions carrying out testing (2015)	No. of laboratories for HIV screening and confirmation tests
Amazonas	2	1
Anzoátegui	10	2
Apure	3	1
Aragua	6	1
Barinas	2	1
Bolívar	11	2
Carabobo	7	7
Cojedes	2	1
Delta Amacuro	3	1
Distrito Capital	15	3
Falcón	6	3 ELISA, 1 Western Blot
Guárico	6	5
Lara	3	4
Mérida	3	1
Miranda	4	2
Monagas	3	1
Nueva Esparta	3	1
Portuguesa	3	1
Sucre	5	2 ELISA, 1 Western Blot
Táchira	6	1
Trujillo	2	4 ELISA, 1 Western Blot
Vargas	2	1
Yaracuy	2	1

Zulia	18	10 ELISA, 1 Western Blot
Total	127	57 ELISA, 42 Western Blot

\* Source: NACP and 2016 Progress Report

HIV tests for adults and for children aged over 18 months are only carried out in laboratories that have the capacity to diagnose HIV according to the current algorithm based on 3rd and 4th generation ELISA tests, and a confirmation test using Western Blot (**Figure 6**).

**Figure 6. Serological diagnosis algorithm in adults and children over 18 months**



A medical referral is required in order to access HIV testing. To date, the voluntary counseling and testing model has not been implemented and, despite the development of an updated algorithm based on the use of rapid HIV testing, a baseline document and an implementation plan with funding (priorities: pregnant women, indigenous populations, prisons), progress has yet to be made in decentralizing access to rapid testing at the primary care level (with the exception of a limited number of rapid tests for pregnant women in 2017/2018). This has mainly been due to the lack of resources allocated by the Ministry of Health. Equally, community screening strategies and testing by trained peers have yet to be implemented.

There are currently no 4th generation ELISA or Western Blot tests available (supplies procured by the Ministry of Health; approximate costs: 4th generation ELISA – US\$ 232/96 tests; Western Blot – US\$ 11/test) (**Table 8**). The INH has reagents for 3rd generation ELISA tests (procured by the INH) (**Table 9**). However, due to the lack of reagents for Western Blot and viral load tests, there is currently no capacity to confirm HIV diagnosis. This has had a significant impact on the

capacity to detect HIV cases and, as such, doctors are relying on their clinical judgment to diagnose people presenting AIDS symptoms.

**Table 8. HIV serology, INH-processed samples per year (2010–2018)**

YEAR	HIV serology (4th generation)		Western Blot	
	Processed samples	Positive samples	Processed samples	Positive samples
2010	2,330	805	842	800
2011	2,080	817	831	816
2012	1,728	801	806	800
2013	2,060	1,127	1,035	1,025
2014	1,849	1,048	246	236
2015	4,559	2,400	661	628
2016	5,690	2,388	1,061	1,055
<b>2017</b>	<b>656</b>	<b>160</b>	<b>0</b>	<b>0</b>
<b>2018</b>	<b>42</b>	<b>0</b>	<b>0</b>	<b>0</b>
	<b>20,994</b>	<b>9,546</b>	<b>5,482</b>	<b>5,360</b>

Source: INH

\*Information updated as at 18 June 2018.

**Table 9. HIV serology, samples processed in public health laboratories per year**

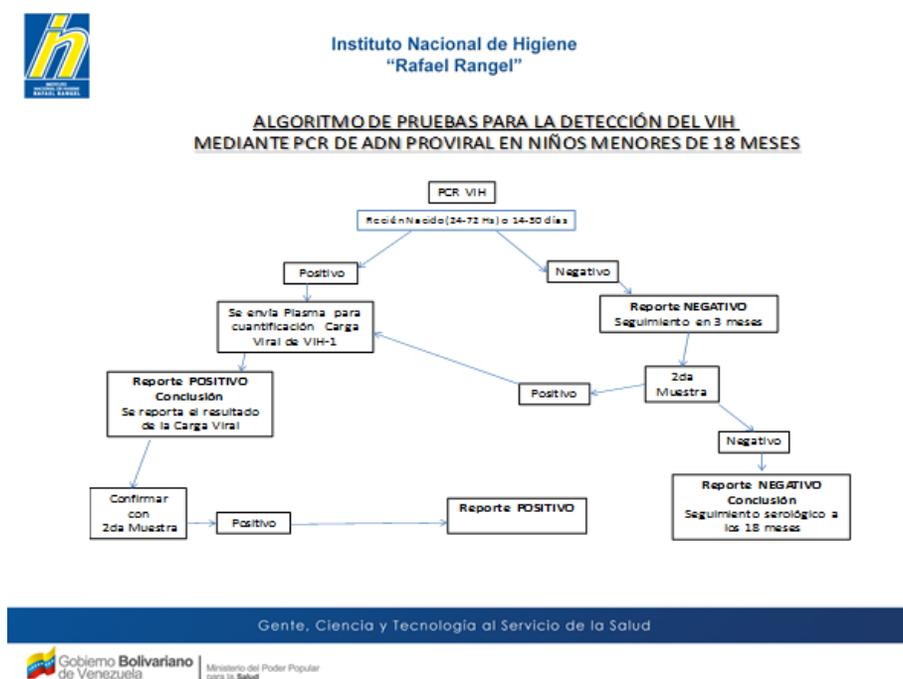
YEAR	HIV serology (3rd generation)	
	Processed samples	Positive samples
2010	182,577	3,955
2011	194,445	4,472
2012	226,117	5,231
2013	220,539	5,260
2014	193,967	5,135
2015	221,022	5,626
2016	226,570	4,801
2017	225,877	7,165
<b>2018</b>	<b>73,770*</b>	<b>1,219</b>
<b>Total</b>	<b>1,691,114</b>	<b>42,864</b>

Source: INH

\*Information updated as at 30 May 2018.

Early diagnosis in children exposed to the disease is performed through DNA PCR testing (Figure 7) that is centralized in the INH, with the plan being to receive samples from all states. Despite the shortage of reagents, the service has not been disrupted, although the number of samples processed has fallen significantly (Table 3).

**Figure 7. Testing algorithm for HIV detection using proviral DNA of children under 18 months**



Blood banks are incorporated into hospital facilities. There are 339 blood banks affiliated with the various institutions that form part of the national health system. However, there are currently no supplies available in the country to assess blood quality. This may have a significant health impact on HIV prevalence among the general population and, consequently, on the profile of the epidemic.

### Preventive supplies

At present, condoms and lubricants are not being distributed within integrated health services to PLHIV, nor within the primary care network.

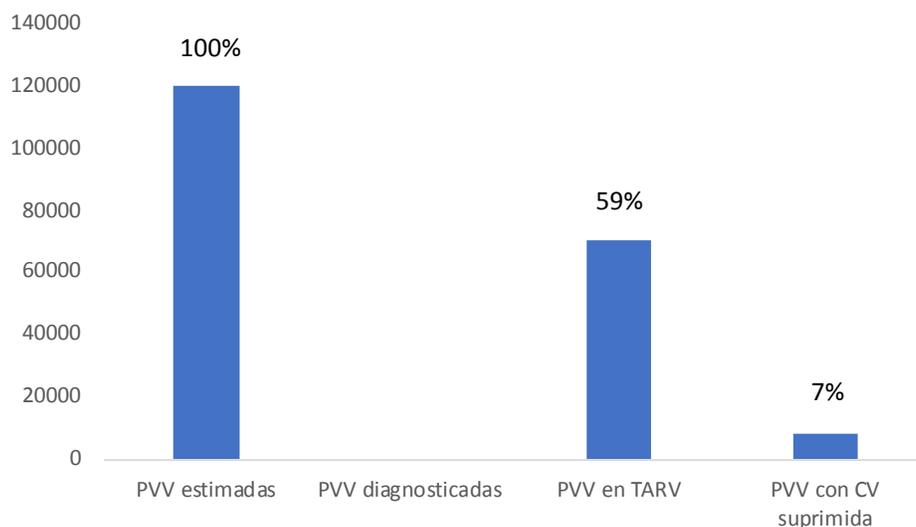
### Comprehensive HIV care and treatment

Under the NACP, the Ministry of Health has been providing free ART to PLHIV since 1999. Since 2016, it has a policy of providing ART to all PLHIV, regardless of their CD4 count. Of the estimated total of 120,000 PLHIV in 2016, 59 percent (55–67 percent, i.e. 71,210 people undergoing treatment) had access to ART and approximately 7 percent had a suppressed viral load.<sup>5</sup> **Figure**

<sup>5</sup> UNAIDS. 2017 data. [http://www.unaids.org/en/resources/documents/2017/data\\_book](http://www.unaids.org/en/resources/documents/2017/data_book)

8 presents the latest available data on the comprehensive care cascade and the 90–90–90 targets in Venezuela. Data for 2017 are not yet available.

**Figure 8. Comprehensive care and HIV treatment cascade and 90–90–90 targets, Venezuela (2016)**



<b>90% of all people living with HIV will know their HIV status</b>	<b>90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy</b>	<b>90% of all people receiving antiretroviral therapy will have viral suppression</b>
<b>Data not available</b>	<b>Not available 59% PLHIV estimated to be receiving ART</b>	<b>12%</b>

**Source: UNAIDS (2017)**

Comprehensive care and ART are currently provided to the majority of PLHIV in 91 specialist clinics located in level III or IV hospitals in the public sector, with each state having at least one clinic (there was an 11 percent increase in clinics between 2015 and 2018) (**Table 10**). A smaller number of PLHIV receive care in facilities affiliated with the military health service, IVSS and PDVSA (all of which are included in the central database of the NACP which provides ART at the national level).

Clinical follow-up for PLHIV is generally carried out by specialist physicians. However, in three states (Yaracuy, Amazonas and Nueva Sparta), PLHIV attend specialist clinics in neighboring states due to a lack of health care professionals (**Table 10**).

ARVs are dispensed in 51 pharmacies located near the HIV clinics (there was a 13 percent increase in the number of dispensing points between 2015 and 2018). These clinics fall under the supervision of 24 state coordinating bodies (one in each state) that monitor the inventory of ARVs and request monthly distributions from the NACP in accordance with consumption and stock levels.

To date, no plans have been made to start decentralizing comprehensive care and treatment to less complex health care facilities. However, the joint mission team agreed that this would be a medium/long-term priority once staff training needs have been addressed and referral/repeat visit and specialist monitoring processes have been determined.

**Table 10. HIV clinics, specialists and ARV dispensing centers (2015–2018)**

States	No. of clinics (2015)	No. of clinics (2018)	No. of ARV dispensing centers (2015)	No. of ARV dispensing centers (2018)	No. of specialists (2018)
AMAZONAS	2	1	1	1	0
ANZOATEGUI	4	4	6	6	4
APURE	2	2	1	1	2
ARAGUA	7	4	3	3	8
BARINAS	2	1	1	1	1
BOLIVAR	3	5	2	2	12
CARABOBO	6	5	2	2	13
COJEDES	2	2	1	1	2
DELTA AMACURO	1	2	1	1	1
DISTRITO CAPITAL	15	13	10	9	18
FALCON	3	9	1	4	6
GUARICO	3	1	1	1	3
LARA	5	6	2	2	5
MERIDA	2	5	1	1	3
MIRANDA	3	2	1	2	5
MONAGAS	2	10	1	1	12
NUEVA ESPARTA	2	0	2	1	0
PORTUGUESA	2	1	1	4	1
SUCRE	2	3	2	2	3
TACHIRA	3	2	1	2	5
TRUJILLO	2	3	1	1	3
VARGAS	1	2	1	1	1
YARACUY	2	0	1	1	0
ZULIA	6	8	1	1	20
<b>TOTAL</b>	<b>82</b>	<b>91</b>	<b>45</b>	<b>51</b>	<b>128</b>

\*Source: NACP

According to the NACP database, 79,467 PLHIV were undergoing treatment in Venezuela at the end of 2017. However, in the first quarter of 2018, the NACP carried out a review of the database with state coordinating bodies, following which this number was updated to 69,677 people receiving ART. This discrepancy may be due to various factors (e.g. duplicate data, deaths,

migration of PLHIV), although it is not possible to measure how each one specifically impacts the figures. **Table 11** shows the number of PLHIV undergoing treatment by state, up to date for 2018.

Since 2017, the economic crisis has led to difficulties in the supply of ARVs, such that there have not been enough to cover all patients' ART regimens. These supply issues have also affected drugs for prophylaxis and treatment of opportunistic infections, and reagents for CD4, viral load and resistance tests, thus compromising continued access to ART and adequate laboratory monitoring.

**Table 11. Number of people undergoing treatment and proportion that received drugs, by state (April 2018)**

States	No. of PLHIV in treatment (updated 2018)	No. of PLHIV who received ARVs in April 2018	% of ARV coverage
AMAZONAS	671	155	23
ANZOATEGUI	3,581	572	16
APURE	301	35	12%
ARAGUA	2,756	468	17
BARINAS	1,386	458	33
BOLIVAR	4,998	797	16
CARABOBO	4,296	447	10
COJEDES	284	28	10
DELTA AMACURO	249	15	6
DISTRITO CAPITAL	20,304	4,060	20
FALCON	983	98	10
GUARICO	727	72	10
LARA	2,918	466	16
MERIDA	2,500	149	6
MIRANDA	587	58	10
MONAGAS	3,580	843	24
NUEVA ESPARTA	1,475	177	12%
PORTUGUESA	735	73	10
SUCRE	1,108	110	10
TACHIRA	5,078	195	4
TRUJILLO	543	54	10
VARGAS	860	77	9
YARACUY	420	42	10
ZULIA	9,337	1,588	17
<b>TOTAL</b>	<b>69,677</b>	<b>11,037</b>	<b>16</b>

Source: NACP

\*Cleaned data (2018)

**Tables 12 and 11** provide data on ARV distribution to states in 2018, and on people undergoing treatment and ART coverage in April 2018, respectively. Both tables show significant gaps in the continuity of supplies and in access to ARVs in all states, and that approximately 58,000 PLHIV would be facing a drug shortage from April 2018, if not before. In interviews with key informants, stock-outs were also confirmed for approximately 70 percent of children with HIV receiving

follow-up at the José Manuel de Los Ríos Children's Hospital in Caracas, with stock-outs lasting approximately four months, on average.

**Table 12. Distribution of antiretrovirals in 2018**

Number	Type of supply	First distribution, 23 Feb 2018 (tablets)	Second distribution, 19 Apr 2018 (tablets)	TOTAL
1	ABACAVIR ORAL SOLUTION 20 mg/ml x 240 ml	400	329	729
2	ABACAVIR 300 mg x 60 tablets	93,960	111,120	205,080
3	ABACAVIR/LAMIVUDINE 60 mg/30 mg x 60 dispersible tablets	0	56,400	56,400
4	ABACAVIR/LAMIVUDINE 600 mg/300 mg x 30 tablets	417,990	225,240	643,230
5	ABACAVIR/LAMIVUDINE/ZIDOVUDINE 300/150/300 mg x 60 tablets	13,740	12,660	26,400
<b>6</b>	<b>ATAZANAVIR/RITONAVIR 300/100 mg x 30 tablets</b>	<b>83,100</b>	<b>0</b>	<b>83,100*</b>
7	DIDANOSINE 400 mg x 30 capsules	0	0	0
8	DARUNAVIR 600 mg x 60 tablets	0	0	0
9	EFAVIRENZ 200 mg x 90 capsules	4,860	4,140	9,000
10	EFAVIRENZ 600 mg x 30 capsules	0	0	0
<b>11</b>	<b>EFAVIRENZ/EMTRICITABINE/TENOFOVIR (EFV/FTC/TDF) 600 mg/200 mg/300 mg x 30 tablets</b>	<b>0</b>	<b>660</b>	<b>660**</b>
12	ENFUVRTIDE 90 mg/ml x 60 vials	120	120	240
13	ETRAVIRINE 100mg x 120 tablets	0	0	0
14	TENOFOVIR DISOPROXIL FUMARATE 300 mg x 30 tablets	0	0	0
15	TENOFOVIR/EMTRICITABINE 300 mg/200 mg x 30 tablets	0	30	30
16	LAMIVUDINE 10 mg/ml x 240 ml	532	161	693
17	LAMIVUDINE 150 mg x 60 tablets	412,440	0	412,440
18	LAMIVUDINE/ZIDOVUDINE 30 mg/60 mg x 60 dispersible tablets	0	83,700	83,700
19	LAMIVUDINE/ZIDOVUDINE 30 mg/60 mg x 60 tablets	0	0	0
20	LOPINAVIR/RITONAVIR 80/20 mg x 160 ml	280	281	561
21	LOPINAVIR/RITONAVIR 100/25 mg x 60 tablets	0	180	180
<b>22</b>	<b>LOPINAVIR/RITONAVIR 200/50 mg x 120 tablets</b>	<b>0</b>	<b>0</b>	<b>0**</b>
23	NEVIRAPINE 200 mg x 60 tablets	25,860	30,900	56,760
24	RALTEGRAVIR 400 mg x 60 pills	100,620	68,400	169,020
25	RITONAVIR 100 mg x 30 tablets	0	0	0
26	ZIDOVUDINE 10 mg/1ml x 200 ml	174	148	322
27	ZIDOVUDINE 100 mg x 60 capsules	7,400	3,240	10,640
28	ZIDOVUDINE 300 mg x 60 tablets	259,500	0	259,500
29	ZIDOVUDINE 20 mg/ml x 20 ml	0	40	40
	<b>TOTAL</b>			<b>2,018,725</b>

Source: NACP

**Notes.**

\*Used in alternative first- and second-line treatment regimens, with approximately 12,145 people using this drug (delivery of 2,770 treatments for one month in April 2018).

\*\*First-line treatment regimen, with approximately 28,590 people using this regimen (delivery of 22 treatments for one month in April 2018).

**\*\*\*Used in alternative first- and second-line treatment regimens, with approximately 18,890 people using this drug (no delivery in 2018).**

RVG+ and Citizen Action Against AIDS (ACCSI) are working together to monitor ARV stocks in dispensing centers, using monitors in most states of the country, and the data presented during the mission are in line with the information reported by the NACP (see stock-outs reports at [www.accsi.org.ve](http://www.accsi.org.ve)). This task is undertaken by monitors, PLHIV and RVG+ members from each state of the country, who visit each of the ARV dispensing centers on a monthly basis, check the quantities of bottles of drugs and record them on a form designed for this purpose. Information gathered from PLHIV during their visits to ARV dispensing centers is also included, to indicate whether they received their drugs. The RVG+ monitors then send the forms containing the information gathered via various channels (Internet, WhatsApp and/or text messages) to ACCSI. An ACCSI working group is responsible for loading the data and information into an Excel database, analyzing and compiling them systematically, and producing monthly reports. These reports give an indication of the country's ARV stock levels, while also justifying and bringing about advocacy actions to support PLHIV in gaining access to ART in Venezuela.

Amid ARV shortages, although incomplete treatments have not been delivered in dispensing centers, interviews with key informants during the mission revealed that there were cases of intermittent drug use, partial self-dosing (e.g. half the daily dose), incomplete treatments, Monday-to-Friday treatment and use of expired ARVs. Aside from going against recommendations, these practices run the considerable risk of creating drug resistance and compromising the effectiveness of treatment. They also risk transmitting and spreading resistance to the population.

### **Prevention of mother-to-child transmission of HIV**

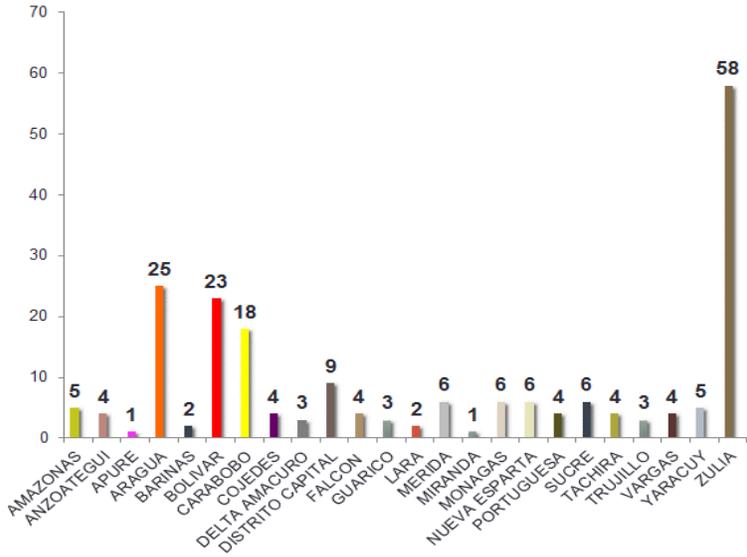
Despite the high coverage of hospital childbirth (>95 percent), coverage of prenatal care in the outpatient network is limited (less than a third of pregnant women attend four consultations or more). Among pregnant women living with HIV, 48 percent (42–53 percent) had access to treatment to prevent mother-to-child transmission in 2016. To improve HIV testing coverage among pregnant women, a pilot intervention for rapid diagnostic tests is being implemented in maternity facilities. At present, milk substitutes are not being offered to children exposed to the disease, with the exception of certain amounts provided by external assistance (e.g. from Caritas). **Table 13 and Figure 9** show data on the number of pregnant women with HIV detected between 2007 and 2016 and partial data for 2018.

**Table 13. Number of pregnant women with HIV, per year (2007–2016)**

Year	Number of pregnant women
2007	374
2008	335
2009	233
2010	272
2011	285
2012	348
2013	432

2014	559
2015	761
2016	331
<b>Total</b>	<b>3,930</b>

**Figure 9. Number of pregnant women, by state (2018)**



Source: NACP, Ministry of Health

**Laboratory monitoring**

The HIV viral load test is carried out in five laboratories across the country (Anzoátegui, Aragua, Carabobo, Distrito Capital, Mérida and Zulia) with a sample referral system for states that do not have capacity to perform this (Table 14). In the east of the country, there is no installed capacity and samples are sent to the INH in Caracas.

In 2016, the INH planned reagents for approximately 80,000 viral load tests (less than estimated for implementing the national viral load monitoring policy twice a year for each PLHIV undergoing ART). Procurement is through open tenders and the INH reports a cost of about US\$ 49 per test.

The last order for nearly 13,000 viral load tests (which was insufficient to monitor all those undergoing treatment) was received in July/August 2017. Since late 2017, there have been no viral load reagents at the INH, which has the highest number of samples. The week before the mission, reagents were moved from the Mérida laboratory to the INH to cover approximately 670 tests. These supplies were exhausted within a few days, with priority given to newly diagnosed cases, pregnant women, infants, children and adolescents, older adults, and inpatients and outpatients with evident organ failure. Equipment is currently available on loan from Roche and includes an operational technical maintenance service. This is despite the fact that there have been no purchases from the manufacturer within the last year.

In terms of monitoring viral load in children with HIV within the country, it is important to note that although in some cases, blood samples are taken in Ministry of Health laboratories and sent by public transport to the Rafael Rangel National INH in Caracas, in other cases, HIV-positive mothers and their children with HIV are taken by bus to the INH in person, sometimes traveling for over 14 hours.

Although there is capacity to carry out viral load testing in private laboratories (at an approximate cost of 26 million Bolivars), the Venezuelan Institute for Scientific Research (IVIC) only has a capacity of about 200 tests per month and at the IVSS, testing is only available to those with insurance.

CD4 counting equipment (BD FACSCount) is available on loan in 18 public health laboratories in the 24 states (**Table 14**) and with maintenance included. However, reagents have not been purchased and tests have not been carried out for more than a year. The cost per test is approximately US\$ 30.

The INH previously had the capacity to carry out HIV-resistance testing using the TruGene genotyping kit until it was discontinued by Siemens in 2015 (240/year). It also has the capacity to perform genotyping using an in-house method thanks to technology shared by IVIC (Dr Flor Pujol ). This in-house method has been validated as equivalent to the TruGene method. The in-house method requires the use of an Applied Biosystems 3500 Genetic Analyzer (Hitachi). There are currently no reagents available and no resistance tests have been carried out since 2016. There used to be a resistance committee that met monthly to review requests and genotyping test results, in order to advise on changes to treatment regimens. The INH has an Illumina MiSeq system for end-to-end sequencing. It also conducts serology for hepatitis B, hepatitis C and bacterial serology (cryptococcal, histopathology) for screening and diagnosing co-infections and opportunistic infections.

INH audits, monitors and oversees state laboratories, but for about 10 years, the INH and the other public health laboratories have not participated in external quality control programs.

**Table 14. Laboratory capacity for viral load and sample references**

States	Viral load equipment (COBAS AmpliPrep/TaqMan HIV-1 Roche) (2018)	Reference lab for viral load tests	CD4 laboratory capacity (BD FACSCount) (2018)	Staff for immunovirological testing
AMAZONAS		DISTRITO CAPITAL	x	
ANZOATEGUI	x**	ANZOATEGUI	x	2
APURE		ARAGUA		
ARAGUA	x**	ARAGUA	x	2
BARINAS		DISTRITO CAPITAL		
BOLIVAR		DISTRITO CAPITAL	x	
CARABOBO	x**	CARABOBO	x	3
COJEDES		CARABOBO		
DELTA AMACURO		DISTRITO CAPITAL	x	
DISTRITO CAPITAL*	x***	DISTRITO CAPITAL	x	4
FALCON		ZULIA	x	
GUARICO		ARAGUA	x	
LARA		ZULIA	x	
MERIDA	x**	MERIDA	x	3
MIRANDA		DISTRITO CAPITAL		
MONAGAS		ANZOATEGUI	x	
NUEVA ESPARTA		DISTRITO CAPITAL	x	
PORTUGUESA		MERIDA	x	
SUCRE		DISTRITO CAPITAL	x	
TACHIRA		MERIDA	x	
TRUJILLO		ZULIA		
VARGAS		DISTRITO CAPITAL		
YARACUY*		CARABOBO	x	
ZULIA	x**	ZULIA	x	2
<b>TOTAL</b>	<b>6</b>		<b>18</b>	<b>16</b>

Source: NACP, Ministry of Health and the INH

\*Plans to install additional equipment in 2018

\*\*COBAS AmpliPrep/TaqMan HIV-1 48 (Roche)

\*\*\*COBAS AmpliPrep/TaqMan HIV-1 96 (Roche)

### 3.4 Access to TB prevention, diagnosis and treatment services

#### TB health services

Interventions for TB prevention and control in Venezuela are part of the National Strategic Plan (NSP) for TB Prevention and Control 2016–2019. There are 3,858 health services that care for people with TB (including those that depend on the Ministry of Health (MPPS), ministries, municipalities and the Venezuelan Institute of Social Security (IVSS)). The National Tuberculosis Control Program (NTCP) does not receive information from the private service providers, comprehensive diagnosis centers (CDIs) or the people's clinics. However, there is potential to expand TB services by integrating 16,000 people's clinics and 10,000 doctors into the community care network of the Barrio Adentro Mission (primary care level).

The TB service network is organized by levels of care with defined roles: national, state, integrated community health area (ASIC) and/or district/municipal area, and by degree of complexity.

- The national level regulates the network and is responsible for epidemiological surveillance and programmatic management, in addition to interprogrammatic and cross-sector coordination; the national TB reference laboratory is reliant upon the NTCP and not upon the National Institute of Hygiene (referral center for public health laboratories), as it should be.
- The state level adopts the NTCP standard, programs activities in conjunction with the ASICs, calculates drugs and supplies, organizes and implements the transport of samples and delivery of results, and provides technical advice, supervision, monitoring and evaluation.
- The facilities at the ASIC level (district/municipal) adapt the actions carried out at the state level to their level. The CDIs and people's clinics implement the NTCP's operational activities in terms of prevention, diagnosis, treatment and follow-up.

All the health services visited experienced severe power and water outages, preventing their proper functioning and hygienic conditions, and each of them indicated recent thefts of equipment and materials that limit their ability to provide effective services.

Hospitals and clinics are triaged to identify people with respiratory symptoms and give them priority care. The active search for TB cases has fallen since 2010. In 2017, only 33 percent of anticipated respiratory symptoms were identified.

The system for the referral and counter-referral of people with TB, samples and results between the different levels of care falls largely to patients and their families. The dispatch of biological material and TB reports from the states to the national reference laboratory and the NTCP relies upon the willingness and resources of the program's health workers and of the patients' families.

Comorbidities (HIV, diabetes, etc.) are treated independently and, in the same way, access to services and referral and counter-referral fall to patients and their family. As there is currently no ELISA HIV testing in the public sector, the cost of testing is borne by the patient. There are no facilities with integrated TB/HIV care. Everything is conducted through referral between services.

There is little access to chest X-rays as a diagnostic tool among vulnerable populations, but if TB services were expanded to CDIs, many of the needs would be met.

All newborns are prescribed a Bacillus Calmette–Guérin (BCG) vaccination. According to the NTCP, this vaccine has good coverage and there are very few cases of meningeal TB.

Based on interviews with several TB patients, they experienced multiple consultations and treatments in different health care facilities prior to diagnosis, there were delays in their diagnosis, and in some cases they arrived at hospital in an advanced state of the disease. During field visits, it was noted that there is currently limited operational research to support NTCP decision-making.

In conclusion, the diagnosis and treatment of TB involves multiple services in various locations and at different times. This complexity affects patients and their families financially and in terms of their time, which leads to patients being lost to follow-up, late diagnosis and risk of death.

### **TB-specific human resources**

At the national level, the NTCP has a team of seven professionals:

- A doctor specializing in internal medicine and pneumology, and who is trained in public health
- A doctor specializing in epidemiology and pneumology, and who is trained in public health
- Two doctors specializing in epidemiology
- A bioanalyst specializing in public health
- Two bioanalysts with extensive training in public health
- It does not have any nurses.

At the state level, respiratory health in the 24 states is covered by:

- 20 doctors (except the states of Apure, Falcón, Lara and Mérida)
- 23 nurses (except Monagas)
- 18 bioanalysts (except Guárico, Miranda, Portuguesa, Trujillo, Vargas and Zulia)
- 2 social workers (only in Bolívar and Delta Amacuro)
- 2 public health inspectors (only in Barinas and Táchira).

The number of skilled TB human resources is falling, thereby increasing the burden on the remaining staff and reducing, among other things, the quality of care. In addition, according to research conducted by academics and scientific institutes, there has been a decrease in the number of teaching staff specializing in pneumology and TB in health care faculties. The training curriculum for medical and nursing careers appears to offer only minimal training on TB, suggesting that the NTCP needs to provide training to people entering these professions.

### **Diagnostic capacity of TB**

The national reference laboratory, which is part of the NTCP, develops norms and standards, maintains up-to-date information on the structure and activities of the laboratory network, centralizes the network information necessary for epidemiological surveillance and drives the quality management program. The national reference laboratory conducts bacilloscopy and culture testing and has a GeneXpert team. In addition, it is the only laboratory currently investigating first- and second-line drug susceptibilities using phenotypic and genotypic methods. The national reference laboratory is the head of the national network of TB laboratories but is not part of the National Institute of Hygiene, which is in charge of all public health networks in the country.

The network of TB laboratories has national coverage. Each state should have a TB reference laboratory and a coordinating bioanalyst, but only eight comply with this guideline. Currently, in the traditional public sector there are 232 sample-receiving centers, 160 laboratories performing bacilloscopy and another 8 laboratories that also perform culture testing. Due to the prevailing situation, the number of active laboratories within the network is decreasing, which has mainly affected the number of cultures tested. None of the CDI laboratories diagnose TB. Bacilloscopy is also performed in 148 private sector laboratories that are not integrated into the network, 15 of which are equipped with GeneXpert machines, but the number of tests carried out is unknown.

Bacilloscopy is the number one diagnostic test for TB in the country. In practice, GeneXpert testing is being used primarily to investigate rifampicin resistance (RR) among cases confirmed by bacilloscopy or culture testing in immunosuppressed patients, patients undergoing re-treatment, diabetics, prisoners, recent immigrants, health workers, drug-resistant TB case contacts, patients with a positive bacilloscopy at the end of the second month of treatment or later, pregnant women and homeless people. Detected cases of RR/MDR-TB and those are isoniazid resistant have access to second-line drug susceptibility testing.

Bacilloscopy is performed by the Ziehl Neelsen method with ready-to-use supplies purchased through the Pan American Health Organization (PAHO) Strategic Fund throughout the network of laboratories, with the exception of the national reference laboratory which uses fluorescence microscopy to diagnose TB. Samples are cultivated in solid media by the Petroff and Ogawa-Kudoh methods. Drug susceptibility is determined by GeneXpert, Line Probe Assay (LPA) for first- and second-line drugs and the ratio method. Reductase nitrate testing is also available, although the test is being replaced by molecular methods. In addition, *Mycobacterium tuberculosis* can be identified by lateral immunochromatography assay.

External quality control of bacilloscopy has also continued. In 2017, 61 percent of laboratories were evaluated and demonstrated good quality. The quality control program is led by the national reference laboratory and is decentralized in the Capital region and the eight states with a reference laboratory. The national reference laboratory demonstrated excellent quality in performing phenotypic susceptibility tests on external controls conducted by the Argentine Supranational Laboratory until 2013, when this control was suspended due to a failure to meet minimum biosafety conditions.

There is no functional system for transporting samples to be tested for TB. The transfer of samples from the health center to the laboratory usually falls to the patient, even though the sample must be delivered to the national reference laboratory which is located far from the capital, making it difficult to access even for patients living in Caracas. Sending materials from states to the national reference laboratory depends on the will and resources of the health workers themselves. This is the biggest barrier to accessing TB diagnosis, especially by WHO-recommended rapid methods. At the same time, it has a critical impact on the patient's treatment expenses.

Laboratory supply management is the responsibility of the Ministry of Health, in line with the requirements estimated by the national reference laboratory and presented by the NTCP. Interruptions in water and electricity supply and the very limited availability of sodium hypochlorite to be used as a disinfectant seriously compromise basic biosafety across the network. As several international visits have repeatedly pointed out, the national reference laboratory has outdated infrastructure and equipment, without preventive or corrective maintenance. It therefore does not meet the minimum biosafety standards defined by WHO for the type of tasks that it carries out. Health workers exposed to TB are not covered by a regular medical control program. There is a shortage of personal protective equipment (PPE) throughout the laboratory network.

The last purchase of laboratory reagents was made in 2016 by PAHO's Strategic Fund. Since 2015, there has been no shortage of bacilloscopy supplies. However, for the past month, the two GeneXpert teams in the country's public sector have been unable to diagnose TB due to a lack of cartridges. Cultures are limited by a lack of resources for purchasing very basic supplies (slides) and, as mentioned, there is a lack of basic disinfectants.

The laboratory information system is based on written records in formats defined by the NTCP. The limited availability of stationery and the lack of direct supervision and interconnectivity compromise the quality of the information collected.

The main laboratory limitations are:

- Lack of a system to transport samples.
- Inadequate national reference laboratory infrastructure and lack of network maintenance.
- Insufficient amounts of equipment and supplies for using GeneXpert as the first diagnostic TB test, even among priority groups.
- Inadequate national reference laboratory conditions to operate at high biological risk.
- Significant loss of trained staff.
- Lack of resources for supervision visits and (re)training.
- Lack of a digital information system and Internet connectivity.

## **TB treatment**

The TB treatment regimen has two phases: the first phase involves rifampicin, isoniazid, pyrazinamide and ethambutol in a fixed-dose combination of ten weeks (daily Monday to Friday) and the second phase involves rifampicin and isoniazid in a fixed-dose combination for 18 weeks (three times weekly), which is slightly longer than recommended by PAHO/WHO. Both phases are directly observed.

There are two regimens: Regimen 1 for patients aged 15 years and above and regimen 2 for children under 15. The difference is in the removal of ethambutol from regimen 2. For TB/HIV, the second phase is administered daily (Monday to Friday).

For patients with RR and MDR-TB, the treatment regimen is prescribed by a specialist physician and authorized by the National Committee for Monitoring the Resistance of TB Drugs. The patient is hospitalized until during the first phase or before if there is sputum conversion.

Contacts of a TB case are registered, but they are not strictly followed up. All contacts under five years of age and people living with HIV (PLHIV) undergo a purified protein derivative (PPD) skin test and those without active infection undergo preventive treatment with isoniazid for nine months.

**Table 15. Cohort results of new cases of TB for regimens 1 and 2, Venezuela (2016)**

NUMBER OF REGISTERED CASES		TREATMENT OUTCOMES									
		CURED		FAILED		DEATH		LOST TO FOLLOW-UP		NOT EVALUATED	
		No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage
NEW CASES AND RELAPSES	8,197	6,741	82.2	8	0.1	575	7.0	775	9.5	98	1.2
PREVIOUSLY TREATED (ABANDONMENT READMISSIONS)	345	215	62.3	15	4.3	11	3.2	15	4.3	89	25.8
HIV-POSITIVE NEW CASES AND RELAPSES	585	471	80.5	1	0.2	51	8.7	62	10.6	0	0

**Table 16: Cohort results of RR-MDR/TB and XDR/TB cases, Venezuela (2015)**

NUMBER OF REGISTERED CASES		TREATMENT OUTCOMES									
		CURED		FAILED		DEATH		LOST TO FOLLOW-UP		NOT EVALUATED	
		No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage	No.	Percentage
RR and MDR	31	22	71.0	1	3.2	4	12.9	4	12.9	0	
XDR	1	1	100	0	0	0	0	0	0	0	0

Cohort presentation and analysis do not follow the latest PAHO/WHO recommendations.

There were shortcomings in the food provided to patients hospitalized with TB. However, patients with TB diagnosis are entitled to two months' sick leave (from work).

### **3.5 Access to malaria prevention, diagnosis and treatment services**

#### **General findings**

- Late and inappropriate treatment helps drive malaria transmission and the ongoing risk of complications and mortality. The treatment of individuals is subject to a data audit regarding persistent stock-outs at the local level, late initiation of treatment and non-treatment of cases not approved in the audit.
- A massive reduction in the operability of the microscopy network due to a lack of diagnostic supplies, coupled with the poor condition of microscopes and limited availability of staff, have also reduced the diagnostic network's coverage.
- The malaria diagnosis quality management system is not operational.
- Though rapid diagnostic tests are readily available (in Amazonas and Sucre), there is an absence of programmatic action (in the areas of distribution, training and monitoring) for their implementation and sustainability.
- There has been progress in incorporating diagnosis (with rapid diagnostic testing (RDT)) into the health network (at people's clinics and CDIs) and through community agents, but the network to diagnose and manage cases, including all community services and actors in malaria outbreak locations, suffers from a lack of coordination.
- Active searches (proactive and reactive) for patients are almost non-existent due to widespread operational constraints.
- Vector control actions recommended for tackling malaria (indoor residual spraying (IRS) and long-lasting insecticidal nets (LLINs)) have not been implemented (lack of an up-to-date vector control guide).
- Duplication and fragmentation in the management and coordination of operations and management of malaria information processes.
- Unchanged key driver of the ongoing epidemic and absence of a strategic framework to manage malaria actions (in general public health) in mining areas.

#### **Access to and coverage of diagnosis and treatment**

The coordination of the response to the epidemic, in particular diagnosis and treatment in Bolívar, is shared between the central level of the Ministry of Health (which coordinates actions in municipalities with high levels of mining activity) and the State Health Institute (which coordinates actions in the rest of the state). In Bolívar, there is an overall reduction in the number of active microscopy centers due to a lack of supplies to carry out thick smears. The Amazonas state microscopy network is also ineffective due to the lack of thick blood smear test supplies. The Sucre microscopy network, which has historically had extensive coverage and integration in health services, is currently not operational in approximately 80 percent of facilities due to the

lack of supplies and microscopes (there is a lack of microscopists in the municipalities). In Anzoátegui, 17 of the 27 microscopy posts are operational. The microscopy quality control system is not operational in any of the states.

Thanks to donations from PAHO, RDT by environmental health teams, community actors and health units has been introduced in Bolívar, but there is a need for improved organization of local networks and the incorporation of other actors. In Amazonas, due to the limitations of the microscopy network, diagnosis in 2018 is based on RDT incorporated into the services network (outpatient services and CDIs), but there is a lack of a programmatic monitoring and supervision strategy. Diagnosis is also based on rapid tests in Sucre state ASICs, which increasingly use RDT in their CDIs, though better organization is needed if this is to be extended to outpatient settings. In Anzoátegui, there is a need for a programmatic approach to implementing RDT (its distribution, use and monitoring).

Largely due to the widespread illegal sale of antimalarials – which is highly complex in mining areas, given the difficulties in accessing treatment and the high costs created by the local economy – the Ministry of Health enforces special control measures for the delivery of drugs to states and municipalities. Malaria treatment does not commence at the time of diagnosis in the health units, but depends on a data auditing process carried out at the central level of the Ministry of Health. This data review leads to the late initiation of the treatment and the absence of treatment for cases that are not approved in the audit. Ongoing failure in the provision of drugs at the state level has been recorded in all four states. In Sucre, it can take up to six weeks after diagnosis for treatment to begin.

Failures in the clinical management of cases due to a lack of knowledge of standards, lack of adequate drugs (specific drugs for severe malaria and comorbidity management) and barriers and delays in the referral and care process for severe malaria are increasing malaria mortality, especially in Bolívar and Anzoátegui. In Anzoátegui, the lack of (and delays in) treatment have resulted in a historically high mortality rate of 1 percent, which persists in 2018.

In Bolívar, the high positivity rate (59 percent) is the result of insufficient detection efforts in the state. In Amazonas, the high slide positivity rate (44 percent) also highlights the need for increased diagnostic capacity.

There are gaps in active searches in the area with the highest incidence in Bolívar. In Amazonas, Anzoátegui and Sucre, there is a lack of both active search actions and supervision due to operational constraints.

The malaria prevention and management strategy in pregnant women is operational only at the pilot level in the capital of Bolívar. There is no strategy to prevent and manage malaria during pregnancy in other states.

### **Malaria prevention actions (vector control)**

In general, in all states, vector control actions are characterized by the absence of IRS actions due to a lack of equipment, insecticides and vehicles. In the states of Sucre and Anzoátegui, IRS is not considered by the state team as an intervention due to the exophilic and exophagic behavior of

A. *aquasalis*. This has previously led to IRS being replaced by insecticidal space spraying. In Bolívar, many areas with high incidence would benefit from IRS. Although timely implementation of LLINs has been carried out in some municipalities, this has been insufficient given the magnitude of the problem. Moreover, there is no programmatic strategy to promote and monitor the use of LLINs, despite the existence of national guidelines. In general, there is currently a lack of LLINs for distribution, coverage is extremely low and there is a lack of comprehensive monitoring and evaluation on their use and maintenance.

PAHO is expected to donate 150,000 mosquito nets in July 2018. The lack of coverage of the two recommended residual impact malaria interventions (LLINs and IRS) contrasts with the investment in equipment, supplies and staff for an insecticidal space spraying campaign (“fumigation plan”) not specifically for malaria. The Environmental Health Directorate includes space spraying among its antimalarial actions, on the basis of vector behavior in different regions.

### **3.6 Monitoring and information management**

#### **HIV**

- The available morbidity information comes from the regular reporting by the Regional Coordinators of the National AIDS/STI Program. This information contains some degree of under-reporting, as the information system used still has weaknesses despite improvements.
- Through its Regional Coordinators, the National AIDS Control Program (NACP) monitors the cohort of people receiving antiretroviral therapy (admissions and patients discharged) and treatment regimens on a monthly basis.
- There is no single, integrated information system that supports connectivity within the laboratory network.
- The lack of integration between existing information systems, particularly between epidemiological information on morbidity, mortality, treatment and laboratory work, makes it difficult to monitor HIV cases longitudinally and to monitor all the key indicators of comprehensive care (“cascade”) and the goals of accelerated action.

#### **TB**

- The TB information system is paper-based, which limits timely analysis and decision-making. This, along with limited training and monitoring at all levels, compromises the quality of information. The very limited levels of connectivity also reduce the effectiveness of information flows.
- The NTCP has multiple records, from treatment cards to the epidemiological sheet. The TB registries and information analysis are still based on bacilloscopy results and whether or not TB cases are pulmonary. For programmatic purposes, the NTCP classifies cases into three categories: P (bacteriologically-confirmed pulmonary cases), N (non-pulmonary) and EP (extrapulmonary). This increases the number of records and complicates analysis, without supporting better decision-making.

- At the state level, NTCP managers hold monthly meetings to analyze information and follow up special cases. At the national level, the NTCP meets annually with all state respiratory health coordinators.
- There is passive pharmacovigilance of the adverse effects of TB drugs.

## **Malaria**

- The malaria information system in Venezuela has maintained local information processes based on the program's tools and procedures, which enable basic information to be systematically recorded for malaria decision-making purposes. Similarly, processes for inputting data into databases are maintained at the local level. These are very useful for the local monitoring of the main operational indicators (time to diagnosis and initiation of treatment, locality affected, etc.). However, malaria information is currently fragmented, limiting information consolidation and effective decision-making at the state level.
- On the other hand, central-level data audit processes are limiting basic malaria operations (immediate treatment), insomuch as the absence of drugs at the time of diagnosis and their late distribution due to data reviews make case registration, reporting and analysis actions pointless. These are critical to the timely capture of new cases of malaria that require immediate treatment.
- Immediate treatment has ceased to be the objective of surveillance, while data collection and registration have been reduced to procedures based on notification at a higher level that are designed to manage drugs.
- There is also a need for computer equipment and human resources for information processes ranging from database inputs to data analysis. Similarly, computing tools and teams are needed for georeferencing, data tabulation and automated analysis at the ASIC and state epidemiological levels.
- There are basic gaps in the investigation of cases of mortality and severe malaria: routine analysis of deficiencies and delays would help correct errors in treatment pathways.
- There are also operational limitations on malaria case and outbreak investigation in receptive malaria-free areas at risk of the re-introduction of malaria.

### **3.7 Supply management (drugs and other strategic supplies)**

The provision of drugs and strategic supplies for public health programs is one of the most important challenges facing Venezuela. There is a critical stock-out of drugs for HIV/STIs, opportunistic infections, preventing congenital syphilis and malaria treatment. This is further exacerbated by the lack of diagnostic tests and monitoring and insufficient reagents and supplies for laboratories and blood banks and insufficient vector control supplies (mosquito nets, insecticides and supporting equipment). This is due to a number of factors, including: lack of funding, fragmented supply management, lack of domestic pharmaceutical suppliers, insufficient

internal controls for managing the distribution of certain drugs, and the illegal drug market, which has exacerbated stock-outs.

Supply management falls to the Deputy Ministry for the Provision of Drugs and Technologies at the Ministry of Health. This department is responsible for the procurement, reception, storage and distribution of drugs and supplies, with five automated warehouses located in Miranda, Barcelona, Barinas, Barquisimeto and Aragua.

Estimates and planning for drug and supply needs are carried out by public health programs that manage procurement at the central level and set out the monthly distribution plan implemented by SEFAR (the ministerial pharmaceutical body). The latter is responsible for using its own information system to control stocks at the central level.

### Procurement of drugs and supplies

- Procurement of drugs and supplies takes place via:
  - a. local direct purchase
  - b. direct international purchases
  - c. purchasing through the PAHO Strategic Fund, and
  - d. donations.

For HIV/STIs, the Ministry of Health procures 4 percent of the actual need for antiretrovirals (ARVs) through government-funded purchases via the Strategic Fund, and direct international purchases from Indian pharmaceutical suppliers. Some drugs and supplies are being provided through donations managed by United Nations organizations such as PAHO/WHO, UNAIDS and UNICEF, although the amounts are not sufficient to meet the required needs.

According to an analysis of the stock and purchases in transit procured through government funds and donations made by UNAIDS, PAHO/WHO, UNICEF and international and national NGOs in the second half of 2017, it is estimated that they will provide a limited supply of approximately one to two months to cover the needs of PLHIV in some adult ART regimens. However, included in this stock are some products that cannot be distributed because of incomplete treatment regimens.

The data presented in **Table 17**, which estimates the number and availability (in months) of treatment based on an analysis of existing and incoming stock in transit, show the clear limitations in access to ART.

**Table 17. Analysis of availability of ARVs**

Treatment regimen	Number of treatments	Availability in months based on average monthly consumption
TDF/FTC/EFV	47,578	2 months
AZT/3TC+LOP/r	11,604	3 months
TDF/FTC + ATV/r	12,145	1 month
ABC/3TC/EFV	12,931	2 months
3TC/AZT+NVP	947	1 month

ABC/3TC/AZT	6,389	16 months
(DRV/r/RAL) without ETV	1,713	2.6 months
AZT IV	60	

A small batch of pediatric ARVs for this year are being purchased through direct international purchase funded by the government and PAHO's Strategic Fund.

Donations have been received from UNICEF and UNAIDS, with UNICEF reporting that in 2017 it made donations of pediatric ARVs and for the treatment of pregnant mothers. Procurement of a new stock of pediatric ARVs and a small batch of rapid tests for diagnosing syphilis is currently under way, and will be delivered in the second half of 2018 (**Table 18**).

**Table 18. HIV drugs to be donated by UNICEF in 2018**

Drug	Units
ABC ORAL SOLUTION 20 mg/ml x 240 ml	3,426
EFV TB 200 mg x 90 tab	216
LAMIVUDINE 10 mg/ml x 240 ml	2,256
LOPINAVIR/RITONAVIR 80/20 mg x 160 ml	1,596
LOPINAVIR/RITONAVIR 100/25 mg x 60 tab	3,444
ZIDOVUDINE 10 mg/1ml x 200 ml	1,080
LOPINAVIR/RITONAVIR 200/50 mg x 120 tab	40
ZIDOVUDINE 10 mg/ml x 20 ml	60

SEFAR distributes the drugs based on the distribution plan presented monthly by the HIV program. There are currently 51 health care facilities, located in third- and fourth-level care facilities, that have been set up to dispense ARVs.

With regard to the provision of diagnostic and monitoring tests (viral load measurement, CD4 and genotyping), there are serious procurement problems. These stock-outs are critical as there are no local branches of the companies that have agreements with the National Institute of Hygiene "Rafael Rangel" (INHRR), there is a lack of rapid testing, and donations for supplies to diagnose HIV in pregnant women have fallen.

The supply of first- and second-line TB drugs has been more regular and no stock-outs have been reported, thanks to the purchase of an 18-month stock using government funds in 2017. There is currently sufficient stock to cover two months of treatment, and a PAHO donation is being managed to cover a three-month period and to avoid stock-outs. The Ministry of Health has requested that state funding and PAHO's Strategic Fund be used to procure sufficient stock to meet annual needs. Some issues were reported in the distribution of TB drugs in early 2018, but these seem to have been overcome between the National Tuberculosis Control Program (NTCP) and SEFAR, the ministerial body responsible for receiving, storing and distributing supplies at the national level.

The NTCP is responsible for quantification and the Distribution Plan for TB Drugs, but the purchase, stock control and distribution of TB drugs is carried out independently by SEFAR. This makes integrated management of these drugs difficult and prevents the use of the QuanTB tool

that would facilitate this drug management and on which the NTCP has received training. Lately, the NTCP has been asked to provide a list of TB patients for drug distribution, which delays timely access to treatment.

The country has included dispersible formulations of pediatric TB drugs since 2005, making it easier to administer drugs to children.

There are also stock-outs of GeneXpert cartridges and critical laboratory supplies for TB diagnosis and monitoring.

The management of malaria drugs and diagnostic supplies has also been irregular. In 2017, antimalarials were purchased through the Strategic Fund using Ministry of Health funding, and donations have also been received from PAHO and UNICEF. Some states have also procured antimalarials through direct purchase from international suppliers (in India). No actual inventory information was available at the national level. In 2018, PAHO has donated artemisinin derivatives and the purchase of a year's supply of antimalarials is being managed through the Strategic Fund using government funding. UNICEF reports that it will be delivering a batch of antimalarials in the second half of 2018 for the pediatric and pregnant populations.

Major challenges in distributing antimalarials were identified, with internal institutional controls causing delays in them being dispensed. The treatment of individuals is subject to a data audit, with ongoing stock-outs at the local level, late initiation of treatment and non-treatment of cases not approved in the audit.

The logistic information system and standard operating procedures governing the logistics supply chain were not verified.

Supplies for screening and blood banks are limited and have been purchased internationally through PAHO/WHO using state funds, as well as donated by PAHO.

There is no stock of penicillin benzatinica to prevent congenital syphilis, and diagnostic supplies are not available: there is also a clear lack of supplies for STI prevention.

The lack of an integrated procurement plan results in fragmented procurement processes and has limited donor coordination and guidance.

This year, PAHO/WHO have supported the implementation of the SUMA platform in 20 Ministry of Health service network facilities. The Humanitarian Supply Management System (SUMA) is an information management tool that helps national authorities to control and organize donations and incoming drugs and supplies. SUMA uses an easy-to-use computerized system to track supplies from the moment they are distributed to the affected population, and is a tool to monitor the receipt of drugs and supplies at the local level (**Table 19**).

This platform is considered complementary to the national information system and supports the control and monitoring of drugs and supplies. Funding is expected to be extended to other hospitals that care for PLHIV and TB patients. The main platform is currently located in PAHO offices.

**Table 19. Relationship between priority hospital facilities and HIV, TB and malaria services (2018)**

LIST OF HOSPITAL FACILITIES*							
	Name of hospital	State	City	ART clinic	Pharmacy ART	TB clinic	Malaria clinic
1	José Gregorio Hernández Hospital	Amazonas	Puerto Ayacucho	NO	NO	YES	YES
2	Luis Razzetti Hospital	Anzoátegui	Barcelona	YES	YES	YES	YES
3	Guevara Rojas Hospital	Anzoátegui	El Tigre	YES	YES	YES	YES
4	Maracay Central Hospital	Aragua	Maracay	YES	YES	YES	YES
5	Ruíz y Páez Hospital	Bolívar	Ciudad Bolívar	YES	YES	YES	YES
6	Raúl Leoni Hospital	Bolívar	Ciudad Bolívar	NO	NO	NO	YES
7	Enrique Tejera Hospital	Carabobo	Valencia	YES	YES	YES	NO
8	Luis Razzetti Hospital	Delta Amacuro	Tucupita	YES	Health Directorate	YES	YES
9	University Clinical Hospital	Distrito Capital	Caracas	YES	YES	YES	YES
10	JM de los Ríos Hospital	Distrito Capital	Caracas	YES	YES	YES	NO
11	Magallanes de Catia Hospital	Distrito Capital	Caracas	YES	YES	YES	NO
12	Concepción Palacios Maternity Unit	Distrito Capital	Caracas	YES	YES	NO	NO
13	Pérez Carreño Hospital	Distrito Capital	Caracas	YES	Other center	NO	YES
14	Jesús Yerena Hospital	Distrito Capital	Caracas	NO	NO	YES	NO
15	Caricuao Mother and Child Hospital	Distrito Capital	Caracas	NO	NO	NO	NO
16	Victorino Santaella Hospital	Miranda	Los Teques	YES	YES	NO	NO
17	Manuel Nuñez Tovar Hospital	Monagas	Maturín	YES	YES	YES	YES
18	Patricio de Alcalá Hospital	Sucre	Cumaná	YES	YES	YES	YES
19	Simón Bolívar Hospital	Táchira	San Cristóbal	YES	YES	NO	YES
20	University Hospital of Maracaibo	Zulia	Maracaibo	YES	NO	YES	NO

**\*Hospitals were selected either for their location in geographical areas with tectonic faults or in priority regions due to the incidence of malaria, diphtheria and measles cases.**

### Drug donations

In light of stock-outs, United Nations organizations, especially PAHO/WHO, UNAIDS, UNICEF, and other international NGOs and countries have managed donations of HIV, STI, TB and malaria

drugs. Their actions have been duly coordinated and approved by the Ministry of Health and the country's health regulatory authority (SACS) (**Table 20**).

In 2017, UNICEF funded treatment for 2,300 children infected with HIV, HIV diagnostic kits, as well as antimalarials and diagnostic laboratory tests to test and treat malaria. UNAIDS donated US\$ 5,183,214.91 during 2018 for ARVs, drugs to tackle opportunistic infections and HIV diagnostic kits. PAHO/WHO have funded the purchase of essential drugs for HIV, TB and malaria, as well chronic diseases, syphilis prevention, nutritional and reactive supplements and diagnostic kits, as well as reagents for blood banks.

The NGO *Acción Solidaria* has donated and distributed ARVs in both 2017 and 2018. Similarly, AID FOR AIDS (under a UNAIDS grant) provided ARVs and drugs for opportunistic infections to the Ministry of Health, which were distributed through state ARV dispensing centers in 2017 and 2018.

The donation process flow is described below:

- The Ministry of Health signs a workplan requesting support from aid agencies for the provision of drugs. The aid agency may also offer supplies as "donations".
- The Ministry of Health authorizes entry and its SACS issues (at the agency's request) an import permit for health products (if one is not already registered in the country). This permit authorizes entry of the product within six months of issue.
- The aid agency carries out the respective customs clearance or it can, by mutual agreement, be carried out by the Ministry of Health.
- Drugs and supplies are delivered to SEFAR, which provides acknowledgement of receipt and distributes these nationwide in line with distribution plans developed by the programs.
- A table summarizing donations received in 2017 and donations received and in transit in 2018 is presented below.

In 2017, PAHO/WHO donated drugs for malaria, HIV, TB, chronic diseases, nutritional supplements, diagnostic supplies and blood banks, first-aid kits, antibiotics and some vaccines worth US\$ 857,533.65. In 2018, these organizations have so far donated essential drugs, immunosuppressants, ARVs, TB drugs, antiparasitics and antimalarials, iron supplements and mental health drugs worth US\$ 615,909.40 (**Table 21**).

**Table 20. Donations made to the Venezuelan Ministry of Health, 2017–2018**

Product description	UNAIDS		UNICEF		Acción Solidaria	Palestinian government
	2017	2018	2017	2018	2017	2018
ABACAVIR 300 mg tab. x 60		15,398				
ABACAVIR 600 mg/LAMIVUDINE 300 mg x 30		90,938			7,500	
ABACAVIR oral sol. 20 mg/ml /BOT-240ml			5,271	3,426		
ABACAVIR/LAMIVUDINE dispersible x 30		110,435				
Alere Determine HIV-1/2, WB set, kit/100	8,000		150			
ATAZANAVIR TB300 mg/RITONAVIR 100 mg x 30						16,435
EFAVIRENZ 200 mg x 90 CAPS			225	216		3,872
EFAVIRENZ x 30		20,637				
TENOFOVIR DISOPROXIL FUMARATE 300 mg x 30 TAB						13,963
LAMIVUDINE / ZIDOVDINE dispersible x 60		29,481				
LAMIVUDINE 150 mg x 60 TAB		17,768				26,550
LAMIVUDINE 150 mg/ZIDOVDINE 300 mg x 60 TB		42,731	613			71,898
LAMIVUDINE oral sol. 10 mg x 100ml			4,956	2,256		
LOPINAVER 100 mg/RITONAVIR 25 mg x 60 TAB			1,788	3,444		4,812
LOPINAVER 200 mg/RITONAVIR 50 mg x 120		43,021		40		
LOPINAVER/RITONAVIR oral sol. 80+20 mg/ml/BOT-160ml			1,346	1,596		
RALTEGRAVIR 400 mg x 60 PILLS						11,620
ZIDOVDINE 300 mg/LAMIVUDINE 150 mg/ABACAVIR 300 mg tablets x 60		8,880				
ZIDOVDINE 300 mg tab. x 100		1,883				
Oral ZIDOVDINE sol.10 mg/ml/BOT-240ml			1,150			
ZIDOVDINE 300 mg x 60 TAB			5,139			5,682
ZIDOVDINE IV,10 mg/ml, 20ml			60	60		
Oral ZIDOVDINE sol.10 mg/ml/BOT-240ml				1,080		
CYPROFLOXACIN tab 500 mg	20,194					
Bioline Syphilis **				500		
Rapid HIV diagnostic tests	2,000	8,000				
MALARIA						
ARTEMETHER 20 mgs + LUMEFANTRINE 120 mgs tab				475		
QUININE/INJ 300 mg				180		
ARTESUNATE/INJ 60 mg				10,000		
CHLOROQUINE BASE 150 mg				21		
QUININE SULFATE tab 300 mg				850		
PRIMAQUINE base tab. 7.5 mg				2,984		
SD Bioline Malaria				7.2		

**Table 21. PAHO/WHO donations, 2017–2018**

<b>Product</b>	<b>2017–2018</b>
Acyclovir 200 mg tablet	15,000
Acyclovir 400 mg Tablet/BOTTLE 500	365
Albendazole 200 mg/5mL oral solution, Jar/10mL	100,000
Amoxicillin 875 mg + Clavunalic Acid 125 mg TABLET, BLISTER 2 X 8	188,125
Amoxicillin 875 mg + Clavunalic Acid 125 mg TABLET, BLISTER 2 X 8	6,250,125
Diphtheria antitoxin	500
Diphtheria antitoxin	200
Artemether 20 mg/Lumefantrine 120 mg	2,520,000
Captopril 25 mg tablets	750,000
Captopril 25 mg tablets	306,800
Cyclosporine tablets 25 mg	8,050
Cyclosporine tablets 50 mg	8,000
CHLOROQUINE BASE 150 mg	15,000
Dexamethasone 4 mg/1 mL vials	46,800
Dexamethasone 4 mg/1 mL vials	53,200
Doxycycline 100 mg	100,000
Efavirenz 600 mg + Emtricitabine 200 mg + Tenofovir 300 mg / 30 Tablets Bottle	3,000
Efavirenz 600 mg + Emtricitabine 200 mg + Tenofovir 300 mg / 30 Tablets Bottle	5,333
Tenofovir disoproxil fumarate 300 mg + Emtricitabine 200 mg x 30 tab.	3,888
Ferrous Fumarate 185 mg + Folic acid 0.4 mg film-coated tablets, BLISTER 100	300,000
Hydralazine 20 mg vials	9,000
Intermediate-acting insulin 100U/mL x vials 10 MI (nph)	1,500
Rapid-acting insulin 100U/mL x vials 10 mL	1,500
Interagency Emergency Health Kit	3
Interagency Emergency Health Kit (severe malaria)	40
Interagency Emergency Health Kit (severe malaria)	12
Interagency Emergency Health Kit (modules: SUPPLEMENTARY DRUGS + SUPPLEMENTARY DISPOSABLES)	15
Anthropometric kits	15
Rapid diagnostic kits	200,000
Rapid diagnostic kits	100,000
Losartan Potassium 50 mg Tablet	521,920
Metformin 500 mg Tablet	750,000

Metformin 500 mg Tablet	250,000
Metformin 500 mg tablet	500,000
Mycophenolate tablet 500 mg	40,000
Misoprostol 200 ucg	80,000
Penicillin G Benzathine 0.6 MIU	50,000
Penicillin G Benzathine 1.2 MIU	50,000
Penicillin G Benzathine 2.4 MIU	10,000
Procaine Penicillin 1.0 MIU	26,100
Primaquine 15 mg/box 10 blister/blister x 10 tablet	11,000
Primaquine 5 mg/box 10 blister/blister x 10 tablet	2,000
Oral rehydration salts 1L	100,000
Iron sulfate 125 mg/5 mL oral solution, bottle/ 30mL	20,000
Nutritional supplements	98,280
Pulmonary surfactant 25 mg/mL	200
Tacrolimus 1.0 mg capsules	300,000
Tacrolimus 1.0 mg capsules	135,000
Tacrolimus tablets 100 mg	40,000

Some of the challenges identified in this process relate to coordination between aid agencies and the Ministry of Health to establish which drugs and supplies are necessary and their amounts, based on national availability or stocks. Currently, there are donations of products that already have large stocks, while donations of other products that complement treatment regimens, especially ART, are lacking.

### **Role of the Strategic Fund**

In its capacity as a mechanism for technical cooperation in managing public health supplies, the Strategic Fund has been supporting the Ministry of Venezuela since it joined in 2010.

Essential drugs and strategic public health supplies and laboratory equipment can be purchased through the fund, thus supporting national planning processes and the procurement of drugs and strategic supplies that meet international quality standards and at affordable prices.

Venezuela, through its Ministry of Health, has had an agreement with PAHO/WHO to use the Strategic Fund since 2010. Over the 2010–2018 period, the country has regularly used this mechanism to procure ARVs, antimalarials, TB drugs, cancer drugs, antiparasitics, laboratory reagents and vector control supplies (mosquito nets).

In 2017, PAHO/WHO signed a tripartite agreement for IVSS purchases with the IVSS and the Ministry of Health, which used the Strategic Fund for immunosuppressive drugs and supplies for chronic diseases throughout 2017.

Venezuela has historically relied on the Strategic Fund to meet many of its procurement needs. In 2015, this resulted in significant savings of up to US\$ 20 million through generic ARV purchases at affordable prices. Between joining the Strategic Fund in 2010 and up to 2016, it received between US\$ 10 million and US\$ 15 million per year.

The Ministry of Health has made efficient use of the Strategic Fund's credit line through its capital account, by making the respective reimbursements.

For the implementation of the master plan, the proposal is that the Strategic Fund with its technical and administrative team from PAHO/WHO at the regional and local levels would be in a position to support the annual procurement of programmed drugs and supplies. The appropriate procurement mechanisms (refundable purchase, corporate purchase or use of the Strategic Fund) established by PAHO/WHO to support member countries would be applied.

In this way, based on the annual procurement plan and with the available funding deposited with PAHO/WHO, corporate purchases will be made in accordance with technical specifications, established quantities and the regulatory requirements set by the country. This procurement process will include the costs of freight and insurance, customs clearance costs, and transportation costs to distribution centers, at an estimated 20 percent of the price of the product.

This process will be governed by the PAHO procedures based on its procurement methods and will source pre-qualified and evaluated vendors from WHO, PAHO and other United Nations organizations.

The procured products will be shipped and consigned to the PAHO/WHO office in Venezuela, which will be responsible for nationalization and customs clearance of the products with the support of the governmental controlling and health regulatory bodies, and delivery to the storage and distribution centers defined by the country in accordance with established procedures and process controls.

Government procurement through the Strategic Fund will continue to employ the procedures that Venezuela has established.

The PAHO regional office will form an administrative technical team represented by PAHO's Health Systems and Services Department, Medicines and Health Technologies Unit, Communicable Diseases and Environmental Determinants of Health Department, Procurement and Supply Management Department and Financial Resources Management to coordinate the implementation of the procurement plan. This team will actively participate in the procurement processes in coordination with the PAHO Venezuela Country Office and the Ministry of Health and will:

- Review the annual procurement plan
- Review and approve price estimates
- Approve and place purchase orders
- Monitor the manufacturing process, technical and administrative documentation, and manufacturers' and suppliers' shipments to the country
- Monitor shipments and compliance with the requirements set out in the purchase order
- Receive and nationalize products at the country level
- Control and monitor reception and distribution
- Present financial reports on the procurement process.

PAHO/WHO will deliver regular financial and technical reports on the procurement processes carried out.

#### **4. Actors**

##### **Multi-sector and community participation in the HIV, TB and malaria response**

###### **HIV**

- Political advocacy and specific actions of Venezuelan civil society groups: joint work between RVG+ and ACCSI (advocacy and monitoring of ARV dispensing centers), *Acción Solidaria* (advocacy, medical care and donation of drugs and supplies), ACCSI, MAVID Foundation, AMAVIDA and *Conciencia por la Vida* (advocacy and monitoring of health centers), Caritas Venezuela (donation of drugs and supplies), the COVIH NGO network (advocacy), *Defendamos la Epidemiología* network (advocacy and epidemiological status report).
- Venezuelan Society of Infectology
- Political advocacy and specific actions of international civil society: AID FOR AIDS (donation of ARVs, drugs for opportunistic infections, rapid HIV testing and lacteal formulas); ICASO (International Council of AIDS Service Organizations: advocacy, drugs, reagents, rapid HIV testing, and condoms); *Corresponsales Clave* (advocacy); AIDS Healthcare Foundation (advocacy, and possibly support for treatment, reagents, rapid HIV testing, condoms and training of health workers); GNP+ (Global Network of People Living with HIV: advocacy); LACCASO (Latin American and Caribbean Council of AIDS Service Organizations: advocacy).

###### **TB**

- There is only limited civil society involvement in TB prevention, control and social protection activities, with the issue mainly falling to the academic sector. There are no patient or ex-patient groups that support the NTCP.

###### **Malaria**

- There are no organizations to support malaria prevention and control activities.

#### **5. Funding**

- The actions of the NACP and those related to malaria are financed by the Venezuelan State. Drug donations and supplies that have been received and that are expected are summarized in Table X.
- The NTCP is currently funded only from Venezuelan State resources. There are no donors.

## 6. Agreed recommendations

This chapter presents the recommendations agreed during the technical working groups by component (HIV, TB and malaria) and by the crosscutting themes of the health services and supply management.

**It is recommended that a multi-programmatic commission be established, comprising the members of the joint mission and including other relevant actors, to monitor the implementation of these recommendations and the execution of the corresponding activity plan (Chapter 7).**

### 6.1 HIV component

Four lines of action were agreed:

- A. Continuing access to comprehensive care and ART**
- B. Capacity building and continuing access to laboratory monitoring for comprehensive care of PLHIV**
- C. Expanding access to HIV prevention, screening and diagnosis**
- D. Improving strategic HIV monitoring and information**

**A. To ensure continued access to comprehensive care and ART, the following actions were agreed:**

- Review of public health guidelines for ART in line with scientific evidence. During their mission, the international and national teams together with representatives from the Venezuelan Society of Infectology discussed and developed a proposal for standardized guidelines for the re-initiation and initiation of ART (**Annex 2**) based on migration from first- and second-line regimens to DTG-based regimens (men and women without contraindications). The NACP will need to prepare a technical document to normalize and disseminate these recommendations.
- Health registration of new ARVs (e.g. DTG, TDF/3TC/DTG, pediatric RAL, LPV oral pellets, dispersible and grooved combined nucleoside reverse transcriptase inhibitors (NRTIs); other drugs for opportunistic infections).
- Adaptation of ARV procurement plans to new guidelines, taking into account stocks, supplies from international cooperation and ongoing purchases (based on the procurement plan for year 1 and projections for years 2 and 3 – **Annex 3**). Projections also include ARVs for post-exposure prophylaxis and prophylaxis in exposed children.
- Plan to restart treatments based on the agreed guidelines, the communication strategy and support from civil society to promote patient recapture.

- Procurement plan for prophylaxis drugs and treatment of co-infections and opportunistic infections and other drugs and supplies for comprehensive care (micronutrients, milk substitutes, proteins, penicillin).
- Use of the PAHO Strategic Fund as the main drug-procurement mechanism for ARVs, prophylaxis and treatment of opportunistic infections, micronutrients, milk substitutes and laboratory and prevention supplies for the Ministry of Health and its cooperation partners.
- Monitoring and follow-up of drug management and referring/directing people in coordination with civil society, social movements and community-based organizations.

**B. To build capacities and continue access to laboratory monitoring for comprehensive care of PLHIV, the following actions were agreed:**

- Procurement plan for HIV viral load reagents to enable at least one viral load to be performed on each PLHIV undergoing treatment in the first year of the plan and two per year in the following years.
- Procurement plan for CD4 reagents for at least one CD4 count per PLHIV (year 1) in the first year of the plan and based on indication (basal CD4 and in the event of therapeutic failure; Annex X) in the following years.
- Expansion of laboratory viral load capacity:
  - Evaluate the need for human resources and capacity building in the current network (year 1).
  - Two additional Roche machines are currently being implemented (Yaracuy and DC) and the referral processes are being reviewed (Lara and Falcón will be able to refer samples to Yaracuy) (year 1).
  - Procurement of GeneXpert machines to cover remote regions (two four-module machines in Bolívar, one four-module machine in Nueva Esparta) and use as an integrated HIV platform (for viral load and polymerase chain reaction (PCR) DNA analysis) in laboratories with equipment purchased for TB diagnosis (year 1).
  - Procurement of GeneXpert machines to meet additional requirements in states with installed laboratory capacity to decentralize viral load analysis and reduce the workload of over-burdened laboratories (DC, Zulia) (years 2–3).
- PCR DNA analysis decentralization (GeneXpert and, if possible, filter paper samples to be sent to the National Institute of Hygiene (INH)).
- Procurement plan for reagents and laboratory capacity building for resistance testing for clinical follow-up (approximately 20/month). Technology transfer and training on integrase inhibitor resistance and use of the Illumina MiSeq platform.
- Participation in external quality control programs (prioritizing viral load testing).
- Test procurement plan for screening and diagnosis of co-infections and opportunistic infections (hepatitis B and C serology, fungal growth).

**C. To expand access to HIV prevention, screening and diagnosis, the following actions were agreed:**

- Design and implement a human resources training plan for those providing services, covering rapid testing, compliance with the diagnostic algorithm, and reducing stigma and discrimination.
- Approve the new diagnostic algorithm and use of rapid tests in the health care services network across the country.
- Define the prompt referral process for rapid initiation of ART (within seven days of diagnosis – as defined by WHO).
- Plan, procure and distribute ELISA tests and rapid testing for HIV and syphilis, condoms and educational materials (year 1 priorities: pregnant women, indigenous people and blood banks; from year 2: key populations).
- Develop and implement a combined prevention and testing strategy for key populations based on the results of ongoing prevalence studies (years 2 and 3).
- Implement specific HIV/TB/malaria actions in primary care through a pilot in selected ASICs which will later be scaled-up nationally.

**D. Actions to improve strategic HIV monitoring and information:**

- Training in the HIV epidemiological surveillance system for health workers and epidemiologists from the various levels.
- Review and incorporate variables into the epidemiological surveillance system that respond to the need to profile the epidemic and the national response.
- National HIV-resistance monitoring (pre-treatment) study coordinated by the INH to adapt treatment guidelines based on the resistance patterns detected (year 1), supported by a regional reference laboratory designated by WHO for HIV-resistance surveillance (e.g. Research Center for Infectious Diseases at the National Institute of Respiratory Diseases (CIENI/INER, Mexico City)).

## 6.2 TB component

Five lines of action were agreed:

### A. Improve TB search and diagnosis

### B. Patient-centered prevention, treatment and care

### C. TB information and monitoring at the national level

### D. NTCP management

### E. Health system strengthening

#### A. To improve TB search and diagnosis

- Strengthen TB diagnostic capacity by procuring GeneXpert machines and cartridges, with a view to replacing bacilloscopy as the initial test for TB and also using GeneXpert for other diseases (e.g. HIV viral load monitoring).
- Establish and implement a crosscutting system for transporting samples to be tested for multiple diseases, including TB, to facilitate rapid diagnosis.
- Use digital portable X-ray machines to strengthen the diagnosis of TB in at-risk populations, focusing on prisoners.

#### B. For patient-centered prevention, treatment and care

- Design informative material on TB to be disseminated on social networks.
- Develop refresher/training workshops for health workers at the primary care level to strengthen the TB prevention and control response capacity.
- These workshops should result in a workplan to coordinate the different actors and services, focused on patient-centered care.
- Consider introducing short-course drug-resistant TB (DR-TB) treatment in Venezuela and including rifapentine in preventive treatment for latent TB infection.
- Strengthen nutritional support for hospitalized TB patients and coordinate the support provided in this regard by NGOs and faith-based organizations.
- Include current and future TB patients in different government missions that provide social protection.
- Encourage groups of patients and former patients to participate in NTCP activities.
- Strengthen the health curriculum by increasing the content on TB prevention and control.

#### C. Access to TB information and monitoring at the national level

- Carry out an epidemiological evaluation (Epi review) of the TB situation with the aim of analyzing the available information to better understand the epidemic in the country, identify gaps and establish concrete recommendations to strengthen TB surveillance and control.
- Migrate to a nominal electronic information system as part of the health information system.
- Strengthen connectivity to enable adequate information flow, thus ensuring timely data availability and epidemiological surveillance.
- Strengthen monitoring mechanisms at all levels.
- Carry out active pharmacovigilance on the increased cases of DR-TB.

#### **D. To improve NTCP management**

- Update the National Strategic Plan for TB in line with the latest guidelines for implementing the End TB Strategy.
- Update the inventory of maintenance needs, supplies and human resources for TB.
- Update guides and manuals in line with current PAHO/WHO TB recommendations, adjusting diagnostic algorithms and treatment regimens and times.
- In the context of one of the six priority programs of the Barrio Adentro Mission for respiratory diseases, incorporate TB within the remit of ASICs, capitalize the potential of the entire community care network to expand prevention, detection, diagnosis and integrated TB treatment and strengthen primary care through broad community participation. Mechanisms should be put in place to introduce these actions into the first 25 ASICs selected as pilots.
- Strengthen TB/HIV collaborative activities, with an emphasis on integrating services at the primary care level.
- Ensure that the Ministry of Health has a system for sending biological material and TB reports from the states to the national reference laboratory and the NTCP.
- Facilitate the management of NTCP drugs and supplies by sharing SEFAR inventory information.
- Consider making the national TB reference laboratory report to the INH to harness the resources and technical capabilities of all national reference laboratories.
- Extend civil society participation to sectors such as NGOs, faith-based organizations and trade associations, among others, using the ENGAGE-TB approach.
- Drive operational research on TB, with academia and scientific societies supporting NTCP interventions.

#### **E. Health system strengthening**

- The state must ensure that the essential services of water and light are provided in health care facilities.
- Establish mechanisms to maintain and encourage TB-trained human resources and promote the inclusion of new human resources.
- Realign the infrastructure of the national reference laboratory and other laboratories in the network, strengthen the equipment to ensure the biosafety of its workers in accordance with WHO standards and ensure connectivity between laboratories.

### 6.3 Malaria component

The Master Plan proposes developing six lines of action that seek to meet the four specific objectives of the National Strategic Plan for Malaria (the Zamora Plan to Eliminate Malaria in Venezuela). A general recommendation in this regard is to manage the implementation of the national plan comprehensively. The action lines are:

- A. Organize the management model for coordinating the response to malaria (functions and structure of the national, state and local levels)**
- B. Make immediate treatment based on early diagnosis the main malaria intervention (to reduce the malaria reservoir and avoid complications and death)**
- C. Strategically address malaria mortality by identifying and correcting failings in care delivery and malaria case management during pregnancy**
- D. Unify malaria information management and promote information and surveillance processes that prioritize local decision-making**
- E. Implement the recommended measures for malaria vector control (LLINs and IRS) within established coverage and quality parameters**
- F. Develop a policy, strategic and operational framework to address urgent public health issues related to mining**

- A. Organize the management model for coordinating the response to malaria (functions and structure of the national, state and local levels)**

This involves organizing the coordination of the response in two respects; (i) coordinating the malaria response between the national and state levels; and (ii) promoting coordinated management at the local level structured under the ASICs to integrate the efforts of the various state bodies (environmental health, ministries, municipality and other local actors) at this local level. In this regard, it is suggested that the following elements be developed:

- Develop ASICs as a local body for organizing the malaria diagnosis, treatment and surveillance network (passive and active search) and local response management.
- Incorporate diagnosis (microscopy or rapid tests) into the service network (people's clinics, CDIs, hospitals) in addition to environmental health points.
- Within ASICs, organize the participation of various community actors (indigenous community leaders, miners, youth employment initiative, church, etc.) in malaria detection, diagnosis, treatment and surveillance.
- Organize a model for the state and national authorities' roles in providing technical support and supervision to the ASICs.

In municipalities selected for their high malaria epidemiology, pilot implementation schemes can be developed to support the implementation of state-coordinated, ASIC-centered malaria response management (in parallel with large-scale implementation in all malaria municipalities and those at risk of re-introduction). The following actions are also suggested:

- Training activities focusing on ASICs (with an emphasis on micro-stratification, malaria epidemiology, analysis, foci approach).
- Resolve operational constraints for ASIC malaria surveillance activities (such as visits to testing centers, information management and RDT supervision).

**B. Make immediate treatment based on early diagnosis the main malaria intervention (to reduce the malaria reservoir and avoid complications and death)**

Making immediate treatment based on early diagnosis the main malaria intervention is key to reducing the symptomatic infection reservoir and avoiding complications and death. It is therefore recommended to reorient the current data audit, making it an activity to clean the data in the analysis rather than a condition for drug delivery. It is suggested that the concept of universal, free and immediate supply should be strategically positioned as the main premise, with improvements in the field discouraging drug commercialization. It is therefore proposed that the greatest efforts should be on organizing a local model that will ensure access to diagnosis and treatment initiation at the time of diagnosis.

The general reactivation of the microscopy network throughout the country, involving the provision of supplies, microscopes and spare parts (purchases), should be a priority, as should the reactivation of the microscopy quality management system. In parallel, continue to implement RDT, but with the development of a technical framework (guides) and training, monitoring and supervision plans for their programmatic implementation.

It is recommended that micro-stratification and local micro-planning (ASIC) be promoted to organize diagnosis and treatment in the network of services at the level of each ASIC: people's clinics, CDIs, hospitals, malaria microscopists, community actors (with RDT). The implementation of coverage and access to diagnosis and timely treatment will also involve actions to actively engage community actors in mining and indigenous populations in malaria detection, diagnosis and treatment activities.

High *P. vivax* malaria relapse rates call for the development of better strategies to improve adherence to antimalarials (advice upon prescription, written instructions, partial supervision). Similarly, Venezuela needs to reactivate surveillance actions for drug resistance (in vivo studies with molecular markers) and other pharmacovigilance actions, especially those to prevent and monitor adverse effects, such as the risk of hemolysis due to the use of primaquine (PQ) in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

**C. Strategically address malaria mortality by identifying and correcting failings in care delivery and malaria case management during pregnancy**

While the main way to reduce the risk of complications and mortality from malaria is by ensuring the immediate treatment of cases (as addressed in the previous recommendation), an additional line of action with specific measures to prevent malaria mortality and actions in different areas of the care process is also recommended. It is suggested that actions should be developed in the following areas:

- Develop and implement a methodology for mortality analysis (analysis of failings and delays in specific areas of the treatment cascade).
- Organize care referral routes, managing severe malaria in specific municipalities (Bolívar and Anzoátegui are priorities).
- Continue training in clinical management of severe malaria.
- Procure drugs for severe malaria and comorbidities and medical supplies.
- Develop guidelines for detecting, diagnosing, preventing and managing malaria during prenatal consultations and attended births (malaria in pregnancy and congenital malaria).
- Develop a risk-communication strategy to address the malaria epidemic.
- Implement the risk-communication strategy for malaria (including various communication activities).

**D. Promote information and surveillance processes that prioritize local decision-making and unify national malaria information management**

- Unify the three information sources (epidemiology, national environmental health and states).
- Develop the data audit more as an epidemiological process to clean the data in the analysis, rather than as a condition for drug delivery.
- Provide training in information management, analysis and micro-stratification at the local level (ASIC) to facilitate decision-making related to malaria and the organization of the screening-diagnosis-treatment process.
- Unify computer processes for database management (cases, slides examined).
- Provide local levels (ASICs) with equipment and software for recording and managing information (computers, software, GPS).

**E. Implement the recommended measures for malaria vector control (LLINs and IRS) within established coverage and quality parameters**

In the vector control component, efforts should be focused on achieving appropriate coverage with insecticide-treated nets or IRS in malaria outbreak locations. Early access to diagnosis and the immediate initiation of treatment are being organized in these locations, which are prioritized according to disease burden and incidence. The following actions are included:

- Development of a technical framework for implementing LLINs with a programmatic focus (prioritization, distribution, promoting LLIN use, monitoring)
- LLIN procurement
- Installing, monitoring and supervising the use of LLINs
- IRS operations (logistics, transport)
- Procurement of Hudson pumps, PPE, and IRS insecticides
- Stratification and profiling of malaria outbreaks as required by health engineering measures
- Entomological and surveillance studies on resistance to insecticides.

## **F. Develop a policy, strategic and operational framework to address urgent public health issues related to mining**

Gold mining in the states of Bolívar and Amazonas, involving mass population movement from different parts of the country, especially to the mining municipalities in Bolívar and between its municipalities, is continuing to impact the transmission and spread of malaria to other receptive areas of the country. Malaria can be indicative of a more complex health problem. Other health problems in this population show the severity of the public health problem (diphtheria). In the absence of an effective framework for malaria management in this context, other efforts and investment in supplies and drugs will have little impact.

It is therefore recommended that a strategic framework be developed for working with the actors and the affected population in the mining areas of the states of Bolívar and Amazonas. This should include the following elements:

- Organize local networks to facilitate early detection and immediate treatment of malaria and appropriate coverage with LLINs
- Engage effectively with local actors and the community
- Explore sustainable measures
- Develop a risk management approach.

Consider previous efforts to plan health actions in the context of mining. Manage the implementation of the Arco Minero Health Plan, which includes basic care strategies, vector control, initiatives to improve living conditions (such as eco-health camps), and the creation of basic health centers and sanitation works. In the short term, and most urgently, it is suggested that agreements for implementing priority measures be developed with local actors, particularly those measures related to access to malaria diagnosis and treatment and the use of LLINs.

### **Areas and scope of the master plan intervention**

When estimating needs for the malaria component, the aim has been to support the national provision of basic malaria diagnosis and treatment supplies, so as to ensure this primary malaria intervention throughout the territory (early initiation of treatment). The lack of basic microscopy supplies is limiting the activity of an existing diagnostic network in endemic states. The unavailability of these supplies (slides, Giemsa, immersion oil and light bulbs) on the national market, in addition to the increasing use of RDT, makes this support necessary. Also within the malaria component, support for the gap in microscopes prioritizes the three states with the highest malaria burden (Bolívar, Amazonas and Sucre).

A second support area of the master plan will be aimed at achieving appropriate LLIN coverage, as a major vector control measure. The prioritized area is, once again, the three states with the highest malaria burden (Bolívar, Amazonas and Sucre). Similarly, the planning exercise considers it necessary to mobilize resources to address transport gaps for vigilance, monitoring and vector control actions. These requirements have also been calculated for only the three states with the highest malaria burden.

Finally, the plan envisages PAHO technical support (consultants and training and monitoring activities) for four states, with an emphasis on four priority municipalities (ASIC) (one per state). With this final component, the plan seeks to help implement comprehensive actions with recommended coverage and standards and through local information-based decision-making, in four ASICs prioritized based on their malaria burden. These ASICs serve as successful examples of malaria control that can be replicated in other territories.

Item	Geographical scope for intervention
Provision of drugs	Year 1: the whole country except Bolívar state, which has purchased drugs in 2018. Year 2: the whole country (taking into account a 30 percent decrease in the number of cases compared with those estimated)
Rapid tests	The whole country
Microscopy supplies	The whole country
Microscopes	Four states analyzed during the mission
LLINs	The three most burdened states. Four selected municipalities can be prioritized (one from each state).
Transportation (malaria diagnosis, surveillance, monitoring and control)	The three most burdened states. Four selected municipalities can be prioritized (one from each state).
Technical support in epidemiology, training and monitoring of malaria actions	Four states analyzed during the mission, with an emphasis on four priority municipalities (one in each state)

#### 6.4 Health service strengthening

Immediate action should be guided by the medium-term strategy of integrating priority public health programs into the strategy for ASICs that have a network of health care facilities.

There are plans for three lines of work to start expanding programmatic action. These will consider all the public facilities in both the specialized outpatient network and the community action network:

##### A. Creation of 24 pilot ASICs that integrate all programs.

A project to strengthen ASIC facilities has been developed to improve structural strengthening, equipment, the flow of drugs and the integration of mother-to-child health priorities, the Expanded Program on Immunization (EPI), malaria, TB and HIV.

##### B. Generation of program-specific measures in conjunction with Barrio Adentro:

- Location of RDT teams
- Malaria detection, diagnosis and treatment
- Training activities
- Community engagement measures
- Availability of TB treatment (directly observed treatment, DOT)
- TB chemoprophylaxis and contact tracing
- Coordination with patient social protection missions

**C. Creation of a functional coordination strategy across the country that includes proposals for structural redefinition.**

This proposal should consider a phase that includes the ministerial network and a second phase that considers IVSS and the Ministry of Education's Staff Pensions and Welfare Institute (IPASME). This requires a high-level decision by the Venezuelan authorities. A technical panel should be set up to design this task as quickly as possible and with the support of PAHO.

## **6.5 Supply management**

One of the short-term recommendations is to begin the procurement processes for drugs and supplies in order to provide the country with essential drugs and make them more accessible and available.

**A. Review and update the regulatory framework for drug supply management** (selection, planning for needs, procurement, storage, distribution, dispensation and monitoring) with all stakeholders involved.

This process needs to be coordinated by the entity leading supply system management at the national level, as the following actions are considered important:

- Update the national list of essential drugs and draw up the list of strategic supplies
- Review the procedures and methodology for quantification and planning for needs, incorporating new modalities such as morbidity
- Review the procedures for procurement and donations
- Review the procedures for the distribution and dispensing of drugs
- Define lines of coordination between the stakeholders and roles and responsibilities in the process from the central level to the local level

**B. Staff training on supply management processes to ensure adequate and timely management at the state and local levels.**

An in-service training program on established procedures should be developed, incorporating public health programs and involving all stakeholders in the process.

**C. Review the logistics management information system and its use by all stakeholders to manage demand and stock control (at the local and central levels).**

- The quality of data generated by the system, information flows and coordination between stakeholders, as well as roles and responsibilities in the system, should be monitored.
- Review information on demand management versus supply.
- Work with SEFAR to revise how the SUMA platform complements the national logistics information system.

**D. Develop the National Integrated Procurement Plan to help guide procurement arrangements (direct purchase, procurement through Strategic Fund or donations).**

- In conjunction with SEFAR and the national programs and facilities that use centralized purchasing, the plan is to develop a national plan that includes the annual requirements

for drugs and critical supplies required by the country. This plan includes actual needs based on annual estimates, reserve stocks, donations, purchases in transit and available stocks, the required budget, purchase patterns and delivery schedules.

**E. Develop the drug and supplies distribution plan in conjunction with the programs and SEFAR.**

- SEFAR and public health programs should jointly develop a comprehensive distribution plan to ensure coordinated and timely deliveries, establishing process procedures, routes, a delivery schedule and compliance indicators for all those involved.

## 7. Activities plan

This plan details the actions needed to ensure continued access to essential, comprehensive and effective health services, drugs and adequate laboratory monitoring from a public health perspective and to minimize the risk of emergence and transmission of resistance. It does not include the costs of actions to maintain the structural capacities of the health system in terms of service provision.

### Overview of the master plan

COMPONENTE	Año1 (valor estimado en US\$)	Año2 (valor estimado en US\$)	Año 3 (valor estimado en US\$)
<b>HIV</b>			
Medicamentos	\$23,208,704.79	\$20,073,762.66	\$20,374,556.94
Laboratorio	\$4,845,778.60	\$7,567,631.72	\$7,779,574.72
Prevención	\$5,479,200.00	\$5,479,200.00	\$5,479,200.00
Fortalecimiento servicios de salud	\$208,650.00	\$173,700.00	\$158,700.00
Vigilancia	\$50,000.00	\$10,000.00	\$10,000.00
<b>TOTAL VIH</b>	<b>\$33,792,333.39</b>	<b>\$33,304,294.38</b>	<b>\$33,802,031.66</b>
<b>TB</b>			
Medicamentos	\$0.00	\$504,914.00	\$673,948.00
Laboratorio	\$1,007,788.00	\$885,088.00	\$885,088.00
Prevención	\$4,800.00	\$7,800.00	\$4,800.00
Fortalecimiento servicios de salud	\$1,005,580.00	\$45,900.00	\$45,900.00
Vigilancia	\$26,200.00	\$15,000.00	\$10,000.00
<b>TOTAL TB</b>	<b>\$2,044,368.00</b>	<b>\$1,458,702.00</b>	<b>\$1,619,736.00</b>
<b>Malaria</b>			
Medicamentos	\$689,007.49	\$982,035.75	\$0.00
Laboratorio	\$2,031,075.26	\$1,364,044.21	\$849,626.53
Prevención	\$4,117,152.50	\$2,438,000.00	\$1,195,000.00
Fortalecimiento servicios de salud	\$1,736,720.00	\$188,000.00	\$163,000.00
Vigilancia	\$140,000.00	\$115,000.00	\$34,000.00
<b>TOTAL MALARIA</b>	<b>\$8,713,955.25</b>	<b>\$5,087,079.96</b>	<b>\$2,241,626.53</b>
<b>TOTAL GENERAL</b>			
TOTAL Medicamentos	23,897,712.28	21,560,712.41	21,048,504.94
TOTAL Laboratorio	7,884,641.86	9,816,763.93	9,514,289.25
TOTAL Prevención	9,601,152.50	7,925,000.00	6,679,000.00
TOTAL Fortalecimiento servicios de salud	256,000.00	185,000.00	160,000.00
TOTAL Vigilancia	890,900.00	830,900.00	506,700.00
<b>TOTAL GENERAL</b>	<b>\$44,550,656.64</b>	<b>\$39,850,076.34</b>	<b>\$37,663,394.19</b>
TOTAL VIH	\$100,898,659.43		
TOTAL TB	\$5,122,806.00		
TOTAL Malaria	\$16,042,661.74		
<b>TOTAL GENERAL PLAN (3 años)</b>	<b>\$122,064,127.17</b>		

## 7.1 HIV component

<b>Support: Drugs</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Adult antiretrovirals (ARVs) (including for pregnant women and post-exposure prophylaxis (PEP)) – <b>Annex 3*</b>	18,044,322.35	15,346,308.00	15,757,242.00
Child ARVs (including post- exposure prophylaxis) – <b>Annex 3*</b>	1,043,208.00	810,743.80	787,886.60
Opportunistic infections (prophylaxis and treatment) and syphilis – <b>Annex 4</b>	2,132,281.00	1,919,053.00	1,727,147.00
Micronutrients (all children)	5,028.48	4,876.42	4,731.26
Proteins (10 percent adults)	1,776,504.96	1,785,421.44	1,890,190.08
Milk substitutes (all children exposed)	207,360.00	207,360.00	207,360.00
<b>TOTAL</b>	<b>23,208,704.79</b>	<b>20,073,762.66</b>	<b>20,374,556.94</b>

\* Year 1 includes 12 months of treatment and 3 months of reserve stock

<b>Support: Laboratory</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Rapid HIV/syphilis testing	525,600.00	1,445,400.00	1,557,000.00
3rd-generation ELISA testing	48,000.00	48,000.00	48,000.00
4th-generation ELISA testing	7,560.00	7,560.00	7,560.00
4th-generation ELISA testing (blood banks)	122,040.00	122,040.00	122,040.00
Virological tests (PCR DNA analysis) for diagnosing exposed children	21,604.80	9,259.20	9,259.20

Viral load – COBAS AmpliPrep/TaqMan HIV-1 (Roche)	2,790,125.00	4,721,750.00	4,936,375.00
Four-module GeneXpert equipment for decentralizing viral load with uninterruptible power supply (UPS), with a three-year warranty for each piece of equipment <b>Annex – GeneXpert TB/HIV integration plan (pending)</b>	119,792.00 <i>Bolívar (2), Nueva Esparta (1), Miranda (1)</i>	269,532.00 <i>Amazonas (1), Anzoátegui (2), Barinas (1), Bolívar (2), Delta Amacuro (1), Sucre (1), Vargas (1)</i>	89,844.00 <i>Barinas (1), Nueva Esparta (1), Zulia (1)</i>
GeneXpert calibration kit	2,160.00	7,020.00	8,640.00
GeneXpert (viral load cartridges)	132,600.00	533,511.00	592,977.00
GeneXpert Qual cartridges	2,160.00	6,480.00	10,800.00
CD4 (BD FACSCount system) (tests, controls, reagents and additional supplies)	1,020,616.80	332,039.52	332,039.52
HIV-resistance testing (in house)	11,520.00	23,040.00	23,040.00
Viral hepatitis and bacterial testing	42,000.00	42,000.00	42,000.00
<b>TOTAL</b>	<b>4,845,778.60</b>	<b>7,567,631.72</b>	<b>7,779,574.72</b>

<b>Support: Prevention</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Condoms (male)	1,800,000.00	1,800,000.00	1,800,000.00
<b>Condoms (female)</b>	<b>3,564,000.00</b>	<b>3,564,000.00</b>	<b>3,564,000.00</b>
Lubricants	115,200.00	115,200.00	115,200.00
<b>TOTAL</b>	<b>5,479,200.00</b>	<b>5,479,200.00</b>	<b>5,479,200.00</b>

<b>Support: Health services strengthening</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Referral project for PLHIV and community monitoring of ARVs (RVG+) (includes human resources, transport and logistics, communication and data management technology and two face-to-face meetings per year)	155,650.00	127,700.00	127,700.00
Laboratory staff training on immunovirological and GeneXpert testing	15,000.00	15,000.00	10,000.00
Training and technical assistance for adapting resistance tests, including integrase and next-generation sequencing	10,000.00	5,000.00	0
Participation in an external quality control program (INH) for viral load, CD4 and resistance testing	5,000.00	5,000.00	5,000.00
Development of educational materials on combined HIV prevention and treatment literacy (treatment, adherence, etc.)	10,000.00	5,000.00	5,000.00
Staff training on rapid testing and reducing stigma and discrimination	13,000.00	16,000.00	11,000.00
<b>TOTAL</b>	<b>208,650.00</b>	<b>173,700.00</b>	<b>158,700.00</b>

<b>Support: Surveillance</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
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HIV-resistance surveillance study (the cost of the resistance test is covered by the regional reference laboratory designated by WHO)	40,000.00	0	0
Training for health workers and epidemiologists at various levels on the HIV epidemiological surveillance system	10,000.00	10,000.00	10,000.00
<b>TOTAL</b>	<b>50,000.00</b>	<b>10,000.00</b>	<b>10,000.00</b>

<b>TOTAL HIV COMPONENT</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
<b>TOTAL (drugs)</b>	23,208,704.79	20,073,762.66	20,374,556.94
<b>TOTAL (laboratory)</b>	4,845,778.60	7,567,631.72	7,779,574.72
<b>TOTAL (prevention)</b>	5,479,200.00	5,479,200.00	5,479,200.00
<b>TOTAL (health services strengthening)</b>	208,650.00	173,700.00	158,700.00
<b>TOTAL (surveillance)</b>	50,000.00	10,000.00	10,000.00
<b>TOTAL</b>	<b>33,792,333.39</b>	<b>33,304,294.38</b>	<b>33,802,031.66</b>

## 7.2 TB component

<b>Support: Drugs</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
TB drugs <b>Annex 5</b>	0	504,914	673,948
<b>TOTAL</b>	<b>0</b>	<b>504,914</b>	<b>673,948</b>

<b>Support: Laboratory</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
14 GeneXpert four-module machines with UPS (US\$ 21,350 per unit) each year to meet needs such as TB diagnostic testing, plus three-year warranty for each piece of equipment (US\$ 7,902)	<b>409,528</b> (for seven priority states: Distrito Capital, Anzoátegui, Aragua, Bolívar, Carabobo, Miranda and Zulia)	<b>409,528</b>	<b>409,528</b>
Calibration kits (14 each year)	<b>7,560</b>	<b>7,560</b>	<b>7,560</b>
GeneXpert MTB/RIF cartridges (US\$ 600 per box of 50)	<b>468,000</b>	<b>468,000</b>	<b>468,000</b>
Two LED microscopes (US\$ 10,000 per unit) + 20 percent processing fee	<b>24,000</b>	-	-
Three UPS devices for biosafety cabinets (US\$ 1,800 per unit) + 20 percent processing fee	<b>6,480</b>	-	-
Refrigerated centrifuge with removable rotor for 15 and 50 ml tubes and with autoclavable tubes (including processing fees)	<b>12,000</b>	-	-
Water distiller with a capacity of 12 liters per hour (including processing fees)	<b>4,320</b>	-	-
150-liter vertical gas autoclave (including processing fee)	<b>72,000</b>	-	-
Three laptop computers (US\$ 1,000 per unit) + 20 percent processing fee	<b>3,600</b>	-	-
Flatbed scanner (including processing fee)	<b>300</b>	-	-
<b>TOTAL</b>	<b>1,007,788</b>	<b>885,088</b>	<b>885,088</b>

<b>Support: Prevention</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
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2,000 N-95 respirators (US\$ 2 per unit + 20 percent processing fee)	<b>4,800</b>	<b>4,800</b>	<b>4,800</b>
Consultation for designing informative TB material for social networks	-	<b>3,000</b>	-
<b>TOTAL</b>	<b>4,800</b>	<b>7,800</b>	<b>4,800</b>

<b>Support: Health services strengthening</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Four regional TB refresher/management workshops for coordinators of 24 selected integrated community health areas (ASICs) and 14 state coordinators (US\$ 25 per day x 5 days + US\$ 75 for transport)	<b>10,000</b>	-	-
Four regional refresher workshops/training sessions in preventing and controlling TB for doctors, nurses and bioanalysts (US\$ 25 per day x 5 days + US\$ 75 for transport)	<b>3,000</b> (for the 24 ASICs initially selected)	<b>3,000</b> (expanded to 24 additional ASICs)	<b>3,000</b> (expanded to 24 additional ASICs)
NTCP supervision visits to states (US\$ 25 per day x 3 days + US\$ 75 for transport)	<b>2,100</b> (13 states)	<b>2,100</b> (13 states)	<b>2,100</b> (13 states)
Supervision visits from NTCP coordinators at the state level to ASICs (one in year 1 and two from year 2 onward)	<b>1,000</b>	<b>2,000</b>	<b>2,000</b>
Consultation for designing suitable infrastructure for the national reference laboratory	<b>10,000</b>	-	-
13 desktop computers for state TB programs (including processing fee)	<b>12,480</b>	-	-

Support for establishing a sample transportation system (US\$ 100 per month)	<b>28,800</b> (for the 24 ASICs initially selected)	<b>28,800</b> (for 24 ASICs to be prioritized)	<b>28,800</b> (for 24 ASICs to be prioritized)
Seven portable digital X-ray machines for health services within the prison system in Anzoátegui, Aragua, Carabobo, Miranda, Táchira, Lara and Bolívar (for prisoners) + 20 percent processing fee	<b>928,200</b>	-	-
Scientific meetings/TB days	<b>10,000</b>	<b>10,000</b>	<b>10,000</b>
<b>TOTAL</b>	<b>1,005,580</b>	<b>45,900</b>	<b>45,900</b>

<b>Support: Information/surveillance and other</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Consultants for Epi review	<b>10,000</b>	-	-
Implementation of Epi review recommendations	<b>5,000</b>	<b>5,000</b>	-
Design of social promotion and community participation guidelines based on the WHO ENGAGE-TB approach	<b>1,200</b>	-	-
Support for ENGAGE-TB interventions	<b>5,000</b>	<b>5,000</b>	<b>5,000</b>
Operational research to improve case detection, reduce patients lost to follow-up, improve mortality studies and address vulnerable populations	<b>5,000</b>	<b>5,000</b>	<b>5,000</b>
<b>TOTAL</b>	<b>26,200</b>	<b>15,000</b>	<b>10,000</b>

<b>TOTALS</b>			
<b>Drugs</b>	-	<b>504,914</b>	<b>673,948</b>
<b>Laboratory</b>	<b>1,007,788</b>	<b>885,088</b>	<b>885,088</b>
<b>Prevention</b>	<b>4,800</b>	<b>7,800</b>	<b>4,800</b>

<b>Health services strengthening</b>	<b>1,005,580</b>	<b>45,900</b>	<b>45,900</b>
<b>Information/surveillance and other</b>	<b>26,200</b>	<b>15,000</b>	<b>10,000</b>
<b>OVERALL TOTAL</b>	<b>2,044,368</b>	<b>1,458,702</b>	<b>1,619,736</b>
	<b>5,122,806</b>		

### 7.3 Malaria component

<b>Support: Drugs</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Procure drugs (excluding Bolívar in year 1 and for the entire country in year 2, but with a 40 percent decrease in malaria throughout the country)	364,586.98	689,759.16	
Procure drugs to treat severe malaria and comorbidities and medical supplies	234,549.97	164,184.98	0
Transport, insurance and other	89,870.54	128,091.62	0
<b>TOTAL</b>	<b>689,007.49</b>	<b>982,035.75</b>	<b>0</b>

<b>Support: Laboratory</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Procure rapid diagnostic tests (RDTs)	1,400,000.00	1,120,000.00	700,000.00
Procure thick smear supplies	57,429.75	57,429.75	34,457.85
Procure microscopes	300,000.00	0	0
Procure spare parts for microscopes	27.00		

Supplies for community worker kits (activities to detect, diagnose and treat malaria in mining areas and among indigenous populations)	10,000.00	10,000.00	5,000.00
Transport, insurance and other	263,618.51	176,614.46	110,168.68
<b>Total</b>	<b>2,031,075.26</b>	<b>1,364,044.21</b>	<b>849,626.53</b>

<b>Support: Prevention</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Procure long-lasting insecticidal nets (LLINs)	1,800,000.00	1,800,000.00	900,000.00
Procure insecticides for indoor residual spraying (IRS)	320,000.00	320,000.00	160,000.00
Procure Hudson pumps	120,000.00	0	0
Procure protective equipment	32,550.00	0	0
Address transport constraints for field activities and monitoring	US\$ 1,503,720.00	0	0
Transport, insurance and other	340,882.50	318,000.00	135,000.00
<b>Total</b>	<b>4,117,152.50</b>	<b>2,438,000.00</b>	<b>1,195,000.00</b>

<b>Support: Health services</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Training in ASICs (case management, micro-stratification, malaria epidemiology and analysis)	10,000.00	10,000.00	0

Training in diagnosing and managing malaria cases in the priority ASICs	9,000.00	9,000.00	9,000.00
Continue training in clinical management of severe malaria	20,000.00	10,000.00	10,000.00
Develop pilot schemes to implement the new malaria management model in selected ASIC municipalities (epidemiologists' salaries)	100,000.00	100,000.00	100,000.00
Develop and implement a mortality analysis methodology	5,000.00	0	0
Develop the proposal for organizing the malaria diagnosis and treatment network under the ASIC structure	10,000.00	0	0
Strengthen the national reference laboratory	5,000.00	5,000.00	5,000.00
Implement guidelines for detecting, diagnosing, preventing and managing malaria during prenatal checkups and delivery care (malaria during pregnancy and congenital malaria)	10,000.00	5,000.00	0
Implement the microscopy quality management system	32,000.00	16,000.00	16,000.00
Local micro-planning (ASIC) to organize diagnosis and treatment in the health services network: people's clinics, comprehensive diagnosis centers (CDIs), hospitals, malaria microscopists, community actors (with RDTs)	20,000.00	20,000.00	20,000.00

Organize care referral routes, management of severe malaria	10,000.00	10,000.00	0
Organize national coordination roles for the malaria response	0	0	0
Re-establish the microscopy network	20,000.00	0	0
Review national procedures for distributing and managing antimalarials, prioritizing their availability at the local level in endemic areas (ASIC)	5,000.00	0	0
<b>Total</b>	<b>256,000.00</b>	<b>185,000.00</b>	<b>160,000.00</b>

<b>Support: Surveillance</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Epidemiological update and risk analysis and needs	5,000.00	5,000.00	0
Communication campaign on installing LLINs	80,000.00	30,000.00	30,000.00
Training in information management, analysis, micro-stratification at the local level (ASIC) for malaria decision-making	5,000.00	5,000.00	5,000.00
Develop agreements with local stakeholders in the short term to implement priority measures (malaria diagnosis and treatment)	5,000.00	0	0
Develop a theoretical framework for programmatic implementation of RDTs	10,000.00	5,000.00	5,000.00

Develop a risk-communication strategy to address the malaria epidemic	10,000.00	0	0
Develop strategies to improve antimalarial adherence	30,000.00	30,000.00	30,000.00
Draft a support paper to regulate essential public health actions in the context of mining activities	0	0	0
Provide equipment and software at the local level (ASICs) for recording and managing information (computers, software, GPS, etc.) and paper records	65,000.00	45,000.00	29,000.00
Stratify and profile malaria outbreaks as required by health engineering measures	20,000.00	0	0
Pharmacovigilance surveillance studies (in vivo) using molecular markers	50,000.00	50,000.00	0
Entomological studies	16,000.00	16,000.00	4,000.00
Computer tools for database management (cases, examined slides, etc.)	10,000.00	10,000.00	0
Implement the Mining Arc Health Plan	0	0	0
Implement actions for active case detection	94,500.00	94,500.00	94,500.00
Implement the risk-communication strategy for malaria (including various communication activities)	50,000.00	50,000.00	50,000.00
IRS monitoring	22,400.00	22,400.00	11,200.00
LLIN installation operations	175,000.00	175,000.00	75,000.00

IRS operations (logistics, transport)	240,000.00	240,000.00	120,000.00
Re-establish the Malaria Advisory Committee	3,000.00	3,000.00	3,000.00
Revise the Antimalaria Law	0	0	0
Intervention follow-up	0	50,000.00	50,000.00
<b>Total</b>	<b>890,900.00</b>	<b>830,900.00</b>	<b>506,700.00</b>

<b>OVERALL TOTAL Malaria</b>	<b>Year 1 (estimated value in US\$)</b>	<b>Year 2 (estimated value in US\$)</b>	<b>Year 3 (estimated value in US\$)</b>
Total – drugs	689,007.49	982,035.75	0
Total – laboratory	2,031,075.26	1,364,044.21	849,626.53
Total – prevention	4,117,152.50	2,438,000.00	1,195,000.00
Total – health services	256,000.00	185,000.00	160,000.00
Total – surveillance	890,900.00	830,900.00	506,700.00
<b>Overall total</b>	<b>7,984,135.25</b>	<b>5,799,979.96</b>	<b>2,711,326.53</b>

## **TB reference documents**

- NTCP document: Monitoring visit – General description of country
- National Strategic Plan for TB Prevention and Control – Venezuela 2016–2019
- Venezuelan Official Standard for the Integrated National Tuberculosis Control Program – Manual for Coordinators and Laboratories. 2006
- Official Standard for the National Program for Respiratory Health – Tuberculosis, Asthma, Chronic Obstructive Pulmonary Disease. November 2016
- Venezuelan Official Standard for the Integrated National Tuberculosis Control Program – Manual for the Community Primary Care Network. November 2016
- Report, June 2018 – Respiratory Health Department, Ministry of Health (MPPS)
- Tuberculosis Control Program research. July 2017
- NTCP presentation: Epidemiological and Operational Situation of Tuberculosis in Venezuela. 20 June 2018

## Annex 1 – Technical mission terms of reference and agenda

### Joint technical mission to strengthen the response to HIV, tuberculosis and malaria in the Bolivarian Republic of Venezuela from a public health perspective

Caracas, Venezuela

18–22 June 2018

<b>PROGRAM</b>
<p><b>Aim of the technical mission</b></p> <p>Strengthen the national response to HIV, TB and malaria to guarantee continued access to comprehensive and effective health services, drugs and adequate laboratory monitoring, maximize the effectiveness of programs for preventing and controlling these diseases, minimize the risk of the emergence and transmission of resistance and ensure sustainability in providing essential services from a public health perspective.</p>
<p><b>General objective of the joint mission</b></p> <p>Facilitate dialogue among all actors involved in the response to HIV, TB and malaria in Venezuela (including government representatives, civil society representatives, health care providers and scientific societies), as well as regional and global partners, with the aim of agreeing on recommendations for urgent priorities and measures that will ensure continued access to effective and quality health services and developing a three-year support plan for Venezuela, addressing these three diseases and allowing for international coordination and cooperation. For the three diseases, the following actions are proposed:</p> <ul style="list-style-type: none"><li>✓ review up-to-date data on the epidemiological situation of HIV, TB and malaria;</li><li>✓ review prevention and control activities for the three diseases in accordance with existing international recommendations;</li><li>✓ review the status of national information systems;</li><li>✓ profile the drugs and supplies logistics chain;</li><li>✓ identify strengths and gaps in the country's response to HIV, TB and malaria;</li><li>✓ draft recommendations agreed by all actors involved and aid partners on strengthening the response and on the urgent cooperation needs to be included in the support plan;</li><li>✓ define coordination mechanisms between technical aid partners and the various actors in the country for implementing the support plan.</li></ul>
<p><b>Expected outcomes</b></p> <ul style="list-style-type: none"><li>✓ Updated analysis of the epidemiological situation and prevention and control activities for the three diseases with strengths and gaps identified.</li></ul>

<ul style="list-style-type: none"> <li>✓ Estimates of up-to-date requirements for drugs, laboratory supplies and prevention supplies with a medium-term continuity plan (three years).</li> <li>✓ Agreed recommendations for strengthening HIV, TB and malaria prevention and control activities and the urgent cooperation needs to be included in a three-year support plan.</li> <li>✓ Key geographic areas for implementing the support plan according to epidemiological priorities and operational feasibility analysis.</li> <li>✓ Coordination mechanisms defined for technical aid partners and the various actors in the country for implementing the support plan.</li> <li>✓ Recommendations for priority actions for the Global Fund “investment case” as part of the support plan.</li> </ul>	
<p><b>Participants</b></p> <p>The working group comprises: representatives of the National HIV and AIDS, TB and Malaria Programs of the Ministry of Health, advisers from the Pan American Health Organization/World Health Organization (PAHO/WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) and representatives of Venezuelan civil society.</p>	
<p><b>AGENDA</b></p>	
Time	Monday 18 June 2018
08:00 to 09:00	PAHO/WHO Venezuela Representatives meeting
09:00 to 9:30	Refreshments
09:30 to 11:00	<p>Technical meeting opening speech</p> <ul style="list-style-type: none"> <li>✓ Dr Maiqui Flores, Deputy Minister of Comprehensive Care and Director of the Office of Integration and International Affairs (OIAI)</li> <li>✓ Dr Jose Moya, PAHO/WHO Representative Venezuela</li> <li>✓ Dr Regina López, Country Director, UNAIDS</li> <li>✓ Dr Massimo Ghidinelli, Head of HIV, STIs, Hepatitis and TB Unit</li> </ul>
	<p>Plenary meeting with all participants: authorities, technical teams and civil society representatives</p> <ul style="list-style-type: none"> <li>✓ Review of mission objectives, work agenda and expected outcomes</li> </ul>
	Presentation on each program’s status:

11:00 to 11:30 11:30 to 12:00 12:00 to 12:30	<ul style="list-style-type: none"> <li>✓ HIV and other STIs situation, Dr Deisy Matos</li> <li>✓ TB situation, Dr Mercedes España</li> <li>✓ Malaria situation, Dr Maria Jorge de Canelones</li> </ul>
12:30 to 13:00	Presentation on the supply management system for drugs and medical supplies, Dr Eli Saul González, Representative of the Deputy Ministry of Health Technologies and Supplies
13:00 to 14:00	Lunch

Time	Working groups		
14:00 to 14:30	HIV component (Room A)	TB component (Room B)	Malaria component (Room C)
14:30 to 16:30	Civil society presentation  National meeting: review of epidemiological data on the HIV epidemic and the programmatic response; review of capacities and gaps in the health system for providing prevention, screening and diagnosis services and comprehensive care, treatment and laboratory monitoring	Analysis of the epidemiological and operational situation of TB control	National Malaria Control Program (NMCP) meeting: analysis of the national epidemiological situation and of the worst affected states; analysis of control activities; identification of major gaps

Time	Tuesday 19 June 2018		
08:00 to 12:30	HIV component (Field visit)	TB component (National Tuberculosis Control Program (NTCP) visit)	Malaria component (Room C)
	Visit to the Rafael Rangel National Institute of Hygiene (INH) and discussion on gaps in the provision of laboratory services for diagnosis and monitoring, and strategies for HIV-resistance surveillance with support from the Regional Laboratory Network designated by WHO	Working meeting with the NTCP team José Ignacio Baldó Hospital Complex, El Algodonal Caracas: <ul style="list-style-type: none"> <li>✓ NTCP</li> <li>✓ National TB laboratory</li> <li>✓ Coordination of the NTCP in Distrito Capital</li> </ul>	Work with the Bolívar team: <ul style="list-style-type: none"> <li>✓ Epidemiological situation</li> <li>✓ Information analysis</li> <li>✓ Case management strategy</li> <li>✓ Vector control actions</li> <li>✓ Operational gaps</li> <li>✓ Drugs management</li> </ul>
12:30 to 13:30	Lunch		
13:30 to 16:30	Integrated health services visit and/or meeting with health care providers and program coordinators to discuss gaps in service provision (for adults, children and pregnant women)	Meeting with the Venezuelan Pneumology Society  Meeting with the Respiratory Health Association (APROSAR)	Work with the Anzoátegui team: <ul style="list-style-type: none"> <li>✓ Epidemiological situation</li> <li>✓ Information analysis</li> <li>✓ Case management strategy</li> <li>✓ Vector control actions</li> <li>✓ Operational gaps</li> <li>✓ Drugs management</li> </ul>
Time	Wednesday 20 June 2018		

08:00 to 12:30	HIV component (Room A)	TB component (Field visit)	Malaria component (Room C)
	<p>Technical meeting to review treatment regimens currently recommended and in use (adults and children), other essential drugs for comprehensive care (opportunistic infections), laboratory diagnosis and monitoring, and to discuss and agree on protocols for essential services for HIV prevention and comprehensive care, harmonized from a public health perspective and in accordance with WHO recommendations</p>	<p>Field visits</p> <ul style="list-style-type: none"> <li>✓ Caracas Outpatient University Teaching Hospital</li> <li>✓ Urban Outpatient Type II El Valle</li> <li>✓ Urban Outpatient Type III San Martín</li> </ul>	<p>Work with the Amazonas team:</p> <ul style="list-style-type: none"> <li>✓ Epidemiological situation</li> <li>✓ Information analysis</li> <li>✓ Case management strategy</li> <li>✓ Vector control actions</li> <li>✓ Operational gaps</li> <li>✓ Drugs management</li> </ul>
12:30 to 13:30	Lunch	Lunch	Lunch
13:30 to 16:30	<p>Update ARV estimates (treatment and prevention of mother-to-child transmission (PTMI)), other drugs (opportunistic infections), prevention supplies and laboratory supplies</p>	<ul style="list-style-type: none"> <li>✓ Simon Bolívar Hospital, José Ignacio Baldó Hospital Complex, El Algodonal, Caracas</li> </ul>	<p>Work with the Sucre team:</p> <ul style="list-style-type: none"> <li>✓ Epidemiological situation</li> <li>✓ Information analysis</li> <li>✓ Case management strategy</li> <li>✓ Vector control actions</li> <li>✓ Operational gaps</li> <li>✓ Drugs management</li> </ul>

Time	Thursday 21 June 2018		
	HIV component (Room A)	TB component (Room B)	Malaria component (Room C)
08:00 to 09:00	Meeting with scientific societies		
09:00 to 10:00	Proposal to integrate health services		
10:00 to 12:30	Technical meeting to discuss and agree on recommendations and needs for the support plan, road map and coordination mechanisms among technical aid partners and national actors	Technical meeting to discuss and agree on recommendations and needs for the support plan, road map and coordination mechanisms among technical aid partners and national actors	Technical meeting to discuss and agree on recommendations and needs for the support plan, road map and coordination mechanisms among technical aid partners and national actors
12:30 to 13:30	Lunch		
13:30 to 16:00	Afternoon: Joint technical meeting: Malaria, TB and HIV Consolidate recommendations and draft the support plan		
16:00 to 16:15	Refreshments		
16:15 to 17:30	Meeting with the United Nations organizations in Venezuela		
Time	Friday 22 June 2018		

09:00 to 12:30	Meeting with health authorities to present the recommendations
12:30 to 14:00	Lunch
14:00 to 15:30	Meeting with PAHO/WHO Venezuela Representatives
15:30 to 16.30	Meeting with all participants and end of technical mission

**LIST OF PARTICIPANTS**

Name	Position
<b>Ministry of Health (MPPS)</b>	
Maiqui Flores Meneses	Deputy Minister for Comprehensive Care Director of the Office of Integration and International Affairs
Moira Tovar	Deputy Minister of Collective Health Networks
Eli Saul González	Representative of the Deputy Ministry of Health Technologies and Supplies
Elba Petit	Director-General of Health Programs
<b>PAHO/WHO</b>	

José Moya	PAHO/WHO Representative
Roberto Fábrega	Adviser on Health Systems and Services
Nora Girón	Adviser on Drugs and Supplies (Strategic Fund/Revolving Fund)
Malhi Cho	Adviser on Health Systems and Services, Venezuela

<b>HIV, Hepatitis and Other STIs Technical Group</b>	
Deisy Matos	NACP Coordinator
Carla Rondón	Prevention component
Carolina Cedeño	Pharmacist
Erika Montzerrat	Information system
Pierina D'Angelo	National Institute of Hygiene
Edgar Rivera	National Institute of Hygiene
Alejandra Corao	UNAIDS
Regina López	UNAIDS
Alberto Nieves	Civil society representative
Feliciano Reyna	Civil society representative
Napoleón Guevara	Venezuelan Society of Infectology
María Gabriela López	Venezuelan Society of Infectology
Massimo Ghidinelli	PAHO/WHO
Giovanni Ravasi	PAHO/WHO
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Luis Raúl Rojas	Molecular Tests, National TB Reference Laboratory
José Ramon García	APROSAR
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<b>Malaria Technical Group</b>	
Moira Tovar	Deputy Minister of Collective Health
Ernesto Flores	National Director of Epidemiology

Maria Jorge de Canelones	Directorate-General for Environmental Health (DGSA)
Domingo Mora	Deputy Director-General for Environmental Health
Eduardo Borges	National Malaria Control Coordinator, DGSA
Rubén Palacios	Director of Vector Control, DGSA
Magda Magris	Amazonian Center for Investigation and Control of Tropical Diseases (SACAICET), Amazonas
Ana Villaroel	Environmental Health Directorate, Amazonas
Armando Ortega	Environmental Health Directorate, Bolívar
Elia Sanchez	Environmental Health Directorate, Sucre
Gustavo Valenzuela	Environmental Health Directorate, Bolívar
Roberto Montoya	PAHO/WHO
Daniel Vargas	PAHO/WHO
Tulia Hernández	PAHO/WHO
Angel Alvarez	PAHO/WHO

## Annex 2 – Revised guidelines for antiretroviral therapy (ART) and laboratory monitoring for people living with HIV (PLHIV) undergoing treatment

### 1. Restarting ART (adults)

Context	Population	Preferred regimen	Alternative regimen(s)
After interruption of first-line treatment, restart with a non-nucleoside reverse transcriptase inhibitor (NNRTI) (EFV or NVP)* or a protease inhibitor (PI) and second-line treatment with a PI	Men	TDF/3TC/DTG	ABC/3TC+DTG** TDF/FTC+ATV/r TDF/FTC+LPV/r
	Women (not of childbearing age, or who consistently use contraceptives or do not want to become pregnant)		
	Women (of childbearing age or who do not consistently use contraceptives)	TDF/FTC+ATV/r TDF/FTC+LPV/r	ABC/3TC+ATV/r ABC/3TC+LPV/r
	Pregnant women		

\* Potential risk of NNRTI resistance (WHO Recommendations 2017)

\*\* Approximately 2 percent of people have TDF contraindication

Note: Use of DTG in people with TB: DTG 50 mg twice daily

### 2. Restarting ART (children)

Context	Population	Preferred regimen	Alternative regimen(s)

After interruption of first-line treatment, restart <u>with LPV/r</u>	<3 years	ABC/3TC+LPV/r AZT/3TC+LPV/r	ABC/3TC+RAL AZT/3TC+RAL
	3–10 years	ABC/3TC+LPV/r	TDF/FTC(or 3TC)+LPV/r ABC/3TC+RAL TDF/FTC(or 3TC)+RAL

Note: planning to change to ABC/3TC or AZT/3TC combined, dispersible and grooved; change from LPV/r syrup to oral pellets.

Context	Population	Preferred regimen	Alternative regimen(s)
After interruption of first-line treatment, restart with NNRTI*	<3 years	<b>ABC(or AZT)/3TC+LPV/r</b>	ABC/3TC+RAL AZT/3TC+RAL
	3–10 years	<b>ABC(or TDF)/3TC+RAL</b>	ABC/3TC+IP/r TDF/FTC(or 3TC)+IP/r (DTG >12 years; >20 kg under review by WHO)

\* Potential risk of NNRTI resistance

Note: IP/r can be LPV/r or DRV/r according to clinical indication.

Context	Population	Preferred regimen
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<b>Restart after interruption of second-line treatment</b>	<3 years (second-line with LPV/r and previous failure with NVP)	<b>ABC/3TC+LPV/r</b> <b>AZT/3TC+LPV/r</b>
	<3 years (second-line with NVP* and previous failure with LPV/r)	<b>ABC/3TC+RAL ±IP**</b> <b>ABC/3TC+RAL ±IP**</b>
	3–10 years (second-line with IP and prior exposure to NNRTI)	<b>2 NRTI+IP/r</b>
	3–10 years (second-line with EFV* and prior exposure to IP)	<b>2 NRTI+RAL ±IP**</b> (DTG >12 years; >20 kg under review by WHO)

\* Potential risk of NNRTI resistance

\*\* Empirical recovery regimen or based on resistance test (if available)

Note: IP/r can be LPV/r or DRV/r according to clinical indication.

### Other considerations for restarting ART

When restarting third-line/recovery regimens, if possible, maintain the same regimens.

For people restarting ART:

Viral load taken between 12 and 24 weeks after restarting ART (not before 12 weeks)

CD4 (few tests available)

For people whose ART has not been interrupted, carry out viral load test and CD4 count (few tests available)

Viral load priority: for those receiving ART without viral load results in the last six months, pregnant women, those restarting ART between 12 and 24 weeks after resuming treatment.

Perform CD4 counts (when available) for all people on ART to update their immune status.

### 3. Starting ART (adults)

Context	Population	Preferred regimen	Alternative regimen(s)
First-line treatment	<ul style="list-style-type: none"> <li>Men</li> </ul>	<b>TDF/3TC/DTG (Fixed Dose Combination)</b>	ABC/3TC+DTG* or TDF/FTC+ATV/r (or LPV/r)
	<ul style="list-style-type: none"> <li>Women (not of childbearing age, or who consistently use contraceptives or do not want to become pregnant)</li> </ul>		
	<ul style="list-style-type: none"> <li>Women (of childbearing age or who do not consistently use contraceptives)</li> </ul>	<b>TDF/FTC/EFV**</b>	ABC/3TC+ATV/r or LPV/r
<ul style="list-style-type: none"> <li>Pregnant women</li> </ul>	<b>TDF/FTC+ATV/r or TDF/FTC+LPV/r</b>		

\* Approximately 2 percent of people have TDF contraindication

\*\* Revise the following regimen based on results from the national primary resistance study (Q1 2019)

Note: Use of DTG in people with TB: DTG 50 mg twice daily

#### CD4 and viral load

Perform basal CD4 counts (new diagnoses)

Follow-up with viral load testing every six months (people receiving ART)

For people receiving ART with suppressed viral load, suspend CD4 count follow-up – request only if necessary (e.g. virological or clinical failure)

### Annex 3 – Antiretrovirals procurement plan for treating adults and PEP (year 1)

Item	Drugs	Drug form	Unit cost (US\$)	Needs 2019*	Cost 2019 (US\$)	Total 2019** (US\$)
1	TNF 300 mg / 3TC 300 mg / DLG 50 mg	Tablet	6.75	865,754	5,843,839.30	7,012,607.15
2	ABC 600 mg / 3TC 300 mg	Tablet	12.50	49,206	615,079.96	738,095.95
3	DLG 50 mg	Tablet	3.67	38,130	139,937.03	167,924.44
4	TNF 300 mg / FTC 200 mg	Tablet	5.25	74,450	390,860.89	469,033.07
5	LPO 200 mg / RTV 50 mg	Tablet	18.00	72,575	1,306,349.05	1,567,618.86
6	ATV 300 mg / RTV 100 mg	Tablet	15.50	42,733	662,364.16	794,836.99
7	AZT 300 mg / 3TC 150 mg	Tablet	5.25	26,698	140,165.83	168,199.00
8	TNF 300 mg / FTC 200 mg / EFV 600 mg	Tablet	7.00	18,530	129,708.11	155,649.74
9	DRV 600 mg	Tablet	70.00	23,757	1,662,997.91	1,995,597.49
10	RAL 400 mg	Tablet	48.00	5,970	286,570.18	343,884.21
11	ETV 100 mg	Tablet	420.00	5,970	2,507,489.03	3,008,986.84
12	DRV 800 mg	Tablet	855.00	1,547	1,322,417.42	1,586,900.90
13	AZT 10 mg/ml	Solution	9.00	2,535	22,815.00	27,378.00
14	RTV 100 mg	Tablet	4.10	1,547	6,341.42	7,609.70
					15,036,935.29	18,044,322.35

\* Includes 12 months of treatment and three months of reserve stock (for year 1 only)

\*\* Includes freight, transport and insurance

**Antiretrovirals procurement plan for treating children and post-exposure prophylaxis in children (year 1)**

Item	Drugs	Drug form	Unit cost (US\$)	Needs 2019*	Cost 2019 (US\$)	Total cost 2019**
1	ABC 60 mg / 3TC 30 mg (dispersible tablet)	Dispersible tablet	4.15	15,990	66,358.50	79,630.20
2	Lopinavir 40 mg / ritonavir 10 ml (oral pellets)	Pellets	19.20	8,145	156,384.00	187,660.80
3	AZT 60 mg / 3TC 30 mg (dispersible tablet)	Dispersible tablet	1.90	3,075	5,842.50	7,011.00
4	Lopinavir 100 mg / ritonavir 25 mg	Tablet	29.00	1,125	32,625.00	39,150.00
5	TDF 300 mg / FTC 200 mg	Tablet	5.25	2,760	14,490.00	17,388.00
6	DRV 75 mg	Tablet	250.00	1,305	326,250.00	391,500.00
7	Raltegravir 100 mg (chewable tablet)	Chewable tablet	48.00	5,550	266,400.00	319,680.00
8	AZT 50 mg/5 l (240 ml)	Suspension	2.15	400	860.00	1,032.00
9	NVP 10 mg/ml (100 ml)	Suspension	1.30	100	130.00	156.00
					<b>869,340.00</b>	<b>1,043,208.00</b>

\* Includes 12 months of treatment and three months of reserve stock (for year 1 only)

\*\* Includes freight, transport and insurance

**Annex 4 – Procurement plan for prophylaxis drugs and treating opportunistic infections and syphilis (year 1)**

<b>Item</b>	<b>Drugs</b>	<b>Drug form</b>	<b>Unit cost (US\$)</b>	<b>Needs 2019</b>	<b>Cost 2019 (US\$)</b>	<b>Total cost 2019 (US\$)</b>
1	Folinic acid	Tablet	2.10	100,000	210,000.00	<b>252,000.00</b>
2	Itraconazole	Capsules	0.16	126,000	20,160.00	<b>24,192.00</b>
3	Ganciclovir	Vial	48.00	1,200	57,600.00	<b>69,120.00</b>
4	Pyrimethamine	Tablet	0.10	208,000	20,800.00	<b>24,960.00</b>
5	Trimethoprim/ sulphamethoxazole	Tablet	0.03	120,000	3,600.00	<b>4,320.00</b>
6	Trimethoprim/ sulphamethoxazole	Solution	3.82	3,800	14,516.00	<b>17,419.20</b>
7	Valaciclovir	Tablet	1.23	20,000	24,600.00	<b>29,520.00</b>
8	Valganciclovir	Tablet	27.00	30,000	810,000.00	<b>972,000.00</b>
9	Fluconazole	Tablet	0.15	100,000	15,000.00	<b>18,000.00</b>
10	Fluconazole	Vial	7.09	3,000	21,270.00	<b>25,524.00</b>
13	Amphotericin B liposomal	Vial	18.00	8,000	144,000.00	<b>172,800.00</b>
14	Flucytosine	Vial	280.29	1,500	420,433.20	<b>504,519.84</b>
15	Doxorubicin	Vial	3.54	300	1,062.00	<b>1,274.40</b>
16	Penicillin G Benzathine 2.4 milli-International Units (mIU)	Vial	3.42	3,000	10,260.00	<b>12,312.00</b>
17	Crystalline penicillin 1.0 mIU	Vial	4.00	900	3,600.00	<b>4,320.00</b>
					1,776,901.20	<b>2,132,281.44</b>

## Annex 5 – TB drugs plan for year 2 and year 3

2019 2do AÑO PLAN ESQUEMA: RR/MDR: 5( Am-Mox- Eto-Z-E-H ) / 16 ( Eto-Mox-Eto-E-H) + ESQUEMA XDR						
PROGRAMA: SALUD RESPIRATORIA/ ANTITUBERCULOSOS						
Pacientes: 13600 casos TB SENSIBLE (13000 mayores de 15 años + 600 menores a 15 años ) + 70 casos RR/MDR + 20 casos XDR						
MPPS/VICEMINISTERIO DE REDES Y SALUD COLECTIVA						
n°	Medicamento /Insumo	Requerimiento anual (tabletas)	Costo unitario (USD)	Costo estimado (USD)/año	flete+ seguro	Costo Total estimado (USD)/año
1	ISONIACIDA 150 mg + RIFAMPICINA 150 mg/TABLETAS CDF	2,808,000	0.033	92,664.00	18,532.80	111,196.80
2	PIRAZINAMIDA 500 mg /TABLETAS	500,000	0.0312	15,600.00	3,120.00	18,720.00
3	ISONIACIDA 300 mg /TABLETAS	1,000,000	0.035	35,000.00	7,000.00	42,000.00
4	ISONIACIDA 100 mg /TABLETAS	800,000	0.009	7,200.00	1,440.00	8,640.00
5	RIFAMPICINA 300 mg /TABLETAS	400,000	0.070	28,000.00	5,600.00	33,600.00
6	ETHAMBUTOL 400 mg /TABLETAS	400,000	0.030	12,000.00	2,400.00	14,400.00
7	RIFAMPICINA SYRUP 100 mg/5 mL 60 ml /FRASCOS	1,000	2.000	2,000.00	400.00	2,400.00
8	RIFAMPICINA 75 mg + ISONIACIDA 60 mg/ TABLETAS CDF	130,000	0.036	4,680.00	936.00	5,616.00
9	RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg/TABLETAS CDF	120,000	0.025	3,000.00	600.00	3,600.00
10	ISONIACIDA 75 mg+ RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ ETHAMBUTOL 275 mg/ TABLETAS CDF	2,600,000	0.060	156,000.00	31,200.00	187,200.00
11	AMIKACIN 500mg /2ml AMPOLLAS	16,800	0.619	10,397.52	2,079.50	12,477.02
12	MOXIFLOXACINA 400 mg/TABLETAS	19,000	0.390	7,410.00	1,482.00	8,892.00
13	ETHIONAMIDE 250 mg/ TABLETAS	50,000	0.064	3,200.00	640.00	3,840.00
15	DELAMANID 50 mg/Capsulas	3,600		0.00	0.00	0.00
16	CLOFAZIME 100 mg /TABLETAS	19,000		0.00	0.00	0.00
17	CICLOSERINA 250 mgs /Capsulas	20,000	0.268	5,360.00	1,072.00	6,432.00
18	LINEZOLID TABLETS 600mg/TABLETAS	5,500	5.500	30,250.00	6,050.00	36,300.00
19	PAS ACID SHET = 4g aminosalicylec acid/SOBRES	6,000	1.333	8,000.000	1,600.00	9,600.00
<b>COSTO TOTAL ESTIMADO (USD)</b>				<b>420,761.520</b>	<b>84,152.30</b>	<b>504,913.82</b>

## PROGRAMA: SALUD RESPIRATORIA/ ANTITUBERCULOSOS

Pacientes: 13600 casos TB SENSIBLE (16.900 mayores de 15 años + 650 menores a 15 años ) + 94 casos RR/MDR + 26 casos XDR

## MPPS/VICEMINISTERIO DE REDES Y SALUD COLECTIVA

n°	Medicamento /Insumo	Requerimiento anual (tabletas)	Costo unitario (USD)	Costo estimado (USD)/año	flete+ seguro	Costo Total estimado (USD)/año
1	ISONIACIDA 150 mg + RIFAMPICINA 150 mg/TABLETAS CDF	3,650,400	0.033	120,463.20	24,092.64	144,555.84
2	PIRAZINAMIDA 500 mg /TABLETAS	600,000	0.0312	18,720.00	3,744.00	22,464.00
3	ISONIACIDA 300 mg /TABLETAS	1,300,000	0.035	45,500.00	9,100.00	54,600.00
4	ISONIACIDA 100 mg /TABLETAS	1,000,000	0.009	9,000.00	1,800.00	10,800.00
5	RIFAMPICINA 300 mg /TABLETAS	500,000	0.070	35,000.00	7,000.00	42,000.00
6	ETHAMBUTOL 400 mg /TABLETAS	500,000	0.030	15,000.00	3,000.00	18,000.00
7	RIFAMPICINA SYRUP 100 mg/5 mL 60 ml /FRASCOS	1,000	2.000	2,000.00	400.00	2,400.00
8	RIFAMPICINA 75 mg + ISONIACIDA 60 mg/ TABLETAS CDF	140,000	0.036	5,040.00	1,008.00	6,048.00
9	RIFAMPICINA 75 mg + ISONIACIDA 50 mg + PIRAZINAMIDA 150 mg/TABLETAS CDF	130,000	0.025	3,250.00	650.00	3,900.00
10	ISONIACIDA 75 mg+ RIFAMPICINA 150 mg+ PIRAZINAMIDA 400 mg+ ETHAMBUTOL 275 mg/ TABLETAS CDF	3,380,000	0.060	202,800.00	40,560.00	243,360.00
11	AMIKACIN 500mg /2ml AMPOLLAS	28,200	0.619	17,452.98	3,490.60	20,943.58
12	MOXIFLOXACINA 400 mg/TABLETAS	34,300	0.390	13,377.00	2,675.40	16,052.40
13	ETHIONAMIDE 250 mg/ TABLETAS	131,400	0.064	8,409.60	1,681.92	10,091.52
14	DELAMANID 50 mg/Capsulas	7,200		0.00	0.00	0.00
15	CLOFAZIME 100 mg /TABLETAS	32,000		0.00	0.00	0.00
16	CICLOSERINA 250 mgs /Capsulas	20,000	0.268	5,360.00	1,072.00	6,432.00
17	LINEZOLID TABLETS 600mg/TABLETAS	9,500	5.500	52,250.00	10,450.00	62,700.00
18	PAS ACID SHET = 4g aminosalicylec acid/SOBRES	6,000	1.333	8,000.000	1,600.00	9,600.00
<b>COSTO TOTAL ESTIMADO (USD)</b>				<b>561,622.780</b>	<b>112,324.56</b>	<b>673,947.34</b>