**STRENGTHENING THE NATIONAL REFERENCE LABORATORY**

**Situation analysis**

With respect to the duties of the National Reference Laboratory (NRL), the Ministry of Health (MINSAL) is struggling to meet current and future laboratory, teaching and research requirements. This is due to various restrictions, including the absence of additional land for expansion to cover the current and future needs of the NRL at the present site, which is approximately 4,560 m2.

A structural study of the current building found that it was inhabitable subject to certain restrictions, as it had been built in the 1940s, did not reflect the new building and structural design regulations in force since the 1990s, and therefore required structural reinforcement due to the damage caused by earthquakes in 1986 and 2001. It required strengthening with an estimated cost at March 2014 of US$ 1,130,000.00 (document: Ref.: LD-EST-047, PRESENTACIÓN SOBRE EL DIAGNÓSTICO DEL LABORATORIO CENTRAL “MAX BLOCK” [PRESENTATION OF ANALYSIS OF “MAX BLOCK” CENTRAL LABORATORY] conducted by Civil and Structural Engineer Leonidas, G. Delgado, dated 21 March 2014 and sent to the Global Fund on 9 December 2015).

This document also explains that the load on the building exceeds the optimal limit and must be reduced to prevent risk to human life and equipment, and likely environmental pollution due to the potential future impact of earthquakes, as it is located next to the Hospital Nacional Rosales, in a densely populated area in the center of San Salvador.

In addition, the current electrical system is outdated and lacks capacity, as it was originally designed for teaching facilities, not to supply technological and biomedical equipment. This represents a major restriction on laboratory, training and administrative work as the fluctuations in energy supply damage the equipment and reduce its working life. The central air-conditioning system is affected by the same issues, causing damage to equipment and increasing maintenance costs. The drainage system is inadequate and during the rainy season the resultant humidity affects the operation of equipment, damaging laboratory materials and office supplies. The basement of the building floods, making it difficult to work in this area.

As a result, it is not possible to expand or modernize the NRL equipment as there is nowhere to house it, and the electrical and mechanical infrastructure is inadequate, as is the drainage system. It is also not possible to expand the specialist workforce due to the lack of physical space, combined with the fact that the building does not offer a safe working environment or adequate conditions to protect and maintain the health of the staff working in it, or that of the inhabitants of neighboring areas.

It should also be noted that the building, consisting of three floors and a basement, does not have elevators; these were not required by the regulations at the time of construction. This hinders the movement of equipment, furniture and staff.

As a result, in financial terms, structurally strengthening the building that currently houses the NRL is an expense rather than an investment because, in addition to the need for structural reinforcement and complete replacement of the electrical and drainage systems, the restricted nature of the site would not permit growth. Furthermore, it would pose a threat to the life and health of those working there and those living and working nearby, and it would not permit modernization of the laboratory and research equipment and processes, compliance with the quality standards required of a laboratory of its standing, or any improvement in the capacity of the laboratory to respond to the health needs of the population (particularly those related to the control of HIV, TB and malaria).

To respond to existing needs and expand the activities that a laboratory of this standing should provide, the Department of Health Infrastructure of MINSAL has estimated that the NRL should measure approximately 8,000 m2. This would enable it to host the National Health Institute, which includes the NRL and which directs, coordinates and monitors research, ongoing education in health, and laboratory-related teaching.

The National Institute for Health (Instituto Nacional de Salud – INS) is housed in its own building, measuring approximately 650 m2. This site does not provide adequate conditions, as it is a residential building that has been adapted for office use, and for which MINSAL pays an annual rent of US$ 43,392, not including energy, water, security charges etc., which could instead be invested in supplies for the NRL.

It should also be noted that the Department of Health Infrastructure has conducted the necessary inquiries, and neither the central government nor MINSAL have sites large enough to accommodate the NRL and the INS.

As a result, the acquisition of a new building is a health investment that would ensure that the objectives of principal recipients and sub-recipients related to programs supported by the Global Fund in the control of HIV, TB and malaria would be promoted, together with other research areas for other diseases. This building would have the capacity to house the NRL and the INS; to expand their laboratory activities and enlarge the laboratory science, teaching and research staff; to modernize equipment, processes and procedures to satisfy mandatory standards and deliver an improved response to the existing and future health needs of the population.

The NRL with its four laboratory areas has a regulatory, teaching and training relationship with the laboratory network of the different care levels of MINSAL, performing quality control on the results analysis of disease samples for epidemiological surveillance, the environment, food quality control and cancer screening.

The smear test department performs quality control on slides for the national screening program for cervical cancer. It also provides a training program for cytotechnologists for the country’s clinical laboratory network.

The epidemiological surveillance laboratory department of the NRL reviews and confirms infectious agents, and performs quality control on the results of different programs to ensure compliance with the protocols, technical and quality standards for test results. This includes testing to detect HIV, TB, malaria, and other diseases associated with certain types of cancer caused by viruses such as human papillomavirus.

It also participates in international quality control programs to apply this process to the clinical laboratory network, providing quality control on the various processes involved in applying a diagnostic test and developing regulatory documents.

The food and toxicology quality control laboratory department monitors the quality of food and water and, in coordination with local networks, studies cases of food poisoning and poisoning by toxic products.

The health and environmental laboratory department monitors the quality of water for human use or that could represent a threat to the health of populations. This includes rivers, wells and other water that the population comes into contact with and which affects the state of health of the population. This is particularly important for those suffering from illness or immunodeficiency syndromes, which render them more susceptible to infectious and contagious diseases.

The INS, with the NRL, also conducts research to gather evidence regarding care for non-contagious diseases, such as chronic kidney disease and certain types of cancer.

**Expected benefits**

Having a new, more modern building that complies with all the requirements with respect both to physical space and security would make it possible to:

Implement an IT system linked to the national laboratory network, facilitating information management and reporting, to make laboratory work more efficient and more effective.

This system would enable distance learning for staff of the national laboratory network and would make it possible to coordinate research with other MINSAL institutions.

With regard to ensuring promotion of the objectives of the programs supported by the Global Fund in the fight against HIV, TB and malaria, providing new facilities for the NRL would represent both a qualitative and quantitative improvement given that, at present, there is no department within the NRL to confirm and monitor HIV, ELISA, Hepatitis B, Hepatitis C, syphilis, viral load and CD4 tests. As a result, only between three and five brands of ELISA test (and none of the other tests) have been verified, because there is no space for devices for other testing and verification technologies. This limits the brands that can be used, as their performance is unknown, and it limits the offer of brands and market prices. Having a building with a validation department would give the country the opportunity to verify all these tests and to make verified reagent brands available to all institutions within the National Health System.

At present, the country has departments for performing genotyping tests. However, if the platform changes and the technology has to be updated, the lack of space will be an issue. This would cause the service to be suspended during installation and testing of new equipment, posing a threat to continuity of care and ultimately stopping the collection not only of genotyping samples (approximately 30 tests per month), but also of other tests such as viral load and CD4 (approximately 1,400 tests each per month). This would negatively affect progress toward the 90-90-90 targets.

Improving the infrastructure of facilities would make it possible to apply to the national accreditation body (Organismo Salvadoreño de Acreditación – OSA) for ISO-standard accreditation of tests.

With respect to TB, the move to new facilities would represent both a qualitative and quantitative improvement in care, as it would improve the implementation of infection control, improve natural and mechanical ventilation, provide adequate respiratory protection measures, and deliver improvements to management and administrative processes.

The current artificial ventilation and air-conditioning system of the NRL is shared by all areas, which poses a threat to the health of those working there. As a result, the ventilation system has been turned off in the TB department to prevent the biological risk, despite the fact that this hinders work.

A new, expanded site would make it possible to implement new diagnostic methods, as it is not currently possibly to comply with the recommendations of international evaluations to use liquid diagnostic methods such as Mycobacteria Growth Indicator Tube (MGIT). This would reduce the response time to between 14 and 21 days (currently 40 days), thus establishing more timely treatment to assist patient recovery.

The increased physical space will make it possible to process more TB tests, as there will be separate working areas (at present, physical working areas are shared for the purpose of performing tests) and to implement international measures regarding work flows from clean areas to less clean areas, thereby increasing biosecurity measures in working areas.

Areas for washing and sterilizing materials and glass and disposing of bioinfectious materials will be provided in accordance with standardized international protocols for each of the diseases. The quantity of equipment will also be increased, with the number of biosecurity cabinets rising from two to three or four, to enable timely processing of samples while complying with biosecurity measures. For example, in the event of accidental contamination, there are no emergency showers or eye washers; just a shared area for all diseases, which would contaminate the other departments.

With respect to laboratory surveillance of malaria, this would improve substantially with the gradual implementation of molecular diagnostic techniques (Polymerase Chain Reaction – PCR) as a result of technology transfer. Ongoing education would also be provided to diagnostic laboratory professionals, thus strengthening the reliability of diagnosis, improving case detection in passive searches, and reducing transmission. The current mixture of technical and administrative areas would also be eliminated, guaranteeing biosecurity.

With respect to research, a new building would allocate the appropriate technology to a specific area, given the importance of risk factors for multidrug-resistance in diagnosis and prescribed treatments, and the outcomes obtained with regard to patient recovery.

In summary, this would eliminate the contamination that is currently fostered by the mixing of different areas. This would enable the country to aspire to becoming a regional reference laboratory in the quality control of laboratory tests and tests for HIV, TB and malaria.

**Options**

To seek alternatives that meet the need for a larger site to house the NRL and that meet the necessary criteria, a public call for tenders of buildings for sale was issued. A ministerial decree established a commission to draw up the terms of reference (ToR), the announcement was published in one of the two newspapers with highest national circulation, and tenders were invited. The commission also drew up the criteria used to evaluate the tenders and choose a winner.

In response to the publication in the newspaper dated 9 November 2015, a single tender was received. It was evaluated and found to meet the requirements requested by MINSAL to house the NRL and INS. This was then set out in a deed, signed and sealed by the members of the commission. The Ministry of Taxation is currently assessing the value of the proposed building to identify its true value, and this will influence the negotiation with the owners when the project is approved.

As regards a cost-benefit analysis, it should be noted that it was not possible to publish a call for tenders based on a rental-purchase contract with a promise of sale, a simple rental agreement or other, similar forms of acquiring a property. However, the Department of Health Infrastructure has studied the issue and presented the following comparative table of rental costs:

**Different rental costs per square meter of infrastructure in the San Salvador and Antiguo Cuscatlán area.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **BUILDING** | **M2** | **MONTHLY COST****US$**  | **ANNUAL COST****US$**  | **COST OF ADAPTING BUILDING****(one-off)****US$**  | **MONTHLY RENTAL COST PER M2****US$**  |
| **National Drugs Department** | **12,190.00**  |  **56,500.00** | **678,000** |  **779,259.00** |  **4.64** |
| **Building of commercial premises located on calle La Mascota, Colonia Escalón** | **50.00** |  **960.00** | **11,550.00** |  **5,000.00** |  **19.20** |
| **Building of commercial premises located in Antiguo Cuscatlán** | **36.00**  |  **700.00** | **8,400** |  **4,500.00** |  **19.44** |

Data analysis of the table shows that the option of renting a property with the characteristics required for the NRL from a private landlord is not practical, because it would not be sustainable over the long term for MINSAL. Based on the current rental costs of the National Drugs Department – which is a regulatory body and thus does not require the adaptations and installation of equipment and biosecurity systems required by the NRL – the annual rental charge for a property of approximately 8,000 m2 would be approximately US$ 500,000.00. If we consider a market rent for real estate in an area of San Salvador, such as Colonia Escalón, rental for a similar building in the region of 8,000 m2 would be approximately US$ 1,843,200. This figure is not sustainable for MINSAL, and would mean that any investment in modern technological equipment, or in technological, electrical, mechanical and biosecurity systems, would be an expense, because the investment would be in infrastructure that did not belong to MINSAL. In addition, MINSAL does not have the budget to cover rent of this magnitude and cannot acquire it from its general budget. In addition, as described below, it would not be permitted by the Savings and Austerity Policy 2015.

Moreover, given that the Global Fund will gradually reduce its support for the Latin America region including El Salvador, and that this support is expected to fall to minimum levels by 2020, it is important to acquire a building that guarantees laboratory work, training and investigation to make it possible to meet any needs that may arise. It must provide a platform for sustainability, avoiding the need to allocate resources to the payment of rent instead of the purchase of drugs, equipment and other valuable supplies in the fight against HIV, TB and malaria, and other emerging diseases.

With regard to other forms of property procurement, we have already noted that neither the central government nor MINSAL have properties or infrastructure of these dimensions and that meet the minimum requirements, as shown in the supporting documentation.

It should be noted that the President of the Republic, as part of his commitment to reduce current expenditure and allocate more resources to benefit the population, has established a Savings and Austerity Policy 2015 for the Executive. This policy obliges central government institutions to improve and streamline their use of resources and to provide better services. In this respect, the Savings and Austerity Policy 2015 establishes restrictions for the rental of property, in article 7, point g):

**g) Property rental**

To rationalize the rental of properties, starting with a review of the inventory of properties of the State contained in the online Computer System of Unused Properties, designed by the Department for Citizens’ Participation, Transparency and Anti-corruption of the President of the Republic, or by seeking institutional and inter-institutional support to meet requirements. Where indispensable, the use of space in properties should be optimized, with rents that are accessible and reflect the location of the property, which should be compatible, in terms of minimum characteristics and conditions, with the type of office to be installed or operated, and this process must be documented, making use of the available written and technological means. In so far as possible, properties must be rented through procedures that promote competition, in order to provide various options, prior to taking the relevant decision, and thereby to enable comparison of the value of the rent offered in the rental area. When renting properties for official events, the rental of public sites, such as the International Fair and Convention Center of El Salvador (CIFCO), is recommended. Negotiation of these rental agreements must be conducted directly with the owners of the properties, without any intervention by intermediaries.

During the previous five-year period, MINSAL began a Health Reform process based on the human right to health, the prioritization of primary health care throughout the country, and the expansion of service coverage through the creation of community health teams. During the current five-year period, this reform has continued and expanded to include interdepartmental actions to address the impact of violence on the health of the population and the social and environmental factors that affect health, especially among the poor. MINSAL, in addition to continuing to promote and expand universal coverage and universal access in rural areas, has begun to implement an urban health program that addresses the aspects of urban life that affect the health of the population.

While it is true that, over the last seven years, the government has increased the percentage allocated to health annually, to the point where this now accounts for almost 13 percent of total government spending, this continues to be insufficient for all of the actions needed. The annual budget of MINSAL is currently US$ 627,811,390.00, of which almost 70 percent covers salaries.

Although the Ministry of Taxation has made great efforts to improve tax collection, which have led to an increase in the tax base, reductions in tax evasion, fraud and smuggling, and increased receipts, this is not sufficient to cover all of the needs of the various population sectors in the country.

MINSAL therefore has to seek funding to obtain a building that satisfies the requirements to house the NRL and the INS and thereby seeks to improve the quality of the services provided to the population, health investigation, and the training of specialist human resources.

**Indicators**

We hope that this project will enable substantial improvements in the performance of the following indicators, which contribute to the national response to the HIV, TB and malaria programs.

MALARIA

Verification percentage for quality of slide reading for suspected malaria cases in the clinical laboratory network of the National Health System.

Percentage of clinical laboratory staff of the National Health System trained in reading slides of suspected malaria cases.

Percentage of diagnostic confirmation of suspected malaria cases using molecular methods.

Percentage of results that meet the standard response time.

TB

Verification percentage for quality of slide reading for sputum tests of suspected TB cases in the clinical laboratory network of the National Health System.

Percentage of results that meet the standard response time for molecular tests.

Percentage of variation in performance of molecular tests to detect patients with TB.

Percentage of clinical laboratory staff of the National Health System trained in technologies to diagnose bacteriologically positive patients.

Percentage of characterization of resistance to anti-TB drugs.

Percentage of patients diagnosed with TB/HIV co-infection by laboratory tests.

Percentage of first-time diagnosis of HIV and other sexually transmitted infections (STIs).

Percentage of tests of efficacy of antiretroviral therapy (ART; measurement of viral loads and CD4).

Percentage of detection of resistance mechanisms to antiretrovirals (ARVs).

Percentage of identification of opportunistic infectious agents in immunodepressed patients.

**Performance-based funding:**

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| --- | --- | --- |
| **OPTION 1:**  |  |  |
| **Results** | **Debt swap** | **Counterparty: MINSAL** **(Origin World Bank)** | **Total budgeted** |
| **R1:** Building acquired |  US$ 4,000,000.00  |  US$ 4,000,000.00  |  US$ 8,000,000.00  |
| **R2:** Adaptation of working areas, electrical installation, air-conditioning, hydraulics, gas, information technology |  US$ 5,346,328.00  |  US$ 113,672.00  |  US$ 5,460,000.00  |
| **R3:** Transfer and installation of equipment from departments of NRL and INS |  US$ 2,285,000.00  |   |  US$ 2,285,000.00  |
| **TOTAL** |  **US$ 11,631,328.00**  |  **US$ 4,113,672.00**  |  **US$ 15,745,000.00**  |

|  |  |
| --- | --- |
| **OPTION 2:**  |  |
| **Results** | **Debt swap** | **Counterparty: MINSAL** **(Origin World Bank)** | **Total budgeted** |
| **R1:** Building acquired |  US$ 8,000,000.00  |   |  US$ 8,000,000.00  |
| **R2:** Adaptation of working areas, electrical installation, air-conditioning, hydraulics, gas, information technology |  US$ 1,346,328.00  | US$ 4,113,672.00  |  US$ 5,460,000.00  |
| **R3:** Transfer and installation of equipment from departments of NRL and INS |  US$ 2,285,000.00  |   |  US$ 2,285,000.00  |
| **TOTAL** | **US$ 11,631,328.00**  | **US$ 4,113,672.00**  | **US$ 15,745,000.00**  |

The schedule below contains a series of stages; the plan is to move the departments of the NRL on a gradual, section-by-section basis, in order to ensure that the service provided by the various laboratories is not interrupted during the process.

**Schedule of activities:**





