DNDi AMÉRICA LATINA

Drugs for Neglected Diseases *initiative*
Iniciativa Medicamentos para Doenças Negligenciadas
Iniciativa Medicamentos para Enfermedades Olvidadas

CHAGAS ACCESS

The pilot experience in Colombia

JANUARY 2021

"When I was pregnant, I had tests done, and it came back positive. From the time it was detected until I started the treatment, it took more than two years"

Herminda Jaimes, Santander, Colombia

Content

Introduction

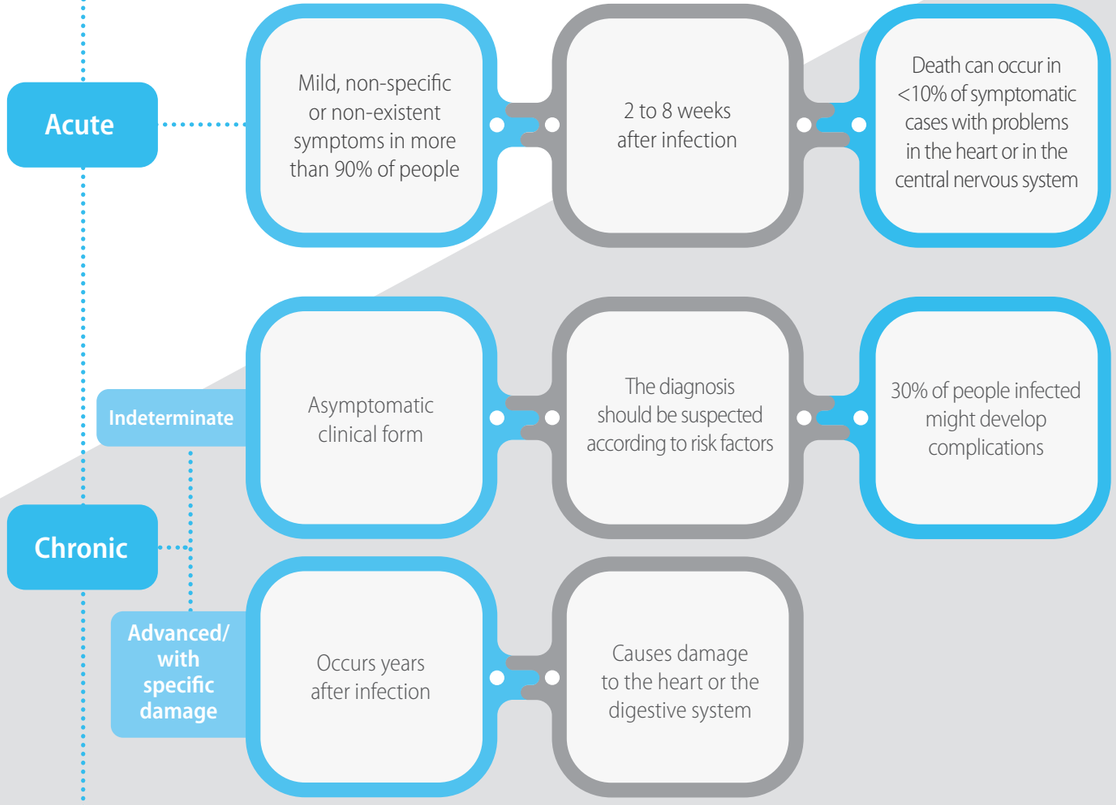
Over 6 million people worldwide are infected with *Trypanosoma cruzi*, the protozoan that causes Chagas disease. Endemic in 21 Latin American countries, the disease can be transmitted by vector insects called triatomines — also known as "kissing bugs" —, foods or beverages contaminated with the parasite, blood transfusions, organ transplants, or congenitally during pregnancy or delivery.

There are only two drugs available to treat Chagas disease, nifurtimox and benznidazole, both discovered almost half a century ago. Antiparasitic drugs are effective in the acute and chronic phases of the disease, but the treatment lasts 60 days and has side effects such as gastrointestinal intolerance, rashes and neuromuscular issues, among others.

Since the 1990s, Latin America has made significant progress in controlling the vector transmission of Chagas disease. However, providing diagnosis and treatment to the people affected by one of the world's most neglected diseases remains a challenge. Fewer than 10% of those at risk of contracting the disease in the Americas have been tested, and only about 1% of those with the disease have received treatment.

While researching to improve the treatment regimens with benznidazole and develop new therapeutic alternatives, the Drugs for Neglected Diseases *initiative* (DND*i*) has been conducting, since 2015, an access program to implement solutions that help overcome barriers to the diagnosis and treatment of Chagas disease. Colombia's pilot experience, developed in partnership with the Ministry of Health and Social Protection and the country's National Institute of Health, has been able to simplify the diagnostic process and reduce the time until treatment starts, strengthening local systems and contributing to eliminate Chagas disease as a public health issue.

The stages of Chagas disease



Chagas disease in Colombia

It is estimated that 438,000 people are infected with *T. cruzi* and that 131,000 have already developed heart conditions related to Chagas disease in Colombia[1]. Access to diagnosis and treatment is a concerning challenge: only 1.2% of the population at risk has been tested and less than 0.4% have received antiparasitic drugs[2].

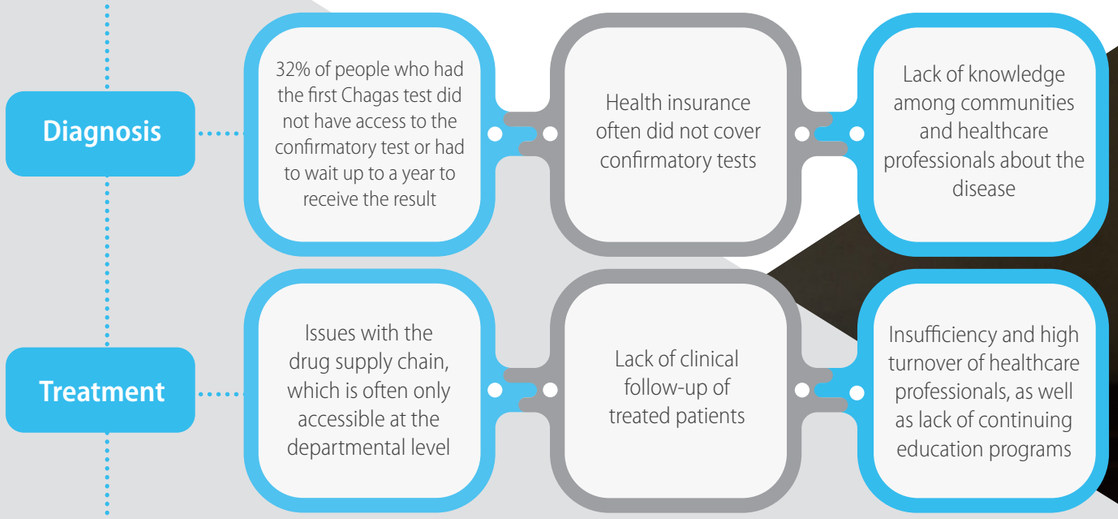
In 2008[3], the country launched the National Program for Control, Prevention and Treatment of Chagas Disease. While the initiative has resulted in significant progress in the control of domestic vector transmission and reduction of the lethality of acute cases, delays in confirmatory tests, difficulty in obtaining coverage for tests from the mandatory health plan, and lack of knowledge and awareness among health professionals and communities persisted.

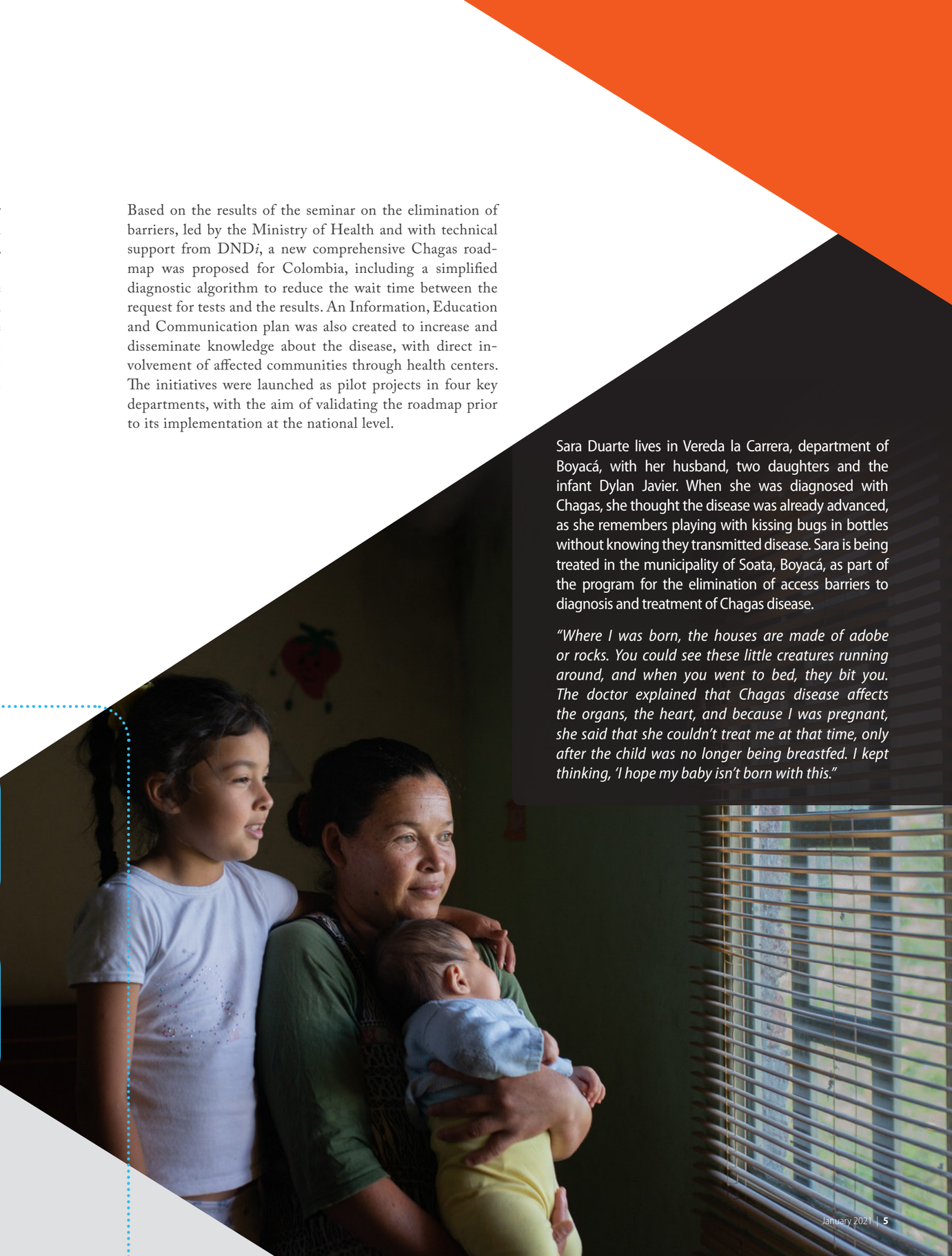
This scenario favored the partnership between DND*i* and the Ministry of Health and Social Protection, which was solidified during the seminar "Towards the elimination of barriers in the access to diagnosis and treatment of Chagas disease in Colombia." During the meeting, the main obstacles to care for Chagas disease in the country were identified, as well as proposals to potentially overcome them.

Based on the results of the seminar on the elimination of barriers, led by the Ministry of Health and with technical support from DND*i*, a new comprehensive Chagas roadmap was proposed for Colombia, including a simplified diagnostic algorithm to reduce the wait time between the request for tests and the results. An Information, Education and Communication plan was also created to increase and disseminate knowledge about the disease, with direct involvement of affected communities through health centers. The initiatives were launched as pilot projects in four key departments, with the aim of validating the roadmap prior to its implementation at the national level.

The seminar "Towards the elimination of barriers in the access to diagnosis and treatment of Chagas disease in Colombia" took place in April of 2015 in Bogotá. The event was organized by the Ministry of Health, DND*i*, the National Institute of Health and the Chagas Network Colombia, and brought together local health organizations, researchers and patient associations. The participants outlined the various obstacles to diagnosis and treatment of Chagas disease in Colombia from three perspectives: that of people living with Chagas, that of healthcare providers and that of insurers, the organizations that must ensure effective access and quality in the provision of healthcare services in the country.

Main barriers to diagnosis and treatment of Chagas disease in Colombia





Sara Duarte lives in Vereda la Carrera, department of Boyacá, with her husband, two daughters and the infant Dylan Javier. When she was diagnosed with Chagas, she thought the disease was already advanced, as she remembers playing with kissing bugs in bottles without knowing they transmitted disease. Sara is being treated in the municipality of Soata, Boyacá, as part of the program for the elimination of access barriers to diagnosis and treatment of Chagas disease.

"Where I was born, the houses are made of adobe or rocks. You could see these little creatures running around, and when you went to bed, they bit you. The doctor explained that Chagas disease affects the organs, the heart, and because I was pregnant, she said that she couldn't treat me at that time, only after the child was no longer being breastfed. I kept thinking, 'I hope my baby isn't born with this."

1 - WHO, 2015

2 - Z.M. Cucunuba et al. / Social Science & Medicine 175 (2017) 187, 198

3 - Marchiol A, Forsyth C, Bernal O, Valencia C, Cucunubá Z, Pachón E, et al. Increasing access to comprehensive care for Chagas disease: development of a patient-centered model in Colombia. Rev Panam Salud Pública. 2017;41:e153.

The DND*i* access strategy

The complex challenges related to Chagas disease motivated the creation of DND*i*'s Program for the Elimination of Access Barriers. DND*i* is a research and development (R&D) organization that has been working since 2003 to provide safe, effective and accessible treatment for millions of people living in vulnerable conditions, without access to healthcare and/or affected by neglected diseases.

To ensure that future treatments reach the patients, DND*i* provides technical support to national and local healthcare systems, encouraging the adoption of new policies, assisting with drug supply and availability, and promoting capacity-building and the implementation of simplified healthcare processes. The access strategy is not a vertical one; the idea is that the ministries of health play the main role and work on small-scale pilot projects, identifying healthcare processes to be followed or adjusted.

The 4D methodology

To analyze the contexts and needs that will guide each project, DND*i* applies the 4D methodology, which includes the stages of diagnosis, design, development and demonstration of impact[4].

1

Diagnosis refers to gathering information on the current state of prevention, diagnosis and treatment of Chagas disease in each country to establish baseline data, identifying the main barriers to access with the stakeholders involved in the health sector: the government, civil society, academia, the private sector and international organizations, among others

2

In the ***design*** stage, access plans are developed to overcome the identified challenges. Consistency between national and local regulations, objectives, training needs and methods for measuring impact are also considered.

3

The implementation of the access plan takes place at the ***development*** stage, with the engagement of local healthcare systems and promotion of comprehensive capacities for health professionals. An Information, Education and Communication strategy is implemented at the community level.

4

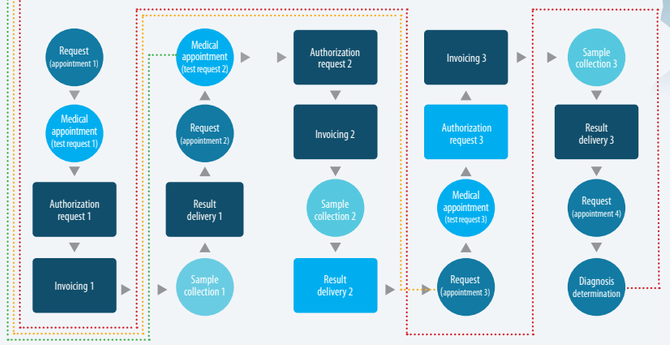
Demonstration of impact includes evaluating results and sharing evidence and lessons learned with healthcare systems, to promote the scaling up of interventions at the national level.

4 - https://iris.paho.org/handle/10665.2/51531?show=ful

The pilot experience and implementation of the roadmap

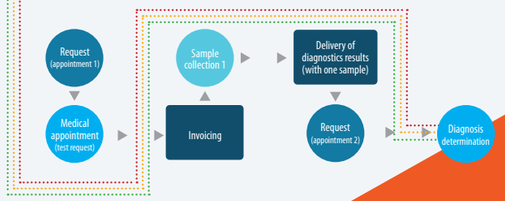
No roadmap

Discarded case - 8 contacts
Confirmed case (2 tests) - 13 contacts
Discordant case - 20 contacts



Ideal roadmap

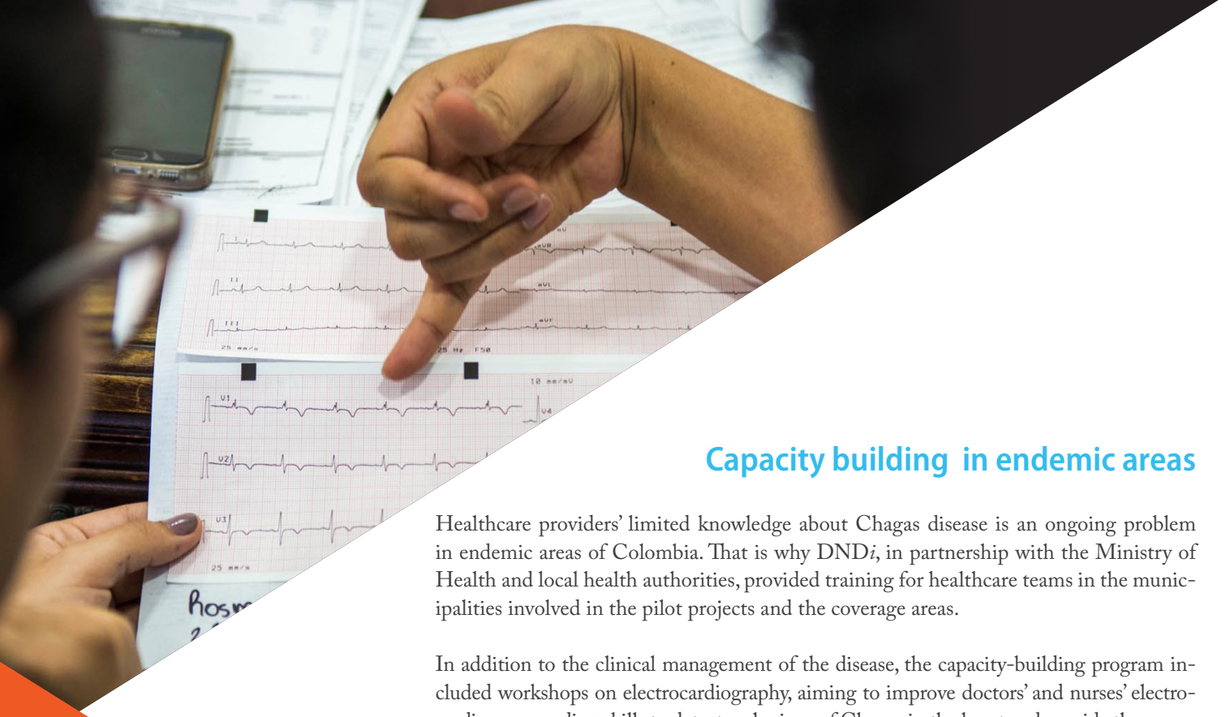
Discarded case - 7 contacts
Confirmed case (2 tests) - 7 contacts
Discordant case - 7 contacts



Colombia's pilot projects were carried out in five municipalities in the departments of Casanare, Boyacá, Arauca and Santander, which are considered endemic areas for Chagas disease in the country.

The comprehensive roadmap for Chagas care was implemented in the municipalities, including all the guidelines the health system must follow for a person with the disease or at risk of contracting it. The roadmap focuses on the patient, articulating primary care with the other levels of the healthcare system to determine potential diagnosis and treatment options in a simpler and quicker manner. This is especially beneficial in rural communities with high poverty rates.

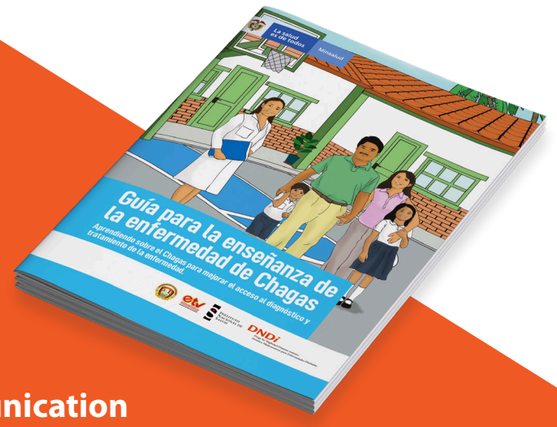
In addition, a study led by the National Institute of Health with DND*i*'s support informed the creation of a new diagnostic algorithm including an ELISA confirmation test in the new roadmap. Unlike traditional immunofluorescence procedures, ELISA tests do not require a robust laboratory structure and can be conducted with just one sample, speeding up response time, reducing costs and helping to overcome one of the major barriers to the elimination of the disease as a public health problem.



Capacity building in endemic areas

Healthcare providers' limited knowledge about Chagas disease is an ongoing problem in endemic areas of Colombia. That is why DND*i*, in partnership with the Ministry of Health and local health authorities, provided training for healthcare teams in the municipalities involved in the pilot projects and the coverage areas.

In addition to the clinical management of the disease, the capacity-building program included workshops on electrocardiography, aiming to improve doctors' and nurses' electrocardiogram reading skills to detect early signs of Chagas in the heart and provide therapeutic guidance. Moreover, four doctors — one from each pilot department — went to Bolivia for practical training with the Chagas Platform in Cochabamba, encouraging an exchange between endemic countries of experiences in diagnosis and treatment of Chagas disease.



Information and communication

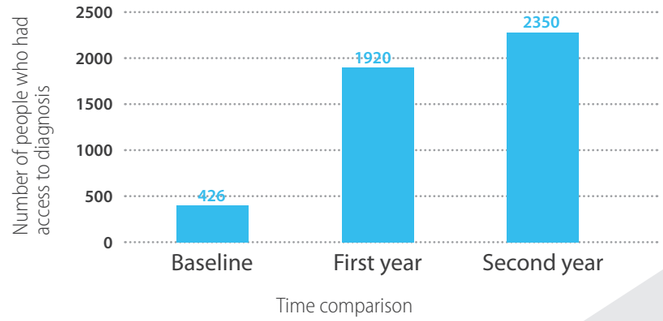
Lack of information about Chagas disease, also identified as a barrier to diagnosis and treatment, led to the creation of an Information, Education and Communication (IEC) plan to raise awareness among the at-risk population and healthcare providers in the municipalities involved in the pilot projects.

As part of the IEC plan development process, patients, local leaders and healthcare providers were interviewed, aiming to create strategies to inform affected communities about the importance of an early diagnosis of Chagas. The DND*i*, alongside the Ministry of Health and the pilot departments, developed various communication actions — including the creation of brochures, posters, workshops, radio campaigns, press interventions and exhibitions — whose key messages were validated by the targeted communities.

Results

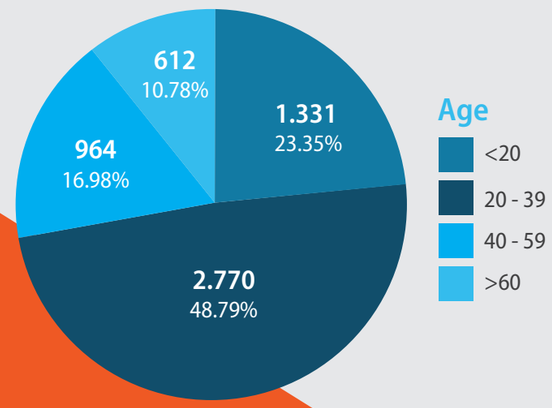
The integrated work carried out by the Ministry of Health, local health systems and DND*i* produced robust results in the four Colombian departments. While before the pilots were implemented, just over 426 people on average had access to Chagas disease diagnosis each year, the annual average exceeded 2,436 people during the implementation of the project — an increase of approximately 471.8%.

Evolution of access to diagnosis in the four pilot departments



Source: DND*i*. The data represent the sum totals of the people who had access in the first and second year of each pilot. The analyzed data for one of the pilots covered only 9 months of the second year.

People diagnosed by age group



The new algorithm with ELISA tests reduced the average wait time between the medical request and the confirmed diagnosis by 92.64%, from 258 days to 19 days. Furthermore, the number of people diagnosed with Chagas disease increased by 635%, from 37 to more than 270 after the roadmap was implemented. The average number of days between the diagnosis and the start of treatment was reduced from 354 to 127, a 64% decrease in the three years of pilot projects.

Of the total number of people served, 71% were under the age of 39, the age segment that can benefit most from early treatment for Chagas, as the complications related to the disease have not yet developed. This age group also represents 22% of all the positive cases and 40% of those for whom treatment is indicated.

In the first three years of the pilot projects, 3,480 women of childbearing age had access to diagnosis, 162 of them tested positive for Chagas and nearly half are already being treated. Testing and treating young women is paramount to preventing congenital transmission of the disease during pregnancy and childbirth.

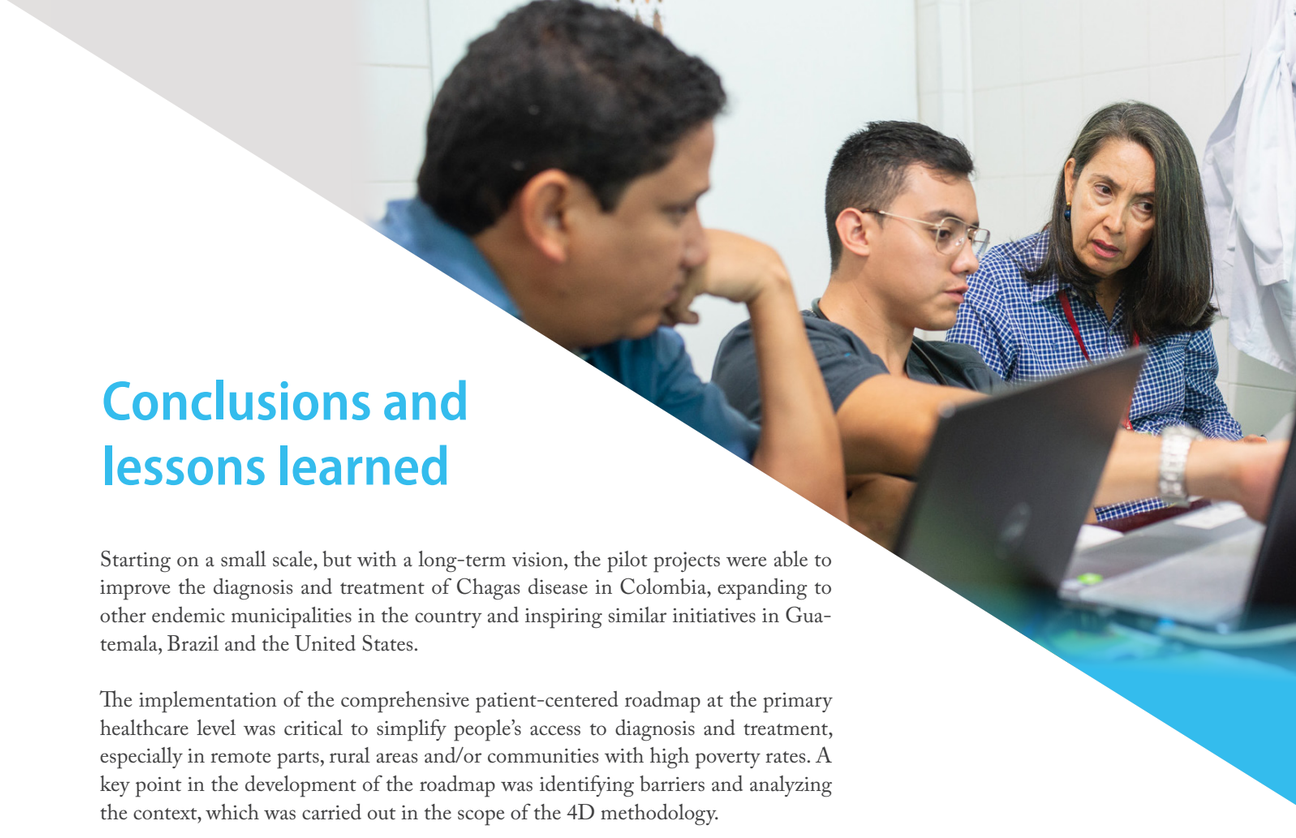
Regarding human capital, DND*i* and the Ministry of Health and Social Protection have already trained more than 900 healthcare providers in the diagnosis and treatment of Chagas disease in the country. Training programs are currently being replicated in other municipalities and departments, aiming to help scale up the patient-centered roadmap and to continue the National Intradomiciliary Certification Plan in Colombia.

Women of childbearing age	Total # %
Diagnosed	3480
Positive result	162
Treatment	73 (45.06%)

Note: Until the closing of this brochure, 87 women had not yet started treatment due to ongoing pregnancy, breastfeeding or pending medical appointment for clinical evaluation.

"Three years ago, we had to rely on the external public health lab. This project has allowed for faster diagnosis, benefitting not only Soatá, but also nearby municipalities. The situation has changed because we have more skilled healthcare personnel, diagnosis is faster because our lab takes care of the whole diagnostic procedure, we are closer to the community, and we can speed up medical appointments and authorizations. In terms of care, the change is noticeable, because it's much more agile now".

Johana Cobos is a technician in the working group of the Vector-Borne Diseases Program in Boyacá. She is assigned to the city of Soatá.



Conclusions and lessons learned

Starting on a small scale, but with a long-term vision, the pilot projects were able to improve the diagnosis and treatment of Chagas disease in Colombia, expanding to other endemic municipalities in the country and inspiring similar initiatives in Guatemala, Brazil and the United States.

The implementation of the comprehensive patient-centered roadmap at the primary healthcare level was critical to simplify people's access to diagnosis and treatment, especially in remote parts, rural areas and/or communities with high poverty rates. A key point in the development of the roadmap was identifying barriers and analyzing the context, which was carried out in the scope of the 4D methodology.

The development of an Information, Education and Communication strategy has helped to raise awareness about Chagas disease among the people affected and healthcare providers, with effective participation and validation of the materials by local communities.

Training and capacity building in the scope of the pilot projects highlighted the importance of early diagnosis, focusing not only on symptoms, but also on risk factors for Chagas. This shift in approach is critical to eliminate such a silent disease as a public health issue.

It is also important to highlight the fundamental role of the political interest and commitment of Colombia's local and national governments in the development of the project. The leadership of the Ministry of Health and Social Protection, with the support of DND*i*, local healthcare providers and insurers, helped to strengthen the country's internal capacity to develop other initiatives to promote access to Chagas diagnosis and treatment. However, a stronger commitment from health management companies is still required for a sustainable simplification of the administrative processes related to healthcare.

Despite the success of the Colombian pilot experience, challenges remain in terms of achieving more simplified roadmaps, reducing diagnostic time even more, and working to validate and implement shorter treatment schemes with fewer side effects and which can more effectively help eliminate Chagas disease as a public health problem in the region.

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DND*i* is a collaborative, patient-needs-driven, not-for-profit research and development (R&D) organization that develops safe, effective, and affordable treatments for the millions of people across the world affected by neglected diseases, notably human African trypanosomiasis (sleeping sickness), leishmaniasis, Chagas disease, filarial infections, paediatric HIV, mycetoma, and hepatitis C.

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Thank you to our partners in the Program for the Elimination of Access Barriers in Colombia

La salud es de todos Minsalud
Instituto Nacional de Salud
Gobierno Departamental
Gobernación de Boyacá
Gobernación de Casanare
Siempre Santander Gobernación