IMPROVING ACCESS TO TESTING FOR CHAGAS DISEASE IN COLOMBIA

DND*i* and partners evaluated the effectiveness of seven available diagnostic tests in Colombia to identify a simpler and more cost-effective approach to diagnosing Chagas disease that could be used widely in local health clinics.

This is a summary of the following peer-reviewed, scientific article:

Comparative Evaluation of Immunoassays to Improve Access to Diagnosis for Chagas Disease in Colombia.

Caicedo Díaz RA, Forsyth C, Bernal OA, Marchiol A, Beltrán Duran M, Batista C, Herazo R, Vera MJ, Pachon E, Valencia-Hernández CA, Flórez Sánchez AC. *International Journal of Infectious Diseases.* 2019;87:100-108. Published online July 26 2019 https://www.ijidonline.com/article/S1201-9712(19)30307-8/fulltext

BACKGROUND

Chagas disease is a neglected and potentially fatal parasitic disease that afflicts over 6 million people, mainly in Latin America. The disease primarily affects marginalized populations with limited access to health care and has historically been overlooked by governments and the pharmaceutical industry. Very few people with Chagas disease are diagnosed and treated.

One of the main barriers is the difficulty of diagnosing the infection. There are several reasons for this. *Trypanosoma cruzi*, the protozoan parasite that causes Chagas disease, is difficult to detect and there are different genetic strains. There is no 'gold standard' test that can be used on its own, so the World Health Organization (WHO) recommends using two different tests to be sure. Some tests may require extensive equipment, supplies, and training, limiting their availability.

In Colombia, an estimated 438,000 people are infected with Chagas disease (WHO data), but only 1% of people at risk have been screened. One study estimated Chagas healthcare costs to be US$ 175 million annually in Colombia.

1 WHY WAS THIS STUDY DONE?

Colombia was using two locally developed tests that were very accurate, but it was difficult to extend availability of these tests outside the capital, Bogota, due to cost, equipment, and training requirements. This created many barriers and lengthy delays for patients who wanted to get tested. Patients often had to travel to distant cities just to give blood samples to confirm their diagnosis, and often their insurance would not cover the testing. Patients therefore had to pay both testing and travel costs. It sometimes took over a year from the time patients screened positive until they could get a confirmed diagnosis, and one third of patients never received confirmation at all. For this reason, very few patients were able to start treatment.

Several commercial Chagas tests developed outside of Colombia are registered in the country. These tests are simple to use and relatively low cost, meaning they could be made widely available. However, the performance of these tests was not well known. This study evaluated whether these easier-to-use and less expensive commercial tests could detect Chagas disease in Colombian patients as accurately as the more complicated tests previously being used by the health system.

2 WHAT WAS EVALUATED AND HOW?

Seven commercially available tests were evaluated and compared to the standard testing process. For the study, 501 blood samples were used from various sources, including Colombia's blood banks and clinics. The National Reference Laboratory first determined whether each sample was positive or negative for Chagas disease using several highly accurate tests. Next, the seven commercially evaluated tests were used on the blood samples to determine whether they could accurately detect the presence of *Trypanosoma cruzi*. This allowed the researchers to determine the sensitivity (the ability to detect a positive result) and specificity (the ability to detect a negative result) of each test, and to predict how different test pairings might perform in Colombia's health system.

3 WHAT WERE THE RESULTS?

All seven tests demonstrated sensitivity and specificity above 90%. Five demonstrated sensitivity greater than 98%, while six showed specificity greater than 97%. The performance of most tests was comparable to that of the existing testing process in Colombia.

Using a reference panel from WHO, the authors concluded that most of the tests were able to correctly identify infections from both of the major genetic lineages of the parasite. The study determined that using two of the commercial tests in combination would accurately detect cases of Chagas disease in Colombia, and this process would be much easier to implement throughout Colombia's health system.

4 SO WHAT DOES THIS MEAN FOR PEOPLE AFFECTED BY CHAGAS DISEASE?

Based on the results of this study, a new testing process was recommended and is now being implemented in a pilot project in Colombia. With the new process, patients only have to give one blood sample, which can be done at a local health care clinic. Patients no longer need to travel to urban labs to give a second or third blood sample. Confirmatory results are now available in about two weeks, and the cost of testing is covered by Colombia's insurance plans. The tests are run on an automatic reader that can be used with minimal training, which facilitates testing for laboratory personnel.

In the first year of piloting the simplified testing process, the number of people tested in one community increased by tenfold. Making testing easier and available in the communities of people affected by Chagas disease means that more people can start treatment before the onset of serious complications. As part of a new patient-centered 'roadmap' for Chagas disease care by the Colombian Ministry of Health, simplified testing could help to increase access to Chagas diagnosis and treatment at local health clinics, improve resource allocation, increase cost effectiveness, and ultimately ensure more people with Chagas receive proper care.

COMPARISON OF OLD AND NEW *T. CRUZI* DIAGNOSTIC ALGORITHMS, COLOMBIA

Previous Algorithm	New Algorithm
Not covered by insurance	Covered by insurance
2-3 blood draws in different facilities; patients travel to departmental capitals for second and third tests	Only one blood draw in a facility closer to patients, eliminating need for costly travel
In-house production of reagents	Commercially available reagents
Extensive training of personnel; complex, expensive equipment	Use of automated readers available in most private and public laboratories
Different equipment for each test	Use of same equipment for both tests
Subjective interpretation of results	Automated results
Unclear guidelines for screening tests	Evidence-based guideline for screening, complementary tests

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