

e-Newsletter:

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# UPDATES ON CHAGAS DISEASE IN THE U.S.



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Mundo Sano

This newsletter provides updates on selected activities related to Chagas disease care and treatment in the United States (U.S.) and is intended for individuals interested in the U.S. situation.

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Provided by Natasha Hochberg – [nhoch@bu.edu](mailto:nhoch@bu.edu)

### Highlighted Publications

- Forsyth CJ, Hernandez S, Flores CA. “You Don’t Have a Normal Life”: Coping with Chagas Disease in Los Angeles, California. *Med Anthropol*. 2021 Mar 30;1-16. doi: [10.1080/01459740.2021.1894559](https://doi.org/10.1080/01459740.2021.1894559). Online ahead of print.
- Nolan MS, Aguilar D, Misra A, et al. *Trypanosoma cruzi* in Nonischemic Cardiomyopathy Patients, Houston, Texas, USA. *Emerging Infectious Diseases*. 2021;27(7):1958-1960. doi: [10.3201/eid2707.203244](https://doi.org/10.3201/eid2707.203244).
- Ridley DB, Ganapathy P, Kettler HE. US Tropical Disease Priority Review Vouchers: Lessons in Promoting Drug Development and Access. *Health Affairs*. 2021 Aug;40(8):1243-1251. doi: [10.1377/hlthaff.2020.02273](https://doi.org/10.1377/hlthaff.2020.02273).

- *Truyens C, Dumonteil E, Alger J, et al. Geographic variations in test reactivity for the serological diagnosis of Trypanosoma cruzi infection.* J Clin Microbiol. 2021 Sep1;JCM0106221. doi: [10.1128/JCM.01062-21](https://doi.org/10.1128/JCM.01062-21). Online ahead of print.
- *Forsyth C, Manne-Goehler J, Bern C, et al. Recommendations for Screening and Diagnosis of Chagas Disease in the United States.* J Infect Dis. 2021 Oct8;jiab513. doi: [10.1093/infdis/jiab513](https://doi.org/10.1093/infdis/jiab513). Online ahead of print.
- *Valdez-Tah A, Ibarra-Cerdeña C. Call to action: a literature review of Chagas disease risk in California 1916-2018.* PLoS Negl Trop Dis. 2021 Feb 25;15(2):e0009035. doi: [10.1371/journal.pntd.0009035](https://doi.org/10.1371/journal.pntd.0009035). eCollection 2021 Feb.
- *Hincapie M, Bernabé K, DeCuir J, et al. 1202. Chagas Disease Awareness in a Hispanic Community of the Greater New Orleans Area,* Open Forum Infectious Diseases, Volume 8, Issue Supplement\_1, November 2021, Page S692, <https://doi.org/10.1093/ofid/ofab466.1394>.

#### Upcoming Events, News and Additional Sources of Information

- **Dr. Natasha Hochberg** was awarded the Bailey Ashford Medal from the American Society of Tropical Medicine and Hygiene. The medal is awarded for distinguished work in tropical medicine. Dr. Hochberg was also selected as the president-elect of the clinical group of ASTMH. In her role as president, she is looking forward to helping raise awareness of Chagas' disease. Learn more about this honor and Dr. Hochberg's role in Tropical Medicine [here](#).
- World Chagas Day 2022, Thursday, April 14<sup>th</sup>
- The Second *Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States* workshop was held in May 2021, in virtual format. A summary of the workshop, and report are available [here](#).

## Screening for *Trypanosoma cruzi* in the United States

### Farmworker Health Fairs

Norman Beatty – [Norman.Beatty@medicine.ufl.edu](mailto:Norman.Beatty@medicine.ufl.edu)

Farmworkers are an essential workforce here in the United States and throughout Florida. Many of our farmworkers in this region are Latin American who have immigrated from endemic regions where Chagas disease is transmitted. Dr. Norman Beatty from the University of Florida (UF) College of Medicine has partnered with Dr. John Diaz (UF Institute of Food and Agricultural Sciences) and Dr. Rhoel Dinglasan (UF College of Veterinary Medicine) to [tackle health disparities among our farmworkers](#). Implementing rapid diagnostic tests for screening common chronic diseases that lie silent for decades, such as Chagas disease and diabetes mellitus among others, Dr. Beatty and his team have launched a statewide program to break barriers for farmworker health. Dr. Colin Forsyth from Drugs for Neglected Diseases Initiative has also been instrumental with aiding in the effort. The objective is to not only screen for these silent diseases but also link our farmworkers to community partners and local health care providers for further health care needs. At each of our health events the farmworkers are also provided with education on the chronic diseases and vaccinations for COVID-19, seasonal influenza, and hepatitis A. Our goal is to build an infrastructure throughout the state of Florida to screen, confirm and treat Latin American farmworkers and their families for these diseases, including Chagas. For more information please email: [norman.beatty@medicine.ufl.edu](mailto:norman.beatty@medicine.ufl.edu).



Rodrigo Alcala, a research assistant working with Dr. Beatty, collects a fingerstick blood sample for rapid diagnostic testing for Chagas disease and diabetes mellitus

### Biorepository of Specimens from Chagas Patients

Natasha Hochberg – [nhoch@bu.edu](mailto:nhoch@bu.edu)

Members of the INSECT Team at BMC have begun the creation of a biorepository of specimens from Chagas patients. Samples are collected prior to, during and after treatment of patients and are accompanied by a well-characterized database of clinical information (demographics, cardiac testing, response to treatment, etc.). We are open to collaboration. For those who are interested, please contact Natasha Hochberg: [nhoch@bu.edu](mailto:nhoch@bu.edu).

## **Diagnostic Considerations for *Trypanosoma cruzi* Infection in High-risk U.S. populations**

### **Updates to Diagnostic Testing**

Provided by Andrew Levin – [alevin@kephera.com](mailto:alevin@kephera.com) and Vashti Irani – [virani@kephera.com](mailto:virani@kephera.com)

### **New CLIA Laboratory to Offer Testing for Chagas Disease**

Kephera Diagnostics (Framingham, MA) is planning to offer testing for Chagas Disease through its CLIA laboratory starting in early 2022. Testing with two different serological assays will be offered initially, in accordance with current guidelines from the US Chagas Diagnostic Working Group. As CLIA laboratory testing for Chagas Disease is a specialty that has not been widely available in the U.S., Kephera aims to improve access to testing with its new offering. For further details please contact: [virani@kephera.com](mailto:virani@kephera.com) or [alevin@kephera.com](mailto:alevin@kephera.com). Additional information will be available on our website [www.kephera.com](http://www.kephera.com) around the time the tests are launched.

### **Rapid Assay for Circulating *T. cruzi* Antigen as a Test of Cure for Chagas Disease**

In September 2021, Kephera Diagnostics was awarded a one-year Phase I SBIR contract from the National Institute of Allergy and Infectious Diseases to support the development of a rapid assay for detection of *T. cruzi* antigens in blood as a Test of Cure for Chagas Disease. This project will be carried out in collaboration with Drs. Natasha Hochberg and David Hamer at Boston University/Boston Medical Center. The aim of the project is to evaluate the feasibility of detection of *T. cruzi* antigens in blood samples as markers of active infection, and their disappearance after treatment as an indication of treatment success. The assays are planned for development in both point-of-care and laboratory formats. BU/BMC will recruit patients undergoing screening and treatment for Chagas disease for this project from its clinical sites in Boston.

### **Biomarker-Based Test of Cure for Chagas Disease**

Kephera Diagnostics was awarded a Phase I SBIR grant from the National Institute of Allergy and Infectious Diseases to develop a serological assay as a Test of Cure for Chagas Disease. The objective of the project is to demonstrate feasibility for an assay that detects the serological response to multiple antigen biomarkers to provide a semi-quantitative measurement of infection status in patients undergoing treatment for Chagas disease. A decline in antibody titer is considered the gold standard for Chagas treatment success, but the timeline for such a decline has generally been many years, and a standardized and validated assay is not yet available. The assay under development at Kephera will be offered as a kit and through Kephera's CLIA laboratory as a service. Serum samples to be analyzed in the project were provided by academic collaborators in the U.S. and Brazil, including long-term studies in which patient blood samples were collected periodically before and at intervals after treatment.

### **Diagnostic Testing Operations for Parasitic Diseases Suspended at CDC**

In September 2021, Centers for Disease Control and Prevention (CDC) [suspended operations for diagnostic testing for “all assays” for parasitic diseases](https://www.cdc.gov/dpdx/index.html). The suspension covers over 20 diagnostic tests for parasitic infections, including molecular and serological methodologies, morphological identification, and *Trichomonas* antimicrobial susceptibility testing. As of March 14, 2022, these services have not yet resumed (except serologic testing for Chagas disease on February 24), and CDC has not provided public dates for resuming other tests. For more information, see: <https://www.cdc.gov/dpdx/index.html>

## **Treatment Programs for Chagas Disease in the United States**

### **Pilot Project to Increase Access to Testing and Treatment for Chagas Disease in Colombia**

Colin Forsyth – [cforsyth@dndi.org](mailto:cforsyth@dndi.org)

Results of a collaborative pilot project to increase accessing to testing and treatment for Chagas disease in Colombia were published in [Acta Tropica](#).<sup>1</sup> The pilot project emerged from a collaboration between Colombia's Ministry of Health and Social Protection, Colombia's National Institute of Health, the Drugs for

Neglected Diseases initiative, and local and departmental health authorities. A roadmap of care for Chagas disease was implemented in five endemic municipalities where vector transmission by *Rhodnius prolixus* had been interrupted. A previous study identified a significant diagnostic barrier in Colombia; only 1.2% of the at-risk population had been screened, and about a third of those screening positive never received diagnostic confirmation.<sup>2</sup> This project simplified the testing process so that patients only needed one blood draw in their local health center; diagnostic process times were reduced from an average of 258 days before the project to 19 days after implementation. Over 5,600 people were tested, including over 2,300 women receiving prenatal care. *T. cruzi* infection was detected in 649 people; 202 had initiated antiparasitic treatment at the time of publication. The roadmap of care for Chagas disease is currently being implemented in other municipalities in Colombia.

- (1) Herazo R, Torres-Torres F, Mantilla CAG, Carillo LP, Cuervo A, Camargo MAM, Moreno JF, Forsyth C, Vera MJ, Díaz RAC, Marchiol A. On-site experience of a project to increase access to diagnosis and treatment of Chagas disease in high-risk endemic areas of Colombia. *Acta Trop*. 2022 Feb;226:106219. doi: 10.1016/j.actatropica.2021.106219.
- (2) Cucunubá ZM, Manne-Goehler JM, Díaz D, Nouvellet P, Bernal O, Marchiol A, Basáñez MG, Conteh L. How universal is coverage and access to diagnosis and treatment for Chagas disease in Colombia? A health systems analysis. *Soc Sci Med*. 2017 Feb;175:187-198. doi: 10.1016/j.socscimed.2017.01.002.

## Health System Strengthening for Chagas Disease

### “Not a Single Baby with Chagas” paved way to the elaboration of the Ibero-American initiative at the SEGIB General Secretariat

Marcelo Abril – [mabril@mundosano.org](mailto:mabril@mundosano.org)

In April 2021, at the XXVII Ibero-American Summit (Andorra), Heads of State and Government approved the Iberoamerican Initiative: "Not a single baby with Chagas: towards new generations free of Chagas Disease". Fundación Mundo Sano leads the Technical Unit of this Initiative, as agreed by consensus by its Member States, and will work along with SEGIB (the Ibero-American General Secretariat), participating member states that include Argentina, Brazil, Colombia, El Salvador, Guatemala, Honduras, Paraguay, and Spain, and other partners, towards the following three strategic objectives:

- Strengthen health systems and services, in terms of norms and guidelines; training of human resources for health and sharing of good practices and experiences (all related to prevention, access to diagnostics and treatment, follow up).
- Expand access to diagnosis and treatment.
- Strengthen epidemiological and entomological surveillance.

The Initiative is aligned with PAHO and WHO guidelines and strategies, such as PAHO's Strategy for the Elimination of Mother to Child Transmission of HIV, Syphilis, Hepatitis B and Chagas; and the WHO [Roadmap for Neglected Tropical Diseases](#) in the context of the 2030 Sustainable Development Goals Agenda.

## Education and Training for Providers

### Implementing Novel Strategies for Education and Chagas Testing (INSECT), a 5-year Cooperative Agreement with the CDC Parasitic Diseases Branch

Natasha Hochberg – [nhoch@bu.edu](mailto:nhoch@bu.edu)

Our project, Implementing Novel Strategies for Education and Chagas Testing (INSECT), a 5-year - Cooperative Agreement with the CDC Parasitic Diseases Branch, aims to increase healthcare providers' awareness of and screening for Chagas disease. As part of this project, we have rolled out screening at Boston Medical Center (BMC) through a coordinated lecture series for providers, trainees, and nurses in primary care (e.g., family medicine, general internal medicine, and pediatrics). We have also identified Chagas champions within these different departments who are helping to ensure that screening is carried out at BMC and identify ways to educate providers at other institutions. Our team developed posters to hang in clinics and postcards to place in waiting rooms; all materials have been translated into Spanish. We are

also developing a handbook for clinics interested in implementing their own Chagas screening program that walks through the steps to develop a successful program. Beyond Boston Medical Center, we have been giving lectures at a number of hospitals and clinics that care for immigrants in New England and beyond to raise awareness of Chagas and encourage them to start screening. To identify optimal strategies to educate providers about Chagas disease, we organized group discussions with primary care and OB-GYN physicians and nurses who serve large immigrant populations across the country; we are analyzing those data currently and will disseminate the findings.

We were accepted to put on a workshop at the 2022 Society of General Internal Medicine (SGIM) conference in April 2022 entitled "Caring for the Cross-Border Migrant: Addressing Equity in Care" where we will discuss Chagas disease, other infectious diseases, mental health, and environmental health and exposures. Lastly, we hosted a contest to design a pin for providers to wear to remind them to screen for Chagas disease. These submissions will be posted to our website. We are happy to share all our materials (the handbook, posters, postcards, lecture series, and pins). Please contact [Chagas@bu.edu](mailto:Chagas@bu.edu); the material will also be made available shortly on our website - <https://sites.bu.edu/chagas/>.

## Publications

- Forsyth CJ, Hernandez S, Flores CA. **"You Don't Have a Normal Life": Coping with Chagas Disease in Los Angeles, California.** *Med Anthropol.* 2021 Mar 30;1-16. doi: [10.1080/01459740.2021.1894559](https://doi.org/10.1080/01459740.2021.1894559). Online ahead of print.

Fifty patients with Chagas disease from Los Angeles, California were interviewed and administered a culture consensus analysis questionnaire to assess the impact of Chagas disease on personal lives and communities. The participants' responses demonstrate how Chagas is a hidden, neglected disease with real life consequences and highlight the importance of going beyond clinical treatment when focusing on elimination of the disease. Specific cultural and historical contexts, as well as political and economic structures must also be considered when working towards progress in this area.

- Nolan MS, Aguilar D, Misra A, et al. **Trypanosoma cruzi in Nonischemic Cardiomyopathy Patients, Houston, Texas, USA.** *Emerging Infectious Diseases.* 2021;27(7):1958-1960. doi:[10.3201/eid2707.203244](https://doi.org/10.3201/eid2707.203244).

This study recruited cardiac patients (those with known nonischemic cardiomyopathy) of Latinx ethnicity for Chagas disease surveillance with the aim of identifying possible cardiac manifestations of Chagas disease. A high prevalence of underdiagnosed infection and discrepant results in clinical diagnostic assays were found within the study population. The findings from this study further indicate a need for *T. cruzi* surveillance of Latinx patients with cardiac disease and risk factors for infection in the United States.

- Ridley DB, Ganapathy P, Kettler HE. **US Tropical Disease Priority Review Vouchers: Lessons in Promoting Drug Development and Access.** *Health Affairs.* 2021 Aug;40(8):1243-1251. doi:[10.1377/hlthaff.2020.02273](https://doi.org/10.1377/hlthaff.2020.02273).

This analysis provides a review of the Tropical Disease Priority Review Voucher program, under which the US FDA awards priority review vouchers to the sponsor of a new drug or vaccine for tropical infectious diseases. These vouchers can then be exchanged for faster review of one drug. Case studies for tropical disease voucher recipients between 2007 to 2018 are described within this article and are used to examine its impact on product innovation and access. The authors provide critiques of the program, lessons learned and recommendations to policy makers regarding the voucher program.

- Truysen C, Dumonteil E, Alger J, et al. **Geographic variations in test reactivity for the serological diagnosis of Trypanosoma cruzi infection.** *J Clin Microbiol.* 2021 Sep1;JCM0106221. doi: [10.1128/JCM.01062-21](https://doi.org/10.1128/JCM.01062-21). Online ahead of print.

The focus of this study is the lack of a gold standard serological test for Chagas disease and how the absence of such a standard complicates measurement of test performance. This study evaluated the reactivity of two rapid diagnostic tests and one ELISA assay, and ultimately underscores needed improvements in serological diagnostics for *T. cruzi* infections. The authors found the test reactivity varied significantly among countries, which was attributed to possible geographic differences in *T. cruzi* parasite strains and/or genetic differences among human populations.

- Forsyth C, Manne-Goehler J, Bern C, et al. **Recommendations for Screening and Diagnosis of Chagas Disease in the United States.** *J Infect Dis.* 2021 Oct8;jiab513. doi: [10.1093/infdis/jiab513](https://doi.org/10.1093/infdis/jiab513). Online ahead of print.



Provided within this article are recommendations for assisting US healthcare providers in the identification and testing of people at risk for Chagas disease. Developed by a group of multidisciplinary clinicians and researchers with expertise in Chagas disease, and based on a review of relevant literature, it gives guidance on how screening and diagnostic testing are key to addressing this public health challenge. Recommendations include testing individuals who were born or resided for prolonged periods of time in endemic countries and utilizing 2 distinct assays for diagnostic testing.

- Valdez-Tah A, Ibarra-Cerdeña C. **Call to action: a literature review of Chagas disease risk in California 1916-2018.** *PLoS Negl Trop Dis.* 2021 Feb 25;15(2):e0009035. doi: [10.1371/journal.pntd.0009035](https://doi.org/10.1371/journal.pntd.0009035). eCollection 2021 Feb.

This article focuses on the need to improve our knowledge of *T. cruzi* infection risk components, particularly in less well studied states where *T. cruzi* transmission may resemble those of other endemic areas. It provides an extensive literature review of data published between 1916 and 2018 for Chagas disease in California, including records of autochthonous *T. cruzi* and human-related data. The authors highlight critical areas needing further research and intervention to aid in accurately assessing the public health risk.

- Hincapie M, Bernabé K, DeCuir J, et al. 1202. **Chagas Disease Awareness in a Hispanic Community of the Greater New Orleans Area,** *Open Forum Infectious Diseases, Volume 8, Issue Supplement\_1, November 2021, Page S692,* <https://doi.org/10.1093/ofid/ofab466.1394>.

This abstract presents a cross-sectional study that aimed to assess the change in Chagas disease and triatomine vector knowledge among Hispanic immigrants living in the Greater New Orleans area. The study included a baseline questionnaire, an educational intervention, and a post-test. The authors concluded that educational intervention could have a positive impact on knowledge about the disease and that increasing awareness of Chagas disease may lead to early detection and prevention of the disease among this population.

## Acknowledgements

We acknowledge that we are living in unprecedented times during the ongoing global coronavirus pandemic and hope that you are all safe and well. During these challenging times, it remains important to continue working on the many ongoing Chagas disease initiatives that will ultimately have a large impact on the care of these patients.

This newsletter is a follow-up activity to the 2018 *Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States* workshop held by the Harvard T.H. Chan School of Public Health along with the Chagas Coalition and *Fundación Mundo Sano*. The Newsletter production team: Jennifer Lashinsky, Johnattan Garcia Ruiz, Emily F. Coles, Jennifer Manne-Goehler, and Michael R. Reich appreciate the contributions of the many individuals who provided text and materials for the newsletter.