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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Highlighted Publications


Upcoming Events, News and Additional Sources of Information

- **World Chagas Day 2021**, April 14th, 2021.

- **World Chagas Disease Day: Raising awareness for Chagas Disease**, April 14th, 2021. Livestream Concert. An initiative from the Digital Worlds Institute, Mundo Sano, the Center for Latin American Studies, and the College of the Arts at the University of Florida. Hosted by Dr. Norman Beatty. For more information visit: https://arts.ufl.edu/in-the-loop/events/world-chagas-day-livestream-concert-with-tremura-lee-and-dr-norman-beatty/


- A follow up to the 2018 Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States workshop is currently being planned for late Spring 2021.
**Screening for *Trypanosoma cruzi* in the United States**

**Update on the Texas Newborn Screening Pilot Project**

Paula Stigler Granados – psgranados@txstate.edu

The Newborn Screening Pilot Project in Texas has overall objectives to: (1) evaluate new methodologies for testing dried blood samples of newborns for Chagas disease, (2) assess the prevalence of Chagas disease among women who have recently given birth in Texas, (3) improve access to care by strengthening clinical care resources available to this population, and (4) use these data to inform Texas policies for screening women of childbearing age and newborn infants. Now that the Weiner Recombinant DNA 3.0 testing kits are readily available in the U.S., the team has started a validation study using the kits on dried blood spots. *T. cruzi* positive samples have been made available from the CDC to evaluate the new methodology. The next step, once the validation study is complete, will be to begin testing the newborn dried blood spots.

The Newborn Screening Pilot Project is a three-year collaboration initiative between the School of Health Administration, College of Health Professions at Texas State University and Fundación Mundo Sano.

**Care for Strong Hearts Chagas Disease Patients in the COVID-19 Pandemic**

Julia Koehler – julia.koehler@childrens.harvard.edu

By early 2020, our new patient coordinator Jim Gomes had caught up on bringing most of the Strong Hearts patients who had been lost to follow-up without a navigator, back into care. We had returned to the congregation of the Most Holy Redeemer church in East Boston to resume Chagas disease information outreach by early February. Then the pandemic struck East Boston and the surrounding communities. With the lockdown, clinic visits for Chagas evaluation and treatment at Boston Medical Center ceased. As Jim called patients in late March to ask them how they were and what they needed, all patients said they needed food, and many needed rent money. A most generous donor provided funds so that we could mail substantial grocery store gift cards to 60 patients. Unfortunately, we were unable to provide support for rent.

Over the summer, as clinic visits resumed remotely and in person, and interrupted anti-parasitic treatment courses were restarted, these needs still remained acute. With additional compassionate donations, we sent out gift cards to more patients, coordinated for food pantry sign-ups and worked with the East Boston Community Soup Kitchen. Jim was able to help patients overcome scheduling, transportation and insurance barriers, and obtain a medical second opinion. But hunger and homelessness are currently the greatest threats to the health of the Strong Hearts patients. In that, and in their risk of COVID-19 infection, they are like many Latino immigrants in the U.S. Injustice remains the underlying force that puts their lives at risk.

**Effective Surveillance of Chagas Disease for U.S. Military Readiness along South West U.S. Mexico Border Ports of Entry Project**

Paula Stigler Granados – psgranados@txstate.edu

In September 2020, Dr. Paula Stigler Granados from Texas State University received a 2-year award from the Department of Defense Global Health Engagement and Readiness Initiative (GHERI). The project is titled “Effective Surveillance of Chagas Disease for U.S. Military Readiness along South West U.S. Mexico Border Ports of Entry.” The goals of the project are to conduct vector and human surveillance of Chagas disease, and to propose policies for improved surveillance of this emerging infectious threat to the Service member population who reside and conduct training in potentially high-risk areas. This project partners with the U.S. Army Public Health Command-Central (PHC-C) Headquarters at Fort Sam Houston (San Antonio, TX), the Navy Environmental Preventive Medicine Unit 5 (NEPMU-5) from San Diego, CA, San Diego State University School of Public Health and the University of Texas at El Paso.

The aims of the project are to conduct vector surveillance at military installations located near the U.S. Mexico border Ports of Entry (POE). A total of six sites have been selected and are scheduled to begin triatomine
collection in Spring/Summer 2021. The Department of Defense Serum Repository will also be used to sample approximately 500 specimens from active-duty Service members from these areas to estimate prevalence and to determine if the repository samples can serve as a means to examine seroprevalence in future research.

**Unitaid Report: Screening and Treatment for Chagas Disease - Technology and Market Landscape**

This 2020 Unitaid Report examines existing technologies used for diagnosis and treatment of Chagas disease. It provides an overview of Chagas disease epidemiology, global targets, current diagnostic and treatment guidelines, and also presents an overview of diagnostic and treatment markets and identifies gaps to be filled. The report highlights improvements in the diagnostics market and expansion of existing treatment methods, along with new treatments and improved market intelligence for demand-side treatment needs. Through an assessment of barriers and opportunities, the report indicates a need for greater support and attention to the technology and market needs of Chagas disease. As such, Unitaid aims to support a shift in screening and treatment programs in low-to-middle income countries by addressing access barriers and supporting introduction of new technologies.

A copy of the report can be found here: [https://www.developmentaid.org/api/frontend/cms/file/2020/04/Screening-and-Treatment-for-Chagas-Disease.pdf](https://www.developmentaid.org/api/frontend/cms/file/2020/04/Screening-and-Treatment-for-Chagas-Disease.pdf)

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

**Distribution of Wiener Chagatest ELISA recombinant v3.0 kits in the USA**

*Martin Manfredi – mmanfredi@exeltis.com*

In 2019, the research team lead by Doctor Caryn Bern at UCSF compared the performance of the four FDA-cleared serological tests in specimens from U.S. blood donors to provide the first systematic evidence to improve laboratory diagnosis of Chagas disease in the U.S. Taking into consideration their findings and in alignment with our mission to further the fight against Chagas disease in the United States, Exeltis is pleased to announce that it started distributing the Wiener Labs Chagatest ELISA recombinant v3.0 in the United States.

We believe this is a major step towards improving the availability of quality diagnostic products for Chagas Disease in the U.S. and that the kits will serve as a catalyst to enhance disease visibility.

For any product inquiries, please feel free to reach out to mmanfredi@exeltis.com.

We would like to extend our gratitude to everyone involved in making this improved access to diagnostic kits a reality.

**U.S. Chagas Diagnostic Working Group Update**

*Colin Forsyth – cforsyth@dndi.org*

Previous research has indicated that low provider awareness of Chagas disease, combined with complexities in the diagnostic process, contribute to low levels of testing in the U.S. Simplifying diagnostic processes for Chagas disease was also a major theme of the Rethinking Chagas Workshop. To help address this issue, a working group was organized with support from the Drugs for Neglected Diseases initiative, and with participation from various experts on Chagas disease in the U.S. The working group launched in late 2019 with a goal of proposing simplified guidance for diagnosis of Chagas disease given the tools available and the epidemiological context in the U.S. The guidance would be constructed using the GRADE methodology, in alignment with current PAHO guidelines for diagnosis and treatment of Chagas disease. In initial meetings held at John Hopkins University and the ASTMH annual meeting, the group agreed on key questions to address. Members divided into six subgroups to tackle different questions, including which at-risk groups to target for
Due to the COVID-19 pandemic, the group met virtually on two subsequent occasions in 2020 and produced a draft guidance document following the GRADE methodology, which assigns a rating both for the strength of the recommendation and the quality of the available evidence. Initial recommendations were determined within each subgroup and then agreed to within the larger group. The draft document is now in the final stages of revisions. The goal is to produce a document that can serve as a tool to facilitate the testing process for primary healthcare providers throughout the U.S.

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

**U.S. FDA Approval of Lampit (nifurtimox)**

In August 2020, The U.S. Food and Drug Administration announced approval of Lampit (nifurtimox) for the treatment of Chagas disease in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg).

Nifurtimox was approved under the accelerated approval program based on results from the Chagas disease in children treated with nifurtimox study. Approval was based on the number of patients who became IgG antibody negative or who showed at least a 20% decrease in optical density on ELISA tests. The study is ongoing with the second part aiming to follow patients for an additional three years to confirm efficacy and safety.

Nifurtimox is the second treatment for Chagas Disease approved by the FDA. In 2017, benznidazole obtained approval for use in children ages 2 to 12. In the case of Nifurtimox, the FDA approved its use for treatment from birth to children less of 18 years of age.

The nifurtimox prescribing information and website can be found here:

- **Prescribing information:** [https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213464s001lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213464s001lbl.pdf)
- **Website:** [https://www.lampit.com/](https://www.lampit.com/)

**Benznidazole Tablets Distribution Update: New Emergency Delivery Forms**

*Martin Manfredi – mmanfredi@exeltis.com*

Since the launch of benznidazole Tablets in 2018, Exeltis has been committed to enhancing the distribution of the medication in the United States. One of the areas that required immediate attention was the expedited delivery of benznidazole for those patients that undergo an emergency. We are pleased to announce that a protocol has been created to expedite the process and delivery of benznidazole for emergency situations. A new “For Emergency Only” Fast Access form can be found at [www.benznidazoletablets.com](http://www.benznidazoletablets.com) that can be utilized in these instances. By having a distinctive form, emergency orders can be easily identified, prioritized, and expedited by the pharmacy in order to meet a 48-hour delivery window. We are happy to continuously strive to enhance access to benznidazole in the United States.

**Making Available Free Paediatric Medicine: Fundación Mundo Sano and WHO Collaboration**

*Mundo Sano Press Release*

Fundación Mundo Sano is pleased to announce that it has entered into a cooperation agreement with the World Health Organization (WHO) with the objective to accelerate the elimination of infection with Chagas disease in children and to prevent congenital transmission in pregnant women.

Mundo Sano, together with Insud Pharma, will provide WHO with 108,000 benznidazole tablets, along with financial support to follow up of patients, distribute the medicine, and organize technical meetings on the elimination of congenital Chagas disease.

Marcelo Abril, chief executive officer of Mundo Sano, said: “Our foundation has been making huge efforts
regarding granting access to Diagnosis & Treatment of Chagas disease, and this Cooperation Agreement with WHO to facilitate access to treatment of congenital Chagas cases renews the commitment that not a single baby shall be born with Chagas disease by 2030.”

Dr. Mwele Ntuli Malecela, Director of the Department of Control of Neglected Tropical Diseases at WHO, stressed the importance of “making benznidazole freely available for the treatment of newborns and children, since it saves future generation from developing the disease and contributes to congenital Chagas disease elimination”.

In addition, Dr. Pedro Albajar Vinas, Medical Officer, Department of Control of Neglected Tropical Diseases at WHO, stated that “screening pregnant women who are at risk of infection and who have not been previously treated with antiparasitic medication provides an excellent opportunity for prevention of later transmission throughout pregnancy and birth.”

WHO source: https://www.who.int/news/item/02-04-2020-making-available-free-paediatric-medicine-can-accelerate-elimination-of-congenital-chagas-disease

Education or Training for Providers

Launch of the U.S. Chagas Providers Network Website

Caryn Bern – caryn.bern2@ucsf.edu, Eva Clark – eva.clark@bcm.edu, and Jeff Whitman – jeffrey.whitman@ucsf.edu


The USCN was established in January 2020 to provide educational resources about Chagas disease to U.S. medical providers and guide them as they evaluate, diagnose, and manage their patients. We hope that the USCN will serve as a resource and community for all U.S. Chagas providers, from students to experienced clinicians and researchers.

The USCN has goals in three major areas:

- Education: Improve the ability of U.S. clinicians to recognize and manage Chagas disease through educational events such as scientific and case presentations.
- Community: Facilitate networking among U.S. Chagas providers. Linking providers allows for direct discussion of regional and national clinical conundrums, rapid access to national and international expertise, and more opportunity to form productive research relationships.
- Research: Advance scientific research on Chagas disease, particularly investigation of the unique challenges encountered by U.S. Chagas providers.

We invite interested providers to visit the website, attend virtual seminars on Chagas disease and join the network.
Atendiendo Chagas Network – Open Access Platform

Marcelo Abril – mabril@mundosano.org

The open access platform Atendiendo Chagas is now available to English speaking users. This network aims to provide resources to all healthcare providers, researchers, and professionals working with Chagas disease. Mundo Sano developed Atendiendo Chagas, hoping it to become a useful resource to the Chagas community and help breach communication and information gaps.

The following features are available to users:

- A repository of documents classified by country: guides, Diagnosis & Treatment regulations, and relevant scientific work.
- A fully georeferenced directory of members with filters by name, country, city, or field.
- Private IM between members. The recipient receives an e-mail notification for pending messages. Soon a group IM feature will become available as well.
- Fora and news spaces regularly checked and updated. The platform administrator refers any consultations made through the fora to the relevant professionals.
- Monthly newsletters with updates and notices.

The platform already has more than 200 members from most South and Central American countries, Mexico, the United States, Sweden, Spain, and Japan.

Fundación Mundo Sano would like to encourage everyone in the U.S. Chagas community to join the network, as it is a collective effort in which user’s feedback and support is essential. You can join by creating a profile at: http://atendiendochagas.mundosano.org/.

Language selection is made by default at login, or manually through a language icon in the welcome page. The design is adaptive to PC, iPad or smartphone formats.

Summary of the University of Florida Chagas Project

Norman Beatty – Norman.Beatty@medicine.ufl.edu

The prevalence of Chagas disease among Latinx populations living in Florida is currently unknown. Epidemiological data among at-risk populations suggest that 18,000 individuals or more are living with the
disease but less than 1% have been diagnosed. Dr. Norman Beatty from the University of Florida College of Medicine, Division of Infectious Diseases and Global Medicine, has now launched a community-based study to address this issue.

The primary objective is to investigate who is at-risk for Chagas in Florida and what are the risk factors among this population. He will also be screening for other comorbidities, such as diabetes, hypertension, obesity, depression and electrocardiographic abnormalities. His team of researchers includes providers from primary care, obstetrics, emergency medicine, and infectious diseases to screen Latin Americans who were born or migrated from endemic regions. Utilizing rapid tests in the field and further serological and molecular-based testing from collected blood samples, Dr. Beatty plans to compare how our available tests are performing here in the United States. With the help of Mundo Sano, the project is now enrolling patients in North Florida, with plans to expand to other regions within the state. Another element of this research is to increase awareness of Chagas disease and provide educational opportunities for providers practicing in Florida. Overall, there is a tremendous need to build a network of researchers and providers who can screen, diagnose, and treat Chagas disease in this state. For more information regarding this investigation, please email our research coordinator at Chagas-Disease@ufl.edu.

Research coordinator Rodrigo Alcala (right) and research assistant, Nelson Luque (top left), conduct an interview at the UF Mobile Outreach Clinic at a local church in Gainesville, Florida.

CDC Funding Opportunity: “Reducing the burden of parasitic infections in the United States through evidence-based prevention and control activities”

The CDC has awarded funding opportunities to ‘continue the work of the Division of Parasitic Diseases and Malaria in CDC’s Center for Global Health to strengthen health care providers’ understanding, identification, treatment and prevention of parasitic infections in the U.S”. Below are summaries of some of the ongoing work related to Chagas disease through these awarded grants. Grant Source: https://www.grants.gov/web/grants/view-opportunity.html?oppId=322341

Boston University:

Our project, Implementing Novel Strategies for Education and Chagas Testing (INSECT), a newly funded 5-year Cooperative Agreement with the CDC Parasitic Diseases Branch as part of their program “Reducing the Burden of Parasitic Infections in the U.S. through Evidence Based Prevention and Control Activities,” aims to expand healthcare providers’ knowledge and awareness of Chagas disease as well as increase screening and testing for the disease. In the first phase of the project, we will focus on gathering perceptions of Chagas disease among primary care providers (e.g., family medicine, general internal medicine and pediatrics) and specialists in obstetrics and gynecology, in addition to learning more about their preferred types of educational
activities and methods of learning. We will also aim to roll out screening programs in Massachusetts (specifically Boston Medical Center and MetroWest Medical Center) and other parts of New England. The overall goal of INSECT is to improve national screening and testing practices and to reduce the rate of congenital transmission of Chagas disease.

David Hamer – dhamer@bu.edu, Natasha Hochberg – nhoch@bu.edu, Maja Carrion – maja@bu.edu, Chagas@bmc.org.

Texas State University:

In September 2020, the CDC awarded a 5-year cooperative agreement to Dr. Paula Stigler Granados at Texas State University to continue raising awareness of Chagas disease in the U.S. The aims of this project are to 1) maintain and build upon the current Texas Chagas Taskforce model used for raising awareness of Chagas disease and expand it beyond just Texas, 2) improve healthcare provider access to expert information by using the Extension for Community Health Outcomes (ECHO) tele-mentoring model, and 3) pilot a national Community Health Worker curriculum on Chagas disease. The overall goals of the project are to increase awareness of the presence of Chagas disease in the United States, improve knowledge regarding appropriate diagnosis and treatments available, and encourage multi-way communication among healthcare providers, regulatory agencies, veterinary medicine, public health networks and the community at large regarding prevention of Chagas disease. Monthly online presentations by experts in the field using the ECHO model will begin in April 2021. Each session will provide CME and CEU opportunities for physicians and other healthcare workers.

Paula Stigler Granados – psgranados@txstate.edu

Highlighted Publications


  This study used an online webinar with pre- and post- tests to evaluate the efficacy of raising awareness, and to determine key focus areas, for improving knowledge of Chagas Disease among U.S. healthcare providers. Following the webinar, there were statistically significant learning increases in multiple categories (including transmission, clinical presentation, diagnostics and treatment). The authors concluded that providing easily accessible learning opportunities through validated testing and evaluations should be further developed.


  This analysis looked at factors that have continued to impact access to benznidazole following commercialization and provides suggestions for ways to expand access. Collecting data from published literature, key informants, and commercial databases, it applied a framework to identify barriers, facilitators, and key actors that influence the ability to access treatment. While an increase in the mean number of persons who obtained benznidazole was found following commercialization, the authors identified nine key barriers to access and suggest six areas for strategic action to further expand access.


  In this editorial, the authors highlight an urgency to establish a new and comprehensive patient registry for individuals with Chagas disease. This registry would be similar to existing national cancer registries in both the United States and Europe that have contributed to improved understanding of the disease, as well as developments in treatment and prevention. They argue that such a tool for Chagas disease could help answer some key questions related to the epidemiology, disease burden, natural history, and treatment of the disease, as well as raise awareness of limited access to essential medicines.


  This study evaluates the diagnostic accuracy of FDA-cleared tests for *Trypanosoma cruzi* infection in the Washington Metropolitan area. Two types of seropositive antibody levels were detected (low and high), with
predominance varying by endemic area. Low antibody levels were the main type of seropositive identified in the most frequent immigrant group to the U.S. Limitations of FDA-cleared tests in the diagnosis of Chagas disease among a diverse community are discussed.


Through an anonymous survey distributed to 178 Obstetrics/Gynecology and Family Medicine practitioners, this study aimed to assess the perceived barriers to Chagas disease screening among these providers at a tertiary care safety net hospital. The authors found that an overwhelming majority of participants supported screening for Chagas disease, with 39% of respondents saying it was very important and 48% responding that it was a somewhat important public health initiative. While most respondents were familiar with Chagas disease, only 32% knew how to order a test and only 22% reported knowing what to do with a positive finding.

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

- **World Chagas Day 2021**, Wednesday, April 14th, 2021.
- A follow up to the 2018 *Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States* workshop is currently being planned for late Spring 2021.

**Acknowledgments**

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.