



SCHOOL OF PUBLIC HEALTH
Powerful ideas for a healthier world



Mundo Sano

2ND
RETHINKING
CHAGAS
WORKSHOP

RESHAPING THE AGENDA
FOR CHAGAS DISEASE
IN THE UNITED STATES

Wednesday May 19
& Thursday May 20

WORKSHOP REPORT

Summary

The Harvard T.H. Chan School of Public Health together with Fundación Mundo Sano hosted the 2nd Rethinking Chagas Workshop on May 19 and 20, 2021. The goal of the workshop was to convene a group of experts on Chagas disease in order to discuss the agenda for action on this neglected disease. The event was divided into three sessions:

1. Models of Care for Chagas Disease in the United States
2. Strengthening Diagnostic Testing for Chagas Disease in the United States
3. Promoting Clinical Excellence in the Care of People with Chagas Disease

The meeting highlighted current and future research and community-based activities that are needed to advance the agenda for Chagas disease in the United States, as a follow on to the first workshop on Rethinking Chagas held in October 2018. Appendix 1 provides a table of progress achieved since the 2018 workshop. The agenda and participant list for the current workshop are included as Appendix 2.

Session 1: Models of care for Chagas disease in the United States

FACILITATOR: Jen Manne-Goehler

SPEAKER 1: Natasha Hochberg and Julia Koehler

SPEAKER 2: Norman Beatty

GENERAL DISCUSSION: Salvador Hernandez

Background

This session focused on current models of care for Chagas disease in the United States as well as the challenges to replicating and expanding these models in other geographic areas. The subject matter included: (1) a discussion of existing models to diagnose and treat patients who are identified through existing projects, and (2) the challenges to expanding and/or replicating these models in other settings. The session focused on current programs in Texas, California, Florida and Massachusetts, with implications for other high-risk geographies such as New York. The relevant themes for discussion included the screening approach, structure of the referral and care programs, and ways in which these programs are financed.

Summary and recommended next steps

The group first discussed the positive example of the East Boston program and the reasons why providers have embraced screening there. Some of the reasons that were mentioned included that an overwhelming majority of the patients are from endemic regions and that providers are familiar with screening for other infectious diseases in this population. There were several suggestions about how screening uptake could

be enhanced here and in other programs. These included: (1) pre-established wellness labs through which Chagas screening could be conducted in all high-risk individuals, (2) an enhanced focus on screening 18-40-year-olds, and (3) an effort to ensure all relatives of positive patients be screened.

Action points

1. Increase cross-context learning regarding successful strategies to increase screening uptake in both clinic-based and community-based settings.

A second theme highlighted by this group was strengthening international collaboration and learning. Participants noted that many aspects of the US efforts to improve care for Chagas disease are similar to those in other non-endemic countries such as Spain or non-endemic regions within Latin America including urban areas. Common lessons could be identified and shared through stronger connections across these efforts, including in areas of local transmission within the US.

Action points

1. Support collaboration and exchange about effective models of care across non-endemic countries and non-endemic and endemic regions within Latin America.

The group then discussed strategies to strengthen existing programs and increase scalability. First, community health workers or patient care navigators (*promotores de salud*) are one important element of successfully ensuring that patients traverse the entire continuum of care and are not lost to follow-up at the stage of evaluation or treatment. Second, participants emphasized the importance of integrating Chagas efforts into the existing care infrastructure and operational procedures, such as including Chagas in newborn screening and prenatal care. Third is the importance of a continued focus on meeting the total health needs of affected communities and considering Chagas disease in the context of larger “wrap-around” services for patients at high-risk. This would include attention to immigration, and food and housing needs, along with other health priorities such as obesity management, diabetes care and COVID-19 vaccination.

These activities create an opportunity to “end the neglect” for Chagas disease. Assessing the results of these efforts to identify and treat Chagas disease will bolster advocacy on behalf of people with Chagas disease and improve the effectiveness of Chagas screening and treatment programs.

Action points:

1. Support efforts to strengthen and scale-up existing models of care in the US, through the use of Chagas disease trained patient-care navigators (promotoras), integration of disease-specific activities into both prenatal and primary care more broadly, and inclusion in efforts to improve the total health and well-being of affected communities.
2. Explore the development of new centers of excellence for diagnosis and treatment in other areas of the US with large immigrant communities from Latin America (such as Chicago).
3. Seek avenues to advocate for policies that will enhance scalability of these efforts and improve care for populations with or at high risk of Chagas disease.

Session 2: Strengthening diagnostic testing for Chagas disease in the United States

FACILITATOR: Sue Montgomery

SPEAKER 1: Colin Forsyth

SPEAKER 2: Caryn Bern

GENERAL DISCUSSION: Sue Montgomery

Background

This session focused on current activities to improve access to and performance of diagnostics for Chagas disease. The discussion centered on the availability of diagnostic tests both for screening and confirmation and the current needs in Chagas disease diagnosis for the United States, obstacles to expanding access to diagnostics and improving performance, and strategies to overcome these barriers.

Summary and recommended next steps

The group identified three main areas of discussion on diagnostic testing for Chagas disease in the US: (1) tests available in the market, (2) commercial laboratory practices, and (3) ongoing knowledge gaps.

One common theme of the workshop was the need for clear guidelines. A committee began addressing this issue in 2019, and has drafted a set of screening/diagnostic guidelines, focused on their use in primary healthcare settings. The committee plans to submit the draft for publication. Adoption of a comprehensive set of management guidelines by IDSA or another society would be an important boost to strengthen both diagnosis and treatment for Chagas disease.

Action points

1. Support the efforts to finalize and publish screening/diagnostic guidelines for Chagas disease.

The group first discussed the limited availability of tests with FDA clearance. Although the Wiener ELISA recombinant v.3 is now available through Exeltis, the Ortho ELISA is still not on the market despite clearance. There is a need to have other tests available as well, particularly tests that can detect infections acquired in Mexico and Central America.

Action points:

1. Re-engage Ortho in discussions to make its *T. cruzi* ELISA commercially available.
2. Explore opportunities to reduce the entry barrier for new tests, including rapid tests.

A second theme was the differences and inconsistencies in how major commercial laboratories are processing tests. When positive results are sent to CDC, state health departments are often left out of the loop. In some cases, insurers are charged for confirmatory testing that is carried out for free by CDC. Quest has shown a strong commitment to using the Wiener; other companies are using Hemagen or even IgM tests. Work is being done on a living guidance document for *T. cruzi* serology. Ideally, commercial labs would all run two FDA-cleared tests and send to CDC in case of discordant results.

Action points

1. Push commercial testing labs to have two tests available, reflex positive results against a second test.
2. At present, the two best diagnostic tests are the Wiener and Ortho ELISAs.
3. Support efforts for commercial testing labs to engage state/local health departments in the confirmatory process.

The group also discussed important research gaps regarding the available diagnostic tools. One major priority is to determine which tools work best in diagnosing infections acquired in Mexico and Central America. Some unpublished research indicates that commercial tests may be missing more than half of infections acquired in southern Mexico. In addition, there is a pressing need to explore new technologies (e.g. CRISPR) that could facilitate diagnosis. Knowledge gained from COVID-19 may open new doors.

Action points

1. Explore diagnostic tools beyond those currently available in the US market, including new technologies, especially tools capable of diagnosing infections acquired in Mexico and Central America.

Conversation with Congressman Ruiz

Congressman Raul Ruiz (CA-36), Chair of the Congressional Hispanic Caucus (CHC), spoke with Workshop participants for 45 minutes and answered questions related to CHC activities, Congressional activities on Hispanic health and immigration, and opportunities to address health system challenges for Chagas disease and communities most affected by this infection in the US.

Action points

1. Organize a “Chagas Congressional Day” where partners meet with their Representatives and Senators to educate them about the challenges of Chagas disease in the US, and actions that Congress can take. Consider holding this event during ASTMH 2021 conference, which is being held in Washington, DC.
2. Explore opportunities for legislative action, such as Corey Booker’s STOP Neglected Diseases of Poverty Act, or a Ryan White Act for Chagas Disease.

Session 3:

Promoting excellence in the care of people with Chagas disease

FACILITATOR: Jamie Maguire

SPEAKER 1: Rachel Marcus

SPEAKER 2: Paula Stigler Granados

SPEAKER 3: Martin Manfredi

GENERAL DISCUSSION: Melissa Nolan-Garcia

Background:

This session focused on efforts to promote and expand excellence for the care of patients with Chagas disease among providers in the US. This included a presentation on forthcoming diagnostic guidelines and their possible expansion, efforts to disseminate health information about Chagas disease to both providers and patients in high-risk areas of the US, and follow-up on plans to advance networks and channels of communication through which providers can gain greater expertise and support in caring for people with Chagas disease. There was also a discussion on how the approval of nifurtimox and its availability in the US may affect such efforts.

Summary and recommended next steps:

The breakout group discussed two main topics related to clinical excellence: (1) the development of guidelines or a consensus agreement for Chagas disease, and (2) strategies for improving clinical effectiveness of Chagas diagnosis and medical care.

On the theme of guidelines, the group agreed that clinical guidelines are urgently needed for large-scale physician buy-in for diagnosis and treatment of Chagas disease. A paired two-guideline approach was recommended: one for screening for Chagas disease, targeting primary care physicians (AAFP), Obstetrics-gynecology (ACOG) and pediatrics (AAP); and a second for treatment and follow-up of Chagas disease patients, targeting infectious disease (IDSA) and cardiology (ACC). The group suggested that the approach should leverage existing guidelines and prior conversations about guidelines, including consideration of the guidelines from PAHO, IDSA, Spain, Brazil and Argentina. The meeting on guidelines held at ASTMH annual meeting in 2019 could also provide useful material. The possibility of developing joint guidelines between disciplines could encourage a quicker roll-out and broader dissemination (for example, partnering between IDSA and ACC).

Action points

1. Develop a working group to continue building the more specific infrastructure for guidelines.
2. Consider hosting a key partner meeting on guidelines at ASTMH 2021 conference.

On the theme of improving clinical excellence of Chagas diagnosis and medical care, the group discussed the importance of assessing effective mechanisms to reproduce and scale-up existing models of care. Two efforts, in particular, deserve consideration: the US Chagas Providers Network (<https://uschagasnetwork.org>) and the CDC-funded cooperative agreements for Texas, New York and Boston physician education projects. It is critical to create the next generation of Chagas-minded practitioners. This will require identifying effective strategies to educate and engage medical students, public health students and allied health trainees (NP/PA). Finally, the group discussed efforts to raise the awareness of current health providers. Efforts could be made, for example, to include Chagas disease education in the context of larger grand round/CME/educational talks to elicit more attention (on topics such as “Neglected Tropical Diseases” or “Diversity, Equity and Inclusion in Clinical Practice”). In addition, it is important to creating Chagas disease champions within key clinical disciplines (modeled on the work done by Norman Beatty at the University of Florida).

Action points:

1. Identify mechanisms to support, reproduce and/or scale-up existing models of care for Chagas disease, including provider networks and CDC-funded physician education projects.
2. Support the development of the next generation of Chagas disease practitioners and researchers, through efforts to introduce Chagas-related topics in the curricula of medical students, public health students and allied health trainees (NP/PA).

Appendix 1

Summary of Progress since Rethinking Chagas 2018 Meeting

Goal	Actions
Strengthening communication channels across the Chagas community	<ul style="list-style-type: none">• Biannual Newsletter• Founding of the United States Chagas Provider's Network in 2020• Renewed support of the Texas Chagas Network by CDC
Expand research initiatives by UCSF/Mundo Sano to improve access to diagnosis.	<ul style="list-style-type: none">• Chagas disease serological test performance in United States blood donor specimens• Comparative Performance of Latest-Generation and FDA-Cleared Serology Tests for the Diagnosis of Chagas Disease
Continue developing pilot projects to improve access to diagnosis and treatment.	<ul style="list-style-type: none">• Chagas Newborn Screening Pilot Project at Texas State University• Prevalence of Chagas disease with comorbidities among Individuals from Latin America at the University of Florida• DoD Surveillance Project at Texas State• Continuous prevention and control efforts in the Boston area from Strong Hearts Project and the Boston University School of Medicine
Improve access to treatment	<ul style="list-style-type: none">• Access to BNZ for patients regardless of insurance coverage• CDC approval for rapid emergency delivery of benznidazole• FDA approval of Nifurtimox for the treatment of patients of < 12 years of age

Appendix 2

Advancing the Agenda for Chagas Disease in the United States Two-Day Virtual Workshop at Harvard University May 19-20, 2021

Wednesday, May 19, 2021

9:00-9:15am:

Opening Remarks, Michael R. Reich

Welcome Remarks, Dean Michelle Williams, Harvard T.H. Chan School of Public Health

9:15-9:20am:

Progress since the last workshop in 2018, Marcelo Abril, Mundo Sano

9:20-10:45am: Session 1 – Models of care for Chagas disease in the United States

This session will focus on current models of care for Chagas disease in the United States as well as the challenges to replicating and expanding these models in other geographic areas. The subject matter will include: (1) a discussion of existing models to diagnose and treat patients who are identified through existing projects, and (2) the challenges to expanding and/or replicating these models in other settings. The session will include a discussion of current programs in Texas, California and Massachusetts, with implications for other high-risk geographies such as New York. The relevant themes for discussion will include the screening approach, structure of the referral and care programs, and ways in which these programs are financed.

FACILITATOR: Jen Manne-Goehler

SPEAKER 1: Natasha Hochberg and Julia Koehler

SPEAKER 2: Norman Beatty

GENERAL DISCUSSION: Salvador Hernandez

10:45am-12:15pm: Session 2 – Strengthening diagnostic testing for Chagas disease in the United States

This session will open with a presentation on current activities to improve access to and performance of diagnostics for Chagas disease. We will also discuss the availability of diagnostic tests for screening and confirmation. Finally, we will address current needs in Chagas disease diagnosis for the United States, obstacles to expanding access to diagnostics and improving performance, and strategies to overcome these barriers.

FACILITATOR: Sue Montgomery SPEAKER 1: Colin Forsyth

SPEAKER 2: Caryn Bern

GENERAL DISCUSSION: Sue Montgomery

12:15-12:45pm

Presentation and Discussion with US Representative, Congressman Raul Ruiz (CA-36), Chair of the Congressional Hispanic Caucus

Thursday, May 20, 2021

9:00-9:15am

Welcome and Introduction to Day 2

9:15-10:45am: Session 3 – Promoting clinical excellence in the care of people with Chagas disease

This session will focus on efforts to promote and expand competence for the care of patients with Chagas disease among providers in the United States. This will include a presentation on forthcoming diagnostic guidelines and their possible expansion, efforts to disseminate health information about Chagas disease to both providers and patients in high-risk areas of the United States, and follow-up on plans to advance networks and channels of communication through which providers can gain greater expertise and support in caring for people with Chagas disease. We will also discuss how the approval of nifurtimox and its availability in the United States may affect such efforts.

FACILITATOR: Jamie Maguire

SPEAKER 1: Rachel Marcus

SPEAKER 2: Paula Stigler Granados

SPEAKER 3: Martin Manfredi

GENERAL DISCUSSION: Melissa Nolan-Garcia

10:45-11:15am: Break out groups

Breakout groups will discuss three key takeaways and one to two suggested actions for next steps, with one group for each theme: (1) models of care, (2) diagnostic testing, and (3) clinical excellence.

11:15-11:45am

Report back to main session (by facilitator or moderator), and open discussion

11:45-11:50am

Closing remarks, Silvia Gold

11:50am-12:00pm

Closing remarks, Michael R. Reich

Participant List

Advancing the Agenda for Chagas Disease in the United States
May 19-20, 2021

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