



HARVARD T.H. CHAN
SCHOOL OF PUBLIC HEALTH

Workshop Report

**Rethinking Chagas:
Reshaping the Agenda for Chagas Disease in the United States**

October 22-23, 2018

**Harvard T.H. Chan School of Public Health
Boston, MA**

Organized by:

Fundación Mundo Sano
Global Chagas Disease Coalition
Harvard T.H. Chan School of Public Health

November 26, 2018



Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States Report of a Workshop, Boston, MA

On October 22, 2018, Harvard T.H. Chan School of Public Health held a workshop in Boston on *Rethinking Chagas: Reshaping the Agenda for Chagas Disease in the United States*. The meeting was co-sponsored by Fundación Mundo Sano and the Global Chagas Disease Coalition and aimed to discuss health system challenges to expand access to care for Chagas disease in the United States.

The meeting had three specific objectives:

- To discuss current health system barriers to widespread and effective screening, diagnosis, treatment and outreach for Chagas disease in the United States.
- To determine how to better leverage current evidence to improve screening, diagnosis, treatment and outreach for Chagas disease in the United States.
- To identify where and how to improve policy for patients with Chagas disease in the United States.

The US FDA approved benznidazole in August 2017 for treatment of children from 2-12 years of age.¹ On May 14, 2018, benznidazole became commercially available from Exeltis USA and no longer available through the CDC-sponsored program.² Despite this change in supply chain, access to care for Chagas disease is expected to remain limited in the United States. During the workshop, 40 experts from the United States, Argentina, Spain, Mexico, and Brazil discussed barriers and opportunities to advance access to care for Chagas patients as well as next steps. The workshop gathered views from multiple stakeholders, including representatives from a patient association, clinicians, researchers, a pharmaceutical company, non-profit organizations, government agencies, and international organizations (see **Appendix 1** for the list of participants).

The workshop opened with remarks from Dr. Joaquim Gascon, on behalf of the Chagas Coalition, and Ms. Jenny Sanchez, President of the Latin American Society of Chagas (LASOCHA). Prof. Michael R. Reich, from the Harvard T.H. Chan School of Public Health, welcomed participants and introduced the objectives of the workshop. Prof. Reich noted that “how to improve access to care for Chagas patients is a tough question to crack; it involves barriers of language, poverty, insurance, and immigration status—challenges grounded in the complexities, inequities, and uncertainties of how the health system works in this country.”

The one-day meeting was structured around four sessions: screening, diagnosis, treatment, and outreach (see **Appendix 2** for the meeting agenda). The following sections summarize the main topics and conclusions from each session.

Session 1: Screening for *T. cruzi* in the United States: opportunities and challenges

Background

The lack of Chagas disease screening guidelines for healthcare providers has been identified as one of the major barriers to diagnosis.³ A recent analysis showed maternal screening to be cost-effective in the United States.⁴ Screening efforts within clinical settings have increased in certain high-risk geographies such as Los Angeles, Virginia, Texas, and East Boston. This session examined three themes: (1) the evidence base for a screening guideline for Chagas disease in the U.S.; (2) existing models for screening for Chagas disease; and (3) screening for special populations.

Conclusions

- Key barriers include the persistent lack of official screening guidelines for healthcare providers and limited data on the costs of screening, particularly for adult patients.
- Two strategies to expand screening efforts include: (1) development of guidelines once diagnostic assays are validated (see next session); (2) partnerships with medical societies, such as the American College of Obstetricians and Gynecologists, to encourage providers to follow screening guidelines (once created); and (3) a focus on screening pregnant women and their newborns, as this has a high public health impact.

Session 2: Diagnostic considerations for *T. cruzi* infection in high-risk U.S. populations

Background

Confirming the diagnosis of Chagas disease by two different serological tests has been challenging in health-care settings. Test reliability has been reported to be highly variable⁵⁻⁸ and only CDC has performed confirmatory tests in the United States.³ This session explored three challenges in diagnosis: (1) the diagnostic infrastructure for Chagas disease in the U.S.; (2) diagnostic discordance and how to optimize confirmatory testing with available diagnostic tools; and (3) barriers to linkage to confirmatory testing after a positive screening test.

Conclusions

- Major challenges include: (1) limited availability of some commercial tests because of problems related to importation or discontinued production; (2) the large number of discordant test results among the four FDA-cleared tests for clinical use, especially among populations from Central America and Mexico; and (3) the potential need for additional reference laboratories in selected states or regions.
- Next steps to improve diagnosis involve an independent study to validate currently available diagnostic assays, using samples from U.S. populations.

Session 3: Treatment programs for Chagas disease in the United States

Background

There is increasing evidence of a large burden of Chagas disease in the United States,^{9–11} but relatively few patients who receive appropriate medical evaluation and treatment after diagnosis. Low physician knowledge and awareness has been repeatedly identified as a major barrier to treatment.^{3,12–15} Optimal dosing of benznidazole is still being studied.¹⁶ This session discussed: (1) current local models of care for Chagas disease; (2) barriers to successful treatment completion for healthcare providers; and (3) strategies for ensuring a stable, affordable supply of benznidazole, given recent changes in its supply chain.

Conclusions

- In addition to the low levels of awareness, major provider-side barriers include uncertainties about how to diagnose and who to treat, time-consuming insurance authorization, difficulty in managing frequent adverse effects, low-budget health clinics, and insufficient research grants.
- After FDA approval, benznidazole became much easier to obtain and continues to be relatively affordable, but concerns have arisen about its appropriate use.
- Two approaches to expanding treatment efforts would be: (1) to establish treatment guidelines that could be disseminated through academic societies; and (2) to establish centers of excellence to share best practices and knowledge as well as educational materials.

Session 4: Social and communication strategies to reach Chagas disease patients

Background

Chagas disease patients often belong to hard-to-reach subgroups in society. Patients are not aware of Chagas disease and often avoid using medical providers.¹⁷ Patients are often from low-income backgrounds with precarious insurance coverage, transportation difficulties, and limited time off.¹⁸ It is necessary, therefore, to create better connections between health systems, health care providers, and populations at risk. This session discussed: (1) patient-side barriers to treatment, including legal status and insurance; (2) physician education to address social, cultural and psychological barriers to care; and (3) strategies to motivate both physicians and patients to use treatment when appropriate.

Conclusions

- Major patient-side barriers also involve fear of being stigmatized, exacerbated by uncertain immigration status in the U.S.
- Strategies to improve patient outreach should aim to increase patient and provider engagement at the same time, using the existing tools or models: pamphlets, online materials, training of patients to

spread the word, and collaboration with community health workers and public agencies.

- Successful approaches involve grass-roots education programs in areas with the greatest need and expansion of successful pilot experiences.

The workshop included three special talks. Dr. Luis Castellanos, Chief of PAHO/WHO's Neglected, Tropical and Vector-Borne Diseases Unit, introduced the global framework to eliminate mother-to-child transmission of diseases, including Chagas disease. Dr. Susan Montgomery, Veterinary Medical Officer of Centers for Disease Control and Prevention, offered CDC's perspectives of the current problems and engagement for the future efforts. Mr. Salustiano Pérez, CEO of Exeltis USA, described how benznidazole is commercialized, financed, and used in the U.S. after FDA approval.

Discussing next steps for Chagas disease diagnosis and treatment in the United States

On October 23, a smaller meeting was convened to discuss specific actions. After a broad ranging review of the previous day, participants agreed on two actions. *First, they agreed to prioritize mother-to-child transmission of Chagas disease, with a focus on Texas as entry point.* This action on pregnant women and newborns was selected for several reasons. The initiative would serve the major public health goal of seeking to prevent mother-to-child transmission of Chagas disease, and would address an important and disregarded health concern for a marginalized population. Pregnant women and children have greater access to healthcare services in general. Finally, mothers are often key decision makers on family welfare in Latino culture. Texas was selected as a starting point because of its large population of Latino immigrants who are potentially at high risk of Chagas disease and because of the existing research groups and infrastructure on Chagas disease in Texas.

The second action taken at the meeting on October 23 was to launch a new organization called the "US Chagas Alliance." This new group will seek to serve as a national platform to exchange knowledge and experience among all actors who want to move forward the agenda of Chagas disease in the United States. A small working group was formed to begin the process of establishing the organization and also to work on a protocol to implement prenatal and newborn screening of Chagas disease in Texas. The Global Chagas Disease Coalition and Fundación Mundo Sano expressed their support for both the new alliance and the screening initiative.

November 27, 2018
Boston, MA, USA

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Appendix 1: List of participants

First-day meeting, October 22, 2018

	Last Name	First Name	Organization
1	Abreu	Kenneth	Exeltis US
2	Abril	Marcelo	Fundación Mundo Sano
3	Almeida	Igor	The University of Texas at El Palo
4	Bern	Caryn	UCSF School of Medicine
5	Brown	Catherine	Massachusetts Department of Public Health
6	Burleigh	Barbara	Harvard T.H. Chan School of Public Health
7	Castellanos	Luis Gerardo	PAHO/WHO
8	Castro	Yagahira	Johns Hopkins University
9	Chuit	Roberto	Fundación Mundo Sano
10	Colli	Enrico	Exeltis US
11	Coyle	Christina	Albert Einstein College of Medicine
12	Edwards	Morven	Baylor College of Medicine
13	Fernandez	Eduardo	Exeltis US
14	Ferrero	Luis	Lab. Elea Phoenix
15	Forsyth	Colin	DNDi
16	Gascon	Joaquim	ISGlobal Chagas Initiative
17	Gold	Silvia	Fundación Mundo Sano
18	Hamer	David	Boston University School of Medicine
19	Hernandez	Salvador	UCLA Medical Center
20	Herrera	Claudia	Tulane University
21	Hochberg	Natasha	Boston University School of Medicine
22	Koehler	Julia	Children's Hospital Boston
23	Maguire	James	Brigham & Women's Hospital
24	Manne-Goehler	Jen	MGH, BWH, Harvard Medical School
25	Marcus	Rachel	Washington Hospital Center
26	Meymandi	Sheba	UCLA Medical Center
27	Montgomery	Susan	CDC (Remote Participant)
28	Nolan-Garcia	Melissa	Baylor College of Medicine
29	Perez	Salustiano	Exeltis US
30	Pinazo	María Jesús	ISGlobal Chagas Initiative
31	Ramsey Willoquet	Janine	Instituto Nacional de Salud Publica
32	Reich	Michael	Harvard T.H. Chan School of Public Health
33	Sánchez	Jenny	LASOCHA
34	Sancho	Javier	Chagas Coalition
35	Sosa-Estani	Sergio	DNDi
36	Sota	Alicia	Fundación Mundo Sano
37	Stigler Granados	Paula	Texas State University

38	Suh	Sandy	Exeltis US
39	Wirth	Dyann	Harvard T.H. Chan School of Public Health
40	Yoshioka	Kota	Harvard T.H. Chan School of Public Health

Second-day meeting, October 23, 2018

	Last Name	First Name	Organization
1	Abreu	Kenneth	Exeltis US
2	Abril	Marcelo	Fundación Mundo Sano
3	Bern	Caryn	UCSF School of Medicine
4	Coyle	Christina	Albert Einstein College of Medicine
5	Fernandez	Eduardo	Exeltis US
6	Forsyth	Colin	DNDi
7	Gascon	Joaquim	ISGlobal Chagas Initiative
8	Gold	Silvia	Fundación Mundo Sano
9	Maguire	James	Brigham & Women's Hospital
10	Manne-Goehler	Jen	Harvard T.H. Chan School of Public Health
11	Marcus	Rachel	Washington Hospital Center
12	Meymandi	Sheba	UCLA Olive View Center for Excellent in Chagas Disease
13	Perez	Salustiano	Exeltis US
14	Reich	Michael	Harvard T.H. Chan School of Public Health
15	Sancho	Javier	Chagas Coalition
16	Sosa-Estani	Sergio	DNDi
17	Stigler Granados	Paula	Texas State University
18	Yoshioka	Kota	Harvard T.H. Chan School of Public Health

Appendix 2: Workshop Agenda

Monday October 22, 2018

Venue: Harvard University, Countway Medical Library, Ballard Room, 5F

- 8:30-9:00 Registration for Participants
- 9:00-9:20 Welcome and Opening Remarks
Joaquim Gascon, Chagas Coalition
Jenny Sanchez, Latin American Society of Chagas (LASOCHA)
- 9:20-9:30 Objectives of the Workshop
Michael R. Reich, Harvard T.H. Chan School of Public Health
- 9:30-10:50 **Session 1: Screening for *T. cruzi* in the US: opportunities and challenges**
Moderator: Jennifer Manne-Goehler, Harvard Medical School
Presenters:
Caryn Bern, University of California San Francisco
Sheba Meymandi, UCLA Olive View Center
- 10:50-11:10 Break
- 11:10-11:20 **Special Talk:** PAHO's framework for elimination of mother-to-child disease transmission - EMTCT Plus
Luis Castellanos, Pan American Health Organization
- 11:20-12:40 **Session 2: Diagnostic considerations for *T. cruzi* in high-risk US populations**
Moderator: Melissa Nolan, University of South Carolina
Presenters:
Colin Forsyth, DNDi
Yagahira Castro, Johns Hopkins Bloomberg School of Public Health
- 12:40-12:50 **Special Talk:** CDC's perspectives (remote participation)
Susan Montgomery, Centers for Disease Control and Prevention
- 12:50-13:50 Lunch
- 13:50-14:00 **Special Talk:** Supply of benznidazole after the FDA approval
Salustiano Pérez, Exeltis USA
- 14:00-15:20 **Session 3: Treatment programs for Chagas disease in the United States**
Moderator: Sergio Sosa-Estani, DNDi
Presenters:
Rachel Marcus, MedStar Health and LASOCHA
Salvador Hernandez, UCLA Olive View
- 15:20-15:40 Break
- 15:40-17:00 **Session 4: Social and communication strategies to reach Chagas disease patients**
Moderator: Christina Coyle, Albert Einstein College of Medicine
Presenters:
Paula Stigler Granados, Texas State University
Joaquim Gascon, ISGlobal Chagas Initiative

17:00-17:50 Open Discussion
 Moderator: Michael R. Reich, Harvard T.H. Chan School of Public Health

17:50-18:00 Concluding Remarks