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AGENDA

MEETING ON DIAGNOSTIC EVALUATION AND ECONOMIC IMPACT ANALYSIS OF NEW DIAGNOSTIC METHODS FOR CHAGAS DISEASE

WELCOME TO OUR

MEETING ON DIAGNOSTIC EVALUATION AND ECONOMIC IMPACT ANALYSIS OF NEW DIAGNOSTIC METHODS FOR CHAGAS DISEASE

6-7 MAY 2024
BUENOS AIRES,
ARGENTINA

ORGANIZED BY

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Diagnóstico para todos

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La mejor ciencia para los más desatendidos

IN COOPERATION WITH

Organización Panamericana de la Salud

CO-ORGANIZED BY

INGEBI
CONICET

MEETING ON DIAGNOSTIC EVALUATION AND ECONOMIC IMPACT ANALYSIS OF NEW DIAGNOSTIC METHODS FOR CHAGAS DISEASE

BACKGROUND

Between 6 and 7 million people worldwide, mostly in Latin America, are estimated to be infected with *Trypanosoma cruzi*, the parasite that causes Chagas disease (CD) and 70 million are at risk of the disease globally. Every year, over 10,000 CD related deaths are reported, and the estimated burden of the disease exceeds USD 690 million in healthcare costs and USD 8 billion in annual economic losses [1]. CD is mainly a chronic condition, and it is a long-term challenge to control and prevent non-vectorial transmission. A substantial number of CD cases are missed, as fewer than 10% of people chronically infected with *T. cruzi* are diagnosed and only about 1% receive etiological treatment [2],[3]. In most cases symptoms are absent and, due to its diverse and nonspecific manifestation, diagnosis is based largely, if not exclusively, on laboratory investigations that require high level facilities. Diagnosis requires at least two different serological tests, making it logistically and financially challenging. *Trypanosoma cruzi* infection is curable if treatment is initiated soon after infection. In chronically infected patients, antiparasitic treatment can potentially prevent or curb disease progression and prevent transmission, for instance, via mother-to-child.

Barriers that limit access to healthcare for people affected by CD include an often cumbersome, time-consuming and costly diagnosis process, limited availability of tools and materials at primary health centers and the lack of integration of diagnosis in Maternal and Child Health policies and practices.

Although there are new point-of-care diagnostic methods (serological and molecular) commercially available and under development in endemic countries, these tests are not widely used; and accord- ing to PAHO and the national guidelines for diagnosis of CD in endemic countries, serological rapid diagnostic tests (RDTs) are indicated only for screening or research purposes. Molecular diagnostic methods have been incorporated in a few endemic countries such as Argentina and Chile.

On the way from disease control to complete elimination of CD, the World Health Organization (WHO) has suggested recommendations in its road map targets for Neglected Tropical Diseases (NTD) in 2030. The recommendations for CD aim to streamline and modernize the diagnostic methods, emphasizing the development and evaluation of point-of-care techniques and diagnostic algorithms.

The endemic countries have started to implement the PAHO's Framework for elimination of moth- er-to-child transmission of HIV, syphilis, hepatitis B and Chagas disease (EMTCT-PLUS), to achieve and sustain the elimination of these preventable

communicable diseases, leveraging on the robust and integrated maternal and child health systems in the region. The proposed actions at the county level to achieve the targets for CD include, among others, to review and optimize testing practices to minimize the time needed for diagnoses and introduce point-of-care testing where feasible and appropriate; and update infant diagnosis practices to ensure early and efficient diagnoses.

In fact, independent evidence about performance and economic impact of new diagnostic algo- rithms at point-of-care in endemic countries is being generated by several institutions. In 2023, Fiocruz, through the CUIDA Chagas project, in cooperation with PAHO, convened a meeting of experts (in Salvador de Bahia, Brazil), to discuss the optimal utilization of existing diagnostic strategies for CD, to warrant tighter applicability of these diagnostic tools. The aims of that meeting were to review the existing evidence supporting the use of serological RDTs and molecular tools for detection of *T. cruzi* infection; to review the regulatory and procurement mechanisms in the region; and to discuss the feasibility of implementation of RDTs and molecular tools as a strategy for diagnosis of CD in Latin America.

As a continuation of the meeting convened by the CUIDA Chagas project in cooperation with PAHO, the need of creating generic study protocols, establishing harmonized standards and procedures was highlighted, as well as the need to deepen insight in the state of the art of molecular tools, mainly Real Time PCR and LAMP. Thus, it is necessary to debate further on these topics including local experts, technical health authorities from the countries, PAHO and WHO, to ensure adoption of cost-effective new diagnostics into health systems in endemic countries, with a special focus on contributing to PAHO's regional initiative targeting the elimination of mother-to-child transmission of CD.

[1] Lee BY, Bacon KM, Bottazzi ME, Hotez PJ. Global economic burden of Chagas disease: A computational simulation model. Lancet Infect Dis. 2013 Apr;13(4):342–8.

[2] Chaves GC, Arrieche MAS, Rode J, Mechali D, Reis PO, Alves RV, et al. Estimación de la demanda de medicamentos antichagásicos: Una contribución para el acceso en América Latina. Rev Panam Salud Publica/Pan Am J Public Heal. 2017 Jun 8;41:e45–e45.

[3] Cucunubá, Z. M., Manne-Goehler, J. M., Díaz, D., Nouvellet, P., Bernal, O., Marchiol, A., Basáñez, M.-G., & Conteh, L. (2017). How universal is coverage and access to diagnosis and treatment for Chagas disease in Colombia? A health systems analysis. Social Science & Medicine (1982), 175, 187–198.

[4] World Health Organization. Ending the neglect to attain the sustainable development goals: a road map for neglected tropical diseases 2021–2030. Geneva, CH: WHO, 2020.

AGENDA

DAY 1 | MONDAY, 6 MAY

Auditorio Fundación Mundo Sano, Paraguay 1535

SCOPE

Our main goal is to achieve consensus among the invited experts, including the scientific community, technical health authorities, PAHO and WHO, about:

01.
Generic research protocol for selecting and assessing appropriate RDTs for chronic *T. cruzi* infection, to ensure high quality studies in the Americas" developed by PAHO.

02.
Performance and operational characteristics, standardized methods and quality controls to assess and to guide future use of molecular tests for diagnosis of *T. cruzi* infection.

03.
The evidence on cost-effectiveness and economic impact necessary to be generated in order to facilitate the integration of new diagnostic methods into the health systems of endemic countries.

ACTIVITIES

- A meeting in person of the invited experts is planned on 6 - 7 may 2024, in Buenos Aires, Argentina, convened and sponsored by FIND and DNDi, with the technical support of PAHO, co-organized by INGEBI-CONICET.

- The selected documentation that will be assessed by the invited experts and guiding questions to give their feedback will be sent by the end of March (before the meeting) and the experts will be requested to send virtually their feedback by the end of April, answering guiding questions.

- The key insights of the invited expert´s input, and the guests' presentations, will be discussed to achieve consensus during the meeting in person (6-7 May 2024).

AGENDA

DAY 1 | MONDAY, 6 MAY

Auditorio Fundación Mundo Sano, Paraguay 1535

8:30	REGISTRATION	
9:00	Opening / introduction	**Presented by** **Laura Bohorquez (FIND)** **Alejandro Schijman (INGEBI-CONICET)** **Maria Jesus Pinazo (DNDi)** **Hector Coto (PAHO)** **Marcelo Abril (FMS)**

EVALUATION OF CD RDTS		PRESENTED BY	MODERATED BY
9:30	Presentation of the generic study protocol to evaluate CD RDTs, developed by PAHO (sent to the invited experts in early April)	**María Isabel Jercic (Instituto Nacional de Salud Pública, Chile)** **Freddy Pérez (PAHO)**	**Julio Alonso Padilla (ISGlobal)** **Rafael Herazo (DNDi)**
9:50	Key insights on the input received from the invited experts in written (by April) about the documentation to evaluate CD RDTs	**Laura Bohorquez (FIND)** **Andrea Marchiol (DNDi)**	
10:10	**BREAK**		
10:40	Discussion of relevant components in the generic study protocol for the evaluation of CD RDTs	**Berra Erkosar (FIND)** **Andrés Caicedo (DNDi)** **Andrea Silvestre (CUIDA Chagas)**	**Laura Bohorquez (FIND)** **Julio Alonso Padilla (ISGlobal)**
11:10	Discussion in plenary about the generic study protocol to evaluate CD RDTs		

EVALUATION OF MOLECULAR DIAGNOSTIC TOOLS FOR CD

		PRESENTED BY	MODERATED BY
11:45	State of the art of LAMP as point of care diagnostic tool for CD	**Alejandro Schijman (INGEBI-CONICET)**	**Margarita Bisio (INP Fatala ANLIS)** **Colin Forsyth (DNDi)**
12:00	State of the art of qPCR for CD	**Otacilio Moreira (Fiocruz)**	
12:15	State of the art, other molecular point of care diagnostic tools that could be adapted for CD	**Elena Ivanova (FIND)** Pre-Recorded Video presentation	
12:30	Controls and standards	**Marcelo Rodriguez (FIND)**	
12:45	**LUNCH**		
14:15	Key insights on the input received from the invited experts in written (by April) about the guiding questions to prioritize the following parameters to evaluate the molecular methods for CD (focus on LAMP and qPCR).	**Alejandro Schijman (INGEBI-CONICET)** **María Jesús Pinazo (DNDi)** **Constança Britto (Fiocruz)**	**Margarita Bisio (INP Fatala ANLIS)** **Colin Forsyth (DNDi)**
14:35	Discussion in plenary about the evaluation of molecular methods for CD		

COST EFFECTIVENESS AND ECONOMIC IMPACT MODELLING OF NEW DIAGNOSTICS FOR CD

		PRESENTED BY	MODERATED BY
15:00	Optimizing CD Diagnosis: Comparing Algorithm Performance and Cost.	**Sarah Girdwood (FIND)**	**Shaukat Kahn (FIND)** **Freddy Pérez (PAHO)**
15:15	Diagnose More Cases, Spend Less: A User-Friendly Shiny App Model for Chagas Diagnosis.	**Kyra Grantz (FIND)**	
15:30	Economic impact linked to out of pocket expenses. The experience of Colombia.	**Rafael Herazo (DNDi)**	

COST EFFECTIVENESS AND ECONOMIC IMPACT MODELLING OF NEW DIAGNOSTICS FOR CD

15:45	Economic impact evidence/cost-effectiveness analyses evaluating the incorporation of new diagnostic methods for CD in the health systems of Brazil, Bolivia, Paraguay and Colombia.	**Yerly Magnolia Useche (Fiorcruz CUIDA Chagas)**	**Shaukat Kahn (FIND)** **Freddy Pérez (PAHO)**
16:00	Economic impact evidence / cost-effectiveness analyses evaluating the incorporation of new diagnostic methods for CD in the health systems.	**Elisa Sicuri (ISGlobal)** Pre-Recorded Video presentation	
16:15	**BREAK**		
16:45	Economic evaluation of new diagnostic methods.	**Santiago Hasdeu (redArets Argentina)**	**Shaukat Kahn (FIND)** **Nasim Iusef (MoH Argentina)**
17:05	Plenary deliberations after the afternoon presentations.		
17:35 - 18:30	**CLOSURE OF THE DAY AND TOAST**		**FIND, DNDi, PAHO, INGEBI-CONICET**

AGENDA

DAY 2 | TUESDAY, 7 MAY

NH Buenos Aires City Hotel, Bolívar 160 / Luis Alberto Room

		MODERATED BY
8:30	Intro about the dynamics to achieve consensus (guiding questions developed and shared previously with the invited experts)	**Laura Bohorquez (FIND)** **Alejandro Schijman (INGEBI-CONICET)**
8:40	Sub-groups discussions, each group will write their main insights / answers to each question (HANDS ON)	
10:15	Discussion in plenary about the sub-group conclusions (HANDS ON)	**Andrea Marchiol (DNDi)** **Freddy Pérez (PAHO)**
11:00	**CLOSURE WITH ALL INVITED GUESTS**	**María Jesús Pinazo (DNDi)** **Laura Bohorquez (FIND)** **Alejandro Schijman (INGEBI-CONICET)**
11:00	**BREAK**	

11:30-13:30	Invited guests could continue in the annual meeting of the Global Chagas Coalition (in the same venue)
15:00-18:00	Consolidation of information, preparation of final reports, and planning next steps (in the same venue)

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