



The Manaus Declaration: Current Situation of Histoplasmosis in the Americas, Report of the II Regional Meeting of the International Histoplasmosis Advocacy Group

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Published online: 27 November 2019

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Abstract

Purpose of Review The aim of this report is to summarize the conclusions of the II Regional Meeting on Histoplasmosis in the Americas held in Manaus, Brazil, on March 22–24, 2019.

Recent Findings Persons living with advanced HIV are at high risk for developing histoplasmosis. Clinical signs and symptoms of this disease are often non-specific, making it difficult to establish a diagnosis. Although with the recent technological advances, in vitro diagnostics and medicines for histoplasmosis are often not available in many regions around the world. In addition, histoplasmosis is often not included in HIV care and treatment programs, resulting in inadequate health system planning and missed opportunities to save lives.

Summary The II Regional Meeting on Histoplasmosis in the Americas gathered a multidisciplinary audience. Developed recommendations to be included in the WHO guidelines for diagnosis and treatment of histoplasmosis in advanced HIV were the product of this meeting, and guidelines are aimed to be published in early 2020.

Keywords Histoplasma · Histoplasmosis · Diagnosis · Treatment · Guidelines · AIDS

Introduction

Histoplasmosis is a disease caused by the fungus *Histoplasma capsulatum*. This disease is most frequently found in the

American continent, but it has also been reported in other places around the world. In persons living with HIV (PLHIV), especially those with advanced disease, progressive disseminated histoplasmosis (PDH) is associated with high

This article is part of the Topical Collection on *Epidemiology of Fungal Infections*

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mortality [1]. PDH symptoms are nonspecific, and among people with advanced HIV disease, these may be similar or indistinguishable to other infectious diseases, especially tuberculosis [1].

Conventional laboratory methods, specifically culture and histopathology, used for the diagnosis of histoplasmosis have many challenges, including need for high-level laboratory infrastructure, need of laboratory personnel trained in medical mycology, long turnaround time for results (median 15 days), and variable test performance. Antibody testing is less sensitive in immunocompromised persons [2]. Molecular assays are promising diagnostic tools, but none are available as commercial kits, making them difficult to implement in clinical laboratories [3]. Detection of circulating *Histoplasma* antigens is the gold standard for rapid diagnosis of PDH due its high analytical performance and rapid turnaround time [4•]. However, antigen testing is limited outside the United States despite availability of commercial kits and recent inclusion of such testing in the second World Health Organization (WHO) list of essential in vitro diagnostics [5•, 6•]. Antifungal therapies recommended for the treatment of histoplasmosis are not widely available in endemic countries due to many factors, including complex national regulations and high costs [7•]. Finally, histoplasmosis, as with many other fungal diseases, is not included in most public health surveillance systems.

The main objectives of this meeting were to determine the availability of in vitro tests for rapid diagnosis and antifungal treatment for histoplasmosis and to discuss strategies for expanded access to optimal diagnostics and treatment. At the first meeting of the International Histoplasmosis Advocacy Group (iHAG), held in Paramaribo, Suriname, during December 4–6, 2015, participants agreed to launch the “80 by 20” initiative, which aimed to provide rapid diagnostic testing and effective treatment access for disseminated histoplasmosis in at least one laboratory per country in 80% of the Americas by 2020 [7•].

Pre-Meeting: Pan American Health Organization/World Health Organization Histoplasmosis Guidelines Development

Pan-American Health Organization (PAHO)/World Health Organization (WHO) facilitated a histoplasmosis Guidelines Development Group (GDG) pre-meeting to discuss the development of WHO Guidelines on the Diagnosis and Management of Progressive Disseminated Histoplasmosis in People living with HIV. On March 22, 2019, before the iHAG meeting, the GDG determined the following key questions to be addressed through systematic reviews using the population, intervention, comparison, outcome (PICO) method (Table 1).

- PICO 1: “Among patients with HIV disease, is antigen testing versus standard microbiological techniques of

diagnosis associated with an increase in the diagnosis of histoplasmosis and a decrease in mortality?”

- PICO 2: “Among people living with HIV infection with disseminated histoplasmosis what are the optimal therapeutic alternatives depending on patient severity and country resource level?”
- PICO 3: “What modification of the HIV or TB therapy need to be made for successful outcome of histoplasmosis on patients co-infected with TB?”

The GDG developed recommendations to be included in the final guidelines document, which has a target publication date of early 2020. PICO questions and members of GDG are described in Table 1.

II Regional Meeting on Histoplasmosis in the Americas (iHAG 2019)

The second meeting of the international Histoplasmosis Advocacy Group (iHAG 2019) was co-organized by the International Histoplasmosis Advocacy Group (iHAG), Instituto Nacional de Pesquisas da Amazônia (INPA-Brazil), Fundação de Medicina Tropical Doutor Heitor Vieira Dourado (FMT-HVD-Brazil), Pan American Health Organization (PAHO)/World Health Organization (WHO), and the Centers for Disease Control and Prevention (CDC). The meeting was supported by the Fundação de Amparo a Pesquisa do Estado do Amazonas (FAPEAM) (Grant No 005/2017 Program to Support the Holding of Scientific and Technological Events in the State of Amazonas—PAREV), Fundação Oswaldo Cruz (Fiocruz), Global Action Fund for Fungal Infections (GAFFI), International Society for Human and Animal Mycology (ISHAM), Mycoses Study Group Education and Research Consortium (MSGERC), Centre d'Investigation Clinique Antilles Guyane (Inserm CIC1424) of the Centre Hospitalier de Cayenne, Universidad del Rosario, Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSA), and Santa Casa de Misericórdia de Porto Alegre.

Dr Marcus Lacerda, João Vicente Souza, and Katia Cruz were the meeting hosts in Manaus, Brazil. The meeting focused on the status of epidemiological surveillance, diagnosis, and treatment throughout the region as well as new developments in both laboratory and treatment options. The agenda included keynote lectures, scientific presentations, country updates, and policy discussions. More information regarding the iHAG 2019 meeting is available at: <https://histoplasmosisadvo.wixsite.com/ihagmeeting2019/preliminary-agenda>.

Specific objectives of the meeting were the following:

- Increase awareness and advocacy for histoplasmosis in PLHIV in the Americas.

Table 1 The PICO questions and members of GDG*Population, intervention, comparison, outcome (PICO) questions*

PICO 1: “Among patients with HIV disease, is antigen testing versus standard microbiological techniques of diagnosis associated with an increase in the diagnosis of histoplasmosis and a decrease in mortality?”

Population: Patients with HIV disease
Intervention: Antigen testing
Comparison: Standard microbiological techniques
Outcomes: Proximal: increased accuracy of diagnosis; Distal: decreased mortality

PICO 2: “Among people living with HIV infection with disseminated histoplasmosis what are the optimal therapeutic alternatives depending on patient severity and country resource level?”

Population: Patients with HIV disease diagnosed with histoplasmosis
Intervention: Liposomal Amphotericin B
Comparison: Deoxycholate amphotericin B and itraconazole
Outcomes: Progression to severe disease, adverse drug effects, reduction of mortality and complication related with disease

PICO 3: “What modification of the HIV or TB therapy need to be made for successful outcome of histoplasmosis on patients co-infected with TB?”

Population: Patients with HIV disease diagnosed with tuberculosis and histoplasmosis
Intervention: Itraconazole with rifampin based anti-TB regimen
Comparison: Itraconazole with non-rifampin based anti-TB regimen
Outcomes: Treatment failure of any of the three diseases (virologic failure, relapse, medication adverse effects, complication, hospitalization time and mortality)

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- Discuss expanding educational opportunities about histoplasmosis for healthcare providers caring for HIV patients.
- Improve laboratory capacity to diagnose histoplasmosis, especially rapid diagnostic tests.
- Strengthen local capacity to conduct surveillance activities, program evaluations, and research.
- Promote establishment of national and regional guidelines for early detection and management of histoplasmosis.

Over 100 participants from 24 countries (21 from the Americas) attended the 3-day meeting to discuss the objectives described previously. The meeting agenda was divided

Table 2. II Regional Meeting on Histoplasmosis in the Americas regional analysis on diagnostics and treatment access and disease surveillance

Region/ country	Availability of rapid test for histoplasmosis ^a			Availability of histoplasmosis treatment			Reportable
	Antigen test	Molecular test	Antigen or Molecular test	ITZ	D-B Amp	Lip B Amp	
North America							
Mexico	No	No	No	Yes	Yes	Yes ¹	No
USA	Yes	Yes	Yes	Yes	Yes	Yes	Yes ²
Central America							
Guatemala	Yes	Yes	Yes	Yes	Yes	No	No
Honduras	Yes	No	Yes	Yes	Yes	Yes	No
Nicaragua	Yes	No	Yes	Yes	Yes	No	Yes
Costa Rica	Yes	No	Yes	Yes	Yes	No	No
Panama	Yes	Yes	No	Yes	Yes	No	No
The Andes							
Colombia	Yes	Yes	Yes	Yes	Yes	Yes	No
Venezuela	No	Yes	Yes	Variable	Variable	Variable	No
Ecuador	Yes	No	Yes	Yes	Yes	No	No
Peru	Yes	No	Yes	Yes	Yes	Yes	No
The Guiana Shield							
Guyana	No	No	No	Yes	No	No	No
Suriname	No ³	No	No	Yes	Yes	No	No
French Guiana	No ³	Yes	Yes	Yes	Yes	Yes	No
Brazil (regions)							
North	No	No	No	Yes	Yes	Yes	No
Northeast	No	No	No	Yes	Yes	Yes	No
Central-West	No	No	No	Yes	Yes	Yes	No
South	No	Yes	Yes	Yes	Yes	Yes	No
Southeast	No	Yes	Yes	Yes	Yes	Yes	No
The Southern Cone							
Chile	No	Yes	Yes	Yes	Yes	Yes	No
Argentina	No	Yes	Yes	Yes	Yes	Yes	No
The Caribbean							
Dominican Republic	Yes	No	Yes	Yes ¹	Yes ¹	Yes ¹	No
Jamaica	No	No	No	Yes	Yes	Limited	No
Total	10/23 (43%)	10/23 (43%)	15/23 (65%)	22/23 (96%)	21/23 (91%)	14/23 (61%)	2/23 (9%)

^a Available at least one laboratory service for routine patient diagnosis

¹ Available in private clinics

² In certain states

³ Research use

ITZ, itraconazole; D-B Amp, deoxycholate amphotericin B; Lip B Amp, liposomal amphotericin B

in seven sections, where participants were able to share experiences and present on current status of histoplasmosis in their respective countries. Country experiences were grouped into seven regions—North America, Central America, The Andean Region, The Guiana Shield, Brazil, The Southern Cone, and The Caribbean (Table 2). In summary, 65% (15 of 23) of the countries had rapid histoplasmosis testing available in at least one laboratory for routine diagnosis. Over 90% of participating countries reported availability of itraconazole and amphotericin B deoxycholate, but access to liposomal amphotericin B was reported in only 61% (14/23). Only two countries (9%), Nicaragua and the United States of America, included histoplasmosis in its surveillance systems. In the

United States, histoplasmosis is reportable in fewer than 15 states.

A regional SWOT analysis (Strength, Weakness, Opportunities, and Threats) was conducted. We asked the participants to share their analyses regarding the following three main topics: (a) access to diagnostic tests (with a focus on in vitro tests for rapid diagnosis); (b) access to specific antifungal therapy; and (c) surveillance of HIV-associated histoplasmosis (focusing on morbidity and mortality). Groups moved between the four SWOT dimensions, aided by a multilingual facilitator at each station. Based on these discussions, we generated an up-to-date situational analysis (Fig. 1) discussed in a closing plenary session.

	Helpful (to achieving the objective)	Harmful (to achieving the objective)
	Strengths	Weaknesses
Internal origin (organization)	<p>Diagnostic</p> <ol style="list-style-type: none"> 1. Areas of expertise in medical mycology 2. <i>Histoplasma</i> EIA KIT commercially available (turn around time <48h) 3. Increase in capacity building (networking) 4. Efficacy and sustainability of a centralized testing strategy in small countries <p>Treatment</p> <ol style="list-style-type: none"> 1. Amphotericin B formulations and itraconazole on the WHO list of essential medicines <p>Surveillance</p> <ol style="list-style-type: none"> 1. Increased awareness of invasive fungal infections 2. Growing surveillance network in the Americas 3. Increase in screening studies of people living with HIV 	<p>Diagnostic</p> <ol style="list-style-type: none"> 1. <i>Histoplasma</i> EIA kit is not registered in most countries 2. <i>Histoplasma</i> EIA available in a few scattered and highly specialized reference laboratories 3. Point-of-care test not commercially available 4. Lack of validation studies out of the context of patients with advanced HIV <p>Treatment</p> <ol style="list-style-type: none"> 1. Amphotericin B and itraconazole licensed but unavailable or not prescribed 2. Lack of evidence in performances (few and old clinical trials) 3. Lack of clinical trials of alternative antifungal drugs 4. Lack of evidence in specific populations (i.e. tuberculosis, pregnancy, liver or renal diseases, children) <p>Surveillance</p> <ol style="list-style-type: none"> 1. Lack of awareness and education among health practitioners and public health authorities 2. Histoplasmosis is not a reportable disease. Burden of disease not fully known 3. Histoplasmosis is not integrated in national or international HIV and TB programs
	Opportunities	Threats
External origin (environment)	<p>Diagnostic</p> <ol style="list-style-type: none"> 1. <i>Histoplasma</i> point-of-care test (LFA) in development 2. PAHO/WHO strategic plan to facilitate registration of new tests 3. PAHO/WHO price control and engage industry 4. Inclusion of <i>Histoplasma</i> EIA in WHO essential diagnostics list 5. Development of a quality insurance program <p>Treatment</p> <ol style="list-style-type: none"> 1. PAHO/WHO price control and engagement of industry 2. PAHO/WHO increasing access to liposomal amphotericin B 3. Collaboration with pharmaceutical industry to increase access to new antifungals and management strategies (i.e. shorter course with higher dosage for amphotericin B) 4. Development of a PAHO/WHO guideline on HIV-associated histoplasmosis <p>Surveillance</p> <ol style="list-style-type: none"> 1. Screening studies in different histoplasmosis risk populations 2. Evaluate impact of new tests on incidence and mortality 3. Develop an electronic standard cases report system 4. Returning travelers or immigrants from known endemic areas diagnosed in high-income countries may help report information from endemic areas 5. Assessment of the environmental risk for histoplasmosis (work, industry, agriculture, tourism) 6. Merging with other programs (TB, HIV, NTDs) within the framework of PAHO/WHO strategic plan 7. Develop advocacy, trainings, and education programs 	<p>Diagnostic</p> <ol style="list-style-type: none"> 1. Limited companies development new test 2. Complexity of EIAs and molecular assays performance 3. Assays performance expensed are linked to number of samples tested (more samples/less cost) 4. No prices control 5. Tests mostly available in private laboratories/hospitals <p>Treatment</p> <ol style="list-style-type: none"> 1. Limited companies development new drugs 2. High costs of liposomal amphotericin B (lack of generics) 3. Prices control and continue supply 4. Serious side effects of amphotericin B deoxycholate 5. Azoles drug-drug interactions (i.e. antiretrovirals and rifampin-based regimen) 6. Azoles drug level monitoring unavailable or unaffordable 7. No indication of histoplasmosis in amphotericin B drug approval <p>Surveillance</p> <ol style="list-style-type: none"> 1. Cases of histoplasmosis out of countries' public health priorities 2. Lack of advocacy and awareness around histoplasmosis 3. Lack of standardized case definition 4. Difficulty in distinguishing clinical features of histoplasmosis and tuberculosis 5. Lack of clinical algorithm in laboratory testing

Fig. 1. Results of the II Regional Meeting on Histoplasmosis in the Americas SWOT analysis (strength, weakness, opportunities, and threats)

Conclusion: The Manaus Declaration

The II Meeting on Histoplasmosis in the Americas gathered a multidisciplinary audience of physicians, laboratory

professionals, epidemiologists, public health practitioners, and representatives from scientific and nonprofit organizations. Based on collaborative deliberation, a consensus emerged that the 80 by 2020 target has been superseded,

given the availability of next-generation diagnostic assays and drugs, and a new target was established. The Manaus Declaration aims to have 100% of countries in the Americas with access to rapid testing for histoplasmosis (antigen or molecular testing) and itraconazole and lipid formulations of amphotericin B by 2025, known as 100 by 25. The III Regional Meeting on Histoplasmosis in the Americas will be held in Panama in 2021 in commemoration of the 115th anniversary of the first report of histoplasmosis during the construction of the Panama Canal in 1906.

Acknowledgments We want to thank all the International Histoplasmosis Advocacy Group (iHAG) members: <https://docs.google.com/spreadsheets/d/189W6gMfVb2zW5StAW2U2AbwVwGhls8bkAc7npZgNdC8/edit?ts=5d6d4758#gid=474498568>. We also want to thank Eduardo Serrão for the meeting logistics and Pooja Gandhi for editing the manuscript. iHAG 2019 co-sponsors: Fundação de Medicina Tropical Doutor Heitor Vieira Dourado (FMT-HVD), Instituto Nacional de Pesquisas da Amazônia (INPA), Global Action Fund for Fungal Infections (GAFFI), International Society for Human and Animal Mycology (ISHAM), Mycoses Study Group Education and Research Consortium (MSGERC), Centre d'Investigation Clinique INSERM, Centre Hospitalier de Cayenne, Universidad del Rosario, Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSA), and Santa Casa de Misericórdia de Porto Alegre.

Compliance with Ethical Standards

Conflict of Interest The findings and the conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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