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Diagnostic and therapeutic capacity for fungal infections in Colombia: An ESCMID-EFISG nationwide multicenter assessment of mycological healthcare

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ABSTRACT

Objectives:: This study aims to evaluate nationwide diagnostic and treatment capacity for IFD across Colombia's diverse healthcare system.
Methods: Between March and September 2024, a cross-sectional survey assessed institutional profiles, diagnostic access (microscopy, culture, antigen, polymerase chain reaction [PCR] testing, matrix-assisted laser desorption/ionization time-of-flight mass spectrometry [MALDI-TOF MS]), antifungal availability, and therapeutic drug monitoring (TDM) practices. Responses were collected from 133 institutions (113 hospitals, 20 research centers) across 26/33 departments.
Results: Among 179 complete responses (94 microbiologists, 85 physicians) *Candida* spp. (39%), *Cryptococcus* spp. (20%), *Aspergillus* spp. (18%), and *Histoplasma* spp. (14%), were the pathogens considered to be more worrisome. Conventional diagnostics showed broad availability (microscopy: 94%, culture: 74%), while advanced tools were limited (e.g., MALDI-TOF MS: 12%). Antigen testing access varied by pathogen (*Cryptococcus* spp.: 54%, *Aspergillus* spp.: 52%, *Histoplasma* spp.: 44%), with metropolitan-rural disparities ($P \leq 0.001$). Antifungal susceptibility testing was available only in 56% of the surveyed institutions. Antifungal access revealed inequities: liposomal amphotericin B (68%), echinocandins (76%), and triazoles (97%) mainly accessible in metropolitan centers. HSCT/solid organ transplant (SOT) recipients had superior access to antifungals. TDM access was limited (voriconazole/itraconazole: 32%).
Conclusion: Conventional mycological methods remain the cornerstone of fungal diagnosis in Colombia. Significant disparities in IFD management capacity persist, with metropolitan centers and transplant recipients disproportionately benefiting from advanced resources. Although Colombia has established clinical guidelines incorporating World Health Organization (WHO)-recommended diagnostics and treatments,

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urgent nationwide implementation efforts are required to translate these recommendations into routine clinical practice and address persistent geographic and socioeconomic inequities in patient care.

Introduction

Colombia, a country with a population exceeding 50 million [1], faces significant challenges in managing invasive fungal diseases (IFD). These challenges are exacerbated by its diverse climate and the presence of a large at-risk population [2]. Immunocompromised individuals, including recipients of solid organ and hematopoietic stem cell transplants (SOT, HSCT), patients in intensive care units (ICU), and those with chronic respiratory diseases, are particularly vulnerable to IFD [3]. The Colombian context is characterized by a convergence of these universal risk factors with a high burden of endemic mycoses and specific epidemiological pressures. The country is hyperendemic for histoplasmosis and a hotspot for other thermally dimorphic fungi, such as *Paracoccidioides* spp. This creates a significant disease burden in both rural and urban populations, particularly among people living with human immunodeficiency virus (HIV, a population of critical importance given that Colombia has the fourth highest incidence rate of HIV/acquired immunodeficiency syndrome [AIDS] among Latin American countries) [4] and those with occupational exposures.

Furthermore, the high incidence of invasive candidiasis, driven by one of the highest rates in Latin America, is compounded by the emergence and spread of multidrug-resistant pathogens such as *Candida auris*, making Colombia a sentinel site for understanding and managing these overlapping threats [3,5,6]. *Candida albicans* persists as the predominant fungal pathogen within the country, leading to severe infections such as sepsis and septic shock, notably in intensive care patients [6,7]. Colombia registers one of the highest rates of invasive candidiasis in Latin America, with 1.96 cases per 1,000 hospital admissions. This incidence rate is significantly higher than that of other countries in the region, such as Chile (0.33 cases per 1,000 admissions), as well as in high-resource settings like Europe and the United States (0.38 and 0.96 cases per 1,000 admissions, respectively) [8–10].

These fungi present a major public health concern, especially for rural populations or individuals exposed to contaminated environments during travel [11,12]. The rising incidence of respiratory viral infections, such as influenza and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has further complicated the situation, escalating the risk of secondary fungal infections and exacerbating demands on the Colombian healthcare infrastructure [13]. Despite the availability of antifungal therapies, significant challenges persist. The lack of diagnostic tools and inconsistent access to rapid diagnostic methods across the country hinder timely treatment initiation, particularly in rural and underresourced areas.

Colombia's healthcare system operates under a hybrid public-private model, legislating universal coverage. However, disparities in healthcare accessibility persist, influenced by geographical differences (metropolitan vs. rural) and socioeconomic factors [14–16]. These disparities significantly impact the timely diagnosis and management of fungal infections. In rural areas, the scarcity of specialized mycological laboratories and limited access to advanced antifungal therapies further exacerbate challenges, adversely affecting patient outcomes. Despite this scenario, the National Institute of Health (INS) serves as the national reference laboratory for surveillance of notifiable mycoses, including cryptococcosis, *Candida auris*, and *Candida* spp. with unusual resistance patterns, work that provides crucial epidemiological data for public health decision-making. Consequently, Public Health Laboratories are required to submit isolates meeting surveillance criteria to the INS [17]. Nevertheless, the prolonged turnaround times for laboratory confirmation and susceptibility results from the INS often render them clinically untimely and of limited utility for guiding therapeutic decisions. Some regional studies from countries like Argentina [18], Brazil [19], Honduras [20], or Peru [21] have explored access to fungal diagnostics and antifungal therapies but do not provide detailed insights fully applicable to the Colombian context.

To address these issues, we conducted a comprehensive nationwide survey to evaluate the current diagnostic and treatment capabilities for IFD within Colombian healthcare institutions. By pinpointing system gaps and strengths, we aim to guide future policymaking and enhance access to essential diagnostics and treatments for IFD, thereby improving patient outcomes.

Methods

This was a multicenter, questionnaire-based study conducted between March and September 2024. Data were collected using an online electronic case report form hosted at www.clinicalsurveys.net/uc/IFI_capacity_Colombia/ following similar methodology employed in comparable studies, including a previous survey conducted in Honduras 20. The survey evaluated various aspects relevant to the diagnosis and treatment of IFD, including (a) institution profile, (b) perceptions of IFD incidence and relevance, (c) microscopy, (d) culture and fungal identification, (e) serology, (f) molecular assays and (g) treatment capacity. The survey captured both diagnostic and treatment capacity through separate questionnaires. Participants were asked to respond dichotomously, indicating whether each method was available at their institution. For serology, antigen detection, and molecular testing, laboratories specified whether these methods were accessible onsite or through outsourcing.

A Likert scale (1 = very low, 5 = very high) was used to estimate perceived IFD prevalence. Clinicians and microbiologists involved in the management of IFD patients (e.g., infectious disease specialists, microbiologists, internists) from all regions (called "Departments") of Colombia were invited to participate. Invitations were sent via mass email to members of key scientific organizations, such as the Colombian Association of Infectious Diseases (ACIN), the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Fungal Infection Study Group (ESCMID), and targeted collaborators across all Colombian departments. Up to 450 potential participants were contacted. Responses were validated for coherence and completeness before analysis. Participating institutions were categorized based on: (a) metropolitan vs. rural location, (b) admission of hematopoietic stem cell transplant (HSCT) and/or solid organ transplant (SOT) patients, and (c) ownership (state vs. private). This sampling strategy ensured the inclusion of a diverse range of healthcare facilities, from high-complexity urban referral centers to smaller regional hospitals or first-aid centers, providing a representative cross-section of the Colombian healthcare system and its capacity gradients.

Data are presented as frequencies and percentages, with proportions compared using Fisher's exact test. A P value <0.05 was

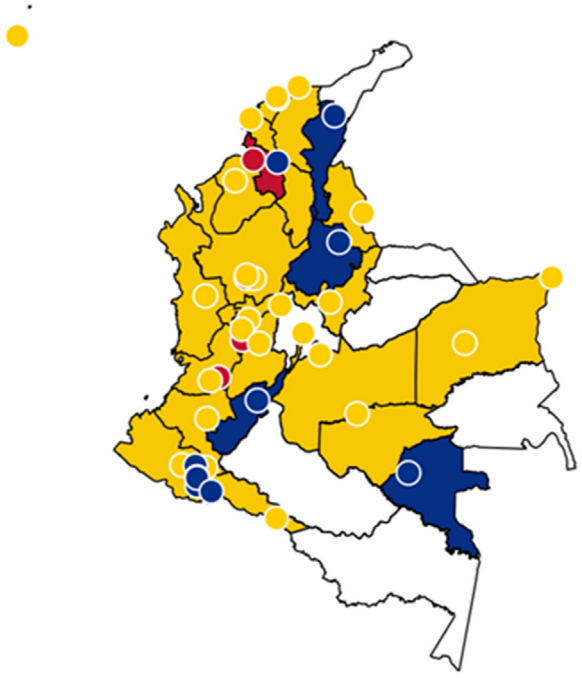

Figure 1. Geographical distribution of participating institutions across departments. A total of 26 out of the 33 departments in the country were represented in this study. Departments with participating institutions are color-coded in blue (microbiologist), red (physicians) and yellow (both), (Colombia flag representation), while those without representation are indicated in white.

considered statistically significant. Statistical analyses were performed using SPSS v27.0 (IBM Corp., Chicago, IL, United States).

Results

Between March and September 2024, we received 209 responses, with 179 completing the full survey from 133 institutions across 26 of Colombia's 33 departments (79% coverage; Figure 1). The diagnostic-focused questions received responses from 94 microbiologists, while 85 physicians (predominantly infectious disease specialists) completed the treatment-related sections. Some institutions contributed both types of responses when both a microbiologist and physician participated. Among the 133 participating institutions, 89 were clinical facilities (including hospitals, clinics, and first-aid centers), while the remaining 44 were laboratories or research institutes without inpatient services. The participating clinical institutions (n=89) represented a wide spectrum of complexity, with bed capacity ranging from 8 to 700 (median: 150; IQR: 281), distributed as follows: <100 beds (n=35, 39.3%), 100-299 beds (n=31, 34.8%), and ≥300 beds (n=23, 25.8%).

Diagnostic capacity

Analysis of diagnostic capacity data (from 94 surveys completed by microbiologist/medical laboratory scientists) showed 42 (44.6%) responses originated from rural areas and 52 (55.3%) from metropolitan regions. Among these, 63 (67.0%) respondents represented private healthcare institutions. The survey revealed that 43 (45.7%) institutions had onsite access to a mycology laboratory. Among the remaining institutions, 29 (30.8%) relied on external laboratories for mycological testing, while 22 (22.9%) had neither onsite mycology facilities nor referral systems for sample analysis. The estimated incidence of IFD, as perceived by laboratory specialists, showed significant variation between metropolitan (e.g., mild: n=17, 32.7%; high: n=2, 3.8%) and rural areas (mild: n=5, 11.9%; high: n=0, 0.0%), with notably higher perceived incidence in metropolitan regions ($P<0.001$). Despite this disparity, most participants characterized the overall IFD incidence as relatively low (metropolitan: n=21, 40.4%; rural: n=34, 81.0%; Table 1).

Among the perceived most clinically significant fungal pathogens, *Candida* spp. (n=88, 93.6%) emerged as the prevalent genus, followed by *Cryptococcus* spp. (n=40, 42.6%), *Aspergillus* spp. (n=31, 33.0%), and *Histoplasma* spp. (n=24, 25.5%). However, differences in *Candida* spp. and *Aspergillus* spp. prevalence were observed across geographical settings (metropolitan vs. rural; $P=0.049$ and $P=0.010$, respectively) (Figure 2).

Conventional mycological methods showed the highest availability. Microscopy was available in 89 (94.7%) of laboratories, with the most frequent methodologies being potassium hydroxide (KOH, n=83, 88.3%), fresh examination (n=69, 73.4%) and China/India ink staining (n=65, 69.1%). Culture techniques were available in 70 (74.5%) laboratories. In general, laboratories equipped for microbial culture typically maintained microscopy facilities as well. The most frequently used culture media were Sabouraud dextrose (n=46, 48.9%) and chromogenic media (n=37, 39.4%); however, these were not widely available in rural areas (n=13, 31.0%, $P=0.002$ and n=9, 21.4%, $P=0.001$, respectively). Advanced diagnostic modalities showed more limited availability: antigen detection tests were accessible in 55 (58.5%) institutions (with most serum measurements performed in outsourced laboratories). Diagnostic assays for *Cryptococcus* spp. (glucuronoxylomannan; n=51, 54.3%), *Aspergillus* spp. (galactomannan; n=49, 52.1%), and *Histoplasma* spp. (histoplasma antigen; n=42, 44.7%), demonstrated the highest availability. The β-D-glucan (BDG) assays remain unavailable in the country. Regarding PCR-based methods, they were present in 42 (44.7%) institutions. PCR-based diagnostic testing shows limited availability nationwide, primarily targeting *Pneumocystis* spp. (n=35, 37.2%), *Candida* spp. (n=33, 35.1%), *Aspergillus* spp. (n=31, 33.0%), and Mucorales (n=26, 27.7%). It was reported a limited access to advanced methods such as matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS) (n=12, 12.8%) and deoxyribonucleic acid (DNA) sequencing (n=3, 3.2%).

Antifungal susceptibility testing (AFST) was available in 53 (56.4%) participating institutions, with significantly higher availability in metropolitan areas (n=39, 75.0% vs. n=14, 33.3%; $P\leq0.001$)). The VITEK 2 was the most employed system (n=45/53, 84.9%), while alternative methods such as FUNGIFAST (n=3/53, 5.7%) and Etest (n=3/53, 5.7%) showed more limited utilization. Reference standard methods for broth microdilution (Clinical and Laboratory Standards Institute (CLSI): n=3/53, 5.7%; and European Committee on Antimicrobial Susceptibility Testing (EUCAST) n=1/53, 1.9%) were restricted to specialized private research centers.

Private institutions (n=36, 57.1%) demonstrated broader methodological capacity (disk diffusion n=2, 5.6%; Etest n=3, 8.3%; VITEK 2 n=29, 80.6%; FUNGIFAST n=2, 5.6%; CLSI n=3, 4.8%; EUCAST n=1, 1.6%), whereas public institutions (n=17, 54.8%) only utilized VITEK 2 (n=16, vvv%) and FUNGIFAST (n=1, 6.7%) systems. The relative frequencies of the methods employed are shown in Figure 3.

The survey also addressed critical public health capacities. Seventy-five percent (n=70) of participating institutions reported submitting mycosis-related public health events to the national surveillance system. Regarding laboratory quality assurance, 49 (52.1%) participated in external quality control programs. Furthermore, 64 (68.0%) respondents confirmed receiving training in WHONET software (a windows-based software developed by the WHO for managing and analyzing microbiology laboratory data, with a primary focus on antimicrobial resistance surveillance).

Table 1
Diagnostic capacity for invasive fungal infections in Colombian healthcare institutions: results stratified by geographic setting (metropolitan vs rural) and healthcare sector (public vs private).

	Diagnostic capacity											
	Overall		Geographical environment					Ownership				
			Rural		Metropolitan		*P* value	Private		Public		*P* value
	n	%	*n*	%	*n*	%		*n*	%	*n*	%	
Estimated IFI incidence							<0.001					0.135
Very low	55	58.5	34	81.0	21	40.4		35	55.6	20	64.5	
Low	15	16.0	3	7.1	12	23.1		12	19.0	3	9.7	
Mild	22	23.4	5	11.9	17	32.7		16	25.4	6	19.4	
High	2	2.1	0	0.0	2	3.8		0	0.0	2	6.5	
Very high	0	0.0	0	0.0	0	0.0		0	0.0	0	0.0	
Most relevant pathogens												
Aspergillus spp.	31	33.0	8	19.0	23	44.2	0.010	23	36.5	8	25.8	0.356
Candida spp.	88	93.6	37	88.1	51	98.1	0.049	60	95.2	28	90.3	0.392
Cryptococcus spp.	40	42.6	15	35.7	25	48.1	0.228	25	39.7	15	48.4	0.507
Fusarium spp.	9	9.6	3	7.1	6	11.5	0.471	5	7.9	4	12.9	0.471
Histoplasma spp.	24	25.5	7	16.7	17	32.7	0.076	16	25.4	8	25.8	1.000
Paracoccidioides spp.	5	5.3	3	7.1	2	3.8	0.479	0	0.0	5	16.1	0.003
Sporothrix spp.	2	2.1	0	0.0	2	3.8	0.199	1	1.6	1	3.2	1.000
Phaeohyphomycetes	3	3.2	1	2.4	2	3.8	0.688	1	1.6	2	6.5	0.252
Mucorales	9	9.6	3	7.1	6	11.5	0.471	6	9.5	3	9.7	1.000
Microscopy	89	94.7	38	90.5	51	98.1	0.103	61	96.8	28	90.3	0.327
Available methods for microscopy												
KOH	83	88.3	33	78.6	50	96.2	0.008	57	90.5	26	83.9	0.496
China ink	65	69.1	20	47.6	45	86.5	<0.001	44	69.8	21	67.7	1.000
Fresh examination	69	73.4	26	61.9	43	82.7	0.023	45	71.4	24	77.4	0.625
Cotton blue lactophenol stain	44	46.8	11	26.2	33	63.5	<0.001	30	47.6	14	45.2	1.000
Grocott-Gomori stain	3	3.2	0	0.0	3	5.8	0.114	3	4.8	0	0.0	0.548
Gram stain	67	71.3	26	61.9	41	78.8	0.071	45	71.4	22	71.0	1.000
Giemsa stain	14	14.9	3	7.1	11	21.2	0.058	10	15.9	4	12.9	1.000
Fluorescence dyes	3	3.2	0	0.0	3	5.8	0.114	3	4.8	0	0.0	0.548
Microscopy use if IFI suspected							<0.001					0.549
Never	27	28.7	21	50.0	6	11.5		16	25.4	11	35.5	
Almost never	14	14.9	4	9.5	10	19.2		12	19.0	2	6.5	
Sometimes	13	13.8	7	16.7	6	11.5		9	14.3	4	12.9	
Almost always	15	16.0	6	14.3	9	17.3		10	15.9	5	16.1	
Always	25	26.6	4	9.5	21	40.4		16	25.4	9	29.0	
Culture	70	74.5	22	52.4	48	92.3	<0.001	47	74.6	23	74.2	1.000
Available media for fungal culture												
Sunflower seed agar	4	4.3	0	0.0	4	7.7	0.066	3	4.8	1	3.2	1.000
Chromogenic agar	37	39.4	9	21.4	28	53.8	0.001	26	41.3	11	35.5	0.657
Potato dextrose agar	14	14.9	1	2.4	13	25.0	0.002	8	12.7	6	19.4	0.539
Sabouraud	46	48.9	13	31.0	33	63.5	0.002	32	50.8	14	45.2	0.664
Sabouraud + chloramphenicol	29	30.9	9	21.4	20	38.5	0.075	19	30.2	10	32.3	1.000
Sabouraud + gentamicin	16	17.0	4	9.5	12	23.1	0.082	12	19.0	4	12.9	0.567
Sabouraud + chloramphenicol + cycloheximide	7	7.4	0	0.0	7	13.5	0.013	5	7.9	2	6.5	1.000
Available tests for species identification												
Germinative tube	37	39.4	10	23.8	27	51.9	0.006	22	34.9	15	48.4	0.263
ChromAgar	38	40.4	7	16.7	31	59.6	<0.001	22	34.9	12	38.7	1.000
Manual biochemical methods	11	11.7	2	4.8	9	17.3	0.060	6	9.5	5	16.1	0.496
Semiautomated identification system	14	14.9	5	11.9	9	17.3	0.464	8	12.7	6	19.4	0.529
Automated identification system	46	48.9	12	28.6	34	65.4	<0.001	30	47.6	16	51.6	0.827
MALDI-TOF MS	12	12.8	1	2.4	11	21.2	0.007	11	17.5	1	3.2	0.096
DNA sequencing	3	3.2	0	0.0	3	5.8	0.114	3	4.8	0	0.0	0.548
Morphological characterization	32	34.0	9	21.4	23	44.2	0.020	18	28.6	14	45.2	0.164
Antifungal susceptibility testing	53	56.4	14	33.3	39	75.0	<0.001	36	57.1	17	54.8	1.000
Disk diffusion	2	3.8	0	0.0	2	5.1	0.388	2	3.2	0	0.0	1.000
E-test	3	5.7	1	7.1	2	5.1	0.780	3	4.8	0	0.0	0.543

(*continued on next page*)

Table 1 (*continued*)

	Diagnostic capacity										
	Overall		Geographical environment					Ownership			
			Rural		Metropolitan		*P* value	Private		Public		*P* value
	n	%	*n*	%	*n*	%		*n*	%	*n*	%	
VITEK® 2	45	84.9	14	100.0	31	79.5	0.066	29	46.0	16	51.6	0.412
FUNGIFAST®	3	5.7	0	0.0	3	7.7	0.285	2	3.2	1	3.2	1.000
CLSI	3	5.7	0	0.0	3	7.7	0.285	3	4.8	0	0.0	0.543
EUCAST	1	1.9	0	0.0	1	2.6	0.545	1	1.6	0	0.0	1.000
Antigen detection	55	58.5	14	33.3	41	78.8	<0.001	35	55.6	13	41.9	0.252
Aspergillus spp., any	49	52.1	11	26.2	38	73.1	<0.001	38	60.3	11	35.5	0.029
Aspergillus spp., ELISA	39	41.5	7	16.7	32	61.5	<0.001	29	46.0	10	32.3	0.267
Onsite	9	9.6	0	0.0	9	17.3		8	12.7	1	3.2	
Outsourced	30	31.9	7	16.7	23	44.2		21	33.3	9	29.0	
Aspergillus spp., LFD	39	41.5	9	21.4	30	57.7	<0.001	31	49.2	8	25.8	0.044
Onsite	7	7.4	0	0.0	7	13.5		6	9.5	1	3.2	
Outsourced	32	34.0	9	21.4	23	44.2		25	39.7	7	22.6	
Candida spp.	29	30.9	7	16.7	22	42.3	0.007	22	34.9	7	22.6	0.246
Onsite	5	5.3	1	2.4	4	7.7		2	3.2	3	9.7	
Outsourced	25	26.6	6	14.3	19	36.5		20	31.7	5	16.1	
Cryptococcus spp., any	51	54.3	12	28.6	39	75.0	<0.001	37	58.7	14	45.2	0.272
Cryptococcus spp., LFD	38	40.4	8	19.0	30	57.7	<0.001	28	44.4	10	32.3	0.275
Onsite	18	19.1	2	4.8	16	30.8		12	19.0	6	19.4	
Outsourced	20	21.3	6	14.3	14	26.9		16	25.4	4	12.9	
Cryptococcus spp., LAT	41	43.6	10	23.8	31	59.6	<0.001	31	49.2	10	32.3	0.129
Onsite	11	11.7	3	7.1	8	15.4		5	7.9	6	19.4	
Outsourced	30	31.9	7	16.7	23	44.2		26	41.3	4	12.9	
Histoplasma spp.	42	44.7	9	21.4	33	63.5	<0.001	33	52.4	9	29.0	0.047
Onsite	3	3.2	1	2.4	2	3.8		1	1.6	2	6.5	
Outsourced	39	41.5	8	19.0	31	59.6		32	50.8	7	22.6	
PCR	42	44.7	12	28.6	30	57.7	0.005	31	49.2	11	35.5	0.271
Aspergillus spp.	31	33.0	9	21.4	22	42.3	0.032	25	39.7	6	19.4	0.063
Onsite	3	3.2	0	0.0	3	5.8		3	4.8	0	0.0	
Outsourced	27	28.7	9	21.4	18	34.6		22	34.9	5	16.1	
Candida spp.	33	35.1	10	23.8	23	44.2	0.039	23	36.5	10	32.3	0.819
Onsite	11	11.7	4	9.5	7	13.5		8	12.7	3	9.7	
Outsourced	23	24.5	8	19.0	15	28.8		17	27.0	6	19.4	
Pneumocystis spp.	35	37.2	9	21.4	26	50.0	0.004	27	42.9	8	25.8	0.119
Onsite	5	5.3	0	0.0	5	9.6		5	7.9	0	0.0	
Outsourced	29	30.9	9	21.4	20	38.5		22	34.9	7	22.6	
Mucorales	26	27.7	8	19.0	18	34.6	0.093	19	30.2	7	22.6	0.475
Onsite	2	2.1	0	0.0	2	3.8		2	3.2	0	0.0	
Outsourced	23	24.5	8	19.0	15	28.8		17	27.0	6	19.4	

DNA, deoxyribonucleic acid; ELISA, enzyme-linked immunosorbent assay; IFD, invasive fungal disease; KOH, potassium hydroxide; LAT, latex agglutination test; LFA, lateral flow assay; MALDI-TOF MS, matrix-assisted laser desorption/ionization-time of flight mass spectrometry; n, sample size; PCR, polymerase chain reaction; spp., species.

Treatment capacity

Analysis of treatment capacity data (from 85 surveys completed by physicians) showed 30 (35.2%) responses originated from rural areas and 55 (64.7%) from metropolitan areas (Table 2). Data revealed geographical differences in IFD incidence estimates. While rural areas consistently reported very low incidence (n=19, 63.3%), metropolitan regions predominantly indicated mild IFD incidence (n=22, 40.0%). Significant variation emerged when stratifying by patient group: HSCT/SOT recipients showed substantially higher IFD incidence compared to non-HSCT/SOT patients (predominantly mild [n=12, 54.5%] and high [n=6, 27.3%] perceived incidence vs. very low [n=25, 39.7%], respectively). On the other hand, treatment capacity data confirmed *Candida* spp. (n=82, 96.5%) as the most prevalent pathogen followed by *Aspergillus* spp. (n=48, 56.5%), *Cryptococcus* spp. (n=47, 55.3%) and *Histoplasma* spp. (n=37, 43.5%) Figure 2. *Aspergillus* spp. (n=18, 81.8%), and *Histoplasma* spp. (n=14, 63.6%) demonstrated significantly higher prevalence in HSCT/SOT recipients versus non-HSCT/SOT patients (n=30, 47.6% and n=23, 36.5%) (P=0.005 and P=0.027, respectively). *Fusarium* spp. (n=3, 13.6%) phaeohyphomycotic (n=1, 4.5%), and Mucorales (n=3, 13.6%) infections occur less frequently ($P\geq$0.05) but maintain clinical significance, particularly among transplant recipients.

While most antifungal agents are generally available in Colombia (i.e., any amphotericin B n=69 (81.2%), echinocandins n=65, 76.5% and triazoles n=83, 97.6%) significant disparities were displayed across geographical regions. Rural areas demonstrate particularly limited access to amphotericin B formulations (deoxycholate n=10, 33.0% and liposomal n=12, 40.0%, versus deoxycholate n=39, 70.9% and liposomal n=46, 83.6%, $P\leq$0.001), all echinocandins (n=15, 50.0%, versus n=50, 90.9%, $P\leq$0.001) and expanded-spectrum azoles (posaconazole n=8, 26.7%, voriconazole n=12, 40.0%, versus posaconazole n=31, 56.4%, voriconazole n=42, 76.4%, $P<$0.001). Isavuconazole was available in 32 institutions (37.6%), with significantly higher availability in metropolitan areas (n=28, 50.9% vs. n=4, 13.3%, $P<$0.001) and for HSCT/SOT recipients (n=14, 63.6% vs. n=18, 28.6%, P=0.003). Furthermore, antifungal availability varies substantially by patient population, with HSCT/SOT recipients having significantly better access compared to non-HSCT/SOT patients. Therapeutic drug monitoring (TDM) showed minimal variation between groups (n=21, 36.2% and n=10, 52.6%, P=0.205). Overall monitoring capability was limited (n=31, 40.3%), with voriconazole and itraconazole (n=24, 32.9% each) being the most frequently assessed drugs. The availability of surgical interventions and advanced diagnostic imaging modalities (e.g., CT and MRI) showed significant disparities across both geography—CT (n=19, 63.3%) versus (n=51, 92.7%); MRI (n=13, 43.3%) versus

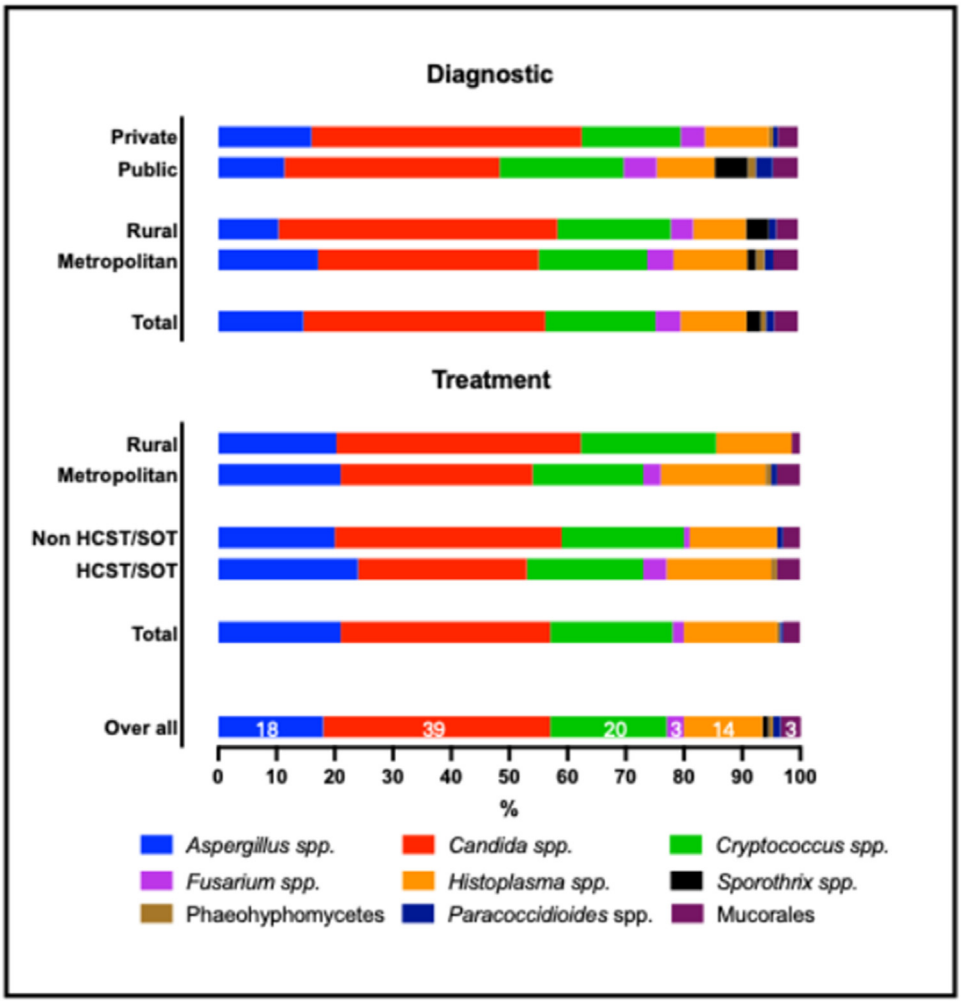

Figure 2. Fungal incidence by healthcare sector and geographical location. This figure illustrates the distribution of fungal incidence across healthcare sectors (private and public) and geographical settings (rural and metropolitan). Diagnostic (responses from microbiologist); Treatment (responses from physicians).

(n=44, 80.0%), $P \leq 0.001$—and patient population—CT (n=48, 76.2%) versus (n=22, 100.0%), $P \leq 0.012$; MRI (n=35, 55.6%) versus (n=22, 100.0%), $P \leq 0.001$.

Discussion

This nationwide study, while providing a detailed assessment of Colombia's IFD capacity, offers critical insights that extend far beyond its national borders. Colombia serves as a representative case study for many middle-income countries grappling with the triple challenge of a high burden of endemic fungal diseases, the emergence of antifungal-resistant pathogens like *Candida auris*, and profound within-country disparities in healthcare access. Our findings on the urban-rural divide, the concentration of advanced resources in transplant centers, and the gaps in essential diagnostics like β-D-glucan and therapeutic drug monitoring are directly transferable to numerous countries across Latin America, Asia, and Africa. Therefore, the strategies required to address Colombia's gaps, such as targeted laboratory strengthening, equitable antifungal access programs, and the inclusion/use of WHO-recommended diagnostics in national guidelines, represent a blueprint for global health action in medical mycology.

This nationwide study shows significant disparities in IFD diagnostic capacity: while conventional methods like microscopy and culture are widely accessible, only 46% of institutions maintain onsite mycology laboratories, and rural areas face shortages of essential culture media (e.g., Sabouraud dextrose and chromogenic media). Advanced diagnostics remain severely limited: antigen testing is available in 58.5% of institutions (though often outsourced), with the highest accessibility for *Cryptococcus* spp., *Aspergillus* spp., and *Histoplasma* spp., detection. Crucially, β-D-glucan assays are nationally unavailable, and molecular methods are sparse, PCR utilization ranges from 27.7% to 37.2% (primarily for *Aspergillus* spp., *Candida* spp., and *Pneumocystis* spp.), while DNA sequencing is accessible in only 3% of institutions. Even MALDI-TOF MS (12.8% availability) is confined to urban reference centers. These gaps underscore systemic inequities in IFD diagnosis across Colombia's healthcare tiers. Treatment inequities are pronounced, particularly for rural areas and nontransplant patients who face significantly reduced access to essential antifungals and advanced diagnostics compared to metropolitan centers and transplant recipients.

Our survey revealed strong agreement regarding the most clinically significant fungal pathogens. *Candida* spp. emerged as the predominant concern, followed by *Cryptococcus* spp., *Aspergillus* spp., and *Histoplasma* spp. This ranking aligns with, yet shows notable variations from, regional and global patterns. Furthermore, the geographic analysis revealed a significantly lower perceived incidence of IFD in rural areas. This expected yet critical finding likely reflects a cycle of under-diagnosis fueled by limited diagnostic capacity and low clinical suspicion, exacerbated by the referral of complex cases to urban centers. Consequently, this disparity highlights a profound diagnostic blind spot in peripheral

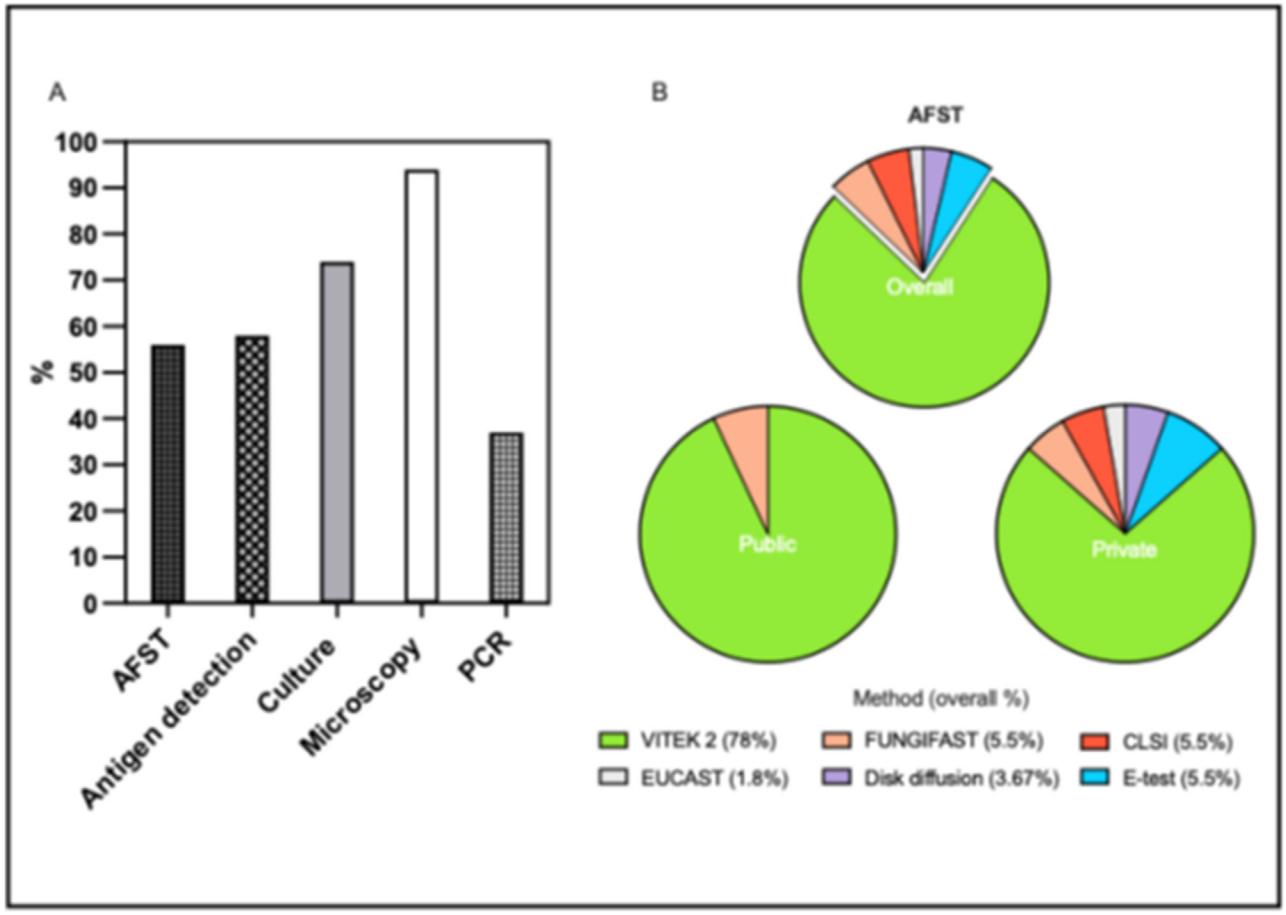

Figure 3. Overview of access to fungal diagnostic methods in Colombia. (**a)** illustrates the availability of fungal diagnostic methods across the country. (**b)** presents pie charts showing the proportional distribution of antifungal susceptibility testing methods across all reported methodologies in public and private institutions. Importantly, these percentages reflect the relative frequency of each method's use among all methods employed. AFST, antifungal susceptibility testing; PCR, polymerase chain reaction; CLSI, Clinical and Laboratory Standards Institute; EUCAST, European Committee on Antimicrobial Susceptibility Testing.

regions, underscoring the need for targeted awareness campaigns alongside resource allocation. Building regional capacity will depend on a well-rounded approach—combining short-term training in advanced mycology laboratories, continuous skill development for clinical and laboratory teams, and strategic investment in core diagnostic tools like culture media, antigen detection, and molecular testing platforms. In Colombia, access to mycological diagnostics remains largely restricted to tertiary hospitals and national reference centers located in major cities such as Bogotá and Medellín, leaving peripheral regions with limited capacity for timely and accurate diagnosis. In comparable Latin American studies, while *Candida* spp. similarly dominated, the subsequent order slily differed (*Aspergillus* spp., *Cryptococcus* spp., and *Histoplasma* spp,) [22]. In the Peruvian study, *Candida* spp. was reported as the primary concern, followed by *Aspergillus* spp. and *Cryptococcus* spp. [21]. In Brazil, *Candida* spp. was also considered highly relevant. Interestingly, *Cryptococcus* spp. and *Histoplasma* spp. ranked higher in clinical importance in Brazil compared to *Aspergillus* spp [19]. European data corroborate the primacy of *Aspergillus* spp. and *Candida* spp. but reveal different secondary pathogens, with Mucorales ranking third, followed by *Cryptococcus* spp. and *Fusarium* spp. [23].These discrepancies likely reflect: i) Colombia's unique endemic mycobiome, particularly the heightened burden of cryptococcosis and histoplasmosis; and ii) differential immunosuppression profiles, e.g., HIV/AIDS and transplantation, driving pathogen prevalence. The consistency of *Candida* spp. as the top-ranking pathogen across all regions underscores its universal clinical impact [24].

The diagnostic infrastructure within the country shows concerning gaps, especially in rural areas where access to essential mycology services remains limited. While microscopy and culture methods demonstrate broad availability across Colombia, advanced diagnostic tools such as MALDI-TOF MS and DNA sequencing remain concentrated in high-complexity metropolitan institutions. This distribution leaves rural centers dependent on less sensitive conventional techniques [14]. Comparative data reveal even more marked limitations in Colombia's advanced diagnostic infrastructure: MALDI-TOF MS availability stands at just 12% of centers (compared to 14% and 20% in the Brazilian and Latin American landscape), higher than the 4.3% in Peru but still low. Crucially, this limited access is characterized by profound geographic concentration, with 11 of the 12 institutions (91.7%) possessing MALDI-TOF MS located exclusively in metropolitan areas. Meanwhile, DNA sequencing access is particularly limited at only 3% (versus 18% regionally) 19,21,22. These findings highlight a critical gap that disproportionately affects diagnostic capabilities, potentially delaying appropriate treatment initiation for IFD. This disparity also exceeds those observed in European countries where even nonspecialized centers maintain substantial diagnostic capabilities [23,25,26].

Our study identifies antigen testing availability as one of Colombia's most significant diagnostic challenges. Specifically, *Aspergillus* galactomannan testing is accessible in 52% of surveyed sites, with

Table 2
Antifungal treatment capacity and access patterns in Colombian healthcare institutions stratified by geographic setting and patient population.

	Treatment capacity											
	Overall		Geographical environment					Target patients				
			Rural		Metropolitan		*P* value	No HSCT/SOT		HSCT/SOT		*P* value
	n	%	*n*	%	*n*	%		*n*	%	*n*	%	
Estimated IFD incidence							<0.001					0.001
Very low	27	31.8	19	63.3	8	14.5		25	39.7	2	9.1	
Low	17	20.0	4	13.3	13	23.6		16	25.4	1	4.5	
Mild	28	32.9	6	20.0	22	40.0		16	25.4	12	54.5	
High	11	12.9	1	3.3	10	18.2		5	7.9	6	27.3	
Very high	2	2.4	0	0.0	2	3.6		1	1.6	1	4.5	
Available antifungals												
Amphotericin B, any	69	81.2	17	56.7	52	94.5	<0.001	47	74.6	22	100.0	0.009
Amphotericin B deoxycholate	49	57.6	10	33.3	39	70.9	<0.001	35	55.6	14	63.6	0.509
Amphotericin B lipid complex	28	32.9	9	30.0	19	34.5	0.670	19	30.2	9	40.9	0.356
Amphotericin B liposomal	58	68.2	12	40.0	46	83.6	<0.001	39	61.9	19	86.4	0.034
Echinocandins	65	76.5	15	50.0	50	90.9	<0.001	45	71.4	20	90.9	0.064
Anidulafungin	37	43.5	6	20.0	31	56.4	0.001	22	34.9	15	68.2	0.007
Caspofungin	65	76.5	15	50.0	50	90.9	<0.001	45	71.4	20	90.9	0.064
Triazoles	83	97.6	29	96.7	54	98.2	0.660	61	96.8	22	100.0	0.398
Fluconazole	82	96.5	28	93.3	54	98.2	0.247	60	95.2	22	100.0	0.297
Mould-active	66	77.6	18	80.0	48	87.3	0.006	46	73.0	20	90.9	0.135
Itraconazole	49	57.6	14	46.7	35	63.6	0.130	34	54.0	15	68.2	0.245
Posaconazole	39	45.9	8	26.7	31	56.4	0.009	24	38.1	15	68.2	0.015
Voriconazole	54	63.5	12	40.0	42	76.4	<0.001	36	57.1	18	81.8	0.038
Flucytosine	36	42.4	10	33.3	26	47.3	0.240	26	41.3	10	45.5	0.732
Terbinafine	11	12.9	6	20.0	5	9.1	0.152	8	12.7	3	13.6	0.910
TDM	31	40.3	7	28.0	24	46.2	0.128	21	36.2	10	52.6	0.205
Flucytosine	11	14.9	5	21.7	6	11.8	0.264	11	19.6	0	0.0	0.042
Itraconazole	24	32.0	5	20.8	19	38.8	0.125	16	28.6	8	47.1	0.155
Posaconazole	15	20.3	2	8.3	13	26.0	0.077	10	17.9	5	27.8	0.362
Voriconazole	24	32.0	5	20.8	19	37.3	0.155	16	28.1	8	44.4	0.194
Surgery	73	85.9	20	66.7	53	96.4	<0.001	51	81.0	22	100.0	0.031
Imaging procedures												
CT	70	82.4	19	63.3	51	92.7	<0.001	48	76.2	22	100.0	0.012
PET CT	20	23.5	4	13.3	16	29.1	0.102	7	11.1	13	59.1	<0.001
MRI	57	67.1	13	43.3	44	80.0	<0.001	35	55.6	22	100.0	<0.001
PET MRI	6	7.1	2	6.7	4	7.3	0.917	1	1.6	5	22.7	<0.001
X ray	73	85.9	25	83.3	48	87.3	0.618	53	84.1	20	90.9	0.432
US	74	87.1	25	83.3	49	89.1	0.450	53	84.1	21	95.5	0.173

CT, computed tomography; IFD, invasive fungal disease; PET CT, positron emission tomography combined with CT; MRI, magnetic resonance imaging; US, ultrasound; HSCT, hematopoietic stem cell transplant; SOT, solid organ transplant; TDM, therapeutic drug monitoring.

the vast majority relying on outsourced services (enzyme-linked immunosorbent assay [ELISA] 41% and for lateral flow assays [LFA] 41%), which contributes to delays in obtaining results and, consequently, in clinical decision-making. While this data is comparable to the 48% reported in prior Latin American and the Caribbean studies [22], it remains lower availability rates than in Asia/Pacific (79%) [27], Europe (94%) [23], Africa (≥60%) [28], or neighboring Argentina (56%) [18]. However, other countries in the region face even greater limitations: Peru (23.9% of institutions) 21 and Brazil (32.3% of centers offering antibody testing for *Aspergillus* spp. [19]. These findings underscore persistent regional disparities, with Latin America lagging global standards in *Aspergillus* antigen detection, a critical shortcoming given the pathogen's clinical significance.

For other antigen tests, Colombia shows modest yet insufficient diagnostic capacity relative to regional standards. While *Histoplasma capsulatum* antigen detection is available in 44% of facilities, β-D-glucan testing remains inaccessible nationwide. In contrast, Peru reported *Histoplasma* antigen detection in 28.3% of centers and β-D-glucan availability in 17.8% 21. Brazil showed slightly better access to *Histoplasma* antigen testing (38.5%) and reported β-D-glucan use in 9.4% of institutions [19]. Despite Colombia outperforming both countries in *Histoplasma* antigen access, it lags in β-D-glucan availability. These figures represent marginal progress over Latin American averages (22% for both tests) [22] but fall significantly below European benchmarks (46% for *Histoplasma* antigen and 62% for β-D-glucan). Colombia's current rates for *Histoplasma capsulatum* antigen align more closely with African availability (~40%) [28]. Access to *Cryptococcus* diagnostics showed marked regional disparities. While Colombia reported 54% availability for antigen testing (CrAg) and 40% for LFA, other regions demonstrated different patterns: Latin America and the Caribbean showed higher LFA availability (75% overall, though Peru reported only 25%), Africa had 60% LFA access (versus 40% for latex testing), and Europe maintained 79% CrAg and 48% LFA availability [21,22,23,28]. The significant disparities in essential biomarker testing availability create substantial barriers to timely fungal diagnosis, particularly when contrasted with global standards of care. Since 2018, the WHO has developed the essential diagnostics list (EDL) [29], yet the current version remains insufficient for comprehensive IFD diagnosis. Our findings reveal Colombia's particular challenges in meeting even these basic standards. This gap between WHO recommendations and on-the-ground reality underscores the urgent need for expansion of the fungal diagnostics included in the EDL; and targeted investments to improve access to these essential tests.

Regarding AFST, availability in Colombia (56.4%), Peru (55.1%) and Brazil (59.4%) approaches the regional average for Latin

America and the Caribbean (61%) [19,21,22], however, identifies critical gaps when compared to European centers (94%) [23]. The observed rates show closer alignment with resource-limited settings in Africa (62.5%) [28] and Asia/Pacific (58.9%) [27]. These disparities become particularly concerning given the rising global reports of antifungal-resistant fungal strains [6,30,31]. Europe's superior AFST infrastructure provides a distinct advantage in combating antifungal resistance compared to other regions. However, even European centers face limitations, as susceptibility testing remains more routinely available for yeasts than moulds, and not all institutions perform these tests consistently [23]. This global landscape underscores the urgent need for expanded AFST capabilities worldwide, particularly in resource-limited settings.

Concerning treatment, our findings reveal a striking gradient in antifungal availability. Europe maintaining near-complete coverage (87-94% for major drug classes, echinocandins, azoles and amphotericin B) [23], followed by Asia/Pacific (72-93%) [27], Latin America and the Caribbean (30-98%) [22], with Colombia showing intermediate availability (58-98%), and Africa facing the most limited access (20-90%) [28]. The data demonstrate consistent patterns when stratified by drug class: while liposomal amphotericin B shows progressive declines in availability from Europe (78%) to Asia/Pacific (57%), Colombia (68%), Latin America and the Caribbean (49%), and Africa (18%), the echinocandin class presents a more complex scenario. Europe leads with 89% overall availability (caspofungin 86%), followed by Colombia (76.5%), Asia/Pacific (72%), Latin America and the Caribbean (30%), and Africa (20%). Regional analysis reveals critical disparities: in Peru, while triazole availability paralleled Colombia's (96.3% overall; fluconazole 94.4%, itraconazole 75.5%) and conventional amphotericin B reached 88.7%, echinocandin access was markedly lower (37%) than Colombia's 76.5% [21]. Brazil showed also some limitations, amphotericin B availability (71.9% overall) was dominated by conventional formulations, with liposomal forms accessible in only 34.4% (versus Colombia's 68.2%), while echinocandin coverage was 55.2% [19]. These disparities become clinically significant when examining first-line treatments for life-threatening fungal infections. For instance, the global guidelines recommended amphotericin B + flucytosine combination for cryptococcal meningitis [32]; however, it remains inaccessible in many resource-limited settings, with flucytosine available in only 43% of Asian/Pacific, 19% of Latin American and the Caribbean, 42% of Colombian (higher than the regional average but still insufficient), and 27% of African centers. Similarly, optimal management of invasive aspergillosis is compromised in non-European regions due to limited access to mould-active triazoles (e.g., voriconazole is available in 89.2% of European centers versus 78.3% in Asia/Pacific, 63.5% in Colombia, 55% in Latin America, and 35% in Africa) (Table 3).

Therapeutic inequities are further exacerbated by the restricted availability of newer antifungals in resource-limited settings, particularly concerning given rising resistance patterns. While Europe benefits from comprehensive access to broad-spectrum triazoles (e.g., isavuconazole 61%) and echinocandins (89%), other regions face critical gaps that may accelerate antimicrobial resistance, as limited drug options often force clinicians to rely on older, less effective, or more toxic agents, and to use suboptimal regimens, creating selective pressure that favors the survival and spread of resistant strains. In Colombia, isavuconazole was available in fewer than 40% of surveyed centers, with access concentrated in metropolitan areas and among transplant recipients. Its limited distribution contrasts with its increasing recommendation in international guidelines for invasive aspergillosis and mucormycosis, underscoring a major therapeutic gap for patients in rural or nontransplant settings. These findings underscore three urgent priorities: *i*) expansion of the WHO EML [33] to include newer antifungals reflecting current treatment guidelines, *ii*) implementation of targeted access programs with tiered pricing for low- and middle-income countries, and *iii*) establishment of regional antifungal stewardship programs incorporating TDM. Without coordinated global action, the growing burden of untreatable fungal infections will continue to disproportionately affect resource-limited settings, highlighting antifungal access equity as both a clinical imperative and global health security priority.

Concerning antifungal TDM, our findings highlight substantial gaps in Latin American healthcare systems. While Colombian centers demonstrate marginally better capacity than regional counterparts, with voriconazole and itraconazole monitoring available in 32% of institutions versus 16% and 10% respectively across Latin America and the Caribbean [22]. TDM was reported in only 2.2% of Peruvian centers while Brazil showed slightly better access at 9.4%, though still far below Colombia [19,21]. Noteworthy, in Colombia, therapeutic drug monitoring for antifungal agents is centralized in a single mycology reference laboratory, leading to delays in processing and result availability. These delays hinder timely dose optimization and could negatively impact outcomes in patients with IFD. These figures remain alarmingly low compared to European standards where over 70% of centers routinely perform TDM [23]. The clinical consequences of this monitoring deficit are particularly significant for triazoles with unpredictable pharmacokinetics, namely voriconazole, posaconazole, and itraconazole, where pharmacokinetic variability directly impacts outcomes. In contrast, TDM is not routinely indicated for fluconazole and isavuconazole due to their more predictable pharmacokinetic profiles [34,35]. Regarding voriconazole, for instance, studies demonstrate that subtherapeutic levels (<1 mg/L) correlate with treatment failure in invasive aspergillosis, while supratherapeutic concentrations (>5 mg/L) increase neurotoxicity risks [36,37].

While our survey achieved broad participation across 26 of Colombia's 32 departments, several limitations should be considered. The cross-sectional design precludes assessment of temporal variations in resource availability. Furthermore, the absence of data from remote regions with limited healthcare infrastructure (e.g., Amazonas, Guainía, Caquetá, and La Guajira) may have resulted in marginally inflated availability percentages, as these underserved areas typically have reduced access to advanced diagnostics and antifungal therapies. As a capacity-mapping study, our design does not capture patient-level data; consequently, we cannot directly link the identified diagnostic and therapeutic gaps to clinical outcomes such as mortality, which remains an important area for future investigation. Additionally, the data on perceived incidence and diagnostic capacity represent a general, institutional-level overview and consequently lack granularity regarding specific underlying diseases (e.g., hematological malignancies, solid tumors, HIV/AIDS) or the distribution of cases across different clinical wards (e.g., intensive care, hematology). In contrast, our analysis of treatment capacity was specifically stratified by the care of HSCT/SOT recipients, providing a precise assessment for this paramount at-risk group. Future studies incorporating detailed, patient-level epidemiological and outcome data from all clinical settings are warranted to fully characterize the burden and impact of IFD in Colombia. To account for clustering effect and to ensure that no single institution was overrepresented in the aggregated analysis, data for institutional-level characteristics (e.g., bed capacity, location, ownership) are reported and analyzed per institution (n=133). Analyses of perceptions and practices (e.g., perceived incidence, pathogen relevance) are presented per respondent (n=179) to reflect the individual clinical and laboratory perspectives. Nevertheless, this study provides the first comprehensive national assessment of mycological diagnostic and treatment capacity, establishing a crucial baseline for future antimicrobial stewardship interventions.

Table 3
Antifungal availability by region (% of healthcare institutions).

Antifungal agent	Europe [23]	Asia/Pacific [27]	Africa [28]	Latin America and Caribbean [22]	Colombia (current study)
Amphotericin B formulations					
Deoxycholate	41.0	61.3	52.5	72.0	57.6
Liposomal	77.6	57.4	17.5	49.0	68.2
Echinocandins					
Anidulafungin	64.7	34.5	5.0	32.0	43.5
Caspofungin	86.3	55.7	20.0	30.0	76.5
Micafungin	65.5	56.2	22.5	41.0	-
Triazoles					
Fluconazole	93.3	92.3	90.0	98.0	96.5
Mould-active					
Isavuconazole	61.6	33.2	2.5	1.0	[a]
Itraconazole	80.7	69.8	52.5	71.0	57.6
Posaconazole	77.3	51.1	5.0	21.0	45.9
Voriconazole	89.2	78.3	35.0	55.0	63.5
Other					
Flucytosine	49.7	43.4	27.5	19.0	42.4
Terbinafine	52.1	51.1	62.5	-	12.9

[a] Recently introduced to the country.

Overall, this study reveals significant disparities in Colombia's capacity to diagnose and manage IFD with pronounced inequities between metropolitan and rural settings, public and private sectors, and transplant versus nontransplant populations. While diagnostic and therapeutic resources exist in major centers, their limited availability in peripheral regions, particularly for advanced diagnostics (e.g., MALDI-TOF MS, PCR) and newer antifungals (echinocandins, broad-spectrum triazoles), underscores an urgent need for health system strengthening. The findings highlight critical gaps in essential services that likely contribute to Colombia's elevated invasive fungal disease burden 3. Addressing these challenges through targeted laboratory capacity building, antifungal stewardship programs, and inclusion of WHO-recommended diagnostics in national guidelines should be prioritized to improve patient outcomes across all regions.

Transparency declarations

OAC reports grants or contracts from iMi, iHi, DFG, BMBF, Cidara, DZIF, EU-DG RTD, F2G, Gilead, MedPace, MSD, Mundipharma, Octapharma, Pfizer, Scynexis; Consulting fees from Abbvie, AiCuris, Basilea, Biocon, Boston Strategic Partners, Cidara, Elion, Gilead, GSK, IQVIA, Janssen, Matinas, MedPace, Menarini, Melinta, Molecular Partners, MSG-ERC, Mundipharma, Noxxon, Octapharma, Pardes, Partner Therapeutics, Pfizer, PSI, Scynexis, Seres, Seqirus, Shionogi, Prime Meridian Group; Speaker and lecture honoraria from Abbott, Abbvie, Al-Jazeera Pharmaceuticals/Hikma, amedes, AstraZeneca, Gilead, GSK, Grupo Biotoscana/United Medical/Knight, Ipsen Pharma, Medscape/WebMD, MedUpdate, MSD, Moderna, Mundipharma, Noscendo, Paul-Martini-Stiftung, Pfizer, Sandoz, Seqirus, Shionogi, streamedup!, Touch Independent, Vitis; Participation on a DRC, DSMB, DMC, or Advisory Board for AstraZeneca, Cidara, IQVIA, Janssen, MedPace, Melinta, PSI, Pulmocide, Vedanta Biosciences, outside of the submitted work. KL received consultancy fees Mundipharma, speaker fees from Pfizer, Gilead, Mundipharma and FUJIFILM Wako chemicals Europe GmbH, a service fee from TECOmedical; a fee for Advisory Board participation from Pfizer and travel support from Pfizer, Gilead and AstraZeneca, outside of the submitted work. JSG has received speaker honoraria from AstraZeneca, Gilead, Pfizer, and Menarini, and has been member of an advisory board for Pfizer, outside of the submitted work. Remaining authors declare no COIs.

Ethical approval

Not applicable.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: JSG has received payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Gilead, Menarini, and Pfizer; and has participated on a Data Safety Monitoring Board or Advisory Board for Pfizer, outside of the submitted work. OAC has received grants or contracts from BMBF, Cidara, EU-DG RTD (101037867), F2G, Gilead, MedPace, MSD, Mundipharma, Octapharma, Pfizer, Scynexis; consulting fees from Abbvie, AiCuris, Biocon, Cidara, Gilead, IQVIA, Janssen, Matinas, MedPace, Menarini, Moderna, Molecular Partners, MSG-ERC, Noxxon, Octapharm, Pfizer, PSI, Scynexis, Seres; payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Abbott, Abbvie, Al-Jazeera Pharmaceuticals/Hikma, Gilead, Grupo Biotoscana/United Medical/Knight, MedScape, MedUpdate, Merck/MSD, Noscendo, Pfizer, Shionogi, streamedup!; Payment for expert testimony from Cidara; a German patent ("Geschlossene Inkubationssysteme mit verbessertem Atemwegszugang für Untersuchungsvorrichtungen", DE 10 2021 113 007.7), filed by the University of Cologne and listing Oliver A. Cornely as one of three inventors; Participation on a Data Safety Monitoring Board or Advisory Board from Boston Strategic Partners, Cidara, IQVIA, Janssen, MedPace, PSI, Pulmocide, Shionogi, The Prime Meridian Group; Stock or stock options from CoRe Consulting, EasyRadiology; and Other financial or nonfinancial interests from Wiley, outside of the submitted work. Other authors declare no competing interest related to the submitted work. All authors had full access to the data and had final responsibility for the decision to submit for publication.

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Author contributors

ACG, IBM and JSG made substantial contributions to the study concept and design, data verification, the statistical analysis and interpretation of data, and drafted the manuscript. All authors made substantial contributions to the acquisition of data for the work, and critically reviewed the manuscript, and gave the final approval for publication.

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