GAFFI in the news

Annual Report 2021

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GAFFI's Vision is 'a world free of suffering and death from fungal disease'

GAFFI revised its strategy in 2020 and in 2021 added some quantifiable goals. GAFFI's high level objective is to ensure that WHO Essential Diagnostics and antifungal drugs are accessible to all, aligned to Universal Health Coverage.

To achieve these ends, GAFFI is **seeking strong partnerships** to further its mission, and make a genuine difference to the millions of people affected by fungal diseases.

EXCUTIVE SUMMARY

During the years 2020 and 2021 there has been increased interest in fungal disease amongst the public and professionals. The second major wave of COVID-19 saw mucormycosis and aspergillosis complicating and antifungal resistance, notably *Candida auris* and a new species of skin fungus called *Trichophyton indotineae*, which are spreading and problematic. GAFFI has issued several Policy Briefs to summarise its views on how to improve access to diagnostics and antifungal therapy globally, and what measures need to be taken to address antifungal resistance.

- Deemed **Essential Diagnostics** by the WHO were *Pneumocystis* PCR to diagnose pneumonia, *Aspergillus* IgG antibody to diagnose chronic pulmonary aspergillosis and *Aspergillus* antigen to diagnose invasive aspergillosis and listed on the WHO's 3rd EDL.
- The WHO accepted inclusion of the 3 echinocandin antifungal drugs (micafungin, caspofungin and anidulafungin) onto the **Essential Medicine List**, following GAFFI's application, which is particularly important for life-threatening *Candida* infections, including the often resistant *Candida auris*.
- **Diagnostic Laboratory Hub in Guatemala:** As a result of GAFFI's project, initiated in late 2015, Guatemala now has the first Diagnostic Laboratory Hub specialised in mycology providing diagnostic services to HIV patients in Central America. From 2017-2019, overall mortality decreased from 34% to 27%. The number of TB diagnoses went down and survival increased by 14.9%, indicative of misdiagnosis of TB early in the programme. Histoplasmosis mortality fell from 32.8% in 2017 to 21.2% in 2019. The success of the programme is such that it has been adopted by the Ministry of Public Health and Social Assistance and expanded. This programme provides a model for other countries, regions and population groups at risk.
- **Diagnostic survey capacity in Africa:** GAFFI has completed a survey of diagnostic procedures and laboratory testing for fungal disease in 50 African countries. This survey focusses on clinical procedures required for sampling (i.e., skin biopsy, bronchoscopy, lumbar puncture, imaging) and laboratory tests (i.e., antigen, microscopy and culture). The results are being assembled for publication and formatted in a major report.
- **Burden of Serious Fungal Diseases**: Six more country burden of fungal disease papers were published including Democratic Republic of Congo, Sierra Leone, Togo, Zimbabwe, Azerbaijan and Indonesia, for a total population of 400 million people.
- **Fungal NTDs:** New maps of chromoblastomycosis and sporotrichosis were published, combined with comprehensive literature reviews. A call for NTD recognition of talaromycosis was made on the basis of its lethal outcome in many patients with AIDS.
- **GAFFI's Ambassadors' activities:** Additional GAFFI Ambassadors were recruited for Sierra Leone, DRC, Malawi, Togo, Benin, Tunisia, Eswatini, Trinidad and Tobago and Vietnam. Multiple educational programmes and awareness have been delivered in multiple countries including Portugal, Indonesia, India, Nigeria, Cameroon, Ghana, Mali, Latin America, sub-Saharan Africa, Saudi Arabia and Vietnam.

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GAFFI board and structure

The international board of Trustees of GAFFI reflects the international work of GAFFI and is currently composed of Oddi Aasheim, Professor Patrick Francioli, Yasuaki Mori and Professor Juan Luis Rodriguez Tudela. We would like to thank Professor Nigel Lightfoot and Victor Rydgren who stepped down in 2021. The executive board consists of Professor David Denning (CEO), Emma Orefuwa (Head of Africa Programmes), Ana Alastruey Izquierdo (Head of Latin America Programmes) and Timothy Moss (Head of Finance and Governance). Emma Orefuwa is reducing her commitment in 2022. GAFFI and GAFFI UK have identical Board membership to facilitate achieving GAFFI's aims. GAFFI runs a very lean and flat organisation concentrating on delivering maximum impact and value.

Donors and supporters

We would like to thank all those that continued to support GAFFI, from organisations including The JYLAG Fondation, The International Society for Human and Animal Mycology, F2G, Gilead Sciences, Pfizer, Pulmocide, Scynexis, Biosergen, MundiPharma, Cidara, MiraVista, OLM Diagnostics, Associates of Cape Cod, Immunomycologics (IMMY), Amplyx, Dynamiker, from private donors including Juan Luis Rodriguez Tudela, Bradford Armstrong and David Denning and contributions and generous donations in kind including office space (Haines Watts re GAFFI UK). Board members' and advisers' contribute their time and skills in attending meetings and providing advice.

Future plans and aspirations

GAFFI has recently released version 1 of its Theory of Change model, which will assist in planning new programmes and set a framework for their evaluation.

Additional burden of disease estimates are anticipated in 2022, including India, Morocco, Eritrea, Mali, Panama and Tunisia and a revised method for estimating chronic pulmonary aspergillosis related to TB.

GAFFI's African Diagnostic survey is virtually concluded and will report its findings in 2022 in collaboration with the African CDC and in a series of research papers authored by GAFFI's Ambassadors and others who contributed to the survey. A component of this survey to be released is a cryptococcal meningitis dashboard, summarising the availability of diagnosis, optimum antifungal therapies and country guidelines. Uganda, Sierra Leone, Cameroon, Tanzania, Ghana and other African countries are undertaking incidence or prevalence studies of histoplasmosis, cryptococcosis or aspergillosis which should report in 2022 or 2023. Following on from the survey, GAFFI is expecting local and national programmes to be developed in partnership with its ambassadors, country leaders and external funders. A similar diagnostic survey in Latin America and the Caribbean is planned in collaboration with PAHO, as well as national surveys in Peru and Mexico, conducted by GAFFI's Ambassadors.

The WHO is issuing its first Fungal Pathogen Priority List in 2022. GAFFI will support its messaging and dissemination of the key information.

Additional reports from the Diagnostic Laboratory Hub in Guatemala will be published as this country programme has, and will act as a beacon for other countries, as well as consolidating the findings from the project into national guidelines.

With initial progress, GAFFI anticipates at least one field trial of one of its AI projects in 2022.

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Goal 1
Increase awareness of the impact of fungal disease

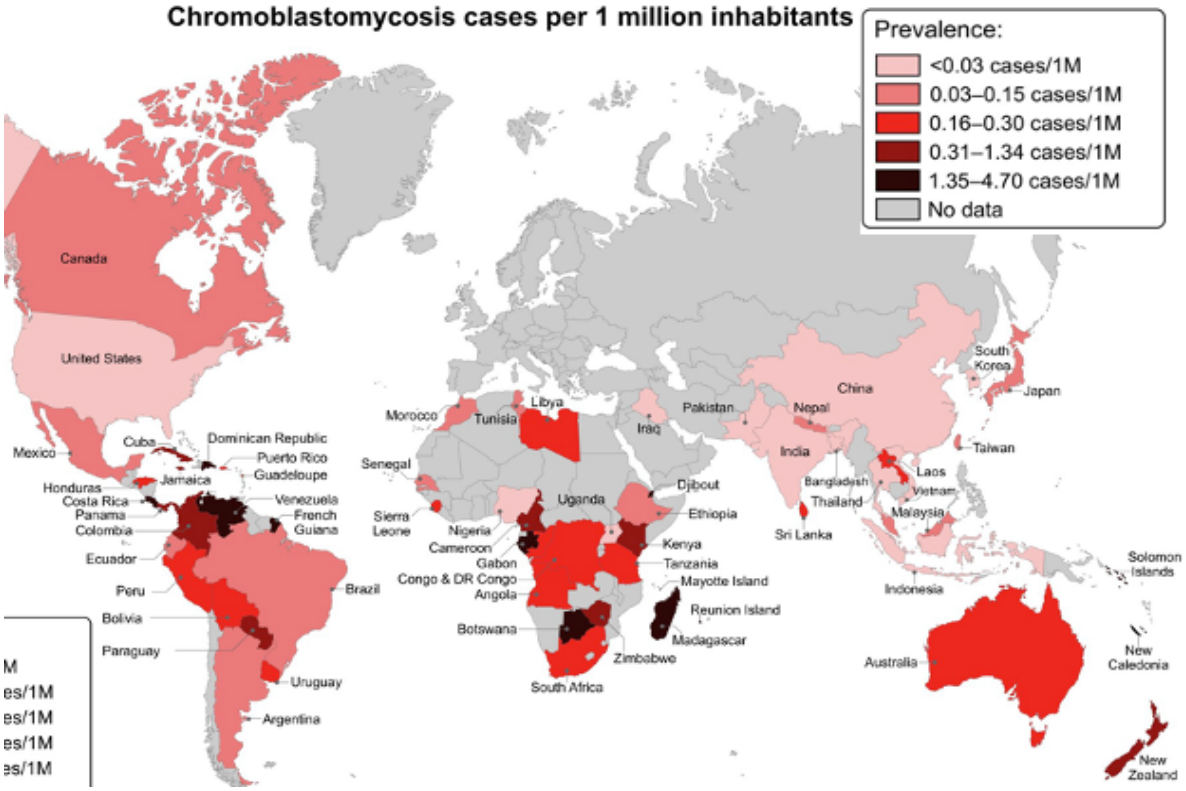
A major GAFFI goal is to increase awareness of fungal disease globally, especially among global health agencies and country medical opinion leaders and decision-makers. GAFFI has approached this in part by estimating the burden of fungal diseases country-by-country, identifying and highlighting diagnostic and therapeutic gaps and supporting epidemiological studies to better define fungal disease locally.

1.1 Burden of fungal disease

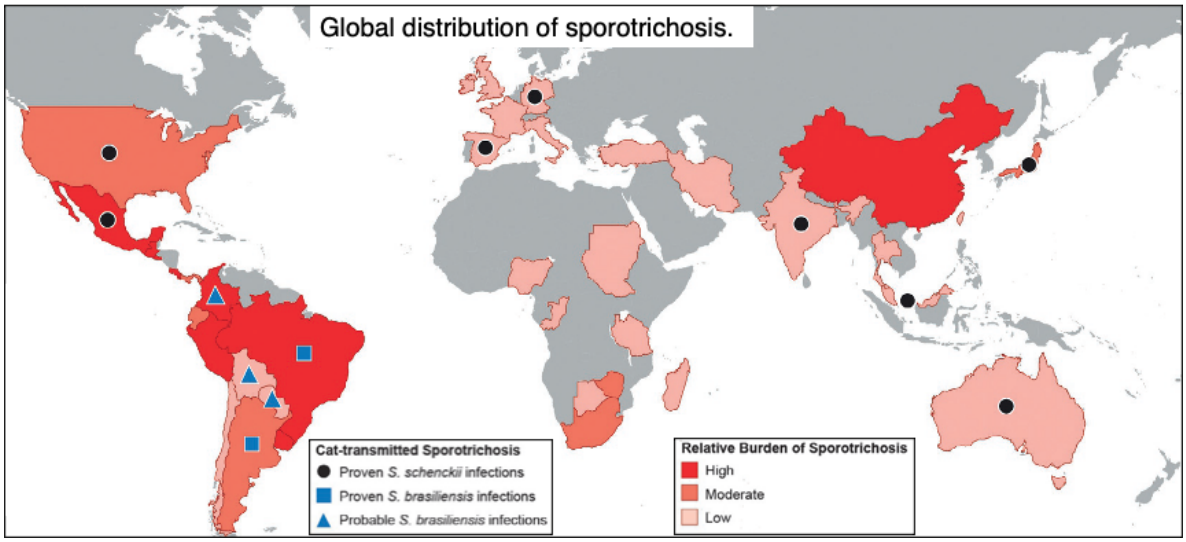
In 2021, estimates of fungal disease were published for a further six countries including Democratic Republic of Congo, Sierra Leone, Togo, Zimbabwe, Azerbaijan and Indonesia, and the estimate was updated for Trinidad and Tobago, principally with improved data from histoplasmosis in AIDS. In DRC, an estimated 5,177,000 people (5.4% of the population) are affected and in Indonesia, ~7.7 million Indonesians (2.89%). The new estimates cover a total population of 400 million people. Fungal disease estimates are now published for 80 countries and close to 80% of the global population as shown here.

1.2 Chromoblastomycosis and Sporotrichosis

Updated mapping of chromoblastomycosis and sporotrichosis was undertaken by GAFFI collaborators and Ambassadors in Brazil. For chromoblastomycosis this involved tracking reports on 7,740 published cases. They noted that the average time between the onset of the first lesion and diagnosis was 9.2 years (range from 1 month to 50 years). 81% of the cases were caused by *Fonsecaea* spp.



Sporotrichosis in Brazil is dominated by zoonic transmission from infected cats. It has spread to neighbouring countries. But it is also an endemic infection with very high rates in certain localities including Albacay, Peru with an annual incidence rate of 48 to 98 cases/100,000, and in Jalisco and Puebla, Mexico with a prevalence of 25 cases/100,000. Other hyperendemic areas include Colombia, Venezuela, Brazil, some localities in China and Japan.



1.3 Mucormycosis complicating COVID-19

GAFFI highlighted the horrendous outbreak of mucormycosis in India's second wave of COVID-19, with probably ~100,000affected. The national response to this emergency was led by GAFFI's Senior Advisor and Ambassador of India, Professor Arunaloke Chakrabarti, and an existing expert group Fungal Infections Study Group, which published key recommendations. A national shortage of amphotericin B was highlighted by this unparalleled emergency.

Goal 2
Improve access to diagnostics for fungal disease

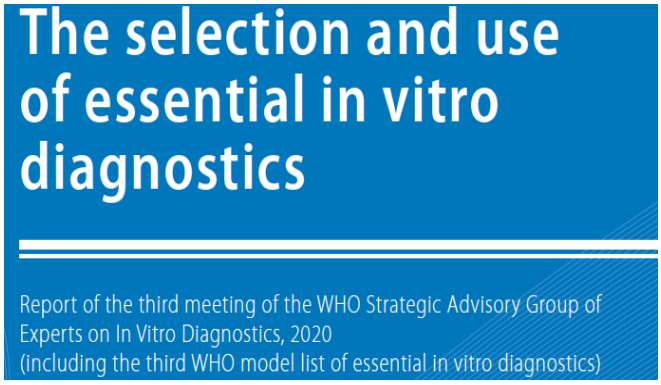
GAFFI is focussed on improving access to diagnosis for fungal diseases, having had major improvements in commercialised tests over the last decade. There are clearly research needs, notably work on implementation strategies for different clinical and geographical settings. Many fungal diseases (other than skin, hair, nail and eye infections) are relatively asymptomatic early in the course of infection and can mimic other illnesses. Specific tests are vitally important for diagnosis. There have been definite improvements in access over the past few years, but still many hospitals and countries have limited diagnostic capability. Complex test formats for some fungal conditions, expense, inadequate laboratory infrastructure and a lack of training are barriers to diagnostic testing.

2.1 Essential Diagnostics for fungal diseases and advanced HIV infection

In January 2021, the WHO issued its 3rd Essential Diagnostic List. It now includes *Aspergillus* antigen, *Aspergillus* IgG antibody and *Pneumocystis* PCR. The applications were made in the autumn of 2019, with COVID-19 slowing down the approval process. These tests are indicated for:

1. *Aspergillus* antigen – critical for the diagnosis of invasive aspergillosis which affects leukaemia, lung cancer, intensive care patients (including those with influenza and COVID-19), HIV and those admitted to hospital with COPD. It is far superior to culture. *Aspergillus* antigen tests commercially available are listed here: http://www.life-worldwide.org/fungal-diseases/antigen-testing

2. *Aspergillus* antibody – critical for the diagnosis of chronic pulmonary aspergillosis which both mimics and complicates TB of the lungs. *Aspergillus* antibody is 80-92% sensitive depending on the test used, again much more sensitive than culture. Antibody tests commercially available are listed here: http://www.life-worldwide.org/fungal-diseases/antibody-testing



3. *Pneumocystis* PCR – about 25% more sensitive than direct microscopy and 10% more sensitive than fluorescence microscopy, and the only test possible in young children with this infection. While doctors often suspect *Pneumocystis* pneumonia in AIDS, over-treatment leads to major drug side effects and no diagnosis is fatal. *Pneumocystis* PCR tests commercially available are listed here: http://www.life-worldwide.org/fungal-diseases/molecular-mycology

2.2 Results of the Partnership between GAFFI and Asociación de Salud Integral in Guatemala

The results of the demonstration project with ASI in Guatemala "**Minimising HIV deaths through rapid fungal diagnosis and better care in Guatemala**" has shown that access to rapid diagnosis is an essential tool to reach the UNAIDS target of reducing annual AIDS deaths. In this programme, rapid diagnostic testing has allowed earlier start of antiretroviral therapy for those who were eligible or to initiate life-saving treatment in those with an opportunistic infection. The analysis of the newly diagnosed HIV cohort of patients showed that 52.1% of the deaths were directly attributable to the infections screened (histoplasmosis, tuberculosis and cryptococcosis). Implementation of the programme resulted in increased treatment (5.1%) at the same time as a reduction in mortality (7% in those with a life-threatening infection (between 2017 and 2018) across the whole network. These results were described in the manuscript "A rapid screening programme for histoplasmosis, tuberculosis and

cryptococcosis reduces deaths in patients with HIV in Guatemala", published in Journal of Fungi. This programme provides direct evidence of the importance of access to recommended treatments for fungal infections such as liposomal amphotericin B and flucytosine, still not currently in place in Guatemala. Besides, the opportunistic screening programme has shown that previous estimates of histoplasmosis cases were underestimated. Our findings, published in 2021 in the journal Microorganism showed that histoplasmosis incidence in the screening programme were about two-fold higher than previous studies. Therefore, more cases should be expected with the implementation of a similar strategy in the region.

Data analysis from the Clínica Familiar Luis Angel Garcia (CFLAG), the biggest HIV health care facility in the network showed a continuing downward trend in opportunistic infection mortality in 2019. It was 25% in 2017 and fell to 19.4% in 2018 and further to 16.6% in 2019. However, similar to other programmes around the word, access to healthcare services and medicines were severely impacted by the COVID-19 pandemic. In the manuscript "Impact of the COVID-19 pandemic for people living with HIV in Guatemala", we evaluated the impact of the COVID-19 on the screening of life-threatening infections. This analysis showed that the number of samples for investigating OIs fell 38% between March and August 2020. Unfortunately, mortality in CFLAG patients with opportunistic infections increased 10.7% compared with the 2019 (27.3%, in 2020 vs. 16.6%, in 2019).

To minimise this impact, UNAIDS and WHO called on governments to provide multi-month dispensing for those PLWHIV who were stable. In Guatemala, a home delivery programme for antiretroviral therapies functioned for the network between 2020 to 2021, which should ameliorate some of the interruptions.

2.2.1 Next steps

- Continue to document the successes and challenges of the project in publications.
- Narda Medina to submit her PhD thesis which includes data analysis of several aspects of the project.
- Finalise a cost analysis of the implementation for OIs in the central DLH in collaboration with the Manchester Centre for Health Economics.
- Facilitate country and government ownership of the project.
- Work with the PAHO to ensure antifungal drug access to affordable prices, including flucytosine and liposomal amphotericin B though the government.
- Work with PAHO to strengthen and integrate the screening programme into the Ministry of Health.
- Assess the value of additional tests in the diagnostic portfolio, including LFA test for histoplasmosis, antigen detection for coccidioidomycosis and tuberculosis.

2.3 Survey of diagnostic capability and access in Africa, in partnership with GAFFI's country Ambassadors

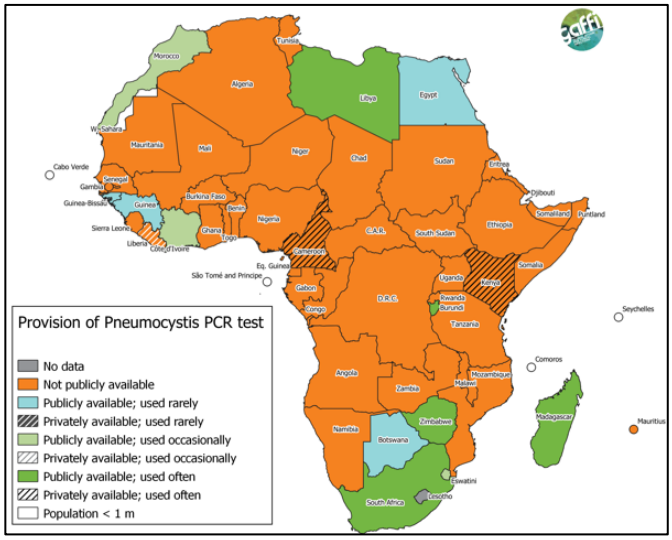
GAFFI has now completed and is analysing a detailed survey of diagnostic practice for fungal disease in 50 countries in Africa. GAFFI's Ambassador network was instrumental in delivering what is the first ever such survey.

One component of the survey was focussed on clinical procedures necessary to make a fungal diagnosis including:

- skin biopsy for fungal NTDs mycetoma, chromoblastomycosis and sporotrichosis,
- lumbar puncture to diagnose meningitis, notably cryptococcal meningitis,
- corneal scraping to diagnose fungal keratitis,
- spirometry to diagnose asthma (including fungal asthma) and COPD,
- bronchoscopy to diagnose invasive aspergillosis and *Pneumocystis* pneumonia.

The second component of the survey was related to radiology, chest X-ray, CT scans and MR scans.

The third component was related to laboratory tests, that are included on the WHO's Essential Diagnostic List, notably cryptococcal, *Histoplasma* and *Aspergillus* antigen, direct microscopy, fungal culture and blood culture, histopathology and *Aspergillus* antibody.



Additional elements included questions about fungal culture and biosafety level 3 laboratories, the level in the health system where testing is done, whether in the public or private sector and who pays for testing. GAFFI will issue a comprehensive report on all procedures and tests and individual country summary reports, as well as a series of medical speciality-related papers. The above map for *Pneumocystis* PCR released on World AIDS 2021, and clearly shows the many country gaps.

2.4 State Mycology Reference Laboratories in India

The Indian Council of Medical Research (ICMR) is now supporting six reference centres:

1. Assam Medical College covering Assam and northeast states
2. KJMC, Lucknow- Uttar Pradesh
3. AIIMS, Bhubaneswar- Orissa
4. AIIMS, Bhupal - Madhya Pradesh
5. AIIMS, New Delhi- Delhi and surrounding area
6. Hinduja Hospital, Mumbai- Maharashtra province

All six centres have a broad diagnostic portfolio. Three of them conducted virtual training workshops. They are engaged in mapping fungal diseases in their respective provinces.

2.5 *Aspergillus* antibody, *Histoplasma* antigen and cryptococcal antigen surveys

Several countries are undertaking surveys of people with advanced HIV disease and/or possible tuberculosis to ascertain the frequency of disease in their population, including Nigeria, Sierra Leone, Benin, Burkina Faso, Cameroon, Tanzania, Kenya, Uganda, Senegal, Vietnam and others. Hopefully these small studies will provide some preliminary estimates of incidence in these countries.

Goal 3
Improve access to appropriate and affordable antifungal therapeutics with a focus on generic agents

Access to affordable antifungal agents remains a critical goal for GAFFI, with limited some progress made in 2021.

3.1 Echinocandin antifungals (caspofungin, micafungin and anidulafungin)

GAFFI's application to the WHO for the echinocandins in partnership with GAFFI Ambassador Guillermo Garcia Effron (Argentina) to be listed as Essential on the 22nd Essential Medicines List was successful as announced here. This is important, especially for life-threatening *Candida* infections. Micafungin is the preferred agent, if available, because of its broader range of usage (special patient populations) in published data, notably neonates and chronic pulmonary aspergillosis in patient's refractory to azole therapy, intolerant to azoles and in those with azole resistant infections.

Country access is shown on the following access maps:

3.2 Single large dose of liposomal amphotericin B is successful therapy for cryptococcal meningitis

Several of GAFFI's Ambassadors and Senior Advisors (notably Professor David Meya in Uganda, Professor Nelesh Govender in South Africa and Professor Tom Harrison in the UK) have lead the recruitment of patients for the AMBITION study which compared a single large dose of liposomal Amphotericin B with 7 days of a lower dose in cryptococcal meningitis in AIDS. All patients also received concurrent flucytosine and fluconazole. The outcomes were broadly similar opening the way to a much simpler regimen for therapy. WHO guidelines are being updated. GAFFI was not a partner in the study but will play a role in disseminating the results widely.

3.3 Flucytosine registration and access

Flucytosine was registered for use in Malawi and South Africa, for the first time. Other registrations are pending in sub-Saharan Africa. Detailed roll out plans have been put in place in South Africa to ensure access across the country.

3.4 Global mapping of current availability and price of antifungal drugs

GAFFI continues to track antifungal access and display this online with maps. Multiple additions have been made including Romania, Mauritania, Libya, Tanzania, Gabon, Pakistan, Sierra Leone, Australia, Eritrea, Burundi and Djibouti.

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Goal 4
Improve education of health professionals about fungal disease

GAFFI's key partners in education are its Ambassador group who have organised a large number of educational events both in their countries and across borders? Although improving laboratory capacity through training is critical for improved care, workshops were not possible in most places in 2021. Nonetheless, the reach of GAFFI's network is impressive.

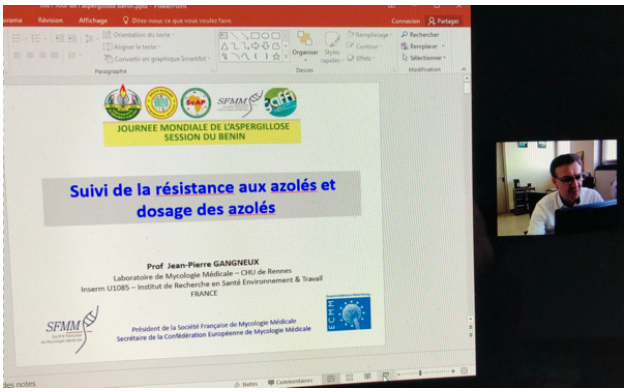
4.1 GAFFI Ambassadors

GAFFI's Ambassadors network expanded in 2021 to include Sulaiman Lakoh from Sierra Leone, Yolande Sissinto from Benin, Akila Fathallah from Tunisia, Samson Haumba from Eswatini, Pocha Kamudumuli from Malawi, Jeffrey Edwards from Trinidad and Tobago and Ngoc Nguyen from Vietnam. All GAFFI's Ambassadors are listed online. GAFFI has 75 Ambassadors in 67 countries. Their contributions to GAFFI's mission for 2021 are found in the publication section (selected outputs) and in the last section of this report.

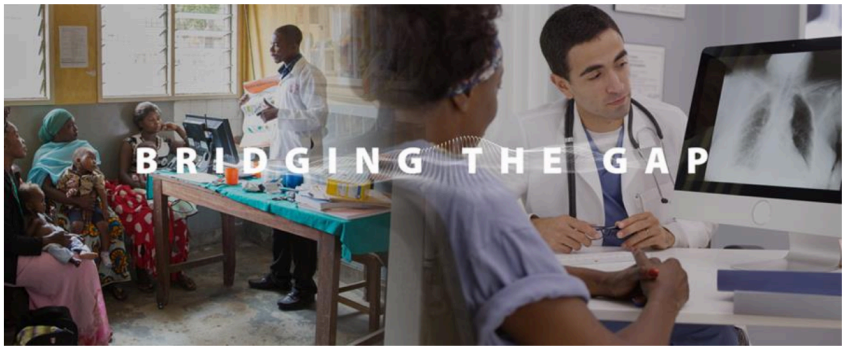
GAFFI is extremely grateful to its Ambassadors for their continuing efforts related to raising the awareness of fungal diseases, direct advocacy, educational initiatives and providing information about their country.

4.2 Educational events

Our Ambassador network held multiple events to celebrate World Aspergillosis Day in February 2021 – across Latin America, in Ghana, Nigeria, Mali, Malawi, Indonesia, Vietnam and Portugal.



In May 2021, GAFFI in partnership with IntriHealth, held a webinar on the use of technology and AI to bridge gaps in fungal disease diagnosis. The application of AI and teleradiology to aid in the diagnosis of chronic pulmonary aspergillosis in low-resource settings, the reduction of chest x-ray turnaround times, and the potential of AI to help 'leapfrog' current diagnostics gaps in Africa was discussed in a fireside chat between IntriHealth CEO, Mike Simpson and Emma Orefuwa (Head of Programmes, Africa).



In August 2021, GAFFI in partnership with Omega Diagnostics co-organised an educational webinar covering the theme 'Identifying Advanced HIV Disease with immediate CD4 testing in Africa'. This webinar included a number of African experts including Dr Moussa Sarr (IRESSEF, Senegal), Tafese Tufa (Arsi University College of Health Sciences, Ethiopia), Dr David Meya (Makerere University, Uganda) and Joseph Oerson (Omega Diagnostics). Presentations were given on VISITECT CD4 point of care test, advantages of POC versus central laboratory testing, slow and fast ART responders and improving access to same day CD4 testing. Over 100 people attended, and CPD/CME points were awarded from the Royal College of Pathologists on request. A recording of the webinar can be found here.

4.3 Online lectures on fungal diseases

GAFFI's educational partner LIFE-Worldwide has relaunched its website on a new URL www.fungaleducation.org. The content is available in English and Spanish, and text is integrated with video to widen its appeal. Over 65 fungal diseases topics are covered, including antifungal chemotherapy. A comprehensive resource on global and regional and many country guidelines for the diagnosis and management of fungal disease is a prominent feature.

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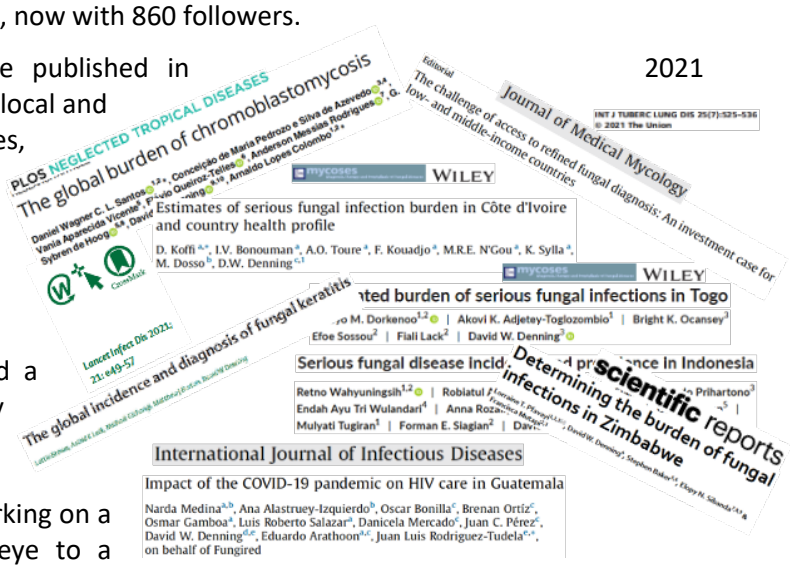
Advocacy and awareness

GAFFI's advocacy has been instrumental in driving awareness. Advocacy has and remains focused on the WHO and its regional offices but is broadening to include country ministries of health and related institutions. GAFFI issued 21 press releases and many more tweets in 2021. Some of its stories hit the headlines. GAFFI has a twitter following with >1,900 followers, a 12% growth over the past year. In addition, GAFFI launched a LinkedIn profile, now with 860 followers.



An unprecedented 43 publications were published in 2021 including burden of fungal disease papers, local and national epidemiology studies, documentation of performance of fungal diagnostic tests, consensus guidelines and position papers. Some of these were highlighted in press releases, others in conference presentations.

GAFFI's advocacy with the WHO has had a number of tangible outcomes including key groups of fungal diagnostics and antifungal agents listed as Essential. Through most of 2021, WHO has been working on a Fungal Pathogen Priority List, with an eye to a combination of public health importance and poor clinical outcomes, partly because of antifungal resistance.

A global strategy for Ending Cryptococcal Meningitis Deaths by 2030 was launched in partnership with multiple partners including the WHO, CHAI, CryptoMAG, CDC, MSF, DNDi, ITPC and several academic institutions. This document lays out keys steps that are required to have a major impact on minimising deaths from cryptococcal meningitis in AIDS including costing tools for antifungals, and evidence-based clinical management actions.

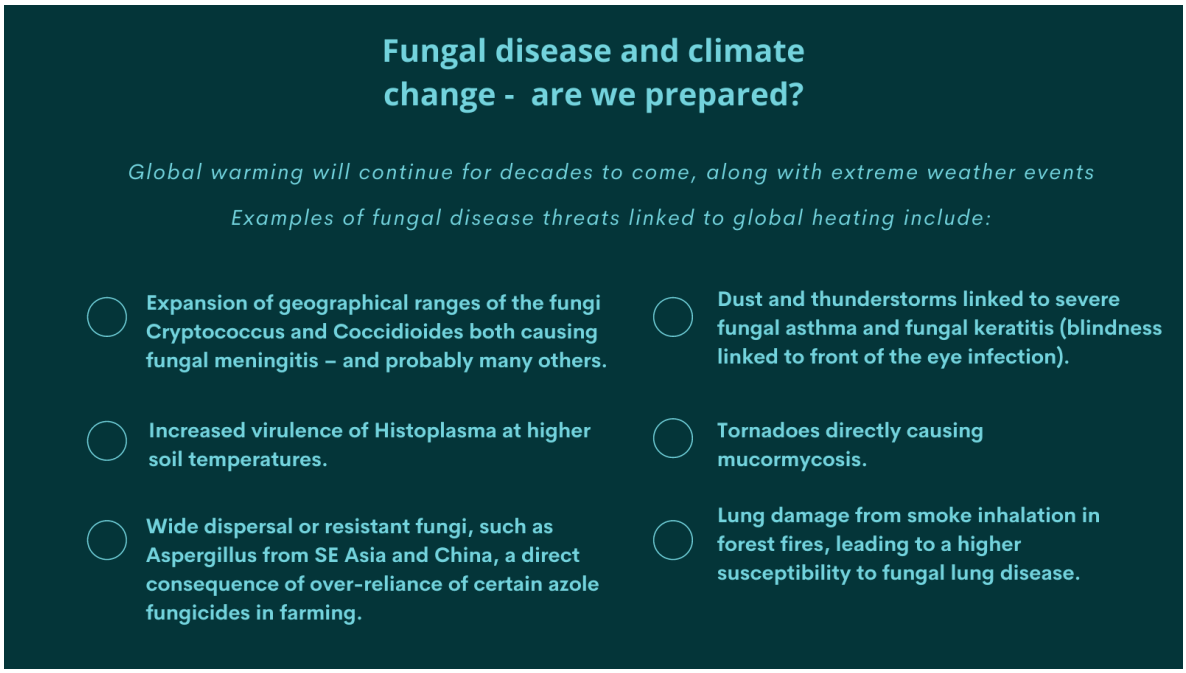
The African Diagnostic survey, conducted in 2021, will have profound repercussions for better management of fungal diseases across the continent. GAFFI is in constant dialogue with Africa CDC and its Ambassadors across Africa to enable significant improvements in diagnostic access.

A call to better address the potentially lethal fungal infection primarily in HIV patients in SE Asia, talaromycosis (caused by the environmental fungus *Talaromyces marneffei*) was issued with a paper published in Lancet Global Health.

As noted above, GAFFI has issued five policy briefs intended to summarise its primary focus of effort and ongoing efforts:

- Access to fungal disease diagnosis in country health systems needed to combat fatalities
- Minimising fungal disease deaths in advanced HIV disease and AIDS
- Chronic pulmonary aspergillosis: global misdiagnosis of TB-like fungal lung disease
- Neglected fungal tropical diseases – truly neglected and not so tropical
- Antifungal drug resistance – a dramatic global problem

Given the incontrovertible global heating events witnessed and ongoing, GAFFI issued a tweet about the likely implications on fungal diseases.


Fungal disease and climate change - are we prepared?
Global warming will continue for decades to come, along with extreme weather events
Examples of fungal disease threats linked to global heating include:
Expansion of geographical ranges of the fungi Cryptococcus and Coccidioides both causing fungal meningitis – and probably many others.
Increased virulence of Histoplasma at higher soil temperatures.
Wide dispersal or resistant fungi, such as Aspergillus from SE Asia and China, a direct consequence of over-reliance of certain azole fungicides in farming.
Dust and thunderstorms linked to severe fungal asthma and fungal keratitis (blindness linked to front of the eye infection).
Tornadoes directly causing mucormycosis.
Lung damage from smoke inhalation in forest fires, leading to a higher susceptibility to fungal lung disease.

GAFFI Ambassadors' awareness and educational initiatives

Latin America

The 19th INFOCUS meeting was held in Cordoba 18-20th November 2021 attracted a total of 500 attendees over 2 days. A wide range of fungal diseases were covered.

World Aspergillosis Day on February 1st, 2021, was marked by an INFOCUS webinar on invasive and chronic pulmonary aspergillosis. Drs Flavio Telles Queiroz and Fernando Riera chaired the meeting and 200 people attended.

GAFFI was involved in the scientific committee of the MyA (Fungal Infections in People with Advanced HIV in the Americas) held online with the following objectives: (i) to generate awareness on critical interventions for reducing morbidity and mortality due to fungal diseases among individuals with advanced HIV disease. (ii) To discuss solutions in implementing rapid diagnostics tests for TB and fungal infections, sharing lessons learned from implementation. (iii) To review and share experiences in the implementation of WHO guidelines in HIV advanced disease, cryptococcal infection and histoplasmosis, identifying challenges and opportunities. (iv) To review scientific advances in the management and treatment of fungal diseases. The results of the Guatemala program were presented by Eduardo Arathoon and Narda Medina, and a talk showcasing GAFFI's vision of future laboratory integration was delivered by Juan Luis Rodriguez Tudela.

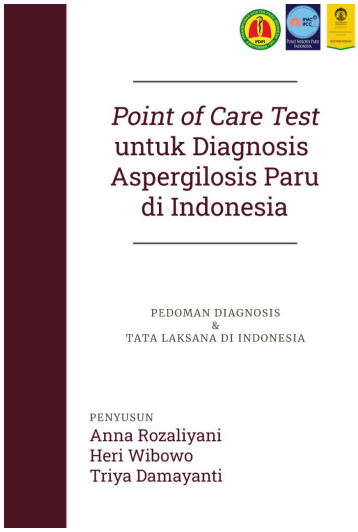
Brazil (Professor Arnaldo Colombo and Flavio Telles Queiroz)

Dr Daniel Wagner Santos from Brazil published an updated global map and comprehensive literature survey of chromoblastomycosis (7,740 patients), with Arnaldo Colombo and Flavio Telles Queiros and colleagues. Flavio Telles Queiros and Professor Alexandro Bonifaz (Mexico) also published (with colleagues) a comprehensive review of sporotrichosis with an updated global map.

Indonesia (Professor Retno Wahyuningsih and colleagues)

The estimated burden of fungal disease in Indonesia was published. Additional work on the detection of *Aspergillus* antibody, compared to western blot was also published.

- The third part of the Pulmonary Webinar series (PULSE) on Allergic pulmonary mycosis and Occupational Mycoses was presented and attracted 270 participants from basic science to clinical application, and several other presentations on aspergillosis.



India (Professor Arunaloke Chakrabarti)

The national response to India's mucormycosis emergency was lead by Professor Arunaloke Chakrabarti, and an existing expert group Fungal Infections Study Group, with many educational events.

Vietnam (Dr Nguyễn Thị Bích Ngọc)
World Aspergillosis Day was marked with a national online meeting of 10 topics covered by 7 speakers and presided over by Professor Prof Nguyễn Viết Nhung the Director of the National Lung Hospital in Hanoi.

Portugal (Dr Raquel Sabino)
For the World Aspergillosis Day 2021, a text on aspergillosis and CAPA was sent to all members of the Portuguese Society of Mycology, and during that day and following week, several posts were made from Raquel Sabino's Facebook personal page, LinkedIn page and from the Facebook page of the Portuguese Society of Mycology and distributed by Pfizer in Portugal.

During 2021, 10 physicians (pathologists and infectious diseases clinicians) performed their training in the Reference Mycology Laboratory at the National Health Institute Dr. Ricardo Jorge. These trainings raised awareness of the majority of fungal infections, etiological agents, epidemiology of those infections and available diagnostic methods. GAFFI leaflets were delivered to all.

Several talks and classes dedicated to raise the awareness on fungal infections and where GAFFI role was disseminated, including postgraduate healthcare students:

- *Aspergillus* as zoonotic agent of infection? I Postgraduate Course on ONE HEALTH – Human, Animal and Environmental Health. Faculdade de Medicina da Universidade de Lisboa 18 December 2021.
- Fungi and Fungal Infections. 16º Postgraduate Course on Infectious Diseases, 15 November de 2021.
- Azole resistances in *Aspergillus*: a problem among CAPA patients? – Workshop on Invasive Fungal Infections during SARS-CoV-2 pandemics. Lisboa, 19 Novembro 2021.
- Phylogenetic analysis and molecular identification of filamentous fungi. The importance of phylogeny, taxonomy, epidemiology, and antifungal resistance. Practical context: from the fungal isolate to molecular identification - III Postgraduate course on Clinical and Laboratorial Parasitology and Mycology, Instituto Universitário Egas Moniz, Lisbon, 24 April 2021.

And to undergraduate students:

"Science on the Screen: *Aspergillus* and aspergillosis: major concerns and epidemiological trends – the perspective of a National Reference Laboratory surveillance programme" Universidade do Minho, 8 de Março 2021.

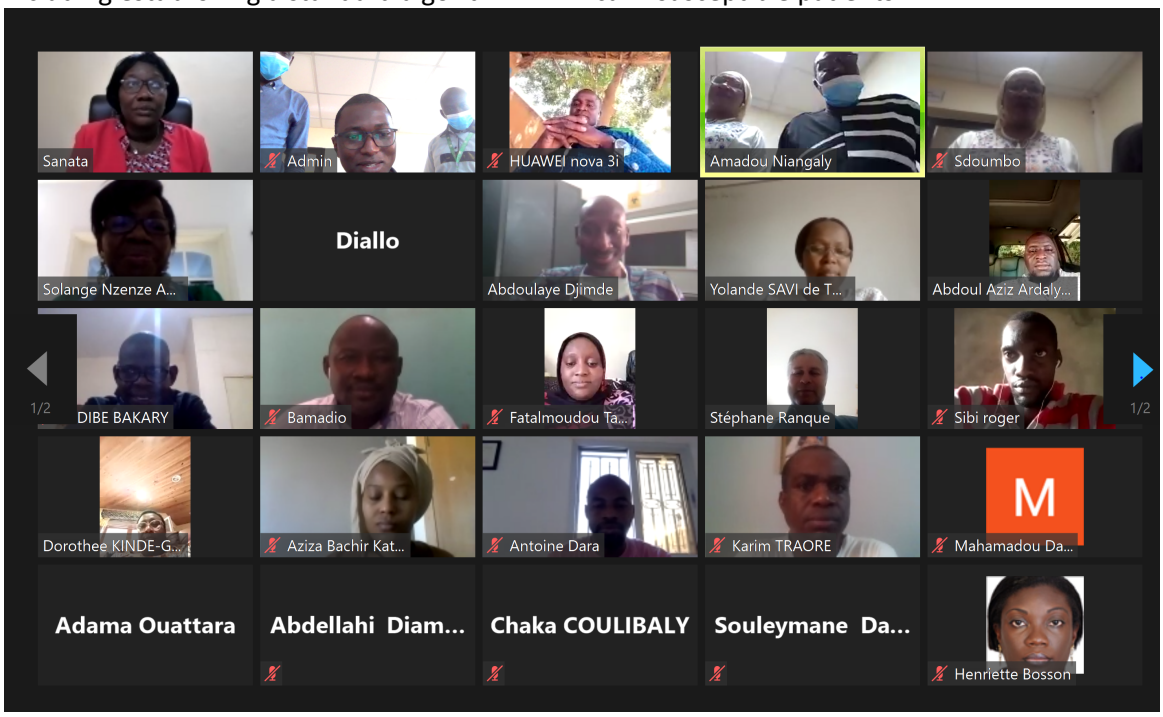
Saudi Arabia (Dr Aiah Khateb)

Presentations made by Aiah Khateb and Ahmed Albarraq to the Saudi Critical Care conference.

A mycology clinical practice and research network has been formed in Saudi Arabia, which will form a nucleus of expertise for the future.

Mali (Professor Safiatou Niare Doumbo)

A hybrid meeting to highlight World Aspergillosis Day was held and attracted 77 participants from Benin, Burkina Faso, Ivory Cost, Senegal, France, Gabon, Niger, Cameroon, The Netherlands. The meeting outcomes included a plan to change the care and diagnosis of aspergillosis in TB patients, including establishing a standard algorithm in Africa in susceptible patients.



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Ghana (Bright Ocansey)

An international seminar was hosted by the Ghana Medical Mycology Group on World Aspergillosis Day and attracted 80 participants from Ghana, Nigeria, Togo, Kenya, Cote D'Ivoire, Indonesia, UK, USA, Rep of Congo, DRC, Cameroon, Uganda and Saudi Arabia. Ghanaian healthcare professionals provided feedback of having learned about chronic pulmonary aspergillosis. In particular, the Heads of the Chest Diseases Unit and Chest Clinic and their colleagues at the Korle-Bu Teaching Hospital (serving as National TB Referral Centre), have adopted *Aspergillus* testing for suspicious cases.

Bright Ocansey also spoke about engagement at the Trends in Medical Mycology meeting in Aberdeen in October 2021.

Nigeria (Dr Rita Oladele and Dr Samuel Fayemiwo)

Several papers were published directly supporting GAFFI's mission in Nigeria including:

- Closing the knowledge gap in mycology in Nigeria by leveraging e-learning: perspectives from the field.
- Determining the cut-off values for *Aspergillus* IgG testing in Nigerians for one commercial assay.
- Laboratory diagnostic capacity for fungal infections in Nigerian tertiary hospitals: A gap analysis survey

An international meeting to highlight aspergillosis was held with 80 participants from Nigeria, Uganda, Ghana, Cote D'Ivoire, Kenya, Tanzania, Ethiopia, Canada, UK, DRC, Republic of Congo, Canada and Cameroon. This meeting resulted in improved awareness of aspergillosis among clinicians and lab staff from a variety of countries and strong engagement from GAFFI ambassadors in other parts of Africa. It also provided an impetus from clinical Heads of Departments to acquire and utilise *Aspergillus* antibody and antigen test kits in Nigeria.

A major study of disseminated histoplasmosis in HIV/AIDS was undertaken in multiple sites in Nigeria by Rita Oladele. She spoke about this at the Trends in Medical Mycology meeting in Aberdeen in October 2021 and plans to publish the full results in 2022.

Democratic Republic of Congo (Dr Guyguy Kamwiziku)

On the 30th September 2021, GAFFI ambassador for the DRC Guyguy Kamwiziku, with colleagues from the Dept of Microbiology in University of Kinshasa and the support of GAFFI, co-organised the first event focused on fungal disease in DRC. The main objective of this event was to sensitise the scientific community in DRC to the burden of fungal disease in the country and across Africa, gaps in treatment and diagnosis. During this meeting, a resolution was passed to establish a medical mycology society in DRC to progress initiatives to improve access to rapid tests, and antifungal medicines in DRC.

Malawi (Pocha Kamudumuli)
An in person seminar was held to highlight aspergillosis in Malawi, possibly for the first time ever. A plan for screening for *Aspergillus* antibody in smear/GeneXpert negative cases was in development after the meeting.

Uganda (Dr Felix Bongomin and Professor David Meya)
Some important papers emanated from Uganda, influencing the field.

- A review of the epidemiology of fungal diseases in Africa,
- Mapping of chronic pulmonary aspergillosis in Africa.
- A summary of the commonalities and differences between pulmonary TB and chronic pulmonary aspergillosis
- A review of the surgical management of chronic pulmonary aspergillosis in Africa.

Many patients have been enrolled into the AMBITION study of shorter, higher doses of liposomal amphotericin B for cryptococcal meningitis, which should report in Q3 2021.

Cameroon (Dr Christine Mandengue)
On World Aspergillosis Day a webinar for both the general public and also for healthcare professionals was held and attracted 250 participants. The focus was on awareness building of aspergillosis across the country.

Several papers highlighting disseminated histoplasmosis in AIDS were published:

- A pilot study of urinary *Histoplasma* antigen detection. The manufacturers cut-off might be too high and further work is necessary.
- A review of histoplasmosis in HIV in Africa.

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Financial summary of GAFFI & GAFFI UK

GAFFI increased its revenue and spending in 2021, compared with 2020.

UNAUDITED COMBINED BALANCE SHEET AS AT 31 DECEMBER 2020

BILAN COMBINE NON AUDITE AU 31 DECEMBRE 2020

	CHF 2021	CHF 2020
ASSETS / ACTIF		
Cash at bank and in hand / Liquidités	**223,901**	141,183
Accrued income / Actif transitoires	**29,114**	2,170
TOTAL ASSETS / TOTAL DE L'ACTIF	**253,015**	143,353
LIABILITIES AND CAPITAL / PASSIF		
TOTAL CURRENT LIABILITIES / TOTAL DES ENGAGEMENTS A COURT TERME	**27,341**	25,052
RESTRICTED FUNDS / FONDS DESIGNES	**113,581**	9,154
CAPITAL / FONDS PROPRES		
Initial Capital/ Capital de base	**50,000**	50,000
Free capital / Fonds libre	**62,093**	59,147
TOTAL LIABILITIES AND CAPITAL / TOTAL DU PASSIF ET FONDS	**253,015**	143,353

UNAUDITED COMBINED STATEMENT OF OPERATIONS FOR THE YEAR ENDED 31 DECEMBER 2021

COMPTE D'EXPLOITATION COMBINE NON AUDITE POUR L'EXERCICE CLOS LE 31 DECEMBRE 2021

	CHF 2021	CHF 2020
INCOME / REVENUS		
Donations general/ Donations générale	**180,448**	174,365
Direct project donations/ Donations project directe	**165,307**	49,200
TOTAL INCOME / TOTAL DES REVENUS	**345,755**	223,565
EXPENSES / CHARGES		
Direct project charges/ charges de project direct	**157,943**	40,046
Other charges/ d'autres charge	**80,439**	38,400
TOTAL EXPENSES / TOTAL DES CHARGES	**238,382**	78,446
SURPLUS (DEFICIT) / SURPLUS (DEFICIT)	**107,373**	145,119

The foregoing financial reports are unaudited combined accounts of GAFFI and GAFFI UK. GAFFI UK accounts are translated into Swiss francs based on an average exchange rate for the reporting year for the statement of operations and at the year end date for the balance sheet. Any inter entity transactions are removed at the actual exchange rate when preparing the combined accounts.

We would like to thank all those organisations and individuals that continued to support GAFFI.

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Glossary of terms, organisations and abbreviations:

AI	Artificial Intelligence
AMR	Antimicrobial Resistance
CDC	Centers for Disease Control and Prevention (USA)
CHAI	Clinton Health Access Initiative
DNDi	Drugs for Neglected Diseases Initiative
EDL	Essential Diagnostics List
ITPC	International Treatment Preparedness Coalition
LATAM	Latin American countries
LFA	Lateral Flow Assay
MSF	Médicines Sans Frontières
LIFE	Leading International Fungal Education
NICD	National Institute for Communicable Diseases (South Africa)
PAHO	Pan-American Health Organisation
PCR	Polymerase chain reaction
SDG	Sustainable Development Goals
TB	Tuberculosis
WHO	World Health Organisation

Publications

Burden of disease papers:

1. Brown L, Leck AK, Gichangi M, Burton MJ, Denning DW. The global incidence and diagnosis of fungal keratitis. Lancet Infect Dis 2021;21:e49-e57.
2. Alfouzan W, Al-Wathiqi F, Altawalah H, Asadzadeh M, Khan Z, Denning DW. Human Fungal Infections in Kuwait-Burden and Diagnostic Gaps. J Fungi (Basel). 2020;6(4):E306.
3. Al-Hatmi AMS, Al-Shuhoumi MA, Denning DW. Estimated Burden of Fungal Infections in Oman. J Fungi 2020;7:5.
4. Koffi D, Ira V. Bonouman IV, Toure AO, Kouadjo F, M'boh N'GRE, Sylla K, DossoM, Denning DW. Estimates of Serious Fungal Infection burden in Côte d'Ivoire and Country Health Profile. J Mycol Med 2021;31:101086.
5. Prakash H, Chakrabarti A. Epidemiology of Mucormycosis in India. Microorganisms 2021;9(3):523.
6. Amona FM, Denning DW, Moukassa D, Develoux M, Hennequin C. Histoplasmosis in the Republic of Congo dominated by African histoplasmosis, *Histoplasma capsulatum* var. *duboisii*. PLoS Negl Trop Dis 2021;15:e0009318.
7. Pfavayi LT, Denning DW, Baker S, Sibanda EN, Mutapi F. Determining the burden of fungal infections in Zimbabwe. Sci Rep 2021;11:13240.
8. Ekeng BE, Edem K, Amamilo I, Panos Z, Denning DW, Oladele RO. Histoplasmosis in children; HIV/AIDS not a major driver. J Fungi 2021:7:530.
9. Nguyen NTB, Le Ngoc H, Nguyen NV, Dinh LV, Nguyen HV, Nguyen HT, Denning DW. Chronic pulmonary aspergillosis situation among post tuberculosis patients in Vietnam: An observational study. J Fungi 2021;7: 532.
10. Lakoh S, Orefuwa E, Kamara MN, Jiba DF, Kamara JB, Kpaka S, Denning DW. The burden of serious fungal infections in Sierra Leone: a national estimate. Ther Adv Infectious Dis 2021;8:1-12.
11. Oladele R, Ogunsola F, Akanmu A, Stocking K, Denning DW, Govender N. Opportunistic fungal infections in persons living with advanced HIV disease in Lagos, Nigeria; a 12-year retrospective study. Afr Health Sci 2021;20:1573-81.
12. Wahyuningsih R, Adawiyah R, Sjam R, Prihartono J, At Wulandari E, Rozaliyani A, Ronny R, Imran D, Tugiran M, Siagian FE, Denning DW. Serious fungal disease incidence and prevalence in Indonesia. Mycoses 2021;64:1203-12.
13. Santos DWCL, de Azevedo CMP, Queiroz-Telles F, Vicente VA, Rodrigues AM, de Hoog GS, Denning DW, Colombo AL. The global burden of chromoblastomycosis. PLoS NTD 2021;15(8):e0009611.
14. Olum R, Osaigbovo II, Baluku JB, Stemler J, Kwizera R, Bongomin F. Mapping of Chronic Pulmonary Aspergillosis in Africa. J Fungi (Basel). 2021;7(10):790.
15. Kamwiziku GK, Makangara JC, Orefuwa E, Denning DW. Serious fungal diseases in Democratic Republic of Congo - incidence and prevalence estimates. Mycoses 2021;64:1159-69.
16. Bongomin F, Adetona Fayemiwo S. Epidemiology of fungal diseases in Africa: A review of diagnostic drivers. Curr Med Mycol. 2021 Mar;7(1):63-70.
17. Huseynov R Javadov SS, Osmanov A, Khasiyev S, Valiyeva SR, Almammadova E, Denning DW. The burden of serious fungal infections in Azerbaijan. Ther Adv Infect Dis 2021;8:20499361211043969.
18. Edwards RJ, Boyce G, Alastruey-Izquierdo A, Denning DW. Updated incidence and prevalence of serious fungal infections in Trinidad and Tobago. Int J Infect Dis Regions 2021;1:34-40.
19. Dorkenoo AM, Adjetey-Toglozombio AK, Ocansey BK, Sossou E, Lack F, Denning DW. Estimated Burden of Serious Fungal Infections In Togo. Mycoses 2021;64:1535–41.

Key papers, reviews and position papers

1. Shroufi A, Chiller T, Jordan A, Denning DW, Harrison TS, Govender NP, Loyse A, Baptiste S, Rajasingham R, Boulware DR, Ribeiro I, Jarvis JN, Van Cutsem G. Ending deaths from HIV-related cryptococcal meningitis by 2030. Lancet Infect Dis 2021;21:16-18.
2. Mandengue CF, Ekeng BE, Oladele RO. Disseminated Histoplasmosis; A Threat in Advanced HIV Disease Population in Sub-Saharan Africa? J Adv Med Meical Res 2021;33:115-144.
3. Banerjee S, Denning DW, Chakrabarti A. One Health aspects and priority roadmap for Fungal Diseases. Indian J Med Res 2021;153:311-9.
4. Medina N, Alastruey-Izquierdo A, Bonilla O, Gamboa O, Mercado D, Pérez JC, Salazae LR, Arathoon E, Denning DW, Rodriguez-Tudela JL. A Rapid Screening Programme for Histoplasmosis, Tuberculosis, and Cryptococcosis Reduces Mortality in HIV Patients from Guatemala. J Fungi 2021;7:268.
5. Rozaliyani A, Setianingrum F, Azahra S, Abdullah A, Fatril AE, Rosianawati H, Burhan E, Handayani D, Arifin AR, Zaini J, Tugiran M, Adawiyah R, Syam R, Wibowo H, Wahyuningsih R, Kosmidis C, Denning DW. Performance of LDBio Aspergillus WB and ICT Antibody Detection in Chronic Pulmonary Aspergillosis. J Fungi (Basel) 2021;7(4):311.
6. Nargesi S, Bongomin F, Hedayati MT. The impact of COVID-19 pandemic on AIDS-related mycoses and fungal neglected tropical diseases: Why should we worry? PLoS Negl Trop Dis 2021;15(2):e0009092.
7. Kuate MPN, Ekeng BE, Kwizera R, Mandengue C, Bongomin F. Histoplasmosis overlapping with HIV and tuberculosis in sub-Saharan Africa: challenges and research priorities. Ther Adv Infect Dis. 2021;8:20499361211008675.
8. Orefuwa E, Gangneux JP, Denning DW. The challenge of access to refined fungal diagnosis: An investment case for low- and middle-income countries. J Mycol Med 2021;31:101140.
9. Kuate MPN, Nyasa R, Mandengue C, Tendongfor N, Bongomin F, Denning DW. Screening for acute disseminated histoplasmosis in HIV disease using urinary antigen detection enzyme immunoassay: A pilot study in Cameroon. J Microbiol Methods 2021;185:106226.
10. Kwizera R, Bongomin F, Olum R, Meya DB, Worodria W, Bwanga F, Fowler SJ, Gore R, Denning DW, Kirenga BJ. Fungal asthma among Ugandan adult asthmatics. Med Mycol 2021;59:923-933.
11. Otu A, Oladele RO, Orefuwa E. Closing the knowledge gap in mycology in Nigeria by leveraging e-learning: perspectives from the field. Ther Adv Infect Dis. 2021 Jun 29;8:20499361211021689.
12. Kwizera R, Bongomin F, Olum R, Worodria W, Bwanga F, Meya DB, Kirenga BJ, Gore R, Denning DW, Fowler SJ. Evaluation of an *Aspergillus* IgG/IgM lateral flow assay for serodiagnosis of fungal asthma in Uganda. PLoS One 2021;16:e0252553.
13. Denning DW. Diagnosing pulmonary aspergillosis is much easier than it used to be: A new diagnostic landscape. Int J Tuberc Lung Dis 2021;25:525-536.
14. Baluku JB, Nuwagira E, Bongomin F, Denning DW. Pulmonary TB and chronic pulmonary aspergillosis: clinical differences and similarities. Int J Tuberc Lung Dis 2021;25:537-546.
15. Osaigbovo II, Bongomin F. Point of care tests for invasive fungal infections: a blueprint for increasing availability in Africa. Ther Adv Infect Dis 2021;8:20499361211034266.
16. Bongomin F, Olum R, Kwizera R, Baluku JB. Surgical management of chronic pulmonary aspergillosis in Africa: A systematic review of 891 cases. Mycoses 2021;64(10):1151-1158.
17. Medina N, Alastruey-Izquierdo A, Bonilla O, Ortíz B, Gamboa O, Salazar LR, Mercado D, Pérez JC, Denning DW, Arathoon E, Rodriguez-Tudela JL; Fungired. Impact of the COVID-19 pandemic on HIV care in Guatemala. Int J Infect Dis 2021;108:422-427.
18. Meya DB, Tugume L, Nabitaka V, Namuwenge P, Phiri S, Oladele R, Jibrin B, Mobolaji-Bello M, Kanyama C, Maokola W, Mfinanga S, Katureebe C, Amamilo I, Ngwatu B, Jarvis JN, Harrison TS, Shroufi A, Rajasingham R, Boulware D, Govender NP, Loyse A. Establishing targets for advanced HIV disease: A call to action. South Afr J HIV Med 2021;22(1):1266.

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20. Van Rhijn N, Denning DW. Is an azole resistant *Aspergillus* hotspot emerging in South-East Asia? [Editorial] Environ Microbiol 2021; 23:7275-7277.
21. Sehgal IS, Dhooria S, Prasad KT, Muthu V, Aggarwal AN, Chakrabarti A, Agarwal R. Anti-fungal agents in the treatment of chronic pulmonary aspergillosis: Systematic review and a network meta-analysis. Mycoses. 2021 Sep;64(9):1053-1061.
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24. Queiroz-Telles F, Bonifaz A, Rossow J, Chindamporn A. *Sporothrix* and Sporotrichosis, Reference Module in Biomedical Sciences, Elsevier, 2021. https://doi.org/10.1016/B978-0-12-818731-9.00046-X

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Press releases and GAFFI news items in 2021 (www.gaffi.org/media/news/)

Launch of the Neglected Tropical Diseases (NTD) Roadmap by WHO focuses on fungal skin disease
Posted 27 January 27 2021.

3rd Essential Diagnostics' List Launch
Posted 29 January 2021.

GAFFI's Chief Executive honoured as a Fellow of the American Academy of Microbiology
Posted 18 February 2021.

GAFFI 's Annual report outlines its new strategy – access to diagnostics and antifungals, the centerpiece of its efforts
Posted 23 March 2021.

Fungal disease diagnosis is lifesaver for patients with HIV and AIDS
Posted 12 April 2021.

University of Manchester helping change the understanding and treatment of Aspergillus disease globally
Posted 22 April 2021.

Special Webinar Announcement: Ending Cryptococcal Meningitis Deaths by 2030: A New Global Initiative
Posted 09 May 2021.

Rapid spread of Mucormycosis, the black fungus, spreading amongst COVID patients suffering from diabetes in India
Posted 10 May 2021.

Dr Ana Alastruey-Izquierdo to coordinate GAFFI's programmes in Latin America and Caribbean
Posted 16 May 2021.

Doctors around the world call for rapid response to deadly mucormycosis (the so-called "black fungus") found in COVID patients in India.
Posted 17 May 2021.

Green fungus' Aspergillus now noticed in India: nearly triples mortality in severe Covid-19
Posted 23 June2021.

Covid-19 reverses gains in survival rates in HIV patients
Posted 06 July 2021.

Double country estimates of fungal disease published for Indonesia and Democratic Republic of Congo
Posted 13 July 2021.

Climbing antifungal drug resistance in South-East Asia 'worrying'
Posted 11 August 2021.

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GAFFI IS NOW LOOKING FOR NEW BOARD MEMBERS
Posted 28 September 2021.

Antifungal echinocandins added to the WHO's Essential Medicines List
Posted 05 October 2021.

Fungal Disease Experts Call for Talaromycosis to be listed as a Neglected Tropical Disease
Posted 25 October 2021.

Less than 15% of African countries have access to life-saving diagnostic for common AIDS-defining respiratory illnesses.
Posted 01 December 2021.

Indonesian study reveals missed diagnosis of fungal infections in treated TB patients, with global implications
Posted 07 December 2021.

Histoplasmosis in PLHIV – the more you look, the more you find in endemic areas
Posted 21 December 2021.