Report on activities for 2015
Summary

GAFFI has progressed its mission to reduce illness and death associated with fungal diseases worldwide during 2014/15, its second year of operation. The disabling and stigmatising fungal tropical skin disease ‘Chromoblastomycosis’ has been added to GAFFI’s five priority diseases.

GAFFI’s key activities have included:

- **‘95-95 by 2025’ 10 year Roadmap**: GAFFI has drawn up a 10 year global roadmap for fungal diseases following a stakeholder meeting in Seattle in February 2015. GAFFI has estimated that with provision of fungal diagnostics, antifungal therapies, and development of expertise through Reference Laboratories in each country, the decrease of opportunistic fungal infections in AIDS will save over a 1,000,000 lives every year.

- **GAFFI called on governments to support the reduction in AIDS deaths from 1,500,000 to under 500,000 a year. The Roadmap was mailed to every Minister of Health and numerous international health agencies, and highlighted in Lancet Infectious Diseases and Thorax journals.**

- **Burden of fungal diseases**: now estimated for 5 billion people (71% of the world’s population)

- **Fungal diagnostics**: A national program of provision and training in fungal diagnostics for AIDS-related infections has been funded in Guatemala by GAFFI. Additional progress has been made on Aspergillus antibody testing with clear indications that many ‘smear negative TB’ cases are actually aspergillosis. A new project to develop a point of care test for fungal keratitis has been funded by GAFFI.

- **Antifungal treatments**: Availability and costs of amphotericin B, flucytosine, fluconazole and itraconazole for most countries has been ascertained and a paper summarizing this drafted. Amphotericin B remains unavailable in 64 countries, flucytosine in 94, fluconazole in 3 and itraconazole in 12.

- **Health professional education**: Efforts to educate healthcare professionals about fungal diseases have intensified with courses in Nigeria, Uganda and Brazil. Masters students in Medical Mycology are now graduating each year. The quarterly LIFE newsletter is emailed to over 9,000 health professionals around the world. Usage of the LIFE website is ~12,000 unique users monthly.
**GAFFI’s Goals:**

GAFFI has completed 30 months of operations from July 2013. GAFFI’s achievements against its Year 2 goals are summarised in this review.

GAFFI has 4 primary long term goals, supported by advocacy:

- **Goal 1** - Increase awareness of the impact of fungal disease
- **Goal 2** - Improve access to diagnostics for fungal disease
- **Goal 3** - Improve access to appropriate and affordable antifungal therapeutics with a focus on generic agents
- **Goal 4** - Improve education of health professionals about fungal disease.

**Goal 1 Outcomes - Increase awareness of the impact of fungal disease**

A major goal is to achieve increased awareness of fungal disease globally. There are very few public health programs in fungal disease worldwide, and clinical suspicion of fungal disease is necessary for a good clinical outcomes. GAFFI’s broad approach to these deficiencies is a combination of estimating of burdens of disease, measuring the impact of fungal diseases on the individual and their community, raising both medical and public awareness and influencing key decision-makers in individual countries and in global health agencies.

**Burden of fungal disease**

Burden of fungal disease estimates have been made for 5 billion people (71% of the world’s population) in 55 countries, (abstracts shown here)\(^1\). Partial or complete estimates of fungal disease burden have been presented as abstracts and/or published as shown in the table below – bold signifying that a papers is published or in press. Of these country estimates, reports from Austria, Russia, Nigeria (Oladele, 2014), Spain (Rodriguez-Tudela, 2015), Belgium (Lagrou, 2015), Czech Republic (Chrdle, 2015), Denmark (Arendrup, 2015), Dominican Republic (Gugnani, 2015), Germany (Ruhnke, 2015), Hungary (Sinko, 2015), Ireland (Dorgan, 2015) and Israel (Ben-Ami, 2015), Nepal (Shrestha, 2015), Qatar (Taj-Aldeen, 2015), Senegal (Badiane, 2015), Sri Lanka (Jayasekara, 2015), Tanzania (Faini, 2015), Trinidad and Tobago (Denning, 2015), Uganda (Parkes-Ratanshi, 2015), Ukraine (Osmanov, 2015), Vietnam (Beardsley, 2015) have been published along with estimates of chronic and allergic aspergillosis in India (Agarwal, 2014). Other

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country burden estimates have been accepted for publication including Jamaica, Kenya and Brazil. The number of adults with cystic fibrosis and either allergic aspergillosis or *Aspergillus* bronchitis (~18,000) was estimated in 30 countries with the highest number of cystic fibrosis patients (Armstead, 2014). An estimation of the burden of recurrent vulvovaginal candidiasis globally (~138 million) and by country has been resubmitted for publication.

The 10 year GAFFI '95-95 by 2025’ Roadmap published in May 2015 used these and provided additional estimates of global burden:

In summary, GAFFI estimates that there are more than 26 million people with fungal infections annually with more than 1.6 million deaths every year. This number of people dying is similar to deaths caused by tuberculosis and triple those caused by malaria. In AIDS patients, the burden of opportunistic infections it is estimated as over 11 million affected with >535,000 deaths annually. In immunocompromised and/or hospitalized patients without HIV infection more than 1.1 million cases happen every year with over 425,000 deaths. Outside of hospital, more than 14 million fungal lung diseases attributable to fungal infection and allergy with more than 700,000 related deaths.

### 1.1.2 Other studies of burden of fungal diseases

Two surveys (one ended and second in progress) have been done to directly measure the chronic pulmonary aspergillosis (CPA) rate following tuberculosis in Gulu, northern Uganda. They show an overall cavitation rate on chest Xray rate of 24% and *Aspergillus* antibody positivity rate of 12% requiring further analysis. This work has been published in abstract at the 46th Union World Conference on Lung Health, Cape Town, 2015.

A multi-institution study of the frequency of CPA following tuberculosis in Kenya has been planned and approved by the ethical committee, and submitted for funding. A study of CPA prevalence in Lagos after tuberculosis is in progress. A study of cryptococcal antigenaemia in HIV positive patient in Lagos is complete and submitted for publication. A multicenter study of invasive aspergillosis in India is in progress.

### 1.1.3 Initiate ‘Demonstration sites’ to show the impact of GAFFI’s programs in reducing morbidity and increasing survival

#### 1.1.3.1 Kenya – the FIP-Kenya program

GAFFI has been working with several leaders in Kenya and the Japanese International Cooperative agency to provide much greater capacity for fungal disease and cancer diagnosis in Kenya. The FIP-Kenya development program aims to provide all 10 of the major urban centers with excellent radiology, histopathology and fungal disease diagnostics and support leading clinical personnel through training, in combination with networking, quality assurance and surveillance programs. The quality of healthcare delivered to a large percentage of Kenyan’s 40 million people will greatly increase, with better antibiotic and antifungal utilization and much reduced morbidity and mortality. It incorporates a unique national training program to accelerate acquisition of diagnostic and clinical skills, using well tried teaching materials.

### Burden estimates done

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At the end of the program period the following will be achieved:

- Shift the current status quo of (very few diagnostic capabilities) to routine use of the most powerful affordable diagnostic tests at appropriate levels of laboratory and clinical sophistication.
- Provide CT scanning and capability for the first time to 6 hospitals, and enhanced capabilities at the 2 referral hospitals and 2 other general hospitals,
- Have trained up a new generation of radiologists on cross sectional imaging interpretation and have them supported through teleradiology.
- Provide, for the first time in several hospitals, the capabilities to do histopathology and autopsy.
- Have trained over 100 technical staff in mycology diagnostics, histopathology tissue preparation and staining, imaging techniques and greatly enhanced diagnostic and forensic histopathology, greatly enhancing capacity.
- Achieve quality assurance and standardization of fungal diagnostic services.
- Have increased clinical skills and capacity for over 500 clinicians and pharmacists in fungal disease diagnosis and treatment.
- Support the government, research institutions and international and local agencies with fungal disease incidence data for public health benefit with a centralized data collection system and lab network.
- Enable major reductions in death and morbidity from fungal diseases across the country.

The technical details of the program and its implementation are in detailed discussion.

1.1.3.2 Guatemala

GAFII has supported a demonstration site in Guatemala, with a focus on histoplasmosis, cryptococcosis, pneumonia caused by *Pneumocystis jirovecii* and chronic pulmonary aspergillosis after tuberculosis as well as other AIDS opportunistic infections including other endemic mycoses. At the end of the program, Guatemala will have the first national reference laboratory specialized in mycology providing diagnostic services to HIV patients in Central America.

In Guatemala, 80% of HIV patients develop opportunistic infections as their presenting HIV illness, and disseminated histoplasmosis is the number 1 killer, cryptococcal meningitis second and TB third. This development will be in Asociación de Salud Integral in Guatemala City under the direction of Dr Eduardo Arathoon and his team. The program will start in 2016. They already have a small fungal reference laboratory and its needs expansion and support in order to create a network in the country for diagnosis and treatment of fungal infections.

The development of this project will achieve the following milestones:

1. Implementation of quick diagnosis of cryptococcal meningitis with rapid antigen test at each HIV treatment centre.
2. For disseminated histoplasmosis, *Pneumocystis* pneumonia and chronic pulmonary aspergillosis centralised rapid testing through strengthening of the Asociación de Salud Integral reference laboratory;
3. Development and roll out of a training program in fungal disease management for health workers in the HIV comprehensive care units of Guatemala;
4. Development of a national registry for fungal infections;
5. Documentation of the nationwide incidence of and survival from these life-threatening infections;
6. Program assessment in terms most useful for global and public health planning.

**Goal 2 Outcomes - Improve access to diagnostics for fungal disease**

Both improved diagnostic tests for low and middle income countries and improved access to diagnostics are critically important GAFFI goals. Fungal disease is often clinically silent and/or mimics other infections and specific diagnostic tests are required for diagnosis. Many hospitals and countries have little or no diagnostic capability. Complex test formats, expense, inadequate laboratory infrastructure and a lack of training are all barriers to diagnostic testing. Accurate assessment of the burden if disease requires accurate diagnosis.

2.1.1 Engage with the manufacturers and distributors of fungal diagnostics worldwide

All major diagnostic companies with *Aspergillus* IgG antibody tests, *Pneumocystis* real-time PCR, cryptococcal antigen, *histoplasma* antigen and IgE tests were invited to the Seattle ‘95-95 by 2025’ Roadmap meeting and sent a copy of the final report. Additional groups and companies not yet in this business have been engaged and some developments anticipated.

The ‘95-95 by 2025’ Roadmap defines what the core diagnostic tests are and the portfolio of tests that should be available in all Mycology Reference laboratories.

Work with the CryptoMag advocacy group has assisted in supporting additional access to cryptococcal antigen testing in AIDS. This includes an update of the WHO cryptococcal guidelines which has access to cryptococcal antigen screening in at risk patients and diagnosis of disease in ill patients as cornerstones of its policy.

2.1.2 Undertake proof of concept studies to demonstrate value of systematic implementation of diagnostic testing for priority diseases

This effort is focussed on the demonstration studies in Kenya and Guatemala. Little progress has been made on mapping the gaps in diagnostic test provision in a formal way. Huge gaps exist in Africa and many other LMIC primarily because expertise in mycology is missing.

2.1.3 Additional Activities

2.1.3.3 Diagnostic developments:

*Pneumocystis* pneumonia: The development of a simpler and quicker sputum fungal DNA extraction system has progress to prototype stage and is being tested in a clinical laboratory. Separately, *Pneumocystis* can be detected in sputum (avoiding bronchoscopy and sputum induction) microscopy and PCR, greatly simplifying the diagnosis of *Pneumocystis* pneumonia.
for many patients (Nowaseb, 2014).

Fungal keratitis: Pilot work on a point of care diagnostic test for fungal keratitis is progressing at the University of Manchester.

Chronic pulmonary aspergillosis: *Aspergillus* antibody testing comparison has been completed and is published (Page, 2015). Two ‘gold standard’ tests have been identified. Alternative cut-offs have been derived, which need evaluation in a wide spectrum of people.

2.1.3.4 Proposal to set up a network of Mycology Reference Laboratories in India and China

GAFFI petitioned India’s Health Minister to set up a network of testing laboratories across India and trained clinical staff to help reduce unnecessary deaths in January 2015. Detailed representations are with India’s Ministry of Health.

A lecture tour of 4 cities in China and a subsequent meeting at the UK-China Health Policy dialogue meeting in London, provided the opportunity to recommend that China set up Mycology Reference Laboratories in each province.

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

The majority of work in this topic has related to mapping access to itraconazole, fluconazole, conventional amphotericin and flucytosine across the world, and understanding documenting local prices. While amphotericin B and flucytosine have been available for over 50 years and are the key drugs for cryptococcal meningitis and other fungal infections, they are unavailable in many countries. Itraconazole and terbinafine are the leading drugs for skin fungal infections but are not on the WHO essential medicines list. GAFFI aims to make all these agents universally available.

3.1.1 Identify the manufacturers and distributors of antifungal agents worldwide

Some progress has been made on this important topic. Engagement via the US based Office of the Global AIDS coordinator of several generic manufacturers has been initiated. An application to fund a full time person to focus on this was not successful. However, some support has been forthcoming, and outline ‘market opportunity plans’ for PEPFAR countries for amphotericin B, flucytosine and itraconazole have been prepared and selectively distributed to interested companies.

3.1.2 Initiate global mapping of current availability and costs of amphotericin B, flucytosine and itraconazole

This work is nearly complete, with maps posted on the GAFFI website and a paper describing the findings drafted. Fluconazole availability and costs have also been ascertained, including the countries fully dependent on the Pfizer’s Diflucan Partnership Program. Some data are still missing, and we expect to add additional data as we find collaborators in countries where our data
is missing. Amphotericin B remains unavailable in 64 countries, flucytosine in 94, fluconazole in 3 and itraconazole in 12. This is the first serious exercise in mapping antifungal drug availability.

3.1.3 Initiate global mapping of current availability of ophthalmic antifungal preparations (especially natamycin)

The manufacturers of ophthalmic preparations of natamycin have been identified, but their distribution and global coverage not yet documented.

Goal 4 Outcomes - Improve education of health professionals about fungal disease

There have been numerous initiatives in this domain, mostly small scale. Health professionals need to have fungal disease at the front of their mind when dealing with patients with complex problems, notably cancer, AIDS, critical care and respiratory disease. Laboratory training is critical for building diagnostic capability. Antifungal prescribing can be complex and pharmacists need to be aware of drug interactions and dose adjustments. GAFFI, in concert with many others, is committed to improving health professional competence related to fungal diseases.

4.1.1 Working with its partner LIFE translation of LIFE website into Arabic, Russian and French

It has not been possible to raise the resource to translate the LIFE website into languages other than English and Spanish. The quarterly newsletter is emailed to over 9,000 health professionals around the world. Usage of the website is ~12,000 unique users monthly.

4.1.2 Develop self-directed learning modules for selected microscopy and histology technicians and medical professionals

The Fungal Infection Trust has supported development of the world’s first online microscopy and histopathology course in fungal disease. The first 3 of 4 modules have been developed at the University of Manchester and piloted across the world. It will be officially launched in Q2 2016, after checking by a highly experienced medical mycologist. An additional grant has been obtained from Gilead to develop module 4 (rare fungi) and to translate the whole course into Spanish, French and Portuguese.

4.1.3 Initiate contact with non-governmental organizations and other potential partners to provide training courses appropriate to selected clinical disciplines

Presentations at numerous scientific meetings have highlighted the burden of fungal diseases, in multiple countries. Two fungal disease postgraduate courses were run in late 2014, in Lagos and Calabar. Prof Richardson spent a week in Kampala educating local clinicians. GAFFI was presented in detail at the INFOCUS meeting (500 attendees from S. America) in Curitiba, Brazil, and subsequently in China.

The University of Manchester Masters in Medical Mycology is now entering its 3rd year. Contact has been made with potential suitable universities in Spain, Uganda, Thailand, USA and China to initiate discussions about licensing this course. These discussions have not yet resulted in a formal licensing arrangement yet. Continuing Professional Development courses are embedded within the Masters program, and attract additional attendees.
Local training courses will be developed in detail for the Guatemala and Kenya programs.

**Advocacy**

### 5.1 Mobilise the international global health funding community to support fungal complications of AIDS and TB

GAFFI arranged, with logistical support from BioVentures for Global Health, the Global Fungal Infection Forum in Seattle\(^2\), February 22nd 2015. Speakers identified concrete steps to reduce 100,000s of deaths from AIDS annually. Organizations represented at the meeting included the World Health Organization, UNAIDS, Bill and Melinda Gates Foundation, Office for Global AIDS Coordination (PEPFAR), Centers for Disease Control (CDC), European Commission, Clinton Health Access Initiative, FHI360, Medicines for Africa and numerous universities and hospitals.

**Professor Tania Sorrell (GAFFI) launching the ‘95-95 by 2025’ 10 year GAFFI Roadmap in Melbourne in May 2015.**

Participants highlighted the lack of diagnostics and access to treatments, including the oldest antifungal drugs, as the major hurdles to improvements in many developing countries. A preliminary economic model to analyze costs associated with treatment and care of fungal infections in Africa was introduced at the meeting. The model indicated that early detection and treatment of fungal meningitis and pneumonia can save lives, for a cost of ‘only $30’ per HIV patient. The importance of addressing serious fungal infections to help achieve the 90-90-90 HIV target was roundly voiced at the meeting. A 10-year Roadmap ‘95-95 by 2025’ is the product of that meeting\(^3\).

**The key conclusions and recommendations for governments, policy makers and international health agencies were:**

- Support the goal of reducing AIDS deaths to under 500,000 by 2020, with a determined focus on the commonest lethal fungal infections: Cryptococcal meningitis, *Pneumocystis* pneumonia, disseminated histoplasmosis and chronic pulmonary aspergillosis after tuberculosis

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\(^2\) [www.gaffi.org/global-fungal-infection-forum/](http://www.gaffi.org/global-fungal-infection-forum/)

\(^3\) [http://www.gaffi.org/roadmap/](http://www.gaffi.org/roadmap/)
• Ensure that 95% of people with serious fungal disease are diagnosed and 95% treated by 2025 (95-95)

To accomplish these goals, it is necessary in each country to:
• Ensure that affordable diagnostic tests for all common and uncommon fungal infections are made available, focused on rapid, non-culture testing
• Develop and maintain at least one laboratory led by an expert in fungal disease diagnostics with a comprehensive diagnostic portfolio and critical mass of healthcare professionals per country
• Develop a network of expert clinicians and ‘train the trainer’ programs, supported by clinical guidelines
• Ensure distribution of antifungal agents on the WHO Essential Medicine List to reach all those who need them
• Establish ongoing surveillance of fungal infections of high burden to inform clinical practice, training and research needs
• Develop local experts in public health mycology

The Roadmap was printed and mailed and/or emailed to every Minister of Health and numerous international health agencies. Local follow up through GAFFI country ambassadors was encouraged.

5.1.2 Lobby for guidelines and antifungal inclusion for *Pneumocystis* pneumonia and disseminated histoplasmosis

GAFFI applied for itraconazole to be placed on the WHO Essential Medicines List in December 2014. This was turned down in May 2015, for reasons that probably reflect competing priorities and limited expertise in fungal disease within WHO. The referees of the proposal appeared to not understand the distinction between fluconazole and itraconazole. A revised application is planned.

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Essentially no progress has been made on this objective with the WHO. There are already WHO and other guidelines in place for the prophylaxis of *Pneumocystis* pneumonia in AIDS, and in some countries for transplant recipients, but none for diagnosis and treatment. The only guidelines for histoplasmosis were published by the Infectious Disease Society of America in 2000. Much of this advice is current, but some advances in diagnosis and therapy have been made. This objective will be rolled over into year 3. Additional parallel work is ongoing to design and get funded a randomised controlled study of different amphotericins for disseminated histoplasmosis in AIDS, to be supported by Gilead as an alternative for an expanded access program. GAFFI supported and participated in the second Histoplasmosis Advocacy Group meeting in Surinam, which has galvanised that community into action across the Americas.

### 5.1.3 Chronic pulmonary aspergillosis after TB

The primary means of initiating the dialogue about chronic pulmonary aspergillosis was the issuing of the ‘95-95 by 2025’ Roadmap. Attendees at the Seattle ‘Roadmap’ meeting included key representatives from the Gates Foundation and WHO.

- Awareness has been increased substantially in India, China, Nigeria, Uganda, Kenya, Iran and Brazil. A prospective CPA registry has been initiated in Brazil.
- A publication from Iran has documented a high frequency of *Aspergillus* antibody after TB (Hedayati, 2015).
- Guidelines on the definitions of disease, diagnosis and management of CPA from the European Society for Clinical Microbiology and Infectious Diseases and the European Respiratory Society have been finalized for publication in the prestigious European Respiratory Journal.
- A review on *Aspergillus* antibody testing was published (Page, 2015), followed up by a comparison of the performance of different commercial tests (Page, 2015).
- A summary of the ‘95-95 by 2025’ Roadmap was published in Thorax, with part of the focus on CPA (Denning, 2015).

### 5.1.4 Engaged key partners from major institutions and global agencies focused on AIDS and TB

This objective was partly accomplished by the Seattle Roadmap meeting and subsequent publication of the ‘95’95 by 2015’ Roadmap. Much additional work needs to be done to make a much larger number of stakeholders aware of the potential for great health improvements by implementation of fungal diagnostics and treatments. A model was built with UNAIDS of the cost of implementing diagnosis and therapy for cryptococcal meningitis and *Pneumocystis* pneumonia. A second model of potential lives saved by enabling the diagnosis and treatment of cryptococcal meningitis, *Pneumocystis* pneumonia, disseminated histoplasmosis and chronic pulmonary aspergillosis as an alternative diagnosis of smear negative TB was also constructed and published as part of the ‘95’95 by 2015’ Roadmap. Assuming that 60-75% of the HIV population has access to the relevant diagnostic tests and treatments and typical treatment response rates, over 300,000 deaths might be saved annually on top of the intended roll out of more anti-retroviral therapy.

### 5.1.5 Chromoblastomycosis added to GAFFIs priority fungal diseases

Chromoblastomycosis is a rare and neglected tropical disease of the skin and subcutaneous tissue. It is treatable and probably partly preventable. After due consideration, GAFFI has added this to its priority fungal diseases. A key future goal will be to get it added to the list of NTDs at the WHO.

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Moving forward - Year 3

Most of GAFFI’s year 2 objectives have been met or are being met. Year 3 will be focus on advocacy of the key recommendations of the ‘95’95 by 2015’ Roadmap and implementing its Demonstration Sites in Kenya and Guatemala. The publication of Aspergillus antibody testing comparison and CPA guidelines opens multiple opportunities for dialogue with the TB community and screening studies in patients with TB. Persuading the governments of India and China to set up a network of Mycology Reference Laboratories is a major priority.

Glossary of organisations:
Gates Foundation – Bill and Melinda Gates Foundation,
CDC – US Centers for Disease Control
CHAI – Clinton Health Access Initiative
Global Fund – Global Fund to fight AIDS, Tuberculosis and Malaria
ICAAC - American Society for Microbiology Interscience Conference on Antimicrobial Agents and Chemotherapy
JICA – Japan International Cooperative Agency
LIFE – Leading International Fungal Education
MSF – Medicines Sans Frontieres
PEPFAR – President’s Emergency Program For AIDS Relief
SIDA – Swedish International Development Agency
UNAIDS – WHO-affiliated and co-located organization focused on AIDS
UNITAID - Agency hosted by WHO in Geneva.
WHO – World Health Organisation

Publications


Nowaseb V, Gaebc E, Fraczek MG, Richardson MD, Denning DW. The frequency of Pneumocystis jirovecii in sputum samples of HIV and TB patients received at the Central Reference Laboratory in Windhoek, Namibia. J Infect Dev Ctries 2014; 8:349-57.


