GAFFI POLICY BRIEF

Theory of Change model for improvements in access to diagnosis and therapy for serious fungal disease



GAFFI's primary mission is to minimize deaths and improve the health with long term fungal disease. Billions of people do not have access to key fungal diagnostics and/or antifungal therapy.

<u>Summary</u>

GAFFI's primary mission of reducing death and suffering from serious fungal diseases requires engagements at all levels of the healthcare ecosystem, and for several major patient groups. Expertise- and data-driven advocacy combined with education and awareness are the key steps to improving diagnosis and clinical care of affected patients. We envisage this model will inform future programs and provide a template for planning and programme evaluations.

There are 4 broad approaches to improve the gaps in clinical care – 1) access to affordable diagnostics and therapy, 2) training of healthcare professionals to maximally utilise these tools, 3) support guideline and policy updates to enable access in each country, and 4) inculcate expertise and monitoring approaches in systems to continuously improve overall care for those unfortunate enough to be affected. These are summarized in GAFFI's high level implementation plan.



Situation analysis

The fundamental problem in fungal disease care is the combination of lack of timely diagnostic access and untrained healthcare workers. Most serious fungal infections do not have distinctive clinical features and so are easily mistaken for other infections. The many gaps in diagnosis usually means that no treatment and either death, visual loss or continued disability, depending on the fungal disease.

GAFFI partnerships have facilitated and provides multiple datasets to understand the current status of fungal disease:

- Summarised the overall burden of fungal disease problem in terms of case numbers and deaths, globally: <u>https://gaffi.org/why/fungal-disease-frequency/</u>
- The actual disease burden by country and by fungal disease (>75 completed): <u>https://gaffi.org/media/country-fungal-disease-burdens/</u>
- Assessed diagnostic capability by test and by country and region: <u>https://gaffi.org/why/diagnostic-deficiencies/</u> and additional data not yet publicized.
- Availability and price of each antifungal medication, by country: <u>https://gaffi.org/antifungal-drug-maps/</u>
- Detailed country analyses for Africa and many other countries in terms of health system capacity. Data not yet publicized.

These partnership datasets, which are continuously monitored and updated, provide a basis for action, because of the large gaps in provision. However there are many competing priorities for limited resources.

Target groups

The main agents of change on the ground are fungal disease champions. Many willing volunteers now are GAFFI country Ambassadors to lead and facilitate improvements in each country: https://gaffi.org/who/our-ambassadors/. There is a growing number of engaged clinicians and laboratory staff globally. GAFFI and its country Ambassadors plan country activities as 'co-creation' of local and national action plans using GAFFI's resources and Ambassadors' volunteer cooperation.

Within each country, most diagnostics are performed in laboratories, so supporting directors of diagnostic laboratories is key. In addition, clinicians working in the main affected specialty groups (i.e., HIV/AIDS, TB and lung diseases, cancer and intensive care) need continuous education about the optimum usage of diagnostic tests and support with prescribing, and encouragement to use simple lateral flow tests close to the patient to yield rapid results. To be successful, these 2 groups need to influence government guidelines and procurement policies. In countries dependent on external aid for healthcare, inclusion on diagnostics and antifungal therapies within the donation envelope is currently key to getting country and citizen access.

Impact

Demonstration of direct benefit for improved survival and health has been difficult to show, unless diagnosis for fungal disease is thoroughly applied, combined with clinical education. But in Guatemala, a partnership between a local NGO and GAFFI has done this with HIV/AIDS: <u>https://gaffi.org/where/demonstration-site/</u>

In Guatemala, overall mortality in over 2000 new HIV patients went down 7% in 2 years - TB deaths down 15% and histoplasmosis deaths down 11%. This was the first public health demonstration of the value of diagnostics for a population.

Numerous other benefits of improved diagnostic provision can be or have been shown, including improved antimicrobial prescribing, healthcare worker job satisfaction, government and international agency engagement and more.

Health systems changes are needed in many countries and regions to enable improvements in care and better outcomes for patients.

<u>Outcomes</u>

Key outcomes of GAFFI's work includes partnerships for inclusion of fungal diagnostics in country and international guidelines in and for LMICs, antifungals listed in country Essential Medicine Lists, and regularly procured at affordable prices, inclusion of fungal diagnostics and some treatments within universal health coverage, so patients and families are not impoverished by fungal disease and promotion to positions of influence of GAFFI Ambassadors.

<u>Activities</u>

GAFFI's main activities fall into 5 categories:

- Data collection and dissemination on disease burden, diagnostic usage, antifungal registrations and availability
- Demonstration of the value of access to diagnostics through demonstration projects and highlighting key research outputs
- Country partnerships through supporting and recruiting GAFFI Ambassadors to foster improved awareness of fungal disease, collect local data and influence country policies and guidelines, and act as a focal point for educational activities
- Liaise with the diagnostics and pharma companies and support educational and research activities in LMICs
- Enable the development of a discrete set of Artificial Intelligence tools to counter the problem of training and personnel gaps in diagnosis.

Change mechanisms

The key to effecting change in LMICs is local engagement and direct support. GAFFI currently enables this through its Ambassador network:

- 1. to facilitate partnerships and engagement with countries,
- 2. to articulate need and potential benefits with donor agencies for specific improvements in the healthcare ecosystem globally,
- 3. to enable locally available diagnostics and antifungals which are on the WHO's Essential listings
- 4. to update international clinical guidelines locally.

Sequencing

Diagnosis is a central task of medical practice, and it is a specific challenge for fungal diseases because in almost all cases, specific diagnostic testing is required, followed by directed antifungal therapy. One without the other leads to poor outcomes. So, a broad disease focus (such as HIV/AIDS or TB and lung diseases, or asthma, or eye ulcers etc.) is the first takeoff point for education and guidelines.

The second step relates to the pace of diagnosis and institution of therapy — rapid results are needed in life- and sight-threatening conditions, but a slower turnaround could be acceptable for other fungal diseases.

The third step is the coordination of diagnosis with the most appropriate therapy and high quality prescribing.

The final step is integration of these critical care elements into the health system framework, with quality standards and continuous quality improvement procedures.



Stakeholders and 'enabling factors'

Fungal disease touches most parts of a healthcare system – clinical care at all levels (community, local hospital, specialist hospital), radiology, microbiology and

histopathology diagnostics, most medical specialties and important infrastructure such sample transport, digital imaging and laboratory information systems. GAFFI and partners have addressed this in detail with Latin America: <u>https://gaffi.org/global-fungal-infection-forum-4-in-lima/</u>

External to individual hospitals and counties, Ministries of Health, regional bodies such as Africa CDC, PAHO, SEARO, WPHO etc. are engaged in supporting improvements in health. Many donor agencies and NGOs are also actively engaged in direct support to countries, especially with respect to HIV/AIDS, TB and neglected Tropical Diseases. Many national and international professional societies and schools of public health and tropical medicine are also directly educating researchers and clinical practitioners, usually at a postgraduate level.

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