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A Call to Action for Mycetoma

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Abstract

Purpose of Review Here, we discuss the current needs and priorities for mycetoma control and prevention, highlight lessons learned from leprosy and podoconiosis, and motivate an urgent need to accelerate progress toward reducing the burden of mycetoma in endemic areas.

Recent Findings In 2015, the World Health Assembly (WHA) added mycetoma, a progressively debilitating disease caused by fungi and bacteria, to the World Health Organization (WHO) list of priority neglected tropical diseases (NTDs). Designation of other diseases as NTDs has raised awareness, enabled global partnerships, and advanced the capacity to combat disease through integrated programming. Although key mycetoma etiologic agents have been identified, many questions remain and mycetoma may similarly benefit from NTD designation.

Summary In collaboration with experts at WHO and elsewhere, we formed a global mycetoma working group to connect partners from a variety of sectors and specialties. We envision that this group will evolve into a formalized partnership that can prioritize strategic planning, advocacy, and research needs, identify funding sources, and coordinate activities related to mycetoma and other NTDs affecting the skin. The experiences gained from other NTDs can help to guide the global mycetoma working group's activities to better address the goals set forth in the WHA resolution.

Keywords Mycetoma · Neglected tropical diseases · Eumyctoma · Actinomycetoma

Introduction

Mycetoma is a granulomatous implantation infection caused by any of several different types of fungi (eumycetoma) and bacteria (actinomycetoma) that are present in the soil in endemic areas and enter the body via breaks in the skin [1••, 2, 3••]. Mycetoma causes progressive subcutaneous tumor-like lesions, usually on the extremities, that can invade muscle and bone. Like other neglected tropical diseases (NTDs) of the skin, mycetoma leads to disability, stigma and lost productivity for individual patients, and to systemic impediments to economic prosperity for affected communities [4]. Treatment decisions and efficacy depend on accurate diagnosis of the etiologic agent and recurrence. Although antibiotic therapy for actinomycetoma is up to 90% effective, antifungal therapy for eumycetoma is < 27% effective, resulting in the frequent need for surgery and amputation as treatment [5]. Nevertheless, both etiologies lead to disease requiring costly long-term treatment, an often-unbearable economic burden for patients, resulting in non-adherence and recurrent disease.

Mycetoma primarily affects low-income agrarian populations in arid, equatorial regions of Africa, Latin America, and Asia, collectively known as the "Mycetoma Belt"

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[1••]. Although described since the mid-1800s, true burden estimates of actinomycetoma and eumycetoma are elusive because, like most diseases associated with poverty, diagnostic capacity is sparse and surveillance requires costly infrastructure. A 2017 burden estimate based on published literature estimated a total of 17,607 cases reported worldwide from 1944 to 2017, with prevalence from 0.1–2 cases per 100,000 population [1, 6••]. Though certainly a vast underestimate, it provides an important baseline for establishing the need for public health support. In 2015, the World Health Assembly resolved that mycetoma be added to the list of NTDs [7]. The resolution acknowledges important gaps in basic epidemiology, prevention activities, intervention studies, and implementation science, and sets forth opportunities to join the skin NTD community in reducing the burden of mycetoma through control, prevention, and treatment. As a recently named NTD, mycetoma has some "catching up" to do in these areas, while avoiding creating its own silo by joining the effort to develop prevention and treatment infrastructure that integrates across all skin NTDs.

Fortunately, this "catching up" has begun with the benefit of a comprehensive scientific and clinical literature base, reviewed elsewhere [1••, 3••, 6••, 8]. This literature includes characterization of key etiologic agents, identification of physiological and immunological hallmarks, genomic studies, and major advances in molecular diagnostics. With a rich research literature base and recognition as an NTD, now is the time to mobilize these findings and develop a global strategy to establish surveillance and simple diagnostics, reduce morbidity, and provide affordable treatment.

Mycetoma: a New Neglected Tropical Disease

Now is the time to address the burden of mycetoma in endemic areas, identify funding partners, and develop and implement data-driven interventions. In the last 5 years, several key organizations accelerated progress toward addressing gaps in mycetoma knowledge and advocacy. As recently as 2013, global interest in mycetoma was minimal, familiar only to those who suffered from and treated it, along with a small group of committed researchers and advocates. This obscurity was evident in its absence from the landmark 2010 and 2013 Global Burden of Disease studies [9–11], and the peripheral attention it received in early discussions of integrated strategies for skin NTD control (e.g., Buruli ulcer, leprosy and yaws). Work on mycetoma expanded rapidly during 2013–2016, including key meetings to define knowledge gaps and a research agenda, molecular diagnostic development, and design of the first clinical trial of a novel antifungal treatment for eumycetoma [6••]. These collective efforts culminated in the addition of mycetoma to the WHO list of Neglected Tropical Diseases following a World Health Assembly (WHA) resolution on May 28, 2016. This resolution was historic not only for mycetoma but also for fungal diseases more broadly. Mycetoma became the first fungal disease recognized as an NTD and was followed closely by the recognition of chromoblastomycosis, another fungal skin NTD, later in 2016. For the first time, WHO, along with national governments and global communities dedicated to skin NTDs, mycetoma, and fungal infections, has a collective roadmap and a framework for accountability.

Nearly two years after the WHA resolution, individual efforts to better understand, diagnose, treat, and prevent mycetoma continue. A survey of WHO member countries about experience with mycetoma is underway, as is an exploration of human genetic risk factors. Recently, a group of researchers launched Open Source Mycetoma (MycetOS), an open-source drug discovery consortium aiming to discover new drug leads through small molecule synthesis and screening [12•, 13]. However, the elevated profile of mycetoma resulting from recognition as an NTD has not yet been fully leveraged; many basic needs remain. These needs were recently discussed and prioritized during the 2017 WHO biennial meeting of the Global Buruli Ulcer initiative and Skin NTDs [14] and the following list (Table 1) was adapted from the resulting document.

This summary of priority needs is necessarily broad in scope. It represents key groundwork needed to describe the epidemiologic burden of disease worldwide, along with fundamental diagnostic, treatment, and intervention breakthroughs. It also illustrates the importance of a global infrastructure to organize, implement, and evaluate these efforts.

This proposed effort supports the need for a global working group with a focus on public health advocacy, strategy, fundraising, and program coordination. Such a body will ideally broaden the community of stakeholders currently supporting mycetoma-related work, and must balance the need to "catch mycetoma up" with more established Skin NTD programs with the need to fully integrate mycetoma within ongoing surveillance, diagnostic and treatment strategies for skin NTDs as a group. Since 2005, the designation "neglected tropical disease" has enabled WHO and global public health organizations to apply strength through numbers to combat tropical diseases associated with poverty that might otherwise remain obscure causes of severe morbidity and mortality for more than 1 billion people worldwide [15]. The value of inclusion on the NTD list has also become clear; treatment coverage through donated medicines has greatly expanded, eradication is now in reach for dracunculiasis, and WHO member states are increasingly publicly declaring their political commitment to cooperate and strengthen their NTD programs [16]. With a focus on one of the most recently named

Table 1 Needs and priorities for global mycetoma prevention, control, and treatment

Priority area	Example activities
Coordination at country level	• Appoint a national focal point responsible for mycetoma in each endemic country
	• Establish a mycetoma program if needed, in coordination with existing skin NTD prevention and control programs
Epidemiology	• Identify priority endemic countries for enhanced surveillance and detailed epidemiological assessment
	• Assess the epidemiological situation on mycetoma at country level by:
	○ completing the WHO questionnaire about endemicity status
	○ Conducting a literature review of the endemicity status
	○ Including mycetoma in surveillance systems of endemic countries
Case management	• Produce a protocol for treatment of mycetoma, including guidelines for diagnosis of actinomycetoma and eumycetoma and appropriate treatment of each
	• Establish regional referral centers and community healthcare worker education programs
	• Identify or build capacity for national and international centers for laboratory diagnostic testing
	• Convene an expert meeting on diagnostics for mycetoma including manufacturers
	• Identify manufacturers of mycetoma medications (e.g., generic itraconazole) to assess quality and cost
	• Address barriers currently limiting access to treatment
Prevention	• Develop a communication strategy and material on awareness and prevention of mycetoma
	• Ensure that health promotion messages focus on:
	○ Wearing protective clothing and shoes to prevent injuries (e.g., thorn bushes)
	○ Encouraging self-reporting in case of suspect lesions
Health systems	• Designate at least one referral center in each endemic country to manage cases that require specialist care
	• Support or develop regional capacity for laboratory diagnostics
	• Include mycetoma into the integrated skin NTDs initiative/framework
Monitoring and evaluation	• Indictors on the impact of treatment should include:
	○ Surgical excision, if needed
	○ Amputation rates
	○ Proportion of patients cured
	○ Loss to follow-up
	○ Disability rates
	○ Recurrence rates
	○ Compliance with treatment
	• Cost studies to evaluate treatment options
	• Other program progress indicators to be developed
Operational research	• Characterize the epidemiology of the causal agents of the disease, its mode of transmission, and risk factors for infection by:
	○ Identifying the primary reservoir and the route of infection of mycetoma including:
	▪ Role of animal reservoirs
	▪ Environmental sampling
	▪ Observational (e.g., case-control) studies
	○ Mapping the etiology of the disease
	• Conduct socioeconomic impact studies
	• Identify potential candidate medicines to treat mycetoma
	• Develop a standardized methodology for clinical trials on drugs
	• Develop point-of-care diagnostic tests for community and clinic-based screening with high sensitivity, non-specific but able to differentiate between fungal and bacterial mycetoma

NTDs, the mycetoma community is fortunate to look toward both young and established NTD programs for examples and guidance to maximize our impact.

Lessons from Established NTD Programs

A nascent global mycetoma working group would do well to study and learn from other Skin NTD programs. Some of these disease, including leprosy, have had dedicated control and prevention programs that have existed for decades and offer a history of challenges and successes. For others, such as podoconiosis, concerted programs are fairly new, and stakeholders have more recently worked through the challenges of the initial planning and strategy phases. We summarize relevant experience from leprosy and podoconiosis initiatives.

In 1991, WHO designated leprosy as a priority for global elimination, a first for the group of diseases now designated as NTDs [17, 18]. In many ways, it captures many of the challenges faced when addressing other skin NTDs, such as mycetoma. Although the cause of leprosy, *Mycobacterium leprae*, was identified in 1873, the exact route of transmission remains elusive, as do the determinants of disease presentation and progression in individual patients [19]. Like mycetoma, leprosy tends to be a disease of poverty, clustering in communities rather than being evenly distributed; in the case of leprosy, a genetic component contributes to this clustering [20]. Both diseases face similar challenges with non-specific clinical manifestations and suboptimal treatments and both require early diagnosis to prevent disability.

The WHO leprosy elimination program highlights both successes and failures that can occur in addressing an NTD. Following announcement of WHO's 1991 goal to eliminate leprosy as a public health problem by 2000 [21], member nations prioritized leprosy programs, and pharmaceutical companies began donating anti-leprosy medications. In 2000, WHO declared that the world had reached the leprosy goal, and all but six countries had reached the goal of end-of-year prevalence below 1 per 10,000 [17]. Following these achievements, many ministries of health disbanded leprosy control programs and funding for research ceased as the disease was no longer perceived to be an important problem [22]. As a result, the global decline essentially plateaued after 2005 and even reversed in some countries [23, 24]. Only recently has WHO redefined their leprosy strategic plans, and as a result countries have begun reconstituting their leprosy programs in response to resurgences in cases [25].

Podoconiosis is a non-infectious form of lymphedema associated with long-term barefoot skin contact with irritant red clay soil [26, 27]. Foundational research in eastern Africa in the 1970s–1980s identified the association between the disease and soil exposure and characterized clinical, epidemiologic, and chemical features of the disease in Ethiopian patients. This scientific basis lay the groundwork for a translation to public health action beginning in the 2000s, involving footwear impact studies, global advocacy and fundraising, and partnerships among local institutions in endemic areas and international organizations [28, 29]. The transition from an early research program to a multidisciplinary and globally inclusive movement led to the addition of podoconiosis to WHO's NTD list in 2011 and subsequent formation of *Footwork*, the International Podoconiosis Initiative. As a skin NTD with socioeconomic consequences similar to mycetoma, the opportunities for overlapping approaches to global strategy, prevention, and advocacy are clear. Because podoconiosis achieved the NTD milestone more recently than others, and only 5 years before mycetoma, there are unique parallels between the two diseases, including the individuals and organizations involved in the global skin NTD community, current global attitudes toward health and poverty, and web technology-enabled improvements in communication and information sharing.

Podoconiosis offers several key insights for Mycetoma work, including the importance of community-based burden estimates and maps, a recognizable network of international partners in diverse sectors, and the translation of research into action for diagnostics, treatment, and prevention. First, burden estimates are challenging to attain, and moving beyond literature-based estimates requires the funding, infrastructure, and expertise to include a new NTD in existing routine surveillance systems or to conduct population-based epidemiologic studies. These goals are in reach for podoconiosis in part because of several community-based burden estimates [30–34] that demonstrated a need for further exploration in endemic areas globally, now funded through a Wellcome Trust grant to establish a Global Atlas of Podoconiosis [35]. Secondly, the *Footwork* partnership established a central global forum for public and private stakeholders to gather around the shared goal of supporting the treatment and prevention of podoconiosis [36]. According to the group's website, *Footwork* "encourages integration of podoconiosis control into efforts to eliminate other neglected tropical diseases, and works with those active in other related diseases of the foot." Their website provides an online forum for members and stakeholders to communicate and share resources. This global connectivity can facilitate the third key insight, which is the impact of translating research findings into action. Two examples include application of a validated disease severity staging system [37] and a disease-specific quality-of-life index [38] in endemic areas of Ethiopia to measure podoconiosis treatment outcomes. As a recently established skin NTD program, ~ 5 years ahead of mycetoma, podoconiosis demonstrates that much is possible in a short timeframe when an inclusive global network of diverse supporters takes an interdisciplinary approach to achieve the shared goal of disease prevention and treatment.

Call to Action: a Global Mycetoma Action Network

In the nearly two years since the WHA resolution on mycetoma, an active group of researchers and advocates worldwide in sectors from academia to industry has continued to fill mycetoma knowledge gaps [6••, 8, 39, 40•, 41–45]. However, there is an urgent need to expand this body of work toward meeting the goals and activities set forth in the WHA resolution on mycetoma [7]. These goals include assessing the burden of mycetoma, establishing or strengthening control activities, developing early detection diagnostic methods, ensuring universal access to effective interventions and treatments, and integrating mycetoma control efforts with other relevant disease control activities, among others. The first progress report on these activities is expected by mid-2019, at the 72nd World Health Assembly.

We therefore make this call to action for a global Mycetoma Action Network dedicated to the prevention and treatment of mycetoma. This network would provide a forum for public and private partners to advocate for inclusion of mycetoma within local, national, and international NTD and health agendas and to support mycetoma prevention and treatment programs in endemic areas. Toward the realization of such a group, in January 2018, after an open call for participants in a new global mycetoma action network, over 30 people from 15 countries met by web conference to share thoughts on the value and purpose of a globally connected group dedicated to mycetoma. Participant feedback indicated a strong interest in continuing these meetings and a willingness to establish a productive global mycetoma partner's network. This group is therefore open to new participants with interest or expertise in mycetoma and skin NTDs, as well as those more broadly involved in global health advocacy, technology, drug development, and philanthropy.

Conclusions

As one of the newest recognized and first NTD involving fungi, mycetoma is poised for an expansion in global awareness and efforts to reduce its burden among endemic communities. Although mycetoma is new on the list of NTDs, it is described in ancient writings in India and was reported as early as 1842 [46]. The collective cost of mycetoma to society and to healthcare over human history has been undoubtedly immense, despite gradual improvements as human societies developed and hygiene improved. The burden today remains among the poor, and, like other NTDs, mycetoma is a proxy for poverty and a reminder of the need for interventions aimed at reducing poverty. We are fortunate to be able to look to established NTD programs' successes and challenges as we work to integrate mycetoma into new and proven interventions and strategies. We submit this call to action at an important time, halfway between the resolution declaring mycetoma an NTD and the deadline for producing evidence of progress toward the goals set out in that resolution. We look forward to accelerated action in the coming years to prevent disfigurement and disability from mycetoma.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no competing interests.

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

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