Report of a WHO informal meeting on the development of a conceptual framework for Tungiasis control

Virtual meeting, 11–13 January 2021
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This report was written by Dr. Ruth Monyenye Nyangacha, Senior Research Scientist at the Center for Traditional Medicine and Drug Research, Kenya Medical Research Institute, Nairobi, Kenya. It was reviewed by Professor Dr. Hermann Feldmeier, Institute of Microbiology, Infectious Diseases and Immunology, Charité University Medicine, Berlin, Germany.
# Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>DLQI</td>
<td>dermatological life quality index</td>
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<tr>
<td>IL-1β</td>
<td>interleukin-1 beta</td>
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<tr>
<td>IL-4</td>
<td>interleukin-4</td>
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<tr>
<td>KMnO4</td>
<td>potassium permanganate</td>
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<td>NTD</td>
<td>neglected tropical disease</td>
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<td>PAHO</td>
<td>Pan American Health Organization</td>
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<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
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<td>SSAT</td>
<td>severity score for acute tungiasis</td>
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<td>SSCT</td>
<td>severity score for chronic tungiasis</td>
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<td>TNF-α</td>
<td>tumor necrosis factor alpha</td>
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<td>WASH</td>
<td>water, sanitation and hygiene</td>
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Executive summary

As a first step towards developing a conceptual framework for the control of tungiasis, the WHO Department of Control of Neglected Tropical Diseases and the PAHO Regional Program of Neglected Infectious Diseases convened an informal virtual meeting of experts in tungiasis on 11–13 January 2021. Several aspects of the disease and its control were discussed and a number of recommendations were made by consensus. The agenda is attached as Annex 1 and the participants are listed in Annex 2.

It was established that the current situation in respect to mapping, surveillance, prevention and treatment of tungiasis is desperate compared to that for other diseases. In most countries, data on tungiasis are lacking and underreporting of cases is a major challenge. Currently it is impossible to deduce the prevalence of tungiasis from health system records because affected individuals rarely seek treatment from health facilities due to stigma, lack of access to health facilities and non-availability of standard treatment for the disease. In addition, national tungiasis surveillance systems are lacking in most countries. A single modelling approach has been recently undertaken to estimate the suitability of countries and regions for tungiasis transmission. However, this model was based on very limited data which were collected from confined locations at widely spaced time-points. Hence, the prediction map lacks accuracy. There is an urgent need to collect sufficient empirical data in all settings endemic for the disease in order to improve mathematical modelling.

Data on risk factors for tungiasis are limited, and risk factors such as the presence of animal reservoirs may vary among settings. Many of the risk factors with a potentially high population attributable fraction are intricately associated with severe poverty as well, hence the difficulty for affected communities to eliminate the disease at an individual level. The challenges for prevention relate also to the epidemiological characteristics of the disease and the biology of the parasite. There is a general lack of knowledge on the developmental biology and ecology of the off-host stages of Tunga penetrans.

Currently, there is no safe and effective treatment available in endemic areas, hence, due to desperation, affected individuals resort to traditional treatments which may cause more harm than good. Use of non-sterile sharp objects intensifies the inflammation and increases the risk of bacterial superinfection. It is also common in endemic communities to share sharp objects such as safety pins, which exposes them to transmission of viral pathogens including HIV and hepatitis B and C viruses. Studies to find suitable a treatment for tungiasis have been unsuccessful except for those on dimeticone oils. The test agents have shown either no or limited effect on embedded sand fleas or have had serious side-effects. However, a mixture of two dimeticones used to treat head lice\(^1\) has shown a high efficacy in two randomized trials. It has been used in Brazil and Colombia to treat tungiasis with good results in small areas. The product is effective and safe, and all efforts should therefore be made to register and distribute it as the best treatment candidate for tungiasis to date.

Tungiasis is a dynamic disease that is affected by diverse factors including the environment, ecology, climatic conditions, social determinants and related factors due to poverty such as access to sanitation, water and waste management, individual behaviour, animal reservoirs and the parasite life cycle which includes off-host stages indoors. In response, a multisectoral approach is needed for sustainable control of tungiasis in highly affected communities. The multidisciplinary approach must involve stakeholders from local communities, local administration officials, nongovernmental organizations and political leaders as well as professionals such as medical doctors, veterinarians, entomologists, anthropologists, civil engineers, specialists in information, education and communication, ecologists and public health professionals.

\(^1\) NYDA\(^*\) (registered as medical product) is a mixture of two dimeticone oils with different viscosity and spreadability.
Finally, research on tungiasis is critical to appropriately estimate the distribution and global burden of this neglected disease. It is also needed to accelerate efforts to identify standardized treatments, effective control measures, eliminate practices that cause more harm than good, identify communities that need urgent attention, help determine the burden of the infection, and to ensure that treatment guidelines are evidence-based and that finite resources are well utilized.
1. Introduction

Tungiasis is a cutaneous ectoparasitosis caused by the sand flea *Tunga penetrans* and, in some countries, *T. trimamillata*. It was added to WHO’s portfolio of neglected tropical diseases (NTDs) in 2017 (1). The disease is also incorporated in the new NTD road map 2021–2030, which was launched by WHO in January 2021 (2), and in the Plan of Action to eliminate neglected infectious diseases in the Region of the Americas 2016–2022 (3). The informal meeting was convened to discuss various aspects of the disease and interventions for its control, with a view to generating recommendations for use by countries. It is envisaged that the meeting report will serve as a starting point for developing a conceptual framework for the control of tungiasis through public health action.

This report of the meeting outlines the discussions and recommendations agreed upon by consensus. The discussions addressed the background of tungiasis, mapping and surveillance, prevention and treatment, opportunities for integrated actions locally and research priorities.

2. Background

2.1 Ecology of *Tunga penetrans*

Tungiasis is one of the oldest parasitic diseases originating from the American continent. Introduced through trading routes, tungiasis is now widespread throughout Africa, South America and the Caribbean (4,5). The disease is caused by the sand flea *T. penetrans* and, rarely, by *T. trimamillata*. *T. penetrans* is one of the smallest flea species in the world and, like other siphonaptera, feeds exclusively on blood.

The adult female sand flea penetrates the skin and remains there for life, whilst the male lives freely. Once embedded, the female starts to expand at the third abdominal segment, a process known as neosomy, to about 2000 times its original size. During this period, the male copulates with the female whilst embedded, to inseminate the eggs that are then shed over a 2-week period (6–8).

*T. penetrans* is largely found embedded in the skin of the host’s feet, which supports the transfer of the eggs to the ground from where the immature stages develop. The larvae require loose soil, sand or dust to develop, protected from direct sun, about 5–10 mm below the surface. The off-host stages (eggs, larvae, pupae) take 2–3 weeks to develop, depending on environmental conditions, before the adults emerge and seek out their hosts. *T. penetrans* infects not only human beings but also companion animals such as dogs and cats, as well as livestock including pigs and goats. In the Region of the Americas, wild animals living in close proximity to people have been found infected (9–12). However, for most endemic areas little is known about the potential animal reservoir and the interactions are poorly understood.

Studies are ongoing in East Africa to identify the locations where off-host stages develop and infect the human host. Tungiasis-infected families largely live in makeshift housing without a built floor, hence providing ideal conditions for the development of off-host stages (13). The Berlese-Tullgren method has shown that off-host stages are consistently found from soil samples collected indoors around the sleeping areas of infected persons (50–80% of samples positive).

Risk factor studies performed in schools suggest a role of classrooms in transmission, when a high number of pupils are infected and classroom floors are unsealed or cracked and covered with dust. Outdoor soil samples rarely contained larvae (< 10% of samples). A correlation has been found between off-host density in the soil and infection intensity in the host. In conclusion, indoor house and school floors have been identified as major risk factors in East Africa and can be targeted for improvement to prevent the disease (13).

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1 At its tenth meeting in 2017, the Strategic and Technical Advisory Group for Neglected Tropical Diseases recommended that scabies should be included in the portfolio of NTDs as a category A disease alongside other ectoparasitic infections. This group includes tungiasis.
Overall, the biology of *T. penetrans* remains poorly understood. There is little knowledge of the underlying processes of neosomy and nothing is known of host-finding cues and the required developmental conditions for off-host stages. A better understanding of the flea’s ecology can help to identify targets for treatment and control, help understand the heterogeneous distribution of the disease and help predict disease risks.

### 2.2 Epidemiology of tungiasis

Tungiasis occurs both in urban and in rural settings but shows a focal distribution and a strong link to resource-poor communities with inadequate living conditions and poor housing. Prevalences reach up to 60% in endemic communities, with schoolchildren and older age groups being those most affected. Morbidity is strongly correlated with prevalence and parasite burden. There is usually a clear seasonal variation, with higher incidences during the dry season. However, when transmission occurs indoors, cases can appear throughout the year.

Tungiasis is a zoonosis, and animal reservoirs play an important role in transmission in some areas. Whereas in urban communities, rats and domestic animals such as dogs have been shown to have high prevalences in Brazil and considerably impact transmission dynamics, in rural settings free-ranging pigs and wild animals can be important drivers. However, in some communities no animal reservoir may be involved, and the transmission occurs mostly among humans. Commonly observed risk factors for infection and severe disease include male gender, school-aged children (4–15 years) and elderly people (aged > 60 years), poor housing conditions (earthen floors inside houses), and presence of domestic and wild animal reservoirs.

A special characteristic is the high disease burden in indigenous populations in South America. Tungiasis also occurs in travellers returning from endemic countries, though with a limited number of embedded fleas and lower morbidity (14), in contrast to severe cases observed in endemic communities. In general, there is little scientific evidence on the epidemiology of tungiasis, and research is urgently needed to provide the basis for the design of effective control measures.

#### 2.2.1 Tungiasis in the African Region

Tungiasis is an NTD caused by the parasitic flea *T. penetrans*. It is common in school-going children aged 5–14 years. The disease leads to isolation and stigmatization, itching, loss of nails and bacterial superinfection. There are limited data on the spatial distribution and burden of tungiasis in the African Region. Control activities and research are ongoing in some countries, for example in Kenya (15) and Uganda (16). However, getting valid data remains a challenge. According to the literature, highly affected areas are the African Great Lakes region (Burundi, Democratic Republic of the Congo, Rwanda and Uganda), the Ethiopian highlands, Kenya, Madagascar and the United Republic of Tanzania.

A risk map of the putative geographical distribution of tungiasis in sub-Saharan Africa, based on a mathematical model, identified Angola, Cameroon, Côte d’Ivoire, Gambia, Guinea-Bissau, Nigeria, Sierra Leone and South Africa as other countries potentially at risk (17). The map shows areas with environmental conditions suitable for *T. penetrans*, not actual cases. This mapping technique is good but is highly influenced by assumptions made concerning the environmental characteristics of tungiasis and the quality of the data used. Some of the data used in this publication are more than 50 years old and presumably no longer relevant currently. However, the approach is considered a good start in the quest to develop mapping of tungiasis.

Taken together, tungiasis may be a major public health problem in several sub-Saharan African countries, but data are very limited. The role of animal reservoirs and the characteristics of local transmission dynamics need to be understood. In addition, the economic and social impact of tungiasis needs to be
assessed, and simple, safe, effective and sustainable means for prevention and treatment of tungiasis provided. Awareness and intersectional cooperation based on the One Health approach are also essential. confirmed reports of scabies or other skin diseases).

2.2.2 Tungiasis in the Region of the Americas

Tungiasis was included as an ectoparasitic infection in the Plan of Action for the elimination of neglected infectious diseases and post-elimination actions 2016–2022 in the Americas, which was approved by the 55th Directing Council of PAHO in 2016 (3). In that plan of action, neglected infectious diseases were divided into three groups:

- diseases which can be interrupted or eliminated;
- diseases which can be prevented, controlled and their burden reduced; and
- diseases for which there is insufficient information on their distribution and magnitude (tungiasis included).

Given the unknown epidemiological situation of ectoparasitic diseases in the Region, a literature review was conducted in 2017 on five selected diseases (scabies, tungiasis, cutaneous larva migrans, myiasis and pediculosis capitis) and a total of 156 papers published during 2007–2017 were analysed. Of the five selected ectoparasitoses, tungiasis had the highest prevalence range.

Most cases of tungiasis (132) were reported in travellers returning from certain countries with the infection, namely Argentina, Barbados, Bolivarian Republic of Venezuela, Brazil, Colombia, Ecuador, Haiti, Mexico, Paraguay, Peru, and Trinidad and Tobago. Generally, however, little is known about tungiasis in the Region. From the few reports available, high prevalence is reported in resource-poor rural and urban communities (range: 10.6–82.6%). Children aged 5–14 years and elderly people older than 60 years of age are the most vulnerable groups. High prevalence positively correlates with high intensity and severe morbidity.

In conclusion, the number of tungiasis studies in the Americas is low, hence data in the literature cannot be relied upon entirely to give the distribution and magnitude of the disease in the Region. The low data quality may be explained by the following factors: the disease is underreported, and there is no funding, interest or capacity from the scientific or public health perspective.

Nevertheless, the few studies performed in the Amerindian populations indicate that prevalence and morbidity can be extremely high. In the past 5–6 years, severe tungiasis infections have been reported in indigenous populations in the Amazon Basin. In Colombia, patients having between 400 and 1300 penetrated sand fleas have been reported (18). Clusters of embedded sand fleas were found at the ankles, knees, elbows, hands, fingers and the anus. Many individuals had preexisting medical conditions and culture-dependent behaviour facilitating continuous reinfection.

Tungiasis actions in Brazil and Colombia since 2015

The two countries have received support from tungiasis experts, although on a small scale. Interventions including prevention, treatment and the One Health approach have been tested. A mixture of two dimeticonic oils (NYDA*) has been used to treat patients with severe tungiasis in Colombia since 2015 and in Brazil since 2018. Both countries participated in a regional meeting in 2019 to delineate a road map for ectoparasitic diseases.

The national regulatory agency in Brazil (ANVISA) authorized exceptional importation of NYDA* in 2018. Hitherto, the product was not registered in Latin American countries, but recent efforts between PAHO and the producer in Germany have made it available for purchase through the PAHO Strategic Fund. It is now accessible to countries interested in using the product to treat tungiasis.
2.3 Tungiasis in the Amerindian population

Tungiasis affects the marginalized populations of South America, the Caribbean and sub-Saharan Africa, being more frequent in people living in extreme poverty. It is brought about by the penetration into the skin of female fleas of *T. penetrans* and *T. trimamillata*, commonly called sand flea, chigoe flea or Bicho do pé, among other names, in the Region of the Americas. In endemic areas, the prevalence can be up to 30% in the general population and 85% in children. The severity of tungiasis is directly related to the number of fleas that enter, and its chronic pathology is characterized by hyperkeratosis, oedema around nail edges, fissures, ulcers, deformation, loss of nails and amputation of the toes (19). Children with tungiasis more often than not have other additional diseases and may also have anaemia due to blood loss.

In the past decade, Latin America reduced poverty and increased the middle class, but indigenous peoples benefitted less than the rest of Latin Americans, with a 2.7 times greater probability of living in extreme poverty than the rest of the population. These peoples are mostly restricted to rural areas with little access to social development programmes (health, education, infrastructure and communications) or marginalized in urban centres where they have been displaced (19).

A risk factor study in Brazil showed the main risk factor for tungiasis was “living in a house with a dirt floor” (20). In the Amazonian indigenous populations, dirt floors, dry, sandy or dusty, living with infected domestic animals, closeness to synanthropic animal reservoirs, perception of the causes of the infection and inappropriate treatment of infections in humans and domestic reservoirs are factors known to increase the disease burden (19). Hunting dogs keep the transmission cycle alive in this setting. Younger dogs were found to have heavier sand flea infection than adult dogs.

In endemic settings such as some indigenous areas of the Amazon, reinfection is the rule and the burden of the parasite gradually accumulates over time (18,19), making tungiasis very severe. Still, the true burden of this devastating condition remains unknown (18). The seasonality with which tungiasis occurs in these areas, the high prevalence in children and adults over 60 years of age, the high vulnerability of the indigenous population due to marginalization, poverty, the non-guarantee of their rights (19,21,22), the effects on the restriction of the quality of life that extends beyond the physical aspects and that translates into mental and emotional tension in affected children (23) as well as the high and probable hidden mortality associated with tungiasis in indigenous populations (18) requires a greater effort by governments to strengthen health systems with an explicit focus on personalized strategies to improve the health of indigenous populations.

2.4 Impact of tungiasis

The most frequently reported sign of tungiasis is local inflammation and secondary bacterial infection leading to pain and itching and the consequent difficulty in walking (21,23,32–34,24–31). In fact, tungiasis is associated with a specific gait as the patient attempts to walk without putting weight on the embedded fleas and inflamed tissues. In a few studies, patients reported the itching and pain also causes sleep disturbance (23,25,27,23,35) and, like many NTDs, it is associated with stigma and shame (23,25,36–40).

In order to quantify the impact of tungiasis on life quality, the commonly used Dermatological Life Quality Index (DLQI) (41) was modified to focus on feet and the categories of impact reported (23). This index asked how much over the past one week tungiasis affected: walking, leisure activities, concentration during classes, sleep, feelings of shame and social exclusion in school-aged children. Each category was scored from 0 to 3 with the assistance of visual analogue scales, resulting in a total maximum score of 18 for the highest impact. This was then piloted in a study in Kenya with 50 purposively selected tungiasis cases among primary-school children. Careful examinations were conducted for flea staging and counts as well as acute and chronic pathologies quantified using a scoring system previously developed for
tungiasis (42). Each child completed the DLQI (20). Of the 50 infected pupils, 54% had more than six viable fleas in both feet, the median acute pathology score was 10 (IQR 7.25–12) and the median chronic pathology score was 6 (IQR 4–7.5). The median mDLQI score was 6 (IQR 4–8); 78% of the children had a DLQI greater than 4, indicating that the majority of them feel tungiasis has a moderate to very large effect on their lives. The most frequent categories of life quality restriction were in sleep disturbance (86% of pupils) and concentration at school (84% of pupils), but more than 60% felt their lives were restricted in all categories. Regression analyses demonstrated a strong positive correlation between the acute pathology score and the mDLQI (rho = 0.73, p < 0.001), as well as the number of viable embedded fleas (rho = 0.51, p < 0.001). There was no correlation with the chronic pathology score (SSCT), nor the number of dead fleas, indicating that live fleas cause the most pathology and impact the children's lives the most. The more fleas a child has, the greater the impact.

There has only been one qualitative study ever reported that explored the stigma associated with tungiasis (39). This was conducted with adults (aged 18–60 years) in an area of central Kenya where the prevalence and intensity of infections have been high for many years. The study specifically set out to identify what it is that sets people with tungiasis aside from the community, how they are labelled and treated, the impact this has on them and how they respond. Stigma is defined as a strong feeling of disapproval or negative beliefs that many people in a society have about an attribute of a subgroup of that society. It is usually unfair and leads to inappropriate, unkind behaviour towards those with the attribute. Stigma reduces the individual that possesses the attribute from a whole, socially accepted person to a disparaged and discredited one (43). The degree of isolation depends in part on society’s perception of whether this attribute is the fault of the person who bears it. Through four focus group discussions with 6–12 people in each, and 12 individual in-depth interviews, tungiasis was found to be “a grotesque disfiguring disease obvious to even the most casual observer” and for affected people to have been called various derogatory names in the local language, meaning “jigger person”. They were frequently labelled as “dirty, negligent, lazy and irresponsible, keeping unhygienic houses or compounds”. These attributes were considered to contravene closely held values in the Gikuyu culture and therefore the infected people to be worthy of discrimination and isolation from society.

While the community considers the sufferers to be to blame for their own disease, they themselves felt it was a curse from God or their ancestors since whatever they tried to do to eliminate the disease, they continued to be severely infected. They believe they must somehow have mistreated an elderly family member who has since died and put a curse on them. Others feel another person is using witchcraft against them and others believe it is a premonition of a death in the family. A society stigmatizes a subgroup of people when they have an attribute which is feared. In the case of tungiasis, the Gikuyu community in the study correctly understood that the fleas embedded in a person’s feet drop eggs into the soil and that is where someone else can then get infected. For this reason, they prevent people with tungiasis from entering their houses and compounds.

There are also incorrect beliefs regarding transmission. For example, they believe one can become infected from the eggs dropping onto food and utensils and therefore those with infected hands were prevented from participating in traditional ceremonies where food is shared. Such exclusion was considered immensely embarrassing and shameful. Being treated with such ridicule and stigmatization has a considerable impact on those at the receiving end. The study participants described how they chose to stay home, not going to public places or social events such as church, weddings and funerals, shutting themselves off completely from society. Some even refused to attend the study focal group discussions, preferring to be interviewed inside their own homes, so no one would see them.

There are other impacts that people working with tungiasis consider likely, but there are only anecdotal reports for these. These impacts include reduced school attendance due to immobility and shame and then the knock-on effect of reduced school achievement, aggravated by sleep disturbance and inability to concentrate in class due to the itching.
2.5 Pathogenesis, morbidity and sequels

Morbidity of tungiasis results from the biological characteristics of the pathogen, epidemiological determinants and inappropriate traditional treatment approaches. As soon as a female sand flea penetrates the skin and is embedded in the epidermis, it starts to grow and increases its volume by a factor of 2000 within 10 days. As any expanding foreign biological body in the epidermis, the enlarging abdomen of the female sand flea exerts pressure on the surrounding tissue. Pressure and hitherto undefined compounds released by the parasite intensify inflammation.

Through a tiny opening in the skin, the rear abdominal cone of the parasite is in contact with the environment. Through its abdominal cone, it takes up oxygen, releases faecal material, gets fertilized and expels eggs. The opening in the skin facilitates bacterial superinfection. The intense itching causes scratching of the lesion, which in turn leads to excoriations enabling pathogenic bacteria to enter the skin (44). Bacteria are also actively carried into the epidermis by a penetrating sand flea. Since the proboscis of the parasite is situated in a blood vessel, systemic bacterial infection leading to septicaemia or tetanus, may ensue. Typically, a dozen or more embedded sand fleas are located in clusters. Cluster formation perpetuates the inflammation.

In the endemic area where reinfection is the rule, acute and chronic inflammation coexist. Chronic inflammation is the origin of sequels, such as oedema, fissures, ulcers, tissue necrosis and lymphangitis, which eventually impair mobility. In Vaupés Department in the Amazon lowland of Colombia, severe tungiasis presenting with cachexia, anaemia and dehydration is documented (18). The patients had hundreds of fleas on top of each other on the feet making them immobile. They also had clusters on other ectopic sites such as the ankles, the anus and the elbows. For treatment, the feet were soaked in NYDA® and treatment was repeated twice. Patients fully recovered after 2 weeks. Tungiasis also causes life-quality impairment, leads to stigmatization, impairs educational achievement and negatively impacts household economics by immobilizing people who should work in the fields and affecting livestock animals such as pigs, which in turn cannot be commercialized properly.

To study the pathogenesis and morbidity of tungiasis in more detail, an animal model was developed (45). Wistar rats were placed in cages in a house where some inhabitants had tungiasis and examined daily. Within 2–3 days, flea penetration took place; 7 days after penetration a full-blown parasite, the size of a pea, was observed and the foot totally inflamed. By day 15 the nail and surrounding skin of the toe became necrotic. On day 26 the affected toes showed necrosis. The type of immune response that takes place after the flea penetrates the skin was determined with this model. Pro-inflammatory cytokines were investigated at regular intervals. Both tumor necrosis factor alpha (TNF-α) and interleukin-1 beta (IL-1β) initially increased then decreased after 2 weeks. TH2-dependent cytokines such as interleukin 4 (IL-4), which are related to itching, increased after penetration of the flea but also decreased over time. The Wistar rat was hence found to be a good animal model in which the pathogenesis and the kinetics of the inflammation can be investigated.
2.6 Diagnosis, staging of disease and rapid assessment methods

Diagnosis of tungiasis is made clinically. No instruments or tests are required. Only in stage II will the use of a dermatoscope or digital (video)-microscope help to diagnose tungiasis, particularly in pigmented skin. Diagnosis is based on the morphological characteristics of the different developmental on-host stages of embedded fleas, according to the Fortaleza Classification (46):

Stage 1: Sand flea in statu penetrandi.

Stage 2: Rapidly growing embedded sand flea presenting as a dark, itching spot in the epidermis with a diameter of 1–2 mm, with or without itching, local pain and other signs of local inflammation.

Stage 3: Mature egg producing sand flea presenting as a lesion with a white halo, measuring about 3–10 mm in diameter. The central black dot corresponds to the last abdominal rear cone protruding above the skin.

Stage 4: Dead, still embedded sand flea presenting as a brownish–black circular crust with or without surrounding necrosis of the epidermis.

Stage 5: A characteristic circular impression remains in the stratum corneum after the remains of the flea are shed from host through normal process of skin regeneration.

Staging can be challenging when the flea is embedded in a hyperkeratotic skin, when the parasites form clusters or if the skin is heavily pigmented. There are several benefits of staging and observation of morphological development. The attack rate can be estimated, for example, when testing for preventive options, viable and nonviable lesions can be differentiated to assess treatment options and, finally, the stage of development can help to infer on place and time of infection.

By means of a dermatoscope or a handheld digital (video)-microscope, viability signs of embedded sand fleas can be observed (47). These are contractions of the intestine, expulsion of eggs, excretion of faecal threads, secretion of faecal liquid and movement of the last abdominal segments protruding above the skin. Indirect signs are eggs (oval, measuring 600 x 320 µm) that stick to the skin of patients and faecal material adhering in the dermal papillae around an embedded sand flea that makes the skin look dirty.

For morbidity assessment, methods for the semi-quantitative assessment of acute and chronic morbidity are the severity score for acute tungiasis (SSAT) and the severity score for chronic tungiasis (SSCT) (42,48). The SSAT score comprises the following signs and symptoms: erythema, oedema, pain upon pressure or spontaneously; itching, sleep disturbance due to itching or pain, difficulty in walking as indicated by an altered gait; abscess, and suppuration as indicators of superinfection; fissures, perilesional desquamation and ulcers as characteristic persistent skin defects. The score can take a value from 0–35 points. It is suitable to detect the severity of disease in an individual or population and to assess prevention and treatment measures. The SSCT ranges from 0 to 30 points and comprises the presence of nail deformation, nail loss, deformation of toes, hypertrophic nail rim and hyperkeratosis; all of those characteristics are indicators of repeated episodes of tungiasis experienced in the past.

People living in endemic communities are usually able to correctly diagnose tungiasis (49). Thus, depending on the given setting and community, self-diagnosis can be an effective means to target prevention and treatment. In a study in three different communities in eastern Africa, sensitivity ranged from 31% to 85% and specificity ranged from 70% to 99%. Sensitivity increased significantly with the number of lesions and with the degree of acute and chronic pathology.

A rapid assessment method for the determination of disease occurrence and intensity of infection has been developed and validated. The most rapid and sensitive method is to examine the periungual region of the feet. Individuals can be examined with minor disturbance and sandals or thongs can be kept on (50).
2.7 Prevention in humans

Several studies have shown that a repellent based on natural plant products is an effective means to prevent tungiasis (48). In a study in Brazil, a lotion comprising coconut oil, jojoba oil and aloe vera (Zanzarin®) registered as a biocide and used as a repellent, significantly reduced the number of penetrating sand fleas by 92% when applied twice a day for 4 weeks on the feet up to the ankle. The regular application of the lotion also reversed all clinical pathology: the severity score for acute tungiasis decreased from 6 to 0 points. However, within a week of stopping the application, the participants of the study acquired newly embedded fleas (51). In another study in Brazil, different regimens of intermittent applications of Zanzarin® were compared after an initial 4 weeks of applying the repellent to each participant. Application twice daily for 1 week, but only every second week, kept the intensity of infection and pathology considerably below the levels of untreated controls; while application for 1 week every 4 weeks did not (52). These findings were corroborated by a community-based study in Madagascar in which a twice daily application of Zanzarin® immediately reduced the attack rate to zero and the pathology to a negligible level within 10 weeks (48), even in very severe cases (53). Commercial production of Zanzarin® was stopped. However, based on its principal ingredient, caprylic acid, a compound of coconut oil, it could be produced locally. It is non-toxic, biodegradable and environmentally friendly. It can be applied by the affected individuals with minimal input from the health sector and should be applied at least in the months of high transmission and to the most vulnerable populations.

Another way to prevent tungiasis is to eliminate risk factors and supporting protective factors. A major risk factor for tungiasis that could be targeted for control is the structure of people’s homes. Risk factor studies in Brazil, Nigeria and Kenya have all identified dirt floors and mud walls as major risk factors for the presence of infection and severe disease, as sand fleas can hide in cracks and holes and larvae will feed on organic materials found in dirty floors (20,54–56). Thus, finding an affordable way for impoverished families to seal their floors is likely to have a large impact on the disease prevalence (56). Cleaning the floor of the house with a broom and/or pouring water into cracks and crevices and sweeping the compound regularly are likewise potential measures for prevention.

Families that have no latrines and use open defecation were found to be at greater risk in Brazil, Nigeria and Kenya. Avoiding open defecation might prevent the off-host cycle to be completed. Similarly, families who use open disposal of waste on their compound were also at greater risk in Brazil (20) and in Kenya (55), as waste attracts cats, dogs and rodents all of which are important reservoirs of tungiasis. The study in rural north-east Brazil found that appropriate waste disposal theoretically would reduce the number of cases by 51% (20).

The risk factor studies in Nigeria and Brazil identified previous use of insecticides inside the house by the family as having a protective effect against tungiasis (20,54). The off-host stages of T. penetrans have been found on the floor of people’s homes, often in the sleeping quarters under the bed, as well as outside in shaded areas, particularly those used by people and their domestic animals for resting. Control should be possible by spraying appropriate, safe insecticides in these areas. However, the risk of development of resistance must be considered if insecticides are applied long term. The toxicity to humans, animals and the environment as well as the cost of insecticide should also be taken into account. An alternative method of prevention is to spray house floors with an aqueous solution prepared by soaking neem leaves in water. The neem tree is widespread in tropical countries and is known for its properties in controlling different insects and ectoparasites. Kenyan families using the neem solution reported that they no longer could see any sand fleas inside the house and that they had less newly embedded sand fleas (55).

No intervention study has been conducted to determine whether tungiasis can be controlled by water, sanitation and hygiene (WASH) interventions. However, there is some evidence from risk factor studies that daily washing of feet with soap may be preventive to some degree: in Uganda, children with dirty feet and dirty clothes had a higher risk than those who were clean. People who report not using soap whenever they wash were at a greater risk of infection in Nigeria (54) and Kenya (55), and for severe infection in Brazil.
A simple intervention that could assist in prevention is the provision of closed shoes. Risk factor studies have identified the lack of closed shoes as a risk factor in Kenya (55). However, a community-based study in Madagascar showed that donated shoes are worn irregularly. Even people who wore the shoes consistently revealed only a moderate decrease in the intensity of infection after 10 weeks (48). Besides, even very solid shoes will only partially protect against invading sand fleas. The protective effect of shoes is also limited since they are not worn when sleeping, which is when exposure inside the house mostly occurs.

2.8 Treatment in humans

So far, there is no access to a safe, available and effective treatment for tungiasis in endemic communities globally. In most communities, the embedded fleas are extracted either by the affected person themselves or by others, using non-sterile sharp implements such as safety pins, plant thorns, knives, scissors or razor blades. This has a high risk of causing more harm including haemorrhage and secondary bacterial infection which is very common. There is a high risk of transmission of blood-borne viral infections such as HIV and hepatitis B and C viruses through sharing a single sharp instrument (5).

Some individuals apply household chemicals topically in an attempt to kill the embedded fleas, such as kerosene which may be harmful if used long term. Veterinary chemicals (acaricides usually) are also used but are not approved for human use and can cause severe damage, such as gangrene and necrosis (56). Several communities are using herbal medicines which are applied topically but whose efficacy is unknown. Herbal medicines can also be harmful as they may contain potent toxins, such as the seeds of *Strychnos madagascariensis* and *Mundulea sericea* which contain strychnine and rotenone respectively, both used as poison for fishing in coastal Kenya (56).

As governments and nongovernmental organizations have attempted to treat and control the disease, they have turned to chemicals available to them. In Kenya, these have included a range of disinfectants including potassium permanganate (KMnO4) and Lysol®. KMnO4 has been tested in two randomized controlled trials (RCTs) both of which have demonstrated to kill only 40% of embedded fleas within 7 days (47,57). KMnO4 is also cumbersome to use and needs careful handling since it irritates the skin. More recently, benzyl benzoate previously prescribed for scabies, is being used in several counties in Kenya, although only anecdotal reports of its efficacy are available.

Only six RCTs have ever been conducted in regard to treatment of tungiasis in humans. Oral treatment with niridazole (30 mg/kg single or double dose) was 100% effective but 16% of subjects had strong side-effects with the central nervous system, hence it is not recommended at all (58). Oral ivermectin (300 ug/kg on two consecutive days) had no efficacy (59). Topical application of ivermectin (0.8%) or metrifonate (0.2%) emulsions were better than a placebo, while topical thiabendazole (5%) either as ointment or as lotion showed no impact on embedded fleas (61).

Following the successful topical use of dimeticones for the treatment of headlice (60), two RCTs have been conducted using a mixture of two dimeticone oils with a different viscosity (47,61). Dimeticone oils are silicon-based inorganic polymers of different lengths with a low surface tension and excellent creeping properties. NYDA®, the trade name of a mixture of two dimeticone oils with different propensities, is produced by Pohl-Boskamp GmbH & Co. KG, Germany, and was originally marketed for treatment of head lice. It is registered under the trademark NYDA®-Tunga for the treatment of tungiasis. The low viscosity enables it to penetrate the respiratory tract, the intestine and the genital tract of the embedded insect and to occlude these vital organs. Dimeticones are safe since they are biochemically inert, non-toxic, non-carcinogenic and non-teratogenic (62,63). Due to the physical mode of action of dimeticones, it is highly unlikely that sand fleas would develop resistance (64). The low-viscosity dimeticone in NYDA® is inflammable, hence individuals should stay away from fire for up to 2 hours after application.

The first RCT (a proof of principle study) was conducted with primary-school pupils in Kenya, enrolling those with at least one embedded viable sand flea per foot. The feet were randomized into two treatment arms: one foot was bathed in a solution of 0.05% KMnO4 while the other foot was wetted with NYDA®.
After a single treatment the sand fleas were monitored for their viability and morphological development for 7 days. The dimeticon killed 78% of embedded sand fleas and 92% showed an abnormal development; among others, no eggs were expelled (47). After the treatment with KMnO4, only 39% of sand fleas were dead.

In a consecutive trial in Uganda, NYDA® was applied directly to the abdominal cone of the embedded sand fleas, which protrudes above the skin and contains a number of vital organs such as the respiratory tract. After this targeted treatment, 98% of fleas were killed within 4 days. In the few remaining viable sand fleas, expulsion of eggs was not observed at any time of the study. If dimeticones are applied systematically in humans and animals, this will lead to an interruption of the off-host life cycle of sand fleas: when no eggs fall to the ground, no adult fleas can develop.

A case series in patients with very severe tungiasis (up to 1300 embedded sand fleas laying on top of each other in hyperkeratotic skin) in Colombia showed that after treatment with NYDA® patients were cured within 2 weeks. In these very severe cases, treatment with NYDA® was repeated after 1 week (18).

Confirmation of the mode of action and safety of dimeticones in treatment of tungiasis has been tested in pigs in Uganda. Preliminary data from this ongoing study show that the mode of action of NYDA® is purely physical and that it creeps into the parasite and not the surrounding host tissue (Mutebi F and Feldmeier H, unpublished observation).

In a recent RCT, a herbal medicine combining oil from the seeds of the neem tree (Azadirachta indica) with coconut oil (Cocos nucifera) was compared to the treatment with KMnO4 (57). Neem has an extensive history of use in ayurvedic medicines in India, and systematic studies have demonstrated its anti-bacterial, anti-fungal and anti-inflammatory effects as well as efficacy against many insect species (65–68). The RCT randomized 96 primary-school pupils with at least one viable flea into two study arms (57). The embedded fleas were monitored for viability and abnormal development. Acute tungiasis-associated morbidity was measured. While the neem product did not kill more fleas in the 7 days than the control KMnO4, it did cause rapid aging in 62% of the embedded fleas compared to only 26% after treatment with the KMnO4. In addition, the neem product significantly reduced the acute pathology, which the KMnO4 did not (54).

2.9 Tungiasis in animals

In the genus Tunga, 14 species have been reported to infect animals. Of these, three are described in domestic mammals; only T. penetrans and T. trimamillata are zoonotic (69). T. trimamillata is reported in Brazil, Ecuador and Peru, whereas T. penetrans has been recorded in the tropical endemic countries of Latin America, the Caribbean islands and sub-Saharan Africa. T. penetrans has the widest host range. It has been detected from eight families and 27 genera of mammalian species; Artiodactyla, Carnivora, Cingulata, Perissodactyla, Pilosa, Primates, Proboscidea and Rodentia. T. trimamillata has been reported from three families: Artiodactyla, Primates and Rodentia. To date, only a few studies have been done to clarify the role of animals in the tungiasis cycle along human infections. In these few studies, T. penetrans infections are described in a wide range of domestic and wild mammalian species which vary among endemic areas. In Latin America, dogs and cats have been reported as the most important animal hosts for T. penetrans (70), whereas in Africa, pigs are the most important (12). Other animal reservoirs include domestic ruminants, peridomestic rodents and synanthropic mammals (71).

Tungiasis in animals presents like human tungiasis. There is inflammation associated with flea penetration which is compounded by superinfections and self-mutilation. Severe cases are accompanied by various sequelae: septicaemia, digital loss, deformities as well as mortalities in endemic communities. Studies allude to the contribution of animals in the persistence of transmission and in amplification of intensities of tungiasis among humans. Prevalences of tungiasis among pig and dog populations are often high and, in some instances, approach 100%. The infection intensities can also be very high, for instance in Uganda where over a thousand fleas have been reported on a single pig.
The intensity of infection correlates strongly between animals and humans living in the same community. The sex of the animal has not been seen to influence the parasite load in both pigs and dogs. In dogs the intensity of infection decreased with age, while in pigs age was not a factor (72). Not much has been done on risk factors for animal tungiasis; however, pigs were found to be more at risk whereas chickens were seen to be protective and could be investigated further as a biological agent for control of tungiasis. Limited efforts have been directed towards identification of an effective and cost–effective treatment for animal tungiasis. Dimeticone oils need to be investigated in comprehensive studies to determine their potential in the treatment of animal tungiasis.

In conclusion, a variety of animals are involved in the epidemiological cycle of zoonotic tungiasis in endemic areas; hence, animal reservoirs should be identified where human tungiasis is endemic. Animal treatment should be integrated in all control interventions to cut off the life cycle of the parasite, consequently reducing human tungiasis in endemic communities. Currently, there is no validated treatment for animal tungiasis; therefore there is an urgent need to identify an effective and affordable treatment. As an initial step that can quickly be done, field trials of commercially available ectoparasiticides indicated for other ectoparasites should be tested for therapeutic and prophylactic effects.

2.10 One Health approach: challenges and opportunities

WHO defines One Health as “an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcome.” Within this context, and considering the specific features of tungiasis, control of this ectoparasitic disease is a paradigmatic example of a case for One Health: there are different domestic (dogs, cats), livestock (pigs, goats) and wild animal species (rats, synanthropic animals) which may act as reservoirs; the life cycle can be completed indoors (especially in the case of inadequate housing) and outdoors; there is an intrinsic link to poverty, social determinants and related factors, such as access to sanitation, water and waste management; and the climate considerably influences the occurrence of tungiasis in both urban and rural communities. Consequently, a multisectoral One Health approach is needed for sustainable control of tungiasis in highly affected communities. The different sectors to be included should focus on the outcome for people, animals and the environment. The multidisciplinary approach should involve, medical doctors, veterinarians, entomologists, anthropologists, education and communication specialists, ecologists and public health professionals.

Diseases are interrelated with each other, and this should be considered in the control and prevention of tungiasis, for example:

- applying a repellent to the feet may have positive effects on other diseases such as hookworms;
- dimeticone oils may also be used in the community for treatment of other diseases such as pediculosis and myiasis;
- preventing pigs from roaming freely might have a positive effect on the occurrence of cysticercosis as well;
- controlling rats might have a positive effect on the occurrence of leptospirosis;
- tungiasis should be included in control programmes for other diseases such as malaria, soil-transmitted helminthiases, onchocerciasis in endemic populations, WASH and school-based interventions;
- tetanus control; and
- Improving house floors will likely protect from soil-transmitted helminths and bacterial diseases of young children.
It is therefore concluded that efficient and sustainable tungiasis control is technically feasible within the One Health approach. Several issues and bottlenecks should be considered.

- Communication between sectors and regions is crucial, and silo mentality must be dismantled.
- Political commitment and priority setting are paramount.
- Collaboration with stakeholders at all levels, including with local communities, nongovernmental organizations and traditional leaders, will ensure sustainability of actions.
- Improvement of living conditions will be key for sustainable control.
- Information, education and communication campaigns will help to reduce stigmatization.

Other NTD control programmes should join forces with tungiasis control measures to improve outcomes, and to increase efficiency. Clearly, more data and systematic research are needed to serve as a basis for evidence-based control measures, in addition to increased advocacy and financing.

The following example illustrates a successful multisectoral tungiasis control approach implemented in Nigeria. A rural community in Nigeria had these population attributable fractions: sand or clay inside the house serving as breeding sites (73.7%); a common resting place outside the house (65.5%); no regular use of footwear (51.1%); and presence of free-roaming pigs in the compound (37.9%) (54). The main pillars of the intervention included banning free-ranging pigs in the community, promoting use of shoes (though not provided), sealing the floors of houses with concrete and practising environmental hygiene. The project followed a multisectoral approach in collaboration with local communities, and achieved considerable reduction of tungiasis morbidity at relatively low cost. The prevalence reduced from 45.2% to 21.3% after one year. The total number of embedded fleas reduced by 80%.

2.11 Integrated approaches for tungiasis control

An integrated approach that combines several interventions may be the best way to reduce the burden of tungiasis. Such an approach may include promoting changes in hygiene behaviour and self-care; improving sanitation inside and outside houses; and modifying the conditions of dirt floors (with the use of brooms, compaction and soil moistening). Community-based surveillance programmes for infections, topical treatment with standard medicines (64), veterinary health of the animals living with people and good coverage of safe ectoparasiticides (73–75) are also important measures. In addition there should be rapid institutional response to care for outbreaks of tungiasis in endemic communities. Below are examples in which integrated actions have been considered.

2.11.1 Tungiasis community-based programme in Kilifi

In 2015, a community group of 30 community health volunteers initiated a local response in Kilifi, a coastal area in Kenya, in response to the high burden of tungiasis (56). They used their own knowledge to design the local programme. They could correctly diagnose their own tungiasis cases and were aware of the interaction the disease had with poverty and poor housing. They also knew the importance of education and hygiene. The volunteers had traditional knowledge of effective local remedies for treatment and prevention as well, namely neem and coconut oil. They designed a multi-pronged community action targeting a population of 30 000 people who they treated with a neem-coconut oil product weekly: house-to-house, in all schools and sprayed floors with a solution made from neem tree leaves (Azadirachta indica) (the neem solution was prepared by soaking the leaves in water for 4 days). The ground inside homes, classrooms and areas of the compound where families spent most of their time was soaked with neem solution weekly. They also partnered with the TOMS “One-for-One Program” to distribute closed shoes free of charge to school-going children to prevent new infections in school. Some 12 000 children received shoes twice a year. The community health volunteers also conducted awareness and education on tungiasis in schools and at local meetings. Stakeholders from the Ministry of Health were engaged throughout implementation of the programme (56). Individuals were evaluated through foot screening...
during TOMS shoe distribution. Tungiasis prevalence among schoolchildren decreased from 17% to < 1% and severe disease was eliminated throughout the observation period between 2015 and 2017. However, the impact of each individual intervention component is unknown since this programme was not set up as a research project.

The same community group was engaged in another project that looked at improving household floors as an intervention method. Non-solid floors with cracks and cervices are considered transmission hotspots. A sealed floor can provide a sustainable solution for tungiasis prevention; however, affordable, improved floors such as standard concrete floors are beyond the reach of affected families in Kenya. Flooring solutions that have a lower cost readily made from local material can prevent sand flea development are needed. In this study in coastal Kenya, where the natural soil has a very high sand content, simple cement-stabilized soil floors were found to be a good available strategy for house improvement. House occupants realized the benefit of having a sealed floor, not only in reducing tungiasis infection but also in reported reduced respiratory infection and a cleaner environment for other family activities. Household prevalence of tungiasis reduced by approximately 50%, in line with previous predictions from population attributable fraction calculations. It was apparent, however, that participant behaviours and movement contributed to highly variable results. Formative research and behaviour change interventions are hence recommended to support interventions for greater impact. New flooring solutions can be promoted through local community-based organizations and nongovernmental organizations.

In conclusion, control of tungiasis, defined as elimination of severe, debilitating disease, is achievable through fairly simple and affordable community-based strategies incorporating both treatment and prevention components.

2.11.2 Tungiasis control project in Homa Bay County, Kenya: description of the setting and strategy

A tungiasis control project under the Nagasaki University–Japan International Cooperation Agency technical partnership cooperation and the Ministry of Health in Kenya is set to commence at two sites in Kenya (Suba South and Ndhiwa subcounties of Homa Bay County) for 5 years from February 2021 to January 2025. As of early 2020, tungiasis was reported in 64 (19.9%) of 321 villages and 47 (25.0%) of 188 schools in Suba South, and in 47 (7.6%) of 620 villages and 38 (16.5%) of 231 schools in Ndhiwa. The project’s purpose is to reduce morbidity of tungiasis in the target area with an overall goal of eventually scaling up into the entire Homa Bay County. The expected outputs will be: strengthening surveillance; mapping and reporting of tungiasis; developing capacity of community health volunteers or qualified health care workers on prevention of tungiasis; and education and awareness on behaviour change for tungiasis prevention in the community. The project will train community health volunteers in case detection of tungiasis, health care workers in treatment, and school teachers in behaviour change communication.

The core strategic component for sustainable control of tungiasis will be a comprehensive approach that includes collaboration with other disease control programmes, community participation, enhanced capacity of community health volunteers, integration with school health and WASH programmes, as well as child-to-parent approach (that is, children taught on hand and foot washing and they in turn teach the rest of the family at home).

In addition to this project, a supplementary intervention through a public–private partnership for improvement of living conditions of households affected with tungiasis will be conducted. A small Japanese building contractor will be involved to flatten and smoothen the floors of classrooms from schools in tungiasis-endemic areas. After which the technical know-how of flattening and smoothening floors will be transferred to the local people to assist them in improving their household floors.
2.11.3 Tungiasis elimination project in Karamoja, Uganda

An ongoing project in Karamoja district, northern Uganda, combines the One Health approach with systematic treatment as the major principles with the goal to eliminate tungiasis as a public and individual health hazard. Trained community health workers treat every infected person and every infected animal at regular intervals, with a mixture of two dimeticone oils (NYDA"). By doing so it is expected that the number of eggs which are expelled and fall to the ground will decrease to zero over time. As a consequence, the systematic treatment of humans and animals should lead to the interruption of the off-host cycle, thereby preventing new infections.

2.11.4 Development of a trap for catching adult sand fleas: entomological background

The use of traps laced with attractants has never been attempted. A trap has the advantage of being ecologically friendly and sustainable, unlike insecticides that bear a risk of drug resistance and toxicity to humans and the environment. Light traps to control different flea species such as cat fleas in Japan are commercially available. However, for sand fleas, no known traps have been developed as a tool for controlling tungiasis. An ongoing study aims to develop a prototype light-trap in an area endemic for tungiasis in Kwale County, Kenya.

As a first step, light attractiveness to sand fleas using commercially available “cat flea traps” with 460 nm blue light was validated by installing the traps under the bed or around the sleeping area in households inhabited by tungiasis patients and evaluated for light attractiveness during the night. As a result, traps with light-on attracted sand fleas more than those with light-off, confirming that blue light attracts sand fleas. Next the study will seek to determine which light wavelength is best in attracting adult sand fleas, among other objectives, which will culminate in the development of a sand flea trap. As an additional step of the trap development, off-host sand fleas habitats inside the house will be surveyed by collecting soil samples to identify suitable locations in which to set the traps in houses in endemic areas.
3. Conclusions, recommendations and next steps from meeting participants

3.1 Tungiasis mapping and surveillance

Mapping and surveillance of tungiasis should be undertaken in order to:

- determine if tungiasis is a significant health issue requiring attention by health authorities nationally and regionally;
- identify geographical areas to be targeted for interventions;
- identify overlap with other disease control programmes for possible co-implementation;
- quantify numbers of prevalence/incidence for budgeting purposes; and
- establish sentinel populations for monitoring and evaluation of intervention programmes.

Underreporting of tungiasis cases is a major challenge. Currently, it is impossible to deduce the prevalence of tungiasis from health system records because affected individuals rarely seek treatment from health facilities due to stigma, lack of access to health facilities and the fact that there is no available treatment.

In countries in the Americas and African regions there is no national tungiasis surveillance system. It has neither been attempted nor standardized. Only small-scale prevalence surveys covering a few villages or schools have been done in some countries, for example in Brazil, Cameroon, Ethiopia, Kenya, Nigeria, Trinidad and the United Republic of Tanzania. In other countries there are no data on prevalence and geographical distribution of tungiasis even though cases are being observed and reported by medical doctors and health care workers. In such situations, baseline data on prevalence and distribution are crucial before control programmes can be initiated. Use of key informants and health care networks from these countries to ascertain whether there is occurrence of tungiasis or not is important. Credibility for tungiasis can be built and resources mobilized if data on the burden and distribution of the infection are obtained.

Recommendations from meeting participants

Underreporting of tungiasis cases can be improved by surveillance and mapping. To collect data, the family health strategy (in some areas referred to as the community health strategy) or primary health care is the ideal approach. Other options include using the market day approach where one asks individuals coming to a market questions regarding tungiasis in the area to understand the magnitude of infection. Another strategy is to integrate tungiasis surveillance in other disease programmes that have funding to maximize the outputs realized. However, this will require that the seasonality of tungiasis is factored in as the disease peaks during the dry season and may be missed if surveys are done at other times of the year.

Underreporting can also be improved by mitigating against stigma through creating awareness of the disease. Education to demystify the infection and to create awareness in endemic settings is important and should be done. Improvement of knowledge, attitudes and behaviour among the entire community will ensure a better reporting outcome.

Classification of areas as low risk and high risk may not be permanent in some instances because the epidemiology may change and hence requires constant monitoring. Community surveillance can be established to better understand the disease burden. This might be done with the help of tribal leaders or community health volunteers.

For the time being, mapping with precision will rely on local communities and using a multidisciplinary approach. Initially, mapping should begin at the local level, the local administrative unit and not the national level. It should mainly serve to ascertain the presence or absence of tungiasis in an area. Here esti-
mates would be required, not necessarily precise figures. Settings should then be characterized according to risk factors. For example, some have animal reservoirs and others do not.

Primary data from real tungiasis cases are needed since they are better than predicted values arrived at by mathematical modelling mapping. For instance, there are cases where a site is identified as endemic when modelled yet in reality it is not, or areas which were endemic in earlier years but are at present not suitable for tungiasis due to factors such as urbanization.

A rapid assessment method previously developed is quick to perform and can be used as a first step. It has been validated in studies conducted between 2001 and 2008 in Africa and South America (50). The method is especially useful when time is short, finances are limited and focus is on understanding the situation in a particular site that has no information on the magnitude and distribution of the disease. Thereafter more comprehensive studies can be performed looking at more detailed factors. The diagnosis of tungiasis unlike other NTDs is simple and does not require any equipment. School-based initiatives can be utilized as well.

Resources for mapping are important and necessary to close this gap. Later, after initially identifying which communities are affected, stakeholders can learn and borrow from other NTD programmes that are more advanced in mapping, since tungiasis is also an NTD.

3.2 Prevention in humans

Elimination of risk factors with a high population attributable fraction could reduce tungiasis prevalence. However, there are limited data available on such risk factors and they vary from setting to setting. In addition, most of the risk factors with a high population attributable fraction are intricately associated with severe poverty and hence challenging for affected communities to eliminate at an individual level. For instance, inadequate classrooms and non-solid or dirt floors with cracks in houses are major risk factors that allow the completion of the Tunga life cycle leading to continuous high-intensity infection in some cases. Sealing of floors with concrete to prevent infection would be ideal but is out of reach for impoverished families who are those most affected by tungiasis.

The challenges for prevention of tungiasis relate also to the epidemiological characteristics of the disease and the biology of the parasite. There is a general lack of knowledge of the biology of *T. penetrans* off-host stages. A good understanding of the flea's ecology, how different climatic seasons and pressures exerted by inadequate control measures affect the larvae as well as the pupae, predators in the environment, host-finding cues and developmental requirements, for instance what the larvae feed on, can help to identify and design targets for control of the off-host stages.

Tungiasis is a zoonotic disease and, in some settings, animal reservoirs are important for maintenance of the transmission cycle. In such areas, control of tungiasis in animals will be required to interrupt transmission between people and animals.

Zanzarin® has been identified as an effective repellent in several studies, but it is not available in endemic communities. Based on its principal ingredient (caprylic acid), it might be considered for local production from coconut oil. However, learning from other disease programmes such as malaria, it is known that uptake of repellents is low as it depends on user compliance. Likewise for tungiasis, use of a repellent may not be the best recommendation for a programmatic approach.

**Recommendations from meeting participants**

At present, there is limited evidence to make conclusive recommendations on prevention of tungiasis. The only data available are from studies with Zanzarin® as a repellent and with shoes. More evidence-based research is needed on other interventions such as house floors, hygiene and sanitation, and different house sprays before concrete recommendations on prevention of human tungiasis can be made.
Several studies have however identified indoor house and school floors as major risk factors, hence these can be targeted for improvement to help with disease prevention initially. Finding affordable ways for impoverished families to improve their floors may have a large impact on disease prevalence.

A better understanding of the flea’s ecology, underlying processes of neosomy, host-finding cues and the required developmental conditions for off-host stages is important. It will help with identifying targets for control, with understanding the heterogeneous distribution of the disease and may help in predicting disease risks, thereby supporting control programmes.

It is difficult to reach remote populations due to lack of funds. To overcome this problem, tungiasis control programmes can be combined with other disease control programmes such as those for malaria that have financing to reach out to the community and build credibility for public health care of the infection.

### 3.3 Treatment in humans

Tungiasis, if left untreated, is likely to develop into severe disease and may become fatal due to secondary infections. Severe disease has direct physiological and psychological impacts, reducing a family’s income and trapping them in a vicious cycle of infection and poverty.

Currently there is no safe and effective treatment available in endemic communities, hence, due to desperation, affected individuals resort to traditional treatments (use of sharp non-sterile instruments, toxic chemicals and plants) which cause excess morbidity and may cause irreversible destruction of tissue surrounding the lesion. In endemic communities, use of unsterile sharp objects such as thorns and safety pins leads to rupture of the parasite, which intensifies the inflammation and increases the risk of bacterial superinfection, gangrene, tetanus, abscess and septicemia. Such sharp instruments are also shared, thus further exposing individuals to transmission of viral pathogens such as HIV and hepatitis B and C viruses.

Previous studies to find suitable treatment for tungiasis have been unsuccessful except for those on dimeticones. The test agents showed either no or limited effect on embedded sand fleas or had serious side-effects. A mixture of dimeticones which are used to treat head lice has shown good activity against the ectoparasite in two randomized trials (NYDA®, registered as a medical device in Europe and overseas). Some countries such as Brazil and Colombia have used NYDA® to treat tungiasis with good results in small areas. No adverse reaction has been reported by participants who have used it to treat tungiasis. Its mode of action is purely physical, hence there is no risk of the fleas developing resistance. When applied in large quantity to the skin, NYDA® is inflammable for about 2 hours. Even though in use in small areas for tungiasis with success, NYDA® is not registered nor available in most endemic countries.

**Recommendations from meeting participants**

Dimeticones are effective and safe and all efforts should be made to register and distribute NYDA® which is the best treatment candidate for tungiasis so far, in all endemic countries. For Latin American countries the product is now available for purchase through the PAHO Strategic Fund. Recent efforts between PAHO and the producer in Germany have ensured the registration of the product in some Latin American countries. Traditional treatment with all its complications is no longer warranted.

### 3.4 Opportunities for integrated action

Elimination of severe, debilitating disease is achievable through an integrated approach in promoting changes in hygiene behaviours and self-care in affected populations, sanitation inside houses, modification of the conditions of dirt floors as well as community surveillance programmes for infections. In addition, affected individuals should also be treated with products which are effective, infected animals living in close proximity to people treated with safe ectoparasitcides. Finally, there should be a rapid
institutional response to care for outbreaks of tungiasis in these communities in collaboration with the public. Community health workers play a leading role in action and communication. Other approaches include using school programmes and collaborating with other diseases control programmes such as the mass drug administration programmes for helminths or vaccination programmes. Collaboration with stakeholders at all levels, local communities, local administration, nongovernmental organizations and political leaders is important if sustainability of tungiasis control actions is to be realized.

**Recommendations from meeting participants**

An interdisciplinary approach to working with all sectors in endemic countries is needed. At present, this approach is only feasible academically: the real challenge is at the political level, which may be assisted by the involvement of WHO and PAHO.

In communities where risk factors are shared by several NTDs, tungiasis surveys and control programmes might be integrated with other disease programmes in ways that will work best for tungiasis with the support of experts. Some programmes such as those for malaria control do not systematically visit all communities as the focus is more on outbreaks, hence some areas may not be covered. When joining other platforms, two factors should be taken into account: (i) that the host programme has resources that can be used; and (ii) the possibility of reaching all communities. If not, then integration of different actions in different programmes may be explored. The other aspect that needs consideration is the seasonality of tungiasis and the settings where it is likely to occur. Preliminary surveys on how integration will be possible should be done initially before this recommendation is made. Having specific surveys for tungiasis, however, would be the most ideal approach if funds allow.

Simple tools that do not cause additional burden to the hosting programme should be developed and provided to community health workers who conduct house-to-house visits. For example, a simple picture tool to assess presence or absence of disease. Other opportunities for integrated approaches include mass drug administration for helminth infections, trachoma control, immunization programmes and polio eradication programmes.

The environment must be taken into account when taking an integrated approach, and issues such as inadequate sanitation, access to water, overcrowding of houses, among others, must be well understood. Interventions should then be linked depending on the context of the local setting.

Global awareness of tungiasis to generate interest among stakeholders is key and can be conducted in a number of ways. As a first step, all the meeting participants will come together to create an expert group to help promote issues on tungiasis. Secondly, different platforms and communication strategies must be used to reach out to important stakeholders such as nongovernmental organizations, civil societies, funding agencies and governments, among others. Simple advocacy materials will need to be developed to share with health ministry officials, health workers and NTD implementing partners.
3.5 Research priorities

Sustained global research on tungiasis is critical. Research is needed to accelerate efforts to identify standardized treatments, effective control measures, improve interventions, eliminate practices that cause more harm than good, identify communities that need urgent attention, help determine the burden of the disease and optimize use of finite resources.

Given the limited resources, it is prudent that research areas are prioritized according to their urgency and the importance of the gaps they intend to close in order to maximize returns. Below is a summary of research areas and actions collated during a brainstorming session. The research topics are not listed in any order of priority.

1. Map the spatial distribution and dimensions of human and animal tungiasis at district and country levels. Actions: Conduct rapid assessments of prevalence and severity of tungiasis combined with IT tools, market day approach, ask the headmaster approach through mobile phones as well as social media.

2. Develop a simple method to identify the presence of larvae/pupae/adults in/on top of soil/floors plus cheap and easy-to-handle traps. Actions: Simplify existing or develop new entomological tools for identification of off-host stages. Develop traps using attractants for adult fleas.

3. Identify the environmental requirements for completing the parasites off-host life cycle, for instance, temperature, humidity, composition of soil needed, among others. Identify predators of off-host stages for example chicken. Actions: Initiate innovative entomological research.

4. Identify novel preventive and therapeutic compounds. Actions: Develop an animal model, for instance goat kids, to test compounds for treatment and prevention. Identify plant oils with a low viscosity at all temperatures and/or repellent activity.

5. Explore low-cost, low-tech abundantly existing natural materials to transform non-solid floors into smooth, easy-to-clean surfaces. Actions: Validate methods already in use in some areas such as cow dung. Identify sources for financing the costs for exploring flooring options and implementation of solid floors.

6. Integrate interventions against tungiasis with other types of interventions such as WASH programmes. Actions: Compare the cost–effectiveness of established methods for control of tungiasis with interventions having additional components such as WASH in different settings.

7. Devise teaching materials on tungiasis for schoolteachers and health care workers specific to the cultural setting of the region where they work. Actions: Research successful materials used for other NTDs, particularly soil transmitted helminthiases.

8. Pursue research into protective factors and effective mechanisms of transfer of knowledge from indigenous communities not affected by tungiasis but living in the same conditions as those affected. Actions: Validate traditional methods used by indigenous communities to keep the prevalence of tungiasis low.

9. Explore the stigma associated with tungiasis. Actions: Understand the type of stigma, its effects and ways to mitigate it.

10. Conduct research into how best to register products that are effective in controlling tungiasis. Action: make NYDA® available and accessible to endemic communities as it is the best available treatment for tungiasis.
3.6 Next steps

WHO, in consultation with PAHO, will access funding to start working on some of the recommendations made at this meeting.

This report of the meeting will be critical and should be distributed to help with advocacy and resource mobilization, and to kick start any federal actions.

The meeting participants should form the core group of experts who will help in addressing tungiasis in the larger NTD framework and, consequently, in becoming the voice and face of fighting tungiasis.

Any learning from past experiences of other diseases in terms of available treatments or tools that can be used to fight tungiasis, even if not perfect, should be used to initiate the process. Research can then be used to improve them. If a perfect tool, treatment or condition is awaited on, stakeholders will be weighed down and starting made difficult.

The most important aspect is advocacy since tungiasis is at its inception stage even at WHO headquarters. It is therefore important to ensure that health ministries and countries include tungiasis in their master plan. Many donors want to see if the disease is in the national or action plan first.

Development of simple, standardized tools is important for prevention and treatment as countries are already overwhelmed with several diseases for which a lot of information is sought.

WHO and PAHO will work together to establish an expert group on tungiasis, which will prepare guidelines on prevention and treatment for consideration by the WHO Guideline Review Committee.
References


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68. Abdel-Ghaffar F, Semmler M. Efficacy of neem seed extract shampoo on head lice of naturally infected humans in Egypt. Parasitol Res. 2007;100(2):329–32.
69. Linardi PM, de Avelar DM. Neosomes of tungid fleas on wild and domestic animals. Parasitol Res. 2014;113(10):3517–33.
## Annexes

### Annex 1. Agenda

**Day 1: Monday 11 January 2021**

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00–12:10</td>
<td>Instructions to participants on logistics of the meeting</td>
<td>Martha Saboya</td>
</tr>
<tr>
<td>12:10–12:15</td>
<td>Welcome by WHO/NTD Department Director</td>
<td>Mwelecele Malecela</td>
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<tr>
<td>12:15–12:20</td>
<td>Welcome by PAHO/CDE/VT unit chief</td>
<td>Luis Gerardo Castellanos</td>
</tr>
<tr>
<td>12:20–12:30</td>
<td>Meeting objectives, brief description of the agenda contents,</td>
<td>Martha Saboya</td>
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<tr>
<td></td>
<td>general introduction of Chair and panellists</td>
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<tr>
<td>12:30–12:50</td>
<td>Updates from the Regions (10 mins each)</td>
<td>Abate Beshah and Martha Saboya</td>
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**II. Background (Timekeeper: Ana Luciañez)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Participants</th>
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<tbody>
<tr>
<td>12:50–13:05</td>
<td>Ecology of <em>Tunga penetrans</em></td>
<td>Ulrike Fillinger</td>
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<tr>
<td>13:05–13:35</td>
<td>Epidemiology of tungiasis - global aspects and characteristics in</td>
<td>Jorg Heukelbach</td>
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<td>different settings</td>
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<tr>
<td>13:35–13:55</td>
<td>Tungiasis in animals – epidemiology, treatment</td>
<td>Francis Mutebi</td>
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<tr>
<td>13:55–14:10</td>
<td>Questions and clarifications</td>
<td>*Conducted by the Chair,</td>
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<td>Ingela Krantz, with all participants</td>
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<tr>
<td>14:20–14:35</td>
<td>Impact of tungiasis</td>
<td>Lynne Elson</td>
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<tr>
<td>14:35–15:05</td>
<td>Pathogenesis, morbidity, and sequels</td>
<td>Hermann Feldmeier</td>
</tr>
<tr>
<td>15:05–15:20</td>
<td>Diagnosis, staging of disease, and rapid assessments methods</td>
<td>Marlene Thielecke</td>
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<tr>
<td>15:20–15:50</td>
<td>Questions and clarifications</td>
<td>*Conducted by the Chair with all</td>
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<tr>
<td>15:50–16:00</td>
<td>Wrap up</td>
<td>Pamela Sabina Mbabazi</td>
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**Day 2: Tuesday 12 January 2021**

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<thead>
<tr>
<th>Time</th>
<th>Item</th>
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<tbody>
<tr>
<td>12:00–12:20</td>
<td>Prevention</td>
<td>Marlene Thielecke</td>
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<tr>
<td>12:20–12:40</td>
<td>Treatment for humans</td>
<td>Marlene Thielecke</td>
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<tr>
<td>12:40–13:00</td>
<td>Questions and clarifications</td>
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<tr>
<td>13:00–13:25</td>
<td>Tungiasis in Amerindian population</td>
<td>Hollman Miller</td>
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<tr>
<td>13:25–13:35</td>
<td>Questions and clarifications</td>
<td>*Conducted by the Chair with all</td>
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<tr>
<td>13:35–13:45</td>
<td>Challenges and opportunities for tungiasis mapping and surveillance</td>
<td>Lynne Elson</td>
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<td>– Experience of the national tungiasis survey in Kenya</td>
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<tr>
<td>13:55–14:40</td>
<td>Introduction (10 min)</td>
<td>Introduction by Per Nordin</td>
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<tr>
<td></td>
<td>How can we determine the geographical distribution and the</td>
<td>Discussion conducted by the Chair with all panelists and participants</td>
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<td>prevalence of tungiasis?</td>
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<td></td>
<td>Discussion and recommendations</td>
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<tr>
<td>14:40–15:05</td>
<td>Challenges for prevention and treatment of tungiasis and options</td>
<td>Hermann Feldmeier</td>
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<td>tailored to specific settings</td>
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<td>15:05–15:15</td>
<td>Development of a trap for catching adult sand fleas: entomological</td>
<td>Ayako Hyuga</td>
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<td>background</td>
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<tr>
<td>15:15–15:25</td>
<td>Tungiasis control project in Homa Bay County, Kenya: Description</td>
<td>Yasuhiko Kamiya</td>
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<td></td>
<td>of the setting and strategy</td>
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<tr>
<td>15:25–15:55</td>
<td>Introduction (5 min)</td>
<td>Introduction by Herman Feldmeier</td>
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<tr>
<td></td>
<td>What are the recommended interventions to prevent tungiasis?</td>
<td>Discussion conducted by the Chair with all panelists and participants</td>
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<td>What are the treatment options for tungiasis and what is needed to</td>
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<td>make them available in endemic areas?</td>
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<tr>
<td>15:55–16:00</td>
<td>Wrap up</td>
<td>Martha Saboya</td>
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### IV. Prevention and treatment (Timekeeper: Ana Luciañez)

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<td>Wrap up</td>
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### V. Opportunities for integrated actions at the local level (Timekeeper: Ana Luciañez)

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<tbody>
<tr>
<td>12:20–12:50</td>
<td>Tungiasis community-based program study</td>
<td>Ulrike Fillinger in Kilifi and new floor</td>
</tr>
<tr>
<td>12:50–13:20</td>
<td>How feasible is the integration of actions for tungiasis at the local</td>
<td>Discussion conducted by the Chair with all panelists and participants</td>
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<tr>
<td></td>
<td>level and with what actions we should integrate? – brainstorming</td>
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<tr>
<td>13:20–13:50</td>
<td>One Health approach – challenges and opportunities</td>
<td>Jorg Heukelbach</td>
</tr>
<tr>
<td>14:00–14:50</td>
<td>Discussion on One Health approach</td>
<td>Discussion conducted by the Chair with all panelists and participants</td>
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<tr>
<td>14:50–15:10</td>
<td>Next steps</td>
<td>Kingsley Asiedu</td>
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<tr>
<td>15:10–15:20</td>
<td>Closing session</td>
<td>Luis Gerardo Castellanos</td>
</tr>
</tbody>
</table>
Annex 2. List of participants

**INVITED EXPERTS**

**Manuel Calvopiña**  
Faculty of Medicine,  
University of the Americas,  
Quito, Ecuador

**Lynne Elson**  
Centre for Tropical Medicine and Global Health,  
University of Oxford;  
Kenya Medical Research Institute-Wellcome Trust,  
Kilifi, Kenya

**Hermann Feldmeier**  
Institute of Microbiology,  
Infectious Diseases and Immunology, Charité University Medicine,  
Berlin, Germany

**Ulrike Fillinger**  
International Centre of Insect Physiology and Ecology,  
Nairobi, Kenya

**Jorg Heukelbach**  
One Health Institute Heukelbach,  
Bruehl, Germany

**Ingela Krantz (Chair)**  
Umeå University, Department of Epidemiology and Global Health,  
Umeå, Sweden

**Hollman Miller**  
Vector-Borne and Neglected Diseases,  
Secretary of Health of Vaupés,  
Colombia

**Ruth Monyenyeye Nyangacha**  
Center for Traditional Medicine and Drug Research, Kenya Medical Research Institute,  
Nairobi, Kenya

**Francis Mutebi**  
College of Veterinary Medicine, Animal Resources and Biosecurity, Makerere University,  
Kampala, Uganda

**Per Nordin**  
Skaraborg Institute for Research and Development,  
Skövde, Sweden

**Marlene Thielecke**  
Institute of Tropical Medicine and International Health, Charité University Medicine,  
Berlin, Germany

**REPRESENTATIVES OF ENDEMIC COUNTRIES**

**Rafaela Albuquerque Silva**  
Ministry of Health,  
Brasília, Brazil

**Diana Gomez Forero**  
Ministry of Health and Social Protection,  
Bogotá, Colombia

**Joyce Mendes Pereira**  
Ministry of Health, Brasília, Brazil

**Yago Ranniere Teixeira Santana**  
Ministry of Health, Brasília, Brazil

**Julian Trujillo**  
Ministry of Health and Social Protection,  
Bogotá, Colombia

**Zaira Zambelli Taveira**  
Ministry of Health,  
Brasília, Brazil
OBSERVERS

Ayako Hyuga
Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan

Yasuhiko Kamiya
School of Tropical Medicine and Global Health, Nagasaki University, Nagasaki, Japan

Satoshi Kaneko
Institute of Tropical Medicine, Nagasaki University, Nagasaki, Japan

Elly Kourany-Lefoll,
ElkoBio, Geneva, Switzerland

Kana Suzuki
School of Tropical Medicine and Global Health, Nagasaki University, Nagasaki, Japan

WHO HEADQUARTERS AND REGIONAL OFFICES

Kingsley Asiedu
Prevention, Treatment and Care, Department of Control of Neglected Tropical Diseases, Geneva, Switzerland

Abate Mulugeta Beshah
Tropical and Vector-borne Diseases, Regional Office for Africa, Brazzaville, Congo

Haroldo Bezerra
Regional Program of Public Health Entomology, Pan American Health Organization, Washington (DC), United States of America

Eva Amelia Carvalho
Tropical and Vector borne Diseases including Malaria and Neglected Tropical Diseases, WHO Country Office, Maputo, Mozambique

Luis Gerardo Castellanos
Neglected, Tropical, and Vector-Borne Diseases, Pan American Health Organization, Washington (DC), United States of America

Giovanini Coelho
Regional Program of Public Health Entomology, Pan American Health Organization, Washington (DC), United States of America

Dennis Navarro Costa
Regional Program of Public Health Entomology, Pan American Health Organization, Washington (DC), United States of America

Daniel Argaw Dagne
Prevention, Treatment and Care, Department of Control of Neglected Tropical Diseases, Geneva, Switzerland

Lise Grout
Prevention, Treatment and Care, Department of Control of Neglected Tropical Diseases, Geneva, Switzerland

Henry Hernandez
Climate and Environmental Determinants of Health, Pan American Health Organization, Washington (DC), United States of America

Ana Luciañez
Regional Program of Neglected Infectious Diseases, Pan American Health Organization, Washington (DC), United States of America

Mwelecele Ntuli Malecela
Department of Control of Neglected Tropical Diseases, Geneva, Switzerland
Pamela Sabina Mbabazi  
Strategic Information and Analytics, Department of Control of Neglected Tropical Diseases, Geneva, Switzerland

Maria Nazario  
Regional Program of Neglected Infectious Diseases, Pan American Health Organization, Washington (DC), United States of America

Ruben Santiago Nicholls  
Regional Program of Neglected Infectious Diseases, Pan American Health Organization, Washington (DC), United States of America

Freddy Perez  
HIV, Hepatitis, Tuberculosis, and Sexually Transmitted Diseases, Pan American Health Organization, Washington (DC), United States of America

Jose Antonio Ruiz Postigo  
Prevention, Treatment and Care, Department of Control of Neglected Tropical Diseases, Geneva, Switzerland

Sheila Rodrigues Rodovalho  
Pan American Health Organization Country Office, Brasilia, Brazil

Martha Saboya  
Regional Program of Neglected Infectious Diseases, Pan American Health Organization, Washington (DC), United States of America

Ronaldo Carvalho Scholte  
Regional Program of Neglected Infectious Diseases, Pan American Health Organization, Washington (DC), United States of America

Bernardino Vitoy  
Pan American Health Organization Country Office, Brasilia, Brazil