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Operational approaches and recommendations to interrupt transmission of *Mycobacterium leprae*

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Summary The Global Partnership for Zero Leprosy (GPZL) Zero Transmission Symposium (May 23–25, 2024, Bergen, Norway) brought together a diverse group of experts to discuss developments over 10 years to interrupt *Mycobacterium leprae* transmission, both in research and operationally. Through a well-structured and participatory agenda, research and operational approaches were discussed.

The operational approaches from the symposium are described here and focus on defining optimal methods for monitoring infection transmission and prevalence using current tools; additional tools to customise implementation based on local context, such as mapping; identifying critical gaps and interventions to accelerate transmission

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interruption through scaled-up programmatic implementation; and expanding community coverage of interventions. Recommendations were developed in diagnostics, active case detection, post-exposure prophylaxis (PEP) and treatment, antimicrobial resistance surveillance, vaccination, and social determinants of health.
Recommendations in diagnostics included forming a diagnostics consortium, global initiatives (including updating WHO Guidelines) and national initiatives to optimise availability of 'point-of-care' tools, active case detection, including contact tracing, integrated programmes, and cluster-based campaigns considering strategic alignment with other disease consortia/initiatives; maximizing the use of molecular techniques and genotyping technologies; and improving epidemiological surveillance.
Overall, considerable progress has been made in interrupting transmission in the last 10 years, especially at the sub-national level. Implementing symposium recommendations will further accelerate interruption of *M. leprae* transmission.

Keywords: Ttransmission interruption, diagnostics, active case detection, social determinants, post-exposure prophylaxis, AMR surveillance

Introduction

This paper accompanies the preceding paper published in this edition of *Leprosy Review* entitled 'Interrupting transmission of *Mycobacterium leprae*: Synthesis of new evidence and research recommendations.' Both papers collectively summarize the outcomes of a symposium, the *Global Partnership for Zero Leprosy (GPZL) Zero Transmission Symposium,* held between 23rd and 25th May 2024 in Bergen, Norway, where the bacillus *Mycobacterium leprae,* the pathogenic organism causing leprosy, was discovered 150 years ago. This symposium took place a decade after a similar symposium was held on 29th and 30th May, 2014, in Houston, USA.[1] The symposium sought to support the focus on zero transmission in the WHO Global Leprosy Strategy 2021–2030.

The preceding paper presents a synthesis of new evidence in the field of *Mycobacterium (M.) leprae* transmission, covering a range of topics relevant to the interruption of transmission (epidemiology, microbiology, immunodiagnostics, genotyping, geospatial monitoring, monitoring leprosy elimination, leprosy post-exposure prophylaxis (PEP), leprosy modelling, the OneHealth concept, environmental transmission, social determinants of leprosy, leprosy control programmes, and the active role of organisations of persons affected in the facilitation of interruption of transmission), based on presentations that were given on the first day of the symposium by experts in the field.[2] The accompanying paper also presents the updated status of the gaps and needs identified in the report *Gaps in our understanding of transmission and identified needs*[1] from the 2014 symposium and the ongoing research gaps related to the interruption of transmission.[3]

This second paper summarizes the outcomes of the discussions during the symposium which reviewed how our current understanding of transmission can be used to develop strategies and improve the deployment of existing tools and interventions, specifically:

(1) Defining optimal ways to monitor transmission/prevalence of infection using currently available tools.
(2) Identifying critical gaps in the tools and interventions required to accelerate the interruption of transmission.
(3) Programmatic implementation and scaling of interventions.

Diagnostics

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

Currently, diagnostic tools are not widely used, and clinical diagnosis is generally relied upon. Diagnostic tools will become increasingly necessary, especially in low-endemic settings, as disease incidence decreases and clinical expertise diminishes over time. In this final phase toward the goal of elimination (zero leprosy), ensuring the reliability of diagnostic procedures is essential.

The rapid developments in diagnostics achieved during the COVID-19 pandemic indicate that we can be more ambitious in other fields, such as neglected tropical diseases (NTDs). Furthermore, the response to COVID-19 has led to the establishment of more robust testing infrastructure and a significant transformation in molecular diagnostics. Across several countries, each district at a sub-national level now has facilities for molecular testing for tuberculosis (TB) and COVID-19. These facilities could be leveraged for leprosy, provided the diagnostic tests demonstrate substantial sensitivity and specificity in *M. leprae* detection. Each bacillus has multiple copies of the *M. leprae*-specific repetitive element (RLEP), which provides a sensitive and specific molecular target, requiring operational molecular platforms. Simpler potential candidate tests for confirmatory diagnosis of leprosy are currently in development or undergoing field trials. Several endemic countries have the necessary capacity and technicians and are in the process of digitising the reporting system. However, depending on the use cases described in target product profiles TPP1 and TPP2 below, the aim is to reduce reliance on laboratory-based tests and to move to point-of-care testing that offers the desired sensitivity and specificity, preferably at low cost.

ACTUAL TESTS BY TARGET PRODUCT PROFILE

TPPs for point-of-care diagnostic tests have been developed;[4] these are:

- TPP1: a diagnostic test used to confirm the diagnosis of leprosy in individuals with clinical signs and symptoms, which guides the initiation of treatment.
- TPP2: a diagnostic test to detect *M. leprae* infection among asymptomatic household or familial contacts of leprosy patients, with the aim of providing these patients with appropriate prophylactic interventions and preventing transmission of *M. leprae*.
- TPP3: a diagnostic test for (active or recent) transmission, which would determine the prevalence of infection and thus confirm interruption of transmission. TPP1 and TPP2 have been approved and published by WHO, and TPP3 is still in process, but the specifications are largely clear already. It was noted that the availability of some tests may be delayed because of the requirement for regulatory approval. Additionally, concerns were raised regarding the affordability of the diagnostic tests and about the need to ensure a robust supply chain and widespread availability, particularly at lower healthcare levels, which will be crucial to maximising the impact of these future diagnostics.

CANDIDATE MOLECULAR TESTS

Currently available PCR tests for detecting the presence of *M. leprae* DNA are carried out in local laboratories and are not yet available commercially. PCR tests are being carried out in some laboratories; e.g., leprosy in immigrants is diagnosed by PCR in referral centres in Brazil, India, and Australia. Rigorous standardisation of PCR tests is crucial in all cases. While commercial development is in progress, carrying out these tests 'in-house' is feasible

and acceptable, provided that proper quality control measures are in place. The use of simple quantitative (q)PCR was recommended, given the technical limitations in many countries.[5]

There are concerns regarding the reliability of DNA-based assays as a measure of viable bacilli, and, in the light of this, bacterial RNA-based viability assays have been developed. However, at present, these are utilized as research tools and are limited by the need for immediate freezing of samples. Unfortunately, in this case, the rapid degradation of RNA is not only an asset (indicating no live bacteria) but a liability as well. In the future, it is hoped that new field-friendly methods for measuring bacterial RNA viability will be developed.

CANDIDATE IMMUNODIAGNOSTIC TESTS

Quantitative immunodiagnostic tests are currently in development and are close to being available commercially. These are in the form of anti-phenolic glycolipid-1 (PGL-1) lateral flow strips, which have undergone field testing.[6,7] While these tests may be used in diagnosing symptomatic individuals (TPP1), they are unable to distinguish between current and past infections. They are therefore most suited for screening contacts (TPP2) or for measuring the prevalence of infections (TPP3). The operational aspects concerning the availability of these tests are country-specific; some countries have the necessary infrastructure in place for the screening and diagnosis of patients, whereas others may require additional devices such as readers to utilize these tests.[6] A qualitative PGL-1 lateral flow assay is already commercially available as a rapid test in Brazil.[8]

INTEGRATION OPPORTUNITIES

The integration of PCR diagnosis of leprosy into the existing reference lab infrastructures presents an opportunity for leprosy diagnostics. For example, BU-LABNET was a network of laboratories in the WHO African Region, with the primary goal of enhancing the diagnosis of Buruli ulcer using standardized PCR testing protocols and external quality assessment programmes.[9] In October 2023, the network transitioned from BU-LABNET to Skin NTD LABNET,[10] with the aim of expanding its molecular platform to include additional skin NTDs and laboratories, thereby optimising cost-effectiveness and broadening access to quality-assured diagnosis. However, expanding to other diseases, including leprosy, requires integrated training and capacity building.

FUTURE OPPORTUNITIES, INCLUDING ARTIFICIAL INTELLIGENCE

Future opportunities in diagnostics include chip-based kits, also known as 'lab-on-a-chip,' a miniaturised device capable of conducting multiple-sample biological and biochemical analyses, including diagnostics on a single platform such as DNA analysis.[11] These kits are close to being available commercially, with ongoing efforts focusing on manufacturing, quality, and logistics.[12,13] Open technologies are preferred as they facilitate integration with external entities.

There is also potential for leveraging artificial intelligence (AI) in leprosy screening and/or confirmatory testing; for example, a smart phone screening app to guide potential individuals affected for further diagnosis. Literacy issues can be addressed using pictorial methods. It was noted that factors unique to leprosy related to light, skin pigmentation, and sun exposure and the need for assessing skin lesion sensibility and nerve palpation make these techniques challenging.

AI is already under development for the WHO Skin NTD app.[14] Currently this app features a logical, offline algorithm to assist health workers in making accurate diagnoses and treatment

decisions. It also includes a 'Skin NTDs Learning' section, with training materials for front-line health workers. The WHO has developed a beta version of the app incorporating two online AI-based algorithms for instant classification of skin lesion photographs.[15] Field trials are ongoing to determine the usability and performance of these AI algorithms under real-world conditions. Images from across the globe featuring different skin colours are needed for machine learning. It was noted that AI should not completely replace clinical diagnosis; it is intended to serve as a guide.

Factors identified that might prevent countries from adopting diagnostic tools include the necessity for test validation and regulatory approval and a perception that these tests are not needed. Similar to other diseases, WHO recommendations and evidence-based guidelines are pivotal.

RECOMMENDATIONS

The group identified several ways of diagnosing leprosy and monitoring transmission and prevalence of infection using currently available tools. The group recommended the formation of a diagnostic consortium (including industry partners) to address the concern that diagnostics work is siloed instead of the ideal of being linked.[16]

While anticipating the availability of 'point-of-care' diagnostic tools, the following initiatives should be undertaken to ensure widespread usage globally and nationally:

- The WHO should provide guidelines to recommend the implementation of diagnostics, along with guidance on how and where these tests should be implemented.
- At the national level, the WHO and non-governmental organisations (NGOs) should educate governments on the need for and advantages of using diagnostic tests for leprosy as a major step towards elimination (zero leprosy), as they facilitate early diagnosis.[17,18]

Existing diagnostic services may be regarded as provisional until tests are commercially available. Diagnostic tests should be accompanied by careful (educational) campaigns targeted at the community and healthcare practitioners, primarily focusing on their benefits and limitations. Furthermore, establishing clear reporting mechanisms of test results is crucial for the benefit of the patients, and ministries of health must be assured of the validity of the new technique(s). The group also recommended exploring funding sources to separate the cost of diagnostic development from the production process to maintain low test costs.

Active case detection

WHAT IS ACTIVE CASE DETECTION?

Active case detection comprises various modalities: tracing household or social contacts; detecting cases on a door-to-door basis; distributing screening questionnaires; conducting rapid village surveys; screening in schools and prisons; organising community skin screening events (e.g., "skin camps"); and a 'blanket' approach.[19] According to the Leprosy Elimination Framework, leprosy elimination involves three phases.[20] The WHO recommends active case detection in Phase 1 through to Phase 2. However, secondary cases do not seem to occur in low-endemic areas (Phase 2 and 3).[21] Active case detection is no longer required in Phase 3.

Jordan and the Maldives have implemented highly successful programmes. In Jordan, the WHO formally verified and acknowledged the elimination of leprosy in 2024, while the Maldives was verified to have interrupted transmission in 2023.

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

Contact screening

The increased risk of leprosy extends beyond the households of index cases.[22] Using an active case detection strategy, the WHO recommends expanding contact screening beyond the household to include a wider circle of contacts. Contacts may include three groups: household, neighbours, and social contacts.[23] A defined number of contacts may also be specified.

In terms of criteria defining the number of contacts to be included in optimal active contact screening, the following factors need to be considered:

- Population density, acknowledging that it is difficult to define the denominator. In small island communities, everyone is a contact.
- The conditions and environment in each country should decide which and how many contacts to include in contact tracing. Factors to consider include the elimination phase of the areas, the expected level of stigma, and resources available for contact screening. Some countries may only want to offer post-exposure prophylaxis (PEP) to immediate contacts (this may be related to stigma).

The recommendation of the symposium group is to include 40 contacts per index case, as this number was deemed to be both feasible and more effective rather than focusing on smaller numbers or screening only household contacts.

In high-endemic clusters, where screening this number would cover more than half of a village or neighbourhood, extending the screening to encompass the whole village or neighbourhood could be considered.

While the WHO recommends contact screening even when PEP is not given, contact screening should preferably be combined with the distribution of PEP. For PEP programmes, the number of contacts to be targeted needs to be estimated to calculate the required amount of rifampicin. It is crucial to adhere to the inclusion and exclusion criteria defined by the WHO before administration of PEP.[23,24]

There is evidence indicating that the risk of leprosy is two to four times higher for those living within 75 m of an index patient[2] and therefore establishing a 'cluster area' based on the boundary of 'distance from the index case' could be beneficial. This may vary significantly depending on the locality, e.g., the density of the local population, the presence of multi-story buildings, etc. It will also vary between areas with different levels of transmission. The 'distance from index case' can be measured using GPS coordinates. Whether the 75 m distance also applies in other countries and settings needs to be confirmed through operational research. However, it can be used as a guide for operationally defining a cluster area where household screenings may be conducted.

Countries need to adopt, adapt, and contextualise guidance on contact screening, which requires local background knowledge.[25] The prevailing view is that setting a boundary is the most applicable approach in high endemic situations, assuming it is possible to measure or estimate the distance between index case households and presumed contact households.

Integrated programmes

There may be further opportunity to integrate leprosy screening with other disease screening programmes, particularly in areas of co-endemicity or geographic overlap. Opportunities for

integrated disease screening could include, for example, skin NTDs, other common skin diseases, and TB.

Leprosy and TB case detection can be conducted in district-wide, cross-disease, door-to-door, or contact-based campaigns. For example, implementing district-wide campaigns, for instance, screening for TB, leprosy, skin diseases, and/or other chronic infections and establishing follow-up. Once completed, the campaign can be moved to the next district. The advantage of this approach is that simultaneous examination and treatment of numerous patients may be more efficient. Integrated programming described above may prove more cost-effective as an incremental cost to the TB programme when compared to maintaining a dedicated leprosy programme, which would require substantial resources.

Additionally, since TB is a contraindication for administering leprosy chemoprophylaxis with rifampicin, contacts of leprosy patients should be screened for symptoms of TB. If present, the leprosy prevention intervention provides a good opportunity for sputum collection in these cases.

WHO recommends the integration of skin NTD activities.[26] Lessons should be drawn from the integrated model implemented in some African countries, where leprosy screening is carried out in combination with other skin diseases. An example from the Republic of the Congo involves screening of families for skin diseases, including leprosy. Upon detection of leprosy, treatment is started. In practice, detection goes beyond the family, and door-to-door contact tracing is also conducted. It is important to make it known that besides leprosy, other skin diseases are treated as well. Leprosy screening presents a valuable opportunity to also assess and treat other skin conditions, as individuals already need to undress for a thorough skin examination. Addressing these conditions aligns with the needs of the population, encouraging participation in screening and treatment, while also expanding access to skin health care, which is often limited.

Other approaches include 'skin camps,' i.e., health camps focusing on dermatological conditions, designed to bring health care closer to the community.[27,28] Contacts of a newly detected patient with leprosy, living in the same neighbourhood, have a higher risk of developing leprosy.[22] Setting up a skin camp involves screening the patient's close contacts and community contacts for leprosy and other skin diseases simultaneously. Using this approach means that it is no longer necessary to disclose the disease status of the index patient.[28] Another option is to 'piggyback' other treatments such as ivermectin on to PEP, for example, in areas where the incidence of scabies is high, known as integrated skin multi-drug therapy.[29] A robust surveillance system is needed while integrated programmes are being developed.

Mass campaigns

Some countries have made the decision to conduct mass screening campaigns.[21] This is dependent on the priorities of the local ministry of health. In Kiribati, a trial on combined case detection and PEP is being conducted for TB and leprosy. The population is screened for active disease. Clinical leprosy is confirmed by skin biopsy, and TB is confirmed by qPCR. Confirmed cases are treated with MDT or short-course chemotherapy (SCC). All other contacts are treated with SDR-PEP for leprosy or with 3HP for TB (12 weekly doses of rifapentine and isoniazid).[30] Another form of mass campaign includes the blanket campaigns for screening and PEP that have been implemented in high-endemic areas in a number of countries.[31]

Regarding active case detection overall, there needs to be a balance between "100% catch-all" rigour and embracing the realities of "on-the-ground" implementation. Programmes may

have to be modified or customized from the "optimal" approach to accommodate the context for local implementation. This is a learning curve, and understanding will evolve as these programmes are rolled out.

INTEGRATED OPPORTUNITIES

Case studies of the successful programme in the Maldives yielded the following lessons:

- Programmes were most effective when delivered via healthcare staff.
- Programmes need to be targeted to specific groups.
- Including leprosy in the migrant health system is important—a separate system was instigated for migrants with no identification papers.
- Case notification should be mandatory; i.e., leprosy should be a notifiable disease.

In the Maldives, no child cases have been reported for 5 years, and thus Phase 1 of the WHO leprosy elimination framework has been completed. There are still a few new adult cases, indicating that the country is now in Phase 2.[24] The country aims to enter Phase 3 (elimination of leprosy disease) by 2030. Phase 3 involves surveillance for 10 years. New cases are being detected in only a few islands; however, surveillance continues. The success of the programme in the Maldives is a source of hope and inspiration for other countries; the challenge is to follow suit.

Jordan, which was in Phase 3 of the WHO Leprosy Elimination Framework at the time of the symposium and has since been the first country where WHO has verified elimination of leprosy,[32] is looking for expert guidance on post-elimination surveillance. Recommendations for post-elimination surveillance included having at least one apex centre for training; a steering committee that continues yearly monitoring of leprosy; and finally, countries should continue to report case numbers annually to the WHO, including zero cases.[33]

RECOMMENDATIONS

Active case detection may be enhanced in the following ways:

(a) Active case detection should still be considered during elimination Phase 2 depending on the approach used. The various approaches should be well defined (household contact screening, cluster-based contact screening, door-to-door screening, and skin camps).
(b) Strategic alignment with other disease consortia/programmes should be investigated, e.g., combined screening and prophylaxis with TB programmes or integrated data collection and integration of skin-related NTD programmes as encouraged by WHO.[26]
(c) Maximising advances in screening techniques, e.g., through the latest PCR and other techniques to improve early case detection and monitoring of transmission and prevalence of infection.
(d) It is recommended that the WHO should develop technical guidance for integrated screening if sufficient evidence is available.
(e) Successful methods should be reported in writing following the example of Jordan.[33] Specifically, the achievements of the Maldives so far should be documented.
(f) Epidemiological initiatives

    - Implement electronic case-based data systems using the WHO DHIS2 module at the country level; these should be integrated where possible.

- Implement mapping of new cases along with strengthening of the data management system.
- Promote use of the Leprosy Elimination Monitoring Tool (LEMT) as standard practice in endemic countries.
- Develop (online) training for staff on handling, analysing, and interpreting data (routine indicators and LEMT data).

Post-exposure prophylaxis and treatment

AVAILABLE REGIMENS

Single-dose rifampicin PEP (SDR-PEP) has been shown to be effective (reduction in risk up to 57%) in the COLEP trial [34]and is the backbone of current prophylactic programmes. In 2018, SDR-PEP was included in the WHO Guidelines for the Diagnosis, Treatment, and Prevention of Leprosy.[35] Nevertheless, rifampicin for leprosy PEP is not readily available in all leprosy-endemic countries, which is being addressed by the WHO Global Leprosy Programme (GLP).

NEWER THERAPEUTICS AND EXPERIMENTAL TREATMENTS

While SDR-PEP is moderately effective and currently recommended by the WHO, potentially more effective PEP regimens are presently being tested, including an enhanced prophylactic regimen (PEP++) against leprosy, comprising multiple doses of rifampicin and clarithromycin,[31] and BE-PEP, a combination of high-dose rifampicin and bedaquiline, which is being compared with standard SDR-PEP in the BE-PEOPLE trial.[36] Single-dose rifapentine is an additional antimicrobial approach to prophylaxis.[37] Telacebec, a bactericidal drug originally developed for the treatment of TB, is highly effective against *M. leprae* in pre-clinical studies and could play a role in either treatment and/or prophylaxis of leprosy.[38]

Challenges to the success of new, potentially more effective regimens include the availability of the individual components of multi-drug PEP regimens and meeting the quality standards and other regulatory requirements of endemic countries. Once sufficient evidence becomes available, there is a need to update the WHO and national guidelines for effective implementation, with global funding for countries dependent on the donation of medicines.

It is important that development and testing of new PEP regimens, which have the potential to be more effective than SDR-PEP, should not compromise the reputation and use of the existing regimen.

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

As discussed above, studies of more effective PEP regimens are underway, including PEP++ and BE-PEP.[37] Strategies should be implemented in preparation for the availability of these potentially more effective regimens. A blanket approach for implementing PEP regimens may be suitable for "hot spots."

Stigma may be a barrier to the acceptability and feasibility of enhanced chemoprophylaxis, as has already been identified with SDR-PEP. While newly diagnosed patients might want to protect their households with SDR-PEP, doing so may require disclosing a stigmatised diagnosis.[39] Various approaches for PEP implementation, such as the blanket campaigns and skin camps, can be employed to ensure the confidentiality of the index case. Teams conducting contact screenings and distributing PEP may use statements to the effect of, 'There is leprosy in your village/neighbourhood, and therefore we offer screening and preventive treatment.'[40]

Countries reluctant to implement chemoprophylaxis may be convinced by published data from the ongoing PEP implementation projects in multiple countries. Hence, prompt publishing of these data is essential so that these reluctant countries are engaged in debate on the science.

Besides integration with other health or preventive interventions, inducements such as provision of vitamins and nutrition, partnerships with NGOs for development, and unconditional cash transfers in very poor communities may also be considered. However, the sustainability of these approaches in a public health setting is yet to be determined.

RECOMMENDATIONS

Recommendations for implementation and other aspects of PEP and treatment:

- For combined prevention of multiple diseases, the possibility of creating 'contact tracing teams' should be investigated, i.e., a cadre of healthcare staff who are responsible for contact tracing and preventive drug implementation for several diseases.
- Ensure learning from other already integrated structures, such as the experience of preventive chemotherapy (PC)-NTDs, to identify what can be integrated and what cannot, as well as previous experience of TB-leprosy integration.
- Implement PEP services, in which PEP is combined with, e.g., training, active case detection, and involvement of persons affected.
- Publish data from ongoing PEP implementation projects from multiple countries to provide updates to the WHO and to inform national guidelines on the present evidence and recommendations.
- Build or strengthen the capacity and capabilities of health systems to implement reporting in line with the published WHO technical guidance "*Leprosy/Hansen disease: Contact tracing and post-exposure prophylaxis.*"[41]
- Ensure that use of the LEMT is standard practice in endemic countries so that priority areas for chemoprophylaxis are identified.[42]
- Ensure access to PEP and other leprosy medication.
- The rights of access to information and informed consent should be fully guaranteed. In this regard, organisations representing individuals affected by leprosy can play an important role in monitoring that such access and informed consent take place and serve as translators between biomedical knowledge, public health, and local culture.

Antimicrobial resistance surveillance

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

While there are no indications to date that widespread SDR-PEP distribution induces rifampicin resistance in *M. leprae* or *M. tuberculosis,* it is essential to monitor for the development of rifampicin resistance and to provide additional evidence that PEP does not produce resistance in these bacilli. Therefore, AMR surveillance/monitoring is required for both MDT and SDR-PEP, as for other antimicrobial interventions. The WHO recommends conducting resistance testing in all retreatment cases at a minimum and in 10% of the total new MB cases notified in the previous year.[43]

Countries find it challenging to adhere to any WHO guidance on AMR surveillance regarding leprosy because leprosy has not been included in the development of AMR guidance (WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS)).[44] Moreover,

there is a general perception that the published guidance is of limited value for implementation. Furthermore, the lack of inclusion of leprosy in budgets and policies is a major barrier to AMR surveillance, due to the high cost associated with shipping samples for testing, especially overseas.

On a global level, potential solutions include lobbying for inclusion of leprosy in the WHO's GLASS system. Discussion could commence within countries on AMR surveillance practice, potentially through a survey conducted by the WHO. This could encourage countries to learn from other countries' experiences. It is also important to obtain access to data from TB programmes on AMR to leprosy chemoprophylaxis.

On a national level, ministries of health should recognise the importance of AMR surveillance for leprosy, as well as emphasise the importance of AMR surveillance with national leprosy programme managers (many of whom are new) through ILEP partners where present. Leprosy should also be included where there is national AMR surveillance and streamlining with other diseases, e.g., TB or other NTDs. In terms of budgeting, suitable national and regional labs should be identified, and the costs of testing kits should be determined.

RECOMMENDATIONS

Recommendations with respect of the WHO guidance and AMR surveillance:

- WHO guidance on AMR surveillance in leprosy programmes should be updated to include PEP.
- The WHO GLP should advocate for leprosy to be included in the WHO's GLASS system.
- WHO and partners should advocate for the inclusion of AMR surveillance for leprosy in national leprosy programmes.
- AMR surveillance for leprosy should be streamlined at the national level with AMR surveillance for other diseases, such as TB and other NTDs.
- Once the WHO starts recommending molecular confirmation of clinically diagnosed leprosy cases, those samples that test positive by RLEP qPCR can be referred for molecular drug susceptibility testing and contribute to AMR surveillance.

Vaccination

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

BCG vaccination is known to offer protection against leprosy.[45] It also has an important role in reducing incidence of transmission and is recommended by the WHO for leprosy as well as TB.[46] However, BCG vaccination offers only partial protection, and more effective vaccines are needed. LepVax, a specific vaccine, is in development for the prevention of leprosy [ClinicalTrials.gov Identifier: NCT03947437].[47] Unlike interruption of transmission of other infectious diseases via vaccines that are based on induction of neutralising antibodies, LepVax is expected to prevent disease through induction of T-cell immunity and therefore would also be beneficial for contacts already infected.[45] *Mycobacterium indicus pranii* (MIP) is a vaccine that has been indigenously developed in India for use in leprosy.[48] To date, it has not been approved for use outside India.

RECOMMENDATIONS

The following approach can be considered for vaccine recommendation:

- While BCG offers partial protection, more effective vaccines for leprosy should be developed for widespread clinical practice.

Social determinants of health

OPPORTUNITIES TO ENHANCE CURRENT IMPLEMENTATION PRACTICES AND PROGRAMMES

Social determinants are known to have an impact on the transmission of *M. leprae*. These include standard of housing, overcrowding, level of education, income, hygiene, sanitation, general poverty, nutrition, health status, extreme stress, stigma, and the health system itself.[49,50] Stigma may specifically delay diagnosis and contribute to ongoing transmission, although evidence for this is sparse.[50] There is also a known association between water, sanitation, and hygiene (WASH) practices and NTDs.[51] Poverty and poor nutrition have been shown to increase the risk of developing leprosy.[49,52] Furthermore, cultural and contextual dimensions are central to understanding leprosy because of the culture-specific ways in which people interact.

INTEGRATED OPPORTUNITIES

Social determinants of transmission could be addressed by educational initiatives, specific tools, e.g., to assess stigma, the empowerment of organisations of persons affected by leprosy, integration with organisations addressing social determinants of other diseases, and related research.

Successful educational initiatives to date have included interventions to reduce stigma associated with healthcare services and to help healthcare workers understand how to approach and communicate with affected individuals.[53] As a result, there is a deeper understanding of the role of education in transmission.[54] It could be useful to determine the transferability of concepts such as the 'Leprosy Friendly Village' in Indonesia[55] and SAPNA[i] in India.

The meeting emphasised the need to identify (or develop) and measure the effectiveness of tools to promote and evaluate authentic participant and community engagement. Sources of information on the disease within the country are required for new (or potential) patients. A repository of available tools and interventions related to social determinants and transmission in multiple languages should be created to raise awareness of existing tools, which could be deployed subject to demonstration of their relevance to leprosy. For example, the NTD Inclusion Score Card (NISC) is a self-assessment tool designed for NTD organisations to track and measure the inclusion and participation of persons affected by NTDs in decision-making processes across seven key domains, helping identify challenges and gaps. It aims to enhance understanding of inclusion and participation within these organisations.[56]

Empowerment of organisations of individuals affected by leprosy is essential. An integrated approach, involving engagement with other organisations/sectors that are also working towards bringing change in known social determinants, was proposed.[57]

Economic and social rights, as well as the right to development, are essential foundations for the study of social determinants of leprosy. Organisations of individuals affected by leprosy

[i]SAPNA is an Indian NGO founded in 2004 with the goal of advancing a people-centric model of development in areas of health, education, gender, community development and social welfare. The NGO is inspired by Gandhian ideals of 'Sewa' i.e. selfless service, and sets as its mission is to work/act as an 'agent of change' to support and empower the poor and the marginalised. SAPNA has so far treated more than 55.000 persons at their institutional facilities in Alwar, India (https://sapnaindia.org/about-us/).

should be supported to conduct advocacy and lobbying in defense of their communities and towards the enforcement of such rights.

RECOMMENDATIONS

- Leprosy programmes and organisations should engage (organisations of) individuals affected by leprosy at every level.
- Surveys should be conducted regularly to monitor the level of stigma among those targeted.
- Interventions and approaches to reduce stigma and discrimination with known effectiveness should be implemented.

Overall symposium conclusions

The following conclusions can be drawn in relation to how current understanding of leprosy transmission can be used to develop strategies and improve deployment of existing tools and interventions:

- Over the last 10 years there has been considerable progress towards interruption of transmission and beyond to elimination, which is especially visible at the sub-national level.
- Once an area, or country, reaches Phase 2 or 3 of the Leprosy Elimination Framework, secondary cases are extremely rare.
- Diagnostic tests and tests for infection are available as in-house tests, but none are commercially available or widely recommended to date. If the WHO amends guidelines to recommend molecular confirmation of clinically diagnosed leprosy cases, this could serve as quality control of clinical diagnosis, especially where expertise is waning.
- The COVID-19 pandemic transformed molecular diagnostics, which can be applied to leprosy diagnostics.
- Active case detection is currently the only way to detect patients with clinical signs who are not contacts of known index cases. Integrated approaches can help early case detection, e.g., skin camps (or similar initiatives for screening multiple skin diseases) or combined screening with TB/other NTDs.
- Large-scale contact screening is effective, even more so when PEP is added.
- PEP services should be implemented, which would include health worker training, community education on leprosy, active case detection, involvement of persons affected, surveillance, etc. Data from ongoing PEP implementation projects in multiple countries should be published as early as possible. This should be done promptly to add to the weight of evidence.
- Evidence shows that in high transmission contexts there is increased risk of leprosy beyond the household (e.g., in Comoros, within a 75-m radius around an index case). This can be used to guide active case detection and PEP distribution, bearing in mind differences in population density and interactional practices by area.
- PEP administration should continue to use screening for inclusion and exclusion criteria before giving chemoprophylaxis.
- Geospatial mapping is being used in several countries, but it needs to be rolled out much more widely to identify hotspots.
- In Brazil and other countries where leprosy-infected armadillos are known to live, public health initiatives should be developed to minimise the risk of infection from armadillos.
- AMR surveillance is not routinely done in most countries, and where it is done, adequate coverage is often not achieved. The AMR surveillance network needs to be extended.

- Social determinants (including standard of housing, overcrowding, level of education, income, sanitation, hygiene, general poverty, nutrition, health status, extreme stress, stigma and 'health system harm,' and access to care) are known to have an impact on the transmission of *M. leprae*. They should be mapped and taken into account in any programmes aiming for interruption of transmission and elimination of leprosy disease.
- Effective interventions to reduce stigma and discrimination should be implemented in areas everywhere where stigma is known to be a problem.
- Empowering and actively involving individuals affected by leprosy in the design and implementation of elimination efforts is essential to ensure their voices shape meaningful and effective strategies.
- The Global Partnership for Zero Leprosy (GPZL) is a diverse group of experts from civil society, non-profits, affected communities, donors, researchers, and technical and policy agencies, collectively committed to eliminating leprosy transmission. The partnership is well-positioned to assist the roll-out of the Global Leprosy Programme through resource mobilisation and advocacy and, through its vast network, assist at country and local community levels.

Conflict of interest

BdJ and EH receive support from Janssen Pharmaceuticals for the BE-PEOPLE trial.

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