Stopping the transmission of leprosy is a complex process that relies on basic science, epidemiological work, surveillance, laboratory work, field trials, service delivery improvement and systems enhancement as well as community level interventions.

A strategy to prevent the transmission of leprosy bacteria is to diagnose all leprosy patients very early and treat them with multidrug therapy (MDT). MDT kills the bacteria and stops the spread of the disease.

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Active Case Detection

Several organisations and institutions are working on establishing new strategies for active case detection. These include reaching and monitoring people who have been in close contact with the diagnosed person, developing targeted community-based health education, identifying effective methods to encourage early voluntary reporting, detection of leprosy infection at a sub-clinical stage, researching transmission of leprosy, including causes of delay, as well as investigating of risk factors of leprosy (why some people are at higher risk than others).
**Research**

**Macro and micro epidemiology of leprosy in Cebu** - Leonard Wood Memorial Centre for Leprosy Research

Despite a declining trend in the Case Detection Rate (CDR) of leprosy in Cebu, the Philippines, the actual number of leprosy cases, particularly the CDR and median age of detection in childhood leprosy, has recently stabilised. This suggests that leprosy transmission on the island is still ongoing. To broaden our understanding of family and community level transmission on the island, currently available data of multi-case families (MCFs) and multi-case villages (MCVs) on the island can further be analysed using stable, modern molecular methods.

**Evaluation of the qPCR in household contact monitoring** - Laboratório de Hanseníase Fundação Oswaldo Cruz (FIOCRUZ)

Is it possible to use a quantitative PCR (and/or a combination or qPCR and PGL-I) to perform a more reliable estimate of the risk to develop leprosy? The aim of this study is to establish new strategies for control and surveillance of contacts, integrating different research tools and contact clinical data management that could provide the health systems better public policies for surveillance of the contacts. The design is based on only one sample collection during the first visit. Then, contacts are followed for three years. Each year the contact will have a dermato-neurological examination, and suspicious cases will be evaluated using all other classical tools for diagnosis: histopathology and bacillary counts.

**A comparison of three types of targeted, community-based health education aimed at promoting early detection** – The Leprosy Mission Trust India (TLMTI)

To aim of this study is to find effective methods to encourage early voluntary reporting. The research question of this study is “is it likely to be cost effective (in terms of staff time needed to detect one new case) to undertake late contact examinations of index cases who were diagnosed more than two years ago and five years ago for PB and MB (or for smear positive as opposed to smear negative index cases) respectively, compared with undertaking only ‘routine’ contact examinations as per standard guidelines?”

**Comparison of Three types targeted community based health education** – The Leprosy Mission Trust India (TLMTI)

This study is planned following on from a pilot done at one location where two of the methods – education and motivation of the index case- bring all contacts for examination, and training of local practitioners, yielded good results in terms of increased new case detection. The pilot was a hospital based study and the research group wanted to test these strategies in the community to see if they can be applied successfully in the field. The research group aims to find out which of the methods that are tested will be more effective in promoting early case detection:

1. Training local non formal practitioners,
2. Health education to newly diagnosed leprosy patients, or
3. Increasing awareness in the community regarding early signs of leprosy.

**Delays in diagnosis and treatment, Nepal** – International Nepal Fellowship (INF)

This project will research and address causes of long delays. Present patterns of delays will be documented and investigated, risk categories identified, and key barriers looked into.
This will be done by a combination of qualitative and quantitative research in two of Nepal’s five Development Regions: the west and the mid-west. Forthcoming ideas about reasons for short versus long delays will be investigated and tools and techniques for shortening of delays will be piloted and pre-tested before the closure of the project, which is believed to make a tangible impact upon leprosy control strategies and Nepal’s pace towards a leprosy-free society.

**Contact cohorts – The Leprosy Mission Bangladesh (TLMB)**

This project in Bangladesh studies households that are now at different time points (1-20 years) after diagnosis and treatment of the first cases, in a cross-sectional approach. The project examines, as far as possible, all household members originally resident with the first case (even if they have since left that household) and newcomers to the household. In this project the number of new cases found each year are reported, and type of case found (classification, sex, adult/child), for members of households examined at the different time points after diagnosis of the first case. Results will be analysed according to both characteristics of the first cases and those of the new cases detected to try and identify factors which mean some people are at higher risk than others. Additionally, results will be analysed to discover the changes in case detection rate amongst contacts over time since the first case diagnosed in that household.

**Earlier detection of leprosy – The Leprosy Mission Trust India (TLMTI)**

While there have been advances in medical aspects of improving diagnosis, other factors that prevent people from being diagnosed early are still not well understood or implemented. These factors, which include psychological, attitudinal, social, community, service related factors (and even structural and environmental issues like transport and organisational or government policies), need to be understood in a more comprehensive and theoretically integrated way. They need to be explored from the perspective of the key people involved, and the research needs to go beyond ‘exploring’ to create real change in local settings. This pilot study will explore how these innovative social science research methods will work to promote early detection of leprosy.

**Active case detection, tracing household contacts and mapping of risk factors** - Deutsche Lepra- und Tuberkulosehilfe (DAHW) and Armauer Hansen Research Institute (AHRI)

Active case detection of new leprosy cases, tracing household contacts and mapping of associated risk factors in Kokosa, Oromia, Ethiopia.

**ILEP Member projects**

ILEP Members worldwide are working on various projects related to transmission. Many projects and programmes are focused on improving and strengthening new case detection and early case detection services. For example, in many projects’ surveillance, follow-up of (former) patients and screening tests are carried out. Improving quality, access to and coverage of leprosy services may also reduce transmission and is a subject of many projects. Complicated cases or people that are not easily diagnosed are referred to specialized hospitals. Furthermore, attention is given to integrated leprosy care and community participation for identification of new cases, including screening of contacts. Many projects give special attention to vulnerable groups like women and children.
Many ILEP Members provide technical and financial support to national programmes. Many projects engage local stakeholders and governments. In addition, special attention is given to improving skills and capacities (training) of public health staff, doctors, nurses, students, dermatologists, village leaders and volunteers. In some cases, training and resources are communicated online through web applications and by SMS. A smartphone app to help health workers recognise skin diseases and symptoms of neglected tropical diseases (NTDs) has also been developed.

Some projects not only focus on leprosy, but additionally focus on people affected by lymphatic filariasis, tuberculosis, diabetes and/or Buruli Ulcer. This is sometimes because local governments run combined programmes.

ILEP Members are not only collaborating with each other on some projects, but are also working together with other partner organisations, government institutions, universities and interest groups for and by persons with disabilities.

**Resistance**

The emergence of drug resistance is a cause of concern for treatment of any infectious disease, including leprosy. Monitoring drug sensitivity patterns in vulnerable settings, such as for example settings with high resistance, is essential to be able to contain and control the disease. Several organisations and institutions are researching immune responses and drug resistance, working on developing tests to detect antibodies against M. leprae, and monitoring resistance to anti-leprosy drugs.

**Research**

A study of the combined effect of chemoprophylaxis with rifampicin, and immunoprophylaxis with BCG, in the prevention of leprosy in contacts - Erasmus, Deutsche Lepra- und Tuberkulosehilfe (DAHW)

Leprosy Post-Exposure Prophylaxis (LPEP) - Netherlands Leprosy Relief (NLR), American Leprosy Missions (ALM), Deutsche Lepra- und Tuberkulosehilfe (DAHW), FAIRMED, Swiss Tropical and Public Health Institute, Erasmus

How can control of mycobacterial diseases be improved? Launched in 2015 in Indonesia, India, Nepal, Myanmar, Sri Lanka and Tanzania. The LPEP project tests the feasibility and effectiveness of a single dose rifampicin as leprosy post-exposure prophylaxis. Rifampicin is given to contacts of newly diagnosed leprosy patients to decrease their risk of developing leprosy.

Field evaluation of novel immunodiagnostic tools – Erasmus

This study aims to identify compounds of the immune system that are characteristic for the occurrence of leprosy. The aim of the study is to understand in more detail how people
respond immunologically to the presence of *Mycobacterium leprae*, the causative bacteria of leprosy, in order to obtain insight into which immunological responses in people indicate that they are susceptible to developing leprosy disease. In addition, since the BCG vaccine can induce protection against leprosy, BCG vaccination of contacts of leprosy patients will allow identification of immune responses that reflect protection against leprosy. For the aim of this study the research group will:

A. Determine the effect of chemo- and immunoprophylactic interventions on biomarkers of *M. leprae* infection and clinical leprosy;

B. Identify immune- and transcriptomic host profiles that indicate infection and/or predict disease development or that are indicative of protection using a two year follow-up approach to estimate which individuals develop disease;

C. Design a biomarker profile applicable in a user-friendly test platform based on the most specific and sensitive diagnostic biomarkers identified in this study.

**Mycobacterium leprae molecular viability assays - National Hansen’s Disease Programs (USA)**

Recently, a reverse transcription-PCR based molecular viability assay (MVA) for *M. leprae* was developed by the research group and found to be rapid and accurate as a biological indicator of bacterial viability in experimental animal tissues. Therefore, with the ultimate goal of translating the MVA to the clinical setting, initial studies in animal models will be used to thoroughly define the technical limits of the MVA, to establish a standardised protocol and data reporting format, and to test potential chemoprophylactic regimens. Concomitantly, the research group will perform MVA analyses on a full range of patient specimens collected by laboratories in leprosy endemic countries and provide training to their personnel to facilitate a rapid deployment of this new technology to clinical settings. The MVA has great potential for determining *M. leprae* viability in clinical specimens. It could be invaluable for monitoring treatment efficacy and possible relapse, ultimately limiting transmission. In addition, implementation of effective chemoprophylaxis in leprosy contacts could also significantly limit transmission. The sensitivity of the MVA lends well to experiments on new drug development, and MVA studies should allow establishment of a short-term model for chemoprophylaxis of contacts and an objective definition of the most practical and effective drug regimens.

**Immuno/chemoprophylaxis**

*In recent years, progress has been made in the areas of preventing leprosy through drugs (chemoprophylaxis) and through vaccination (immunoprophylaxis). Several organisations and institutions are researching many aspects, including the combined effect of chemoprophylaxis and immunoprophylaxis, testing potential chemoprophylactic regimens, testing the feasibility and effectiveness of a single-dose antibiotic, and looking at aspects of the immune system in relation to prophylaxis.*
Research

Surveillance of resistance to anti-leprosy drugs - Eisai, World Health Organization (WHO), Laboratoire de Microbiologie (LRB)
To maintain a good level of network functionality and estimate the prevalence of primary resistance.

Development and application of serological tests that impact on the transmission and prevention of sequelae of leprosy in an endemic population of Colombia - Instituto Colombiano de Medicina Tropical
To develop and standardize an ELISA test using recombinant antigens of M. leprae (IDRI) to detect antibodies. Perform immune monitoring for multibacillary patients to assess antibody titers to predict candidate antigens to predict leprosy reaction.

Basic research at Stanley Browne Laboratory, New Delhi, India – The Leprosy Mission Trust India (TLMTI)
Current research: Cellular and humoral immune responses associated with reactions in leprosy; detection of drug resistance in leprosy using molecular techniques; early diagnosis and T-cell based assay; molecular epidemiology of leprosy; nucleic acid amplification based detection of M. leprae; viability testing of M. leprae using molecular tests.

ILEP Member projects
Some Members are involved in research projects related to immunoprophylaxis and chemoprophylaxis. Members are also involved in the supply of medicines and medical supplies, for example providing a single dose chemoprophylaxis (rifampicin) to close contacts of people diagnosed with leprosy.

Diagnostic Tests

The diagnosis of leprosy is not straightforward. It is normally based on clinical signs and symptoms, but sometimes needs laboratory and other investigations. The development of a diagnostic test to detect early leprosy before it becomes clinically apparent is an exciting new possibility for reducing transmission. Several organisations and institutions are working on a number of different dimensions of development of such tests, using DNA, detecting antibodies, ultrasound imaging of nerves and cell phones to assist in diagnoses.

Research

Evaluation of the qPCR in household contact monitoring – Fundação Oswaldo Cruz (FIOCRUZ) (Brazil) There are no diagnostic tests that could predict whether or not a “contact” will develop the disease. In the past few years, novel technologies to amplify the DNA of the causative agent of leprosy, M. leprae, are available and accurate, faster, and becoming
cheaper. Here, the research group suggests that detection of *M. leprae* DNA, by a specific in vitro amplification, could predict the development of leprosy. This data can help define health policies to preventive treatment to avoid new and severe cases of leprosy.

**Field-compatible diagnostic lateral-flow test** - *Leiden University Medical Center (LUMC, Erasmus*)

Allows the detection of specific IgM and IgG antibodies within 20 minutes of the addition of patient sera and provide objective interpretation that is both quantifiable and consistent.

**NDO-LID® rapid lateral flow tests with a new cell phone-based test reader platform (Smart Reader®)** – *Infectious Disease Research Institute (IDRI)*

This study has been published: Duthie, M. S., Orcullo, F. M., Abbelana, J., Maghanoy, A., & Balagon, M. F. (2016). Comparative evaluation of antibody detection tests to facilitate the diagnosis of multibacillary leprosy. *Applied microbiology and biotechnology, 100*(7), 3267-3275.

**Integration of rapid diagnostic tests to facilitate case management of leprosy** – *Infectious Disease Research Institute (IDRI)*

This project will evaluate the potential of two recently developed tests that detect anti-leprosy antibodies in blood and/or serum samples to address this deficit. The ability of serological tests and scheduled clinical evaluations to identify the development of leprosy among at-risk individuals and also to identify treatment complications within recognised patients will be evaluated in parallel. Within this study, samples will be collected and examined in conjunction with clinical exams, with the clinical exams being used as the benchmark for diagnosis and case management. Samples could, however, be collected and tests conducted by technical staff following only a minor amount of training. The researchers hypothesize that positive tests results could to serve as a simple, quantifiable and robust measurement to facilitate referral for expert clinical exam. Their investigative strategy will determine the acceptance, utility and practicality of these tests within surveillance programs while testing this hypothesis.

**Research on leprosy treatment** – *Faculté de Médecine Pierre et Marie Curie (FMPMC)*

To have a simpler method of monitoring the treatment efficacy than conventional methods of inoculation in mice

**Basic research at Mycobacterial Research Laboratory (MRL), Anandaban Hospital, Nepal – The Leprosy Mission Nepal (TLM Nepal)**

The laboratory at Anandaban Hospital is one of the most important research centres for leprosy in the developing world. It contributes to the development of improved diagnosis and treatment and aims to enlarge the current knowledge base about leprosy. This enables evidence-based policy making decisions by organisations and governments relevant to leprosy-affected populations worldwide.

**ILEP Member projects**

Some ILEP Members are involved in research related to diagnostic tests, and working on various research projects in search for new diagnostics.
Vaccines

The BCG vaccine against tuberculosis helps in preventing leprosy by boosting immunity. It is given at birth in many countries and is also given to contacts of people affected by leprosy in a number of countries. In addition, several organisations and institutions are involved in early trials to test a new vaccine for leprosy. Similar to the MIP vaccine in India, this vaccine is expected to be suitable for post-exposure immunoprophylaxis also.

Research

Development and pre-clinical assessment of a 73 kD chimeric fusion protein as a defined subunit vaccine – Infectious Disease Research Institute (IDRI)

A vaccine which will have an immuno-prophylactic effect, and thus prevent disease in a significant proportion of contacts. The vaccine is developed and safe for vaccination of *M. leprae*-infected armadillos. Development of a large scale manufacturing is in process. The project team is currently seeking funding for clinical trials.

Future Projects

We have no data available yet. Please send us your projects.