A new strategy to curb the incidence of leprosy

Over the past 30 years, the fight against leprosy has helped to cure more than 15 million patients through multidrug therapy (MDT) and the number of new leprosy patients detected has reduced dramatically. But in recent years, the anti-leprosy campaign has become a victim of its own success: with patient numbers falling sharply, efforts to go the last mile in eliminating the disease have stagnated.

Since 2005, both the prevalence and incidence of the disease have plateaued. Today, with around 230,000 people worldwide diagnosed with leprosy every year, the key question is how to interrupt transmission of the infection.

The cornerstones of leprosy management have been early diagnosis and prompt treatment of patients through MDT. Supplied free of charge by Novartis through the World Health Organization (WHO) since 2000, MDT has played a frontline role in both reducing transmission rates and curbing the effects of the disease. But to successfully go the last mile and bring leprosy transmission to zero, a more robust approach is needed.

In June 2013, a group of leading experts met in Geneva, Switzerland, at the invitation of the Novartis Foundation for Sustainable Development, to discuss tools and strategies to combat leprosy. In particular, lessons from other disease elimination and control programs like tuberculosis, Guinea worm and yaws were shared to help inform a new approach. Strong consensus emerged on the key elements of a new strategy for fighting leprosy, which was presented at the International Leprosy Congress in September 2013 in Brussels, Belgium.

The Novartis Foundation remains fully committed to the zero transmission of leprosy. We sincerely hope that the new strategy, presented in this newsletter, will be successful and, as always, we welcome your feedback. Thank you for your ongoing support.

Dr. Ann Aerts, Head of the Novartis Foundation for Sustainable Development
Sound progress, but gaps remain

Novartis has had a longstanding commitment to deliver innovative, patient-centred solutions to those with limited access to healthcare. A flagship example has been the company’s engagement to provide multidrug therapy (MDT) for leprosy patients free of charge to the World Health Organization (WHO) since 2000. In 2012, Novartis committed to extend the drug donation program through to 2020.

Thanks to the availability of MDT, the number of leprosy patients worldwide has fallen dramatically since the 1980s and many countries have eliminated the disease or are close to doing so. According to WHO, more than 15 million patients have been cured and 10 million have been prevented from developing disabilities. Between 1992 and 2010, leprosy prevalence has decreased by 90% and the case detection rate by 60%.

However, over the past decade, progress in reducing the number of patients with leprosy has stagnated and transmission has plateaued at around 230,000 new patients reported each year from over 100 countries. Leprosy remains endemic in parts of Africa, America and Asia and pockets of infection persist in low-burden countries.

A number of shortcomings in leprosy control activities have contributed to this, notably a lack of international coordination and sustained political commitment – especially once prevalence of the disease started to decline. A failure to accelerate comprehensive deployment of MDT to endemic areas and populations and insufficient maintenance of expertise among general health workers have also been contributing factors, as well as inadequate monitoring of progress in leprosy control and epidemiological surveillance.

In addition, relatively little is known about the mode of transmission of leprosy infection and the factors determining how, where and why it occurs. We do not fully understand why some infected people develop the disease while others do not, or why leprosy disappears naturally in some places, even without MDT intervention. Epidemiological evidence on the exact areas where leprosy transmission is ongoing is limited.

While early diagnosis and prompt treatment with MDT remain the cornerstone of leprosy management, we also need to shift from the current emphasis on national efforts to a new, more integrated strategy that leverages lessons from other disease elimination programs, targets intervention toward high-burden pockets and high-risk groups, and ideally also fills remaining research gaps.

Toward an expert consensus

In order to map the best way forward and revitalize leprosy elimination, in June 2013 the Novartis Foundation convened a meeting with leading leprosy experts in Geneva. The group was tasked with developing a ‘zero transmission’ strategy, identifying key success factors and pinpointing remaining obstacles hindering leprosy elimination. Consensus was reached that leprosy transmission can be interrupted in countries where it continues unchecked, provided a number of requirements can be met – namely early diagnosis, prompt treatment, tracing and prophylactic treatment of newly diagnosed patient contacts, together with strict surveillance and response. Post-Exposure Prophylaxis (PEP) should use a single dose of rifampicin, which is currently the only regimen with evidence for preventing the development of leprosy.

Diagnostic tests for infection or biomarkers to define the risk of disease would be great assets. In addition, strict surveillance and response needs to be implemented in endemic countries, to manage contact tracing and preventative treatment, as well as properly defining leprosy ‘hotspots.’ Finally, waning leprosy expertise due to integration into overall health services must be overcome, for example with a specific leprosy e-learning package.
In September 2013, members of the expert group attended the International Leprosy Congress in Brussels to share these conclusions. Along with the Novartis Foundation’s Dr. Ann Aerts, the key elements of the strategy toward zero transmission of leprosy were presented by Professor Cairns Smith from the University of Aberdeen, Dr. Gautam Biswas from the WHO Dracunculiasis Eradication Programme and Dr. SK Noordeen, former director of the WHO Leprosy Elimination Programme.

A three-pillar strategy

The three main pillars of the new strategy are (1) early diagnosis and prompt treatment, (2) contact tracing and preventative treatment using PEP, and (3) strict surveillance and response, leveraging and scaling lessons from other disease elimination and control programs.

1) Early diagnosis and treatment

Dr. SK Noordeen underlined that a central focus should be early detection, measuring the shortest possible interval between the occurrence of the first signs and symptoms of leprosy (incidence) and its diagnosis by a competent person (detection). A number of factors influence the delay in diagnosis, such as limited patient awareness about leprosy; stigma preventing health-seeking behavior and disclosure of the disease; absence of competent leprosy health services; and low incentives to consult health services due to insidious onset of the disease or minimal physical problems. To improve early case detection, it is important to identify high-risk groups and frequently examine these with a combination of active case-finding (selective screening and regular examination of high-risk populations such as patient contacts) and passive case-finding (increasing general community awareness, sensitizing health workers at all levels and ensuring delivery of efficient health services).

Among the challenges in early case detection were incidences of self-healing and suspect cases. To tackle this, as well as the
problem of under-diagnosis due to insufficient health worker training or inadequate referral facilities, a laboratory tool with high specificity and sensitivity would be an extremely helpful asset for confirming or rejecting diagnosis in suspect cases. While laboratory tools are not a panacea for solving early detection problems, they could play a vital role in fighting leprosy. Specifically if there would be a tool to differentiate between infected and non-infected contacts (allowing the more targeted administration of PEP), or to confirm suspect cases of leprosy.

2) Contact tracing and preventive treatment

According to Professor Cairns Smith, the epidemiological image of leprosy has fundamentally changed over the past 25 years: while 3.1 million patients were registered in 1991, by 2012 this had dropped to 232,000. In this new phase of leprosy control, a population-based approach is no longer cost-effective. Instead of working harder, we need to work smarter by focusing on where the new patients are – namely in contacts and other high-risk groups.

There is robust evidence from many countries that contacts are at a higher risk of developing leprosy than the general population. Moreover, the risk to a contact is closely linked to the contact’s physical proximity to the index patient. To minimize risks to contacts, the Enhanced Global Strategy for reducing the disease burden due to leprosy 2011-2015 states that household contacts of new patients should be examined, educated on the early signs of leprosy and their significance, urged to report suspect skin lesions or motor or sensory changes and consider chemoprophylaxis (PEP). This strategy is however not yet frequently applied.

Once a contact has been identified, the first step is to examine them for clinical signs and symptoms of leprosy followed by MDT administration for symptomatic contacts. In addition, all contacts should be informed about the risk of developing leprosy. For contacts without visible signs of disease, the next step should be the administration of PEP. Such an approach can prevent up to 50% of new cases in the first years after contact.

3) Strict surveillance and response

Exploring what lessons can be learned from other programs such as Guinea worm, tuberculosis, and yaws, Dr. Gautam Biswas argued that greater synergy and scale could be achieved by joining forces with those programs fighting other conditions. In Nigeria, for example, Guinea worm has been included in Oral Polio Vaccine tally sheets, which enjoy wide reach and good resourcing. Experience with Guinea worm in a number of African
countries also shows that surveillance sensitivity can be increased by introducing rewards for reporting – an approach that could be applied to leprosy.

To achieve scale, leprosy elimination efforts could be integrated with other local healthcare delivery systems, education systems, community-based surveillance systems or other field programs. Among the benefits of such integration is the low marginal cost, the integrated training of healthcare providers and the more efficient supervision. Challenges also exist: matching needs with skill-sets in other programs can be difficult and there may be reluctance to collaborate. Finally, not all operational aspects can be integrated, some will have to remain leprosy-specific.

To boost anti-leprosy efforts, better information, analysis, surveillance and response monitoring, and meaningful indicators to measure the intensity of transmission are all essential. Meanwhile ongoing work on leprosy diagnostics and vaccines by the Infectious Disease Research Institute (IDRI) in Seattle, Washington, USA and the Initiative for Diagnostic and Epidemiological Assays for Leprosy (IDEAL) promise significant breakthroughs.

**The way forward**

Experts agree that leprosy transmission can be halted in countries where it is currently unchecked, through successful implementation of a ‘zero transmission’ strategy. The most important element of this is active case-finding in high risk zones with PEP of contacts of newly diagnosed patients, combined with judicious passive case-finding. Knowing how leprosy is transmitted, where it persists and who is most likely infected would considerably improve the efficiency of such interventions. Along with tools that deliver greater sensitivity and specificity to diagnose asymptomatic *M. leprae* infection, urgent action is needed at country level to ensure diagnosed patients are properly reported, promptly treated and their contacts examined and offered PEP. However, the key to achieve all this will be a serious national commitment to end leprosy transmission.

**Further information:**

Watch the Geneva expert meeting video on how to curb the incidence of leprosy.

Read more about the Novartis Foundation leprosy initiatives.