Leprosy: too complex a disease for a simple elimination paradigm

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Abstract Can leprosy be eliminated? This paper considers the question against the background of the WHO programme to eliminate leprosy. In 1991 the World Health Assembly set a target of eliminating leprosy as a public health problem by 2000. Elimination was defined as reaching a prevalence of < 1 case per 10 000 people. The elimination programme has been successful in delivering highly effective antibiotic therapy worldwide. However, despite this advance, new-case detection rates remain stable in countries with the highest rates of endemic leprosy, such as Brazil and India. This suggests that infection has not been adequately controlled by antibiotics alone.

Leprosy is perhaps more appropriately classed as a chronic stable disease than as an acute infectious disease responsive to elimination strategies. In many countries activities to control and treat leprosy are being integrated into the general health-care system. This reduces the stigma associated with leprosy. However, leprosy causes long-term immunological complications, disability and deformity. The health-care activities of treating and preventing disabilities need to be provided in an integrated setting.

Detecting new cases and monitoring disability caused by leprosy will be a challenge. One solution is to implement long-term surveillance in selected countries with the highest rates of endemic disease so that an accurate estimate of the burden of leprosy can be determined. It is also critical that broad-based research into this challenging disease continues until the problems are truly solved.

Keywords Leprosy/diagnosis/prevention and control/complications; Chronic disease/therapy; Delivery of health care; Integrated; Drug therapy, Combination; Biomedical research (*source: MeSH, NLM*).

Mots clés Lèpre/diagnostic/prévention et contrôle/complication; Maladie chronique/thérapeutique; Distribution intégrée soins; Polychimiothérapie; Recherche biomédicale (*source: MeSH, INSERM*).

Palabras clave Lepra/diagnóstico/prevención y control/complicaciones; Enfermedad crónica/terapia; Entrega integrada de atención de salud; Quimioterapia combinada; Investigación biomédica (*fuente: DeCS, BIREME*).

Arabic

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Introduction

Leprosy is caused by *Mycobacterium leprae* and manifests as damage to the skin and peripheral nerves. The disease is dreaded because of the damage that occurs in weak and anaesthetic hands and feet, as well as in blindness and facial disfigurement. Worldwide 2 million people are estimated to be disabled by the consequences of leprosy. Multidrug therapy (MDT) for leprosy is highly effective in curing the mycobacterial infection, but treating the nerve damage is much more difficult. In 1991 the World Health Assembly set a target for the "elimination of leprosy as a public health problem" by 2000 (*1*). Elimination was defined as a prevalence of less than 1 case per 10 000 population. Many people found this definition difficult to understand. The "elimination of leprosy" slogan has galvanized activities worldwide but has also dominated the priorities in leprosy work. Here we argue that elimination is not an appropriate goal for leprosy and it is better seen as a chronic disease that requires long-term planning and control. The new challenge is to build on the success of the leprosy campaign and deliver sustainable care for leprosy patients.

The concept of elimination

The success of multidrug therapy provided the basis on which the concept of elimination developed. Multidrug therapy was introduced by WHO in 1982 (*2*). Under this programme, patients are classified as having one of two types — paucibacillary (PB) or multibacillary (MB) — and receive either the combination of rifampicin and dapsone (known as paucibacillary

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multidrug therapy or PB-MDT) or the triple drug combination of rifampicin, dapsone and clofazimine (known as multibacillary multidrug therapy or MB-MDT). The rifampicin and part of the clofazimine component are taken monthly under supervision. PB-MDT is given for 6 months and MB-MDT for 24 months (*3*) or 12 months (*4*). Relapse rates are low (0 to 2.04 per 100 person-years) with the 6-month PB-MDT regimen and the 24-month MB-MDT regimen (*5*). Throughout the 1980s and 1990s the Leprosy Unit at WHO led a successful campaign to implement multidrug therapy worldwide. Nongovernmental organizations (NGOs) were instrumental in supporting governments' commitments to implementing multidrug therapy. Vertical leprosy control programmes were used to identify and treat patients. Between 1994 and 1999 the worldwide cost of multidrug therapy was borne by the Nippon Foundation in Japan (through the Sasakawa Memorial Health Foundation). More than 13 million cases were detected and treated with multidrug therapy between 1982 and 2002 (*6*).

Prevalence and new-case detection rates

Prevalence figures were used to measure progress, and the number of patients with leprosy has fallen from an estimated 12 million in 1985 to 0.6 million in 2002 (Fig. 1) (*7*, *8*). Disease prevalence is measured by counting all patients receiving treatment at a defined moment and expressing this as a ratio using the population as the denominator. Prevalence figures are therefore affected by operational aspects of programmes, such as the length of treatment; for example, halving the duration of treatment for patients receiving MB-MDT from 24 months to 12 months halves the prevalence figures for that group. Additionally, the means of administration may also affect the numbers; for example, patients receiving single-dose treatment (rifampicin, ofloxacin and minocycline) for single skin lesions do not appear in prevalence figures nor do patients who received their 6-month course of PB-MDT early in the calendar year since only patients registered on 31 December are counted for that year.

In 1985, 122 countries in the world had leprosy prevalence of > 1 case per 10 000 population. This prevalence fell to 24 countries in 2000, to 15 countries in 2001 and to 12 by 2002. The largest number of leprosy cases are concentrated in seven countries: Brazil, India, Madagascar, Mozambique, Myanmar, Nepal, and the United Republic of Tanzania (*8*), with India alone accounting for 64% of the prevalence of leprosy and 78% of new cases detected worldwide (*9*).

The picture is different when new-case detection rates are used instead of prevalence figures. The new-case detection rate is a better indicator of disease because it is not affected by changing case definitions or duration of treatment. Comparing the data from India using these two different types of measurement shows that although prevalence has fallen dramatically, the incidence figures have remained almost constant (Fig. 2). Fig. 3 shows new-case detection rates for the countries with the highest rates of leprosy over the past 8 years. In all of these countries new-case detection rates are stable or increasing. There may be operational explanations for these trends, such as increased detection activities, and more people may be presenting for treatment because they have learnt that leprosy is curable. New-case detection rates taken together with the proportion of cases treated with MB-MDT and the high rates among children (about 17%) indicate that leprosy continues to be transmitted in the community (*6*).

Fig. 1. **Global prevalence and new-case detection rate for leprosy, 1994–2003**

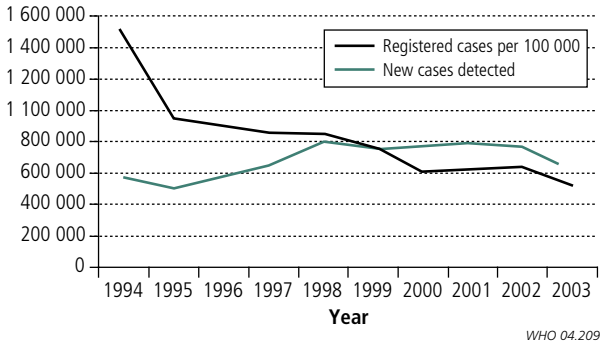
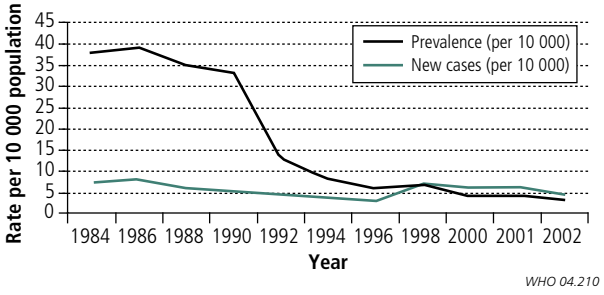


Fig. 2. **Prevalence and new-case detection rate for leprosy in India, 1984–2002**



The idea of elimination was based on the hypothesis that at a prevalence of < 1 case per 10 000 population the transmission of leprosy in the community would be interrupted. The International Leprosy Association's Technical Forum noted that there was little evidence to support this hypothesis but also acknowledged that when new-case detection rates do decline it is often not clear why that decline has occurred (*10*). Leprosy has a long incubation period, ranging from 2 to 20 years (*11*). Patients newly diagnosed with leprosy may have transmitted the disease to others in their family or community long before their disease is detected. Using WHO's definition, South Africa attained elimination in 1924 but new leprosy cases continue to be detected in the northern Transvaal (*12*).

Biological features of *Mycobacterium leprae*

M. leprae is a hardy organism and can survive outside the body for up to 45 days (*13*). In countries where leprosy is endemic, such as Ethiopia and Indonesia, up to 5% of the population carry *M. leprae* DNA in their noses, often transiently and with no evidence of overt disease (*14*). In Ethiopia the organism was found in the nasal passages of 5.9% of villagers in an area where multidrug therapy had been used for the past 16 years (*15*). *M. leprae* is shed from the nasal mucosa of untreated lepromatous patients and probably survives in the environment before infecting the next host. The only significant animal source is the nine-banded armadillo, which lives in the southern United States in Texas and Louisiana; no animal vectors have been identified elsewhere (*16*).

The combination of epidemiological and biological evidence suggests that leprosy cannot be eliminated by multidrug

therapy alone (*17*). This analysis is supported by recent mathematical modelling of leprosy indicators that suggests leprosy is slowly declining but that the rate of decline remains uncertain and a sustained leprosy control effort is required (*18*).

Despite the evidence collected and published by WHO that leprosy is far from eliminated, especially in the areas that have the highest rates of endemic leprosy, in May 2001 WHO announced that leprosy had been eliminated as a public health problem at a global level. This was achieved by including in the denominator of the prevalence the populations of all countries that reported even a single case of leprosy.

Vaccines

None of the vaccines developed against leprosy give high levels of protection. But many randomized controlled trials and case–control studies show that bacille Calmette–Guérin (BCG) gives variable protection against leprosy (20% in Myanmar, 80% in Uganda) (*5*). In Brazil, neonatal BCG vaccination has been shown to protect against leprosy (*19*). Since this vaccine is already widely used in leprosy-endemic countries, the routine use of BCG could be part of WHO's anti-leprosy strategy.

Political effects of elimination

Success of elimination

The advantage of an elimination campaign was that it mobilized people and resources. Governments and NGOs worked together in the campaigns during which leprosy teams and local experts screened thousands of people; in 1998 in Orissa state in India a week-long campaign detected 62 804 confirmed cases (*20*). Leprosy monitoring was done well (*21*). Leprosy attained a high profile, and this is a credit to the Leprosy Unit at WHO.

Downsides

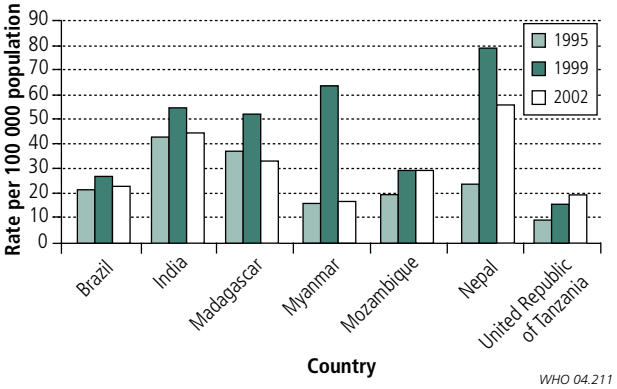
The elimination campaign, however, has also had negative effects on issues such as planning to meet the future challenges of leprosy, the place of leprosy on the research agenda and on the interaction between different leprosy service providers. A major worldwide problem is that people, including health planners and those who fund health care, have not understood the concept of elimination to a prevalence of < 1 case per 10 000 population, thinking instead that it means an absence of cases.

The prospect of elimination has also inhibited leprosy research, with some notable exceptions such as the sequencing of the *M. leprae* genome. Important research sources of funds, such as the Bill and Melinda Gates Foundation, have decided not to fund leprosy research because they no longer perceive it to be an important problem. It is difficult to attract postdoctoral students and clinical fellows to leprosy research: who can build a career on a disease that is perceived as being eliminated? Yet there remain many important research questions that could affect practice and policy.

Effects on partners

NGOs have made a major contribution to the provision of leprosy services. In 1999 the Global Alliance to Eliminate Leprosy (GAEL) was formed as a multisectoral partnership that had the goal of eliminating leprosy. GAEL comprises WHO, the Nippon Foundation, the International Federation of Anti-leprosy Associations (ILEP) and the Novartis Foundation. GAEL mobilized political commitment and created partnerships that ensured that a supply of free medicine and was available in difficult-to-reach areas (GAEL evaluation, unpublished data, 2003). Tensions developed in this partnership and ILEP was asked to leave the alliance in 2000. At the beginning of 2003, WHO invited Richard Skolnik and a team to perform an independent evaluation of the GAEL alliance (*22*).

Fig. 3. **Cases of leprosy detected in seven countries where rates of endemic leprosy are highest, 1995, 1999 and 2000**



The evaluation noted the strengths mentioned above but also observed that the alliance was failing because WHO ignored the concerns of its collaborators. These included concerns over the use of prevalence data and the introduction of new regimens that gave patients all their doses of multidrug therapy at their first visit, thus losing the supervised component of the administration of medicine. These tensions arise partly from differences in perspectives: WHO has a public health perspective whereas the leprosy NGOs focus on the individual (*23*). The evaluation also recommended that the World Health Assembly should pass a resolution that made clear to the world that leprosy had not been eliminated. Key players, such as Trevor Durston, head of Leprosy Mission International, are now suggesting that it is time to focus on bringing together all parties in a way that best meets the needs of people with leprosy (*24*).

Contemporary challenges

Molyneux has argued that leprosy should be seen as one of a group of chronic stable diseases that are being successfully controlled (*25*). However, he cautions that it is vital to maintain the activities that brought these diseases under control. For leprosy this means continuing case detection, providing treatment and meeting the long-term challenge of preventing disability. There are also important research questions to address, such as determining the best way of detecting and treating nerve damage and understanding transmission.

Integration

Many governments are now moving leprosy programmes away from vertical specialized programmes to an integrated approach in which primary health care workers diagnose and treat patients with leprosy. The integrated approach has many advantages including widening the health-care network, thus bringing the diagnostic and treatment services closer to the patient.

Integration is a cost-effective mode for delivering leprosy services given the present levels of prevalence. This advantage could be nullified, however, if there are no staff in primary health care centres. Additionally, there must be a sufficient number of health centres available. For example, in Bihar, India, there is

only one health facility per 200 000 population compared with 1 per 30 000 in southern India (*26*). Effective referral systems are also needed so that complicated cases can easily be sent to specialist centres.

Surveillance and training

Surveillance must be undertaken in an integrated setting using clinically relevant indicators. The number of new cases will probably drop as integration occurs, and it is critical to establish whether patients with leprosy are being missed by the surveillance system (*27*). Special surveillance areas could be set up in regions where integration has occurred; these areas should use active case finding so that an accurate picture of key indicators is maintained. For example, disability rates give an approximate indication of the time to diagnosis, so if these rise it would indicate that there is diagnostic delay. India has low disability rates, and it would be sad were these to rise. Addressing these issues requires effective leadership from governments and WHO. When integration occurs there will be a significant demand for training in countries such as India. Training plays a critical part in ensuring the success of diagnosis, treatment and preventing nerve damage and disability. NGOs have previously worked with vertical programmes and will now need to define new roles for themselves within the framework of an integrated setting.

Diagnosis

The diagnosis of leprosy is simple but it requires skill to differentiate skin lesions and recognize nerve involvement. Diagnosis based on an anaesthetic patch is likely to miss about 30% of the MB cases (*28*). Paramedical workers in the field need to be trained to identify at least two cardinal signs of leprosy: anaesthetic skin lesions and enlarged nerves. This involves training, supervising and monitoring primary health care staff as well as offering refresher training.

Treatment

There are important issues in the treatment of leprosy that require additional research and evidence to guide policy-making. For example, a small percentage of patients have a high bacterial load; they are probably responsible for maintaining infection in their community. Data from India and Mali suggest that relapse rates are high among this group even when they are treated with 24 months of multidrug therapy (*29*). Discovering the optimum way of identifying these patients and providing appropriate treatment should be a public health priority.

Patients' adherence to treatment is problematic in diseases like leprosy and tuberculosis because they require long periods of therapy. Offering supervised monthly doses provides an opportunity to directly observe the treatment as well as educate the patient about the need to take doses regularly and complete the course of treatment. The move to implement accompanied multidrug therapy in which the patient is given the entire 6-month or 1-year course of treatment at the first visit could prove counterproductive. This regimen contrasts with that of tuberculosis treatment programmes where the move has been away from unsupervised regimens towards DOTS; this change occurred after unsupervised regimens led to an increase in treatment failure. The use of uniform short-course multidrug therapy for all patients is being assessed. It is vital that relapse rates are assessed 5 years after treatment in order to detect late relapses.

Reactions and nerve damage

In leprosy, reactions are acute immunological phenomena that occur during the normal course of the disease. Reactions can be disastrous: they cause acute nerve damage. It is important to recognize reactions early and initiate treatment with steroids; this treatment improves outcomes for about 50% of patients. Almost 30% of MB patients develop reactions during the course of their disease. Reactions may occur at presentation, during treatment and after treatment. It is essential that primary health care staff are trained to recognize and treat reactions early. Steroids should be made available at primary health care centres. Clear referral systems should be established to enable primary health care workers to prescribe steroid therapy to patients or refer them to centres for assessment and steroid treatment.

Preventing disability

Preventing patients with nerve damage from progressing to disability and deformity is a challenge that will last for the patient's lifetime. Patients with anaesthesia and muscle weakness need to be taught how to care for their hands and feet: they should inspect their limbs daily and attend to any injuries promptly. Specialist footwear needs to be provided for patients with deformities of their feet to prevent ulceration. Ulcer management forms a large part of any leprosy service. Staff need to work with patients to prevent ulceration from recurring by identifying the cause of the initial injury. Preventing disability is critical to the success of a programme. We need to understand the routes that lead to disability.

Leprosy and stigma

Socioeconomic rehabilitation is another important component of caring for patients. Many patients are marginalized by their communities after being diagnosed (*30*). Stigmatization continues and it needs to be combated using community-based approaches.

Leprosy and poverty

A link between leprosy and poverty has long been suspected, but is difficult to demonstrate at national, community or even individual levels. A study in Malawi showed that at the individual level living in a crowded household was a risk factor as was a lack of education (*31*). A community-level study from Brazil has shown that in an area where the prevalence of endemic leprosy is high, higher levels of inequality were associated with higher levels of leprosy (*32*). Leprosy should be included in the portfolio of diseases associated with poverty, and leprosy work (including detecting and treating cases and reducing disability) should be incorporated into poverty-reduction programmes (*33*).

Role of private practitioners and dermatologists

Private practitioners and dermatologists throughout Africa, Asia and Latin America treat leprosy patients. Although they serve a significant segment of society they have not been included in leprosy programmes and often use non-standard treatment regimens. Leprosy care will be improved if these practitioners are sensitized to leprosy and trained in its diagnosis and management, including how to recognize and manage nerve damage.

Research

A vital question that needs to be addressed is why multidrug therapy has not interrupted transmission. We need to find new approaches to understanding transmission. Chemoprophylaxis may be another useful tool, and several trials of potential agents are in progress. A better understanding of the pathogenesis of nerve damage would also facilitate the move towards better treatment.

Reflections on the leprosy elimination campaign

The leprosy elimination campaign has important lessons for everyone. It was perhaps inadvisable to choose a disease with a biology that does not lend itself readily to elimination. The elimination campaign did, however, achieve great success in terms providing free multidrug therapy worldwide. Nonetheless, there was an underappreciation of the complex problems that leprosy patients present with during treatment and of the long-term needs of patients with disabilities. WHO missed an opportunity to be intellectually open when it failed to acknowledge that leprosy is not going to be eliminated by multidrug therapy alone. If WHO had been able to discuss this with its partners it might have opened up a dialogue leading to new and creative solutions.

We endorse the recommendations of the GAEL evaluation to make it clear that there will continue to be new cases of leprosy, that a range of leprosy activities will need to be carried out, and that governments need to be accountable. We also support the recommendation that the World Health Assembly should pass a resolution that addresses leprosy activities beyond 2005. ■

Conflicts of interest: none declared.

Résumé

La lèpre : une maladie trop complexe pour qu'on lui oppose une politique d'élimination simple

La lèpre peut-elle être éliminée ? Le présent article examine cette question en se référant au programme d'action de l'OMS pour l'élimination de la lèpre. En 1991, l'Assemblée mondiale de la santé avait fixé comme objectif d'éliminer la lèpre en tant que problème de santé publique d'ici l'an 2000. Les spécialistes de l'OMS avaient défini l'élimination comme l'obtention d'un taux de prévalence inférieur à 1 cas pour 10 000 personnes. Le programme d'élimination a obtenu de très bons résultats dans la délivrance de traitements antibiotiques hautement efficaces dans le monde entier. Néanmoins, en dépit de ces progrès, les taux de détection de nouveaux cas restent stables dans les pays où la prévalence de la lèpre, à l'état endémique, atteint les valeurs les plus élevées, tels que le Brésil et l'Inde. On peut donc penser que les antibiotiques seuls ne suffisent pas à juguler cette maladie.

Il est peut être plus correct de classer la lèpre parmi les maladies chroniques stables, plutôt que parmi les maladies infectieuses aiguës, répondant à des stratégies d'élimination. Dans nombre de pays, les activités visant à juguler et à traiter la lèpre s'intègrent dans le système général de soins de santé. Cette situation atténue la stigmatisation associée à une telle maladie. Cependant, la lèpre provoque des complications immunologiques, des handicaps et des difformités durables. Les soins de santé visant à traiter et à prévenir ces handicaps doivent être dispensés dans le cadre d'une structure intégrée.

Il sera peu facile de détecter les nouveaux cas et de surveiller les handicaps provoqués par la lèpre. Une solution consiste à mettre en place une surveillance à long terme dans des pays sélectionnés parmi ceux présentant les plus forts taux d'endémie, de manière à pouvoir obtenir une estimation précise de la charge de lèpre. Il est aussi essentiel de poursuivre des recherches diversifiées sur cette maladie qui pose de multiples problèmes, jusqu'à ce que ceux-ci soient vraiment résolus.

Resumen

La lepra, una enfermedad demasiado compleja para aplicar un modelo simple de eliminación

¿Es posible eliminar la lepra? En el presente artículo se examina esta cuestión con el telón de fondo del programa de la OMS para la eliminación de la lepra. En 1991 la Asamblea Mundial de la Salud estableció la meta de eliminar la lepra como problema de salud pública para el año 2000. Se definió la eliminación como el logro de una prevalencia inferior a un caso por 10 000 personas. El programa de eliminación ha permitido proporcionar una antibioticoterapia altamente eficaz en todo el mundo. Sin embargo, pese a este avance, las tasas de detección de nuevos casos siguen estabilizadas en los países que presentan las mayores tasas de lepra endémica, como el Brasil y la India. Esto indica que el simple uso de antibióticos no ha bastado para controlar adecuadamente la infección.

Tal vez sería más apropiado clasificar la lepra como una enfermedad crónica estable, antes que como una enfermedad infecciosa aguda sensible a las estrategias de eliminación. En muchos países las actividades de control y tratamiento de la lepra están siendo integradas en el sistema general de atención de salud, lo que reduce el estigma asociado a la enfermedad. No obstante, la lepra da lugar a complicaciones inmunológicas, discapacidades y deformidades a largo plazo. Las actividades asistenciales de tratamiento y prevención de las discapacidades se deben ofrecer en entornos integrados.

La detección de los casos nuevos y la vigilancia de la discapacidad causada por la lepra constituirán un desafío. Una solución consiste en implementar medidas de vigilancia a largo plazo en los países que tienen las mayores tasas de endemicidad de esta enfermedad a fin de poder estimar con precisión la carga de lepra. También es fundamental que prosigan las investigaciones generales sobre esta enfermedad que se resiste hasta haber resuelto realmente los problemas.

Arabic

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