

Leprosy elimination—a virtual phenomenon or a reality?

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Why are evidence based policies not guiding the World Health Organization's leprosy elimination campaign, asks Diana Lockwood

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Leprosy is an infectious disease but it has many features in common with neurodegenerative disorders. It results in a chronic neurological illness, which is progressive unless treated; frequently produces long term disability; and is associated with high levels of stigma. As it has a known infective agent, *Mycobacterium leprae*, there is the possibility of disease control. Multidrug treatment with the antibiotic combination rifampicin, dapsone, and clofazimine is highly effective in curing infection, with relapse rates of 1%.¹ It was hoped that having effective antibiotics would permit disease control and thus the concept of leprosy elimination developed. "Leprosy elimination by the year 2000" was first proposed in 1986 and at the 44th World Health Assembly in 1991 modified by the addendum "as a public health problem," defined as less than one case per 10 000 population.² The leprosy elimination campaign has had some notable successes but also illustrates the epidemiological, medical, and political problems of the elimination concept.

Controlling and treating leprosy

Leprosy is a complex mycobacterial disease whose manifestations and complications are determined by the immune response. Many patients experience immune mediated nerve damage, which may occur before, during, or after treatment. Recent field based cohort studies have shown that at diagnosis many patients already have established nerve damage; rates vary from 20% in Bangladesh to 56% in Ethiopia,^{3 4} and these patients have a worse prognosis for disability. Up to 30% of multibacillary patients have acute inflammatory episodes (reactions) affecting skin and nerves. Prednisolone is used to suppress reactions and ameliorates acute nerve damage in about 60% of patients.⁵ Anaesthesia and paresis in the hands and feet put them at risk of secondary damage from trauma and infection, which cause the highly visible deformities of leprosy (fig 1). The purpose of controlling leprosy is to reduce the rate and severity of disability. The key to effective management of leprosy is early diagnosis and treatment and early recognition and management of nerve damage, combined with effective health education.

WHO clinical classification for field programmes¹

- Paucibacillary single lesion leprosy (one skin lesion)
 - Paucibacillary (two to five skin lesions)
 - Multibacillary (more than five skin lesions)
- Neurological assessment and slit skin smears do not contribute to this classification.

Summary points

Leprosy is a leading cause of neurological disability

The World Health Organization's leprosy elimination campaign has treated 11 million patients, but case numbers are still rising in the major countries where leprosy is endemic

New methods for diagnosis and treatment proposed by the WHO risk missing disease and undertreating patients, and an opportunity for implementing evidence based policies may be missed

What has the elimination campaign achieved? People and governments were mobilised, leprosy programmes were revitalised, and drug treatment for leprosy was provided free of cost by the Sasakawa Foundation through the World Health Organization. Imaginative programmes were devised, such as monthly drug delivery circuits by paramedical workers to supervise taking the monthly components of multidrug therapy. Morale among patients and workers improved. Eleven million patients have been given multidrug therapy. The number of registered patients fell from 5 million in 1985 to 0.7 million in 2001. But this fall was almost entirely attributable to a change of case definition that includes patients only during the course of multidrug therapy—that is, those with active infection.⁶ Patients with ongoing complications or disabilities due to the disease are excluded.

In 2001 WHO claimed that leprosy had been eliminated "at a global level," even though 719 330 new patients were registered in 2000 (fig 2).⁷ In the 27 top countries where leprosy is endemic, the incidence did not fall between 1985 and 1999, and in the six countries that account for 88% of new cases the numbers and incidence of new cases are rising (figs 3 and 4).⁹ Children comprise 15% of cases, indicating that active transmission continues. WHO has now rescheduled elimination for 2005. Integration of previous leprosy-only programmes into primary health care is the preferred model. Leprosy is not an easy disease to diagnose, and patients seen at peripheral clinics will go undiagnosed, thus apparently reducing the incidence of the disease further.

Policy changes should be evidence based

The enthusiasm of the WHO for simplifying leprosy management threatens the achievements of the elimi-

nation campaign. Numerous policy changes have emanated from the WHO for direct implementation in the field without prior research. Skin smears, essential for identifying patients with high bacterial loads, have been discontinued and the duration of multidrug therapy for multibacillary patients has been reduced from 24 months to 12 months despite evidence that patients with high bacterial loads are at greater risk of relapse.¹⁰

The latest WHO document, *The Final Push Strategy to Eliminate Leprosy as a Public Health Problem: Questions and Answers*, proposes a new treatment, accompanied multidrug therapy.¹¹ Patients will be given all the medicines for the full six or 12 month course of treatment at their first, diagnostic, visit with the proviso that someone close to the patient will take responsibility for helping the patient complete the course of treatment. This is a curious reversal of policy. Ten years ago the strength of the leprosy programme lay in the monthly supervision of medication, which also meant that nerve damage was picked up early and health education could be ongoing. The new policy contrasts with that of directly observed treatment (DOTS) in the tuberculosis programmes.

Another major policy change relates to the recognition and management of reactions (acute inflammatory episodes). The document minimises the need for giving steroids for leprosy reactions, stating, incorrectly, that most leprosy reactions can be controlled by non-steroidal drugs. There are no data on the effectiveness of non-steroidal drugs in leprosy reactions. The document making these proposals, which will guide policy in leprosy endemic countries, has no authors and no references to published work and states that it is not a formal publication of the WHO. The WHO Technical Advisory Group has now recommended a further untested policy change: that all leprosy patients, regardless of disease type, be given a six month triple drug regimen.¹² This would simplify leprosy treatment but give 60% of patients a third drug that they do not need, and it would undertreat patients with a high bacterial load. It is proposed that this treatment be implemented without a formal trial. Ominously, the document later notes that “a study of which the results will only be published in five years will not help elimination efforts.” Good research is needed to underpin leprosy policies, particularly since integration will increase the difficulties of doing field based research.

Policies for leprosy control can be evidence based, as has been shown by an expert group convened by the International Leprosy Association this year. The group produced evidence based graded recommendations on issues relating to leprosy control, diagnosis and classification, chemotherapy, nerve damage and rehabilitation, and sustainability of leprosy services (www.lepra.org.uk/).¹³ Simplifying diagnosis has been considered by both the WHO and the evidence based group; the WHO document states that in 70% of patients, diagnosis can be made by a single sign: an anaesthetic skin patch. The evidence based group found that the other 30% are multibacillary patients, who are more likely to be infectious and to develop nerve damage.



Fig 1 Nerve impairment with secondary damage. The boy has bilateral ulnar and median nerve involvement affecting the hands, with small muscle wasting and finger clawing; he has lost temperature sensation and burnt his hands when standing by a fire

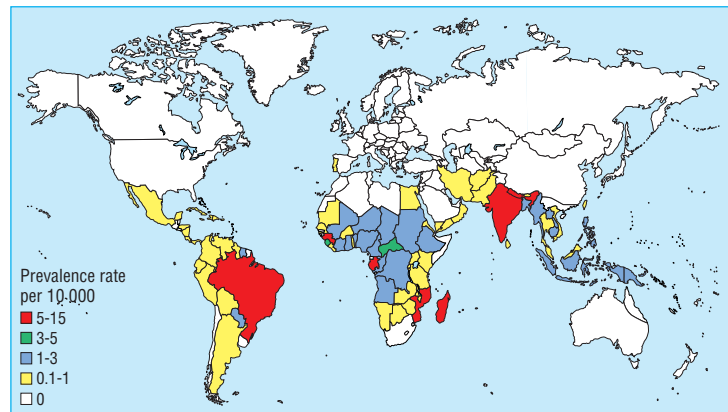


Fig 2 Global prevalence of leprosy

Multisectorial partnerships

In 1999 the WHO created the Global Alliance to Eliminate Leprosy (GAEL) in partnership with the Nippon Foundation, the drug company Novartis, DANIDA (Danish agency for development assistance), and ILEP (International Federation of Anti-Leprosy Associations, the umbrella organisation of the non-governmental organisations for leprosy) to provide multidrug therapy for all patients. But when ILEP members questioned the policies being promoted by the global alliance they were excluded from the partnership. WHO staff have subsequently outlined the WHO's position on a web based leprosy discussion group (noto@cefpa.it). The differences may arise in part from different perspectives. WHO has a global public health view, treating populations, whereas the leprosy non-governmental organisations have a stronger focus on treating individuals. If integration is to succeed then all available leprosy expertise will need to be mobilised and to work together in a multisectorial approach, and the expertise of the non-governmental organisations will be invaluable.

Elimination is not eradication

The elimination of leprosy will be a virtual phenomenon—elimination of registered cases through

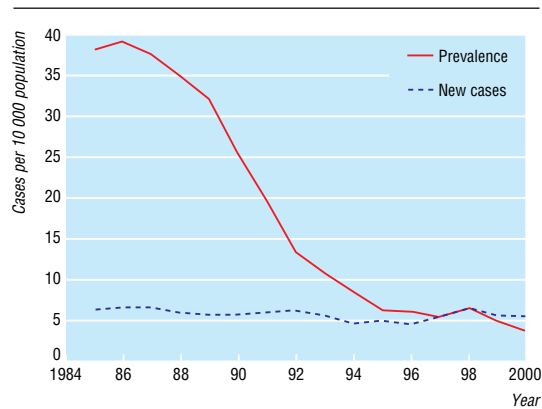


Fig 3 Prevalence and incidence of leprosy in India, 1984-2000

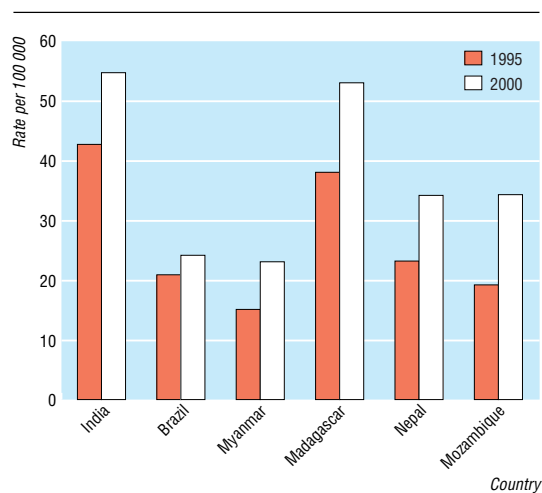


Fig 4 Incidence of leprosy in the top six endemic countries, 1995 and 2000

very short treatment regimens without reducing the number of new cases. The concept of elimination at a prevalence of one case per 10 000 population is a difficult concept to understand, and many people confuse it with eradication. There is no evidence that reaching this predefined prevalence will reduce transmission, incidence, or the annual number of new cases. Who needs this prize, and must it be delivered at all costs? The elimination campaign has shown how difficult it will be to eliminate leprosy in countries where it is highly endemic. The biology of the organism and the

disease mitigate against easy control of transmission. Lepromatous patients are highly infectious through their nasal secretions; the organism can survive many months outside a human host; up to 5% of the population in leprosy endemic areas are nasal carriers of *M leprae* DNA.¹⁴ Lepromatous disease has a mean clinical incubation time of 10 years.¹⁵

If the WHO believes its own rhetoric about eliminating leprosy, then governments of countries where leprosy is endemic may believe it too and disband their control programmes and disperse their skilled staff. But they may be left with many unanswered questions. Who will provide drug treatment after 2005? Who will train the primary health care workers once the vertical programmes have been disbanded? What plans are being made for the long term care of patients with nerve damage, who will continue to present for many years to come? In the 1960s tuberculosis and malaria were pronounced defeated; now we face global emergencies in control and management for both diseases. It would be tragic to see this cycle repeated with leprosy.

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One hundred years ago

The classics in preliminary examinations

Sir - Your article in the British Medical Journal of February 15th, and Sir William Gairdner's letter of the same date, defend Latin learning as a necessity for the proper use of English. It is on that ground that both you and he require its retention.

That view I disbelieve. Newspapers show us that plenty of men who have had a classical education write execrable English. It is equally certain that many write excellently who have had no such training. To write well is to write clearly, to write clearly it chiefly needs to think clearly, and clear thinking is to be gained by many other studies than the learning of Latin.

All men allow that the classics are a fine mental training, and an introduction to cultivated pleasures. That is, however, no reason for claiming that they stand alone. When you and I, sir, were young they formed the only liberal education. It seems doubtful, to judge by the present dispute, if the education was as liberal as we supposed.—I am, etc.,

Wimpole Street, W., Feb. 17th.

W. P. HERRINGHAM.
(*BMJ* 1902;i:485)