Introduction

Leprosy is an ancient, chronic, infectious disease caused by leprae (1). Despite its long history, the epidemiology and several medical aspects are still poorly understood (2). Social stigma for this disease is still strong due to misconceptions, prejudice and ignorance of latest information on its etiology and cure. Until mid-twentieth century, leprosy was considered incurable and only palliative care possible to alleviate the suffering due to deformities and debilitation.

It was during the late 1940’s, a new anti-leprosy drug, the Di-amino-Diphenyl Sulphone, popularly known as DDS or Dapsone ushered in an era of cure for leprosy and gave rise to hopes of finally eradicating this disease (1). In 1953, the Government of India launched the National Leprosy Control Programme (NLCP), using DDS as the sheet anchor (3). Since only leprosy patients were considered the only source of infection, paramedical workers and non-Medical Supervisors were recruited throughout the country to carry out surveys to detect leprosy patients, offer comprehensive health education and treat every case (SET), under the direction of district and local leprosy medical officers.

Need for MDT

While DDS was effective in controlling the disease, patients had to consume it life-long. Further, there were many variations in dosage, considerable irregularities in consumption and inevitable defaulting. During the late 1960’s and early 1970’s, reports began to appear that m.leprae had developed resistance to the drug, and the disease once again became uncontrolled (1,3). Scientists started research on alternative drugs and particularly the concept of using multiple drugs, especially Rifampicin, along with dapsone gained ground. Initial experiences in various centres were promising and the WHO constituted a study group in 1981 to formulate rational therapy. Based on intense analysis of all available scientific evidence, on the ground realities of implementing public health programs and a strong desire to bring about a major impact on the leprosy situation in endemic countries – even if this meant compromising on some less critical scientific requirements. This group of researchers, leprologists, microbiologists, clinicians and public health managers recommended a standardized multidrug therapy (MDT). (4)

For multibacillary patients, the MDT consisted of 3 drugs, viz., Rifampicin, Clofazimine (an anti-inflammatory drug Lamprene) and DDS, while for paucibacillary patients, only 2 drugs, Rifampicin and DDS were recommended (4). The dosages were standardized for adults and children separately, after a period of pilot studies in various areas. The initial reaction of leprosy workers to the WHO-recommended MDT varied widely as it had introduced some revolutionary changes such as treating patients for finite periods of time and simplifying classification of the disease. However, the early result of MDT was accepted in all the endemic countries and programs, and leprosy workers everywhere received it with great enthusiasm, leading to renewed motivation to control the disease (5).

Under the leadership of Prof. M S Swaminathan, the leprosy control programme (NLCP) was changed to National Leprosy Eradication Programme (NLEP) from 1983

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replacing monotherapy with MDT under the same vertical structure, and formulating a 20-year plan, after which the program can become, integrated with the general health system. (3) MDT was found to be robust, safe, effective and acceptable, was introduced initially in a few districts, and later extended to all districts in the country by 1996. For paucibacillary cases MDT was given for only 6 months, but for multibacillary cases with a positive bacterial index (BI), it was given till the patient showed negative results for 3 consecutive months. Based on research evidence, the duration for multibacillary cases was subsequently reduced to 2 years, and more recently recommended for only 1 year (2, 6). The phenomenal reduction in the prevalence of leprosy seen even within five years of the introduction of MDT resulted in further intensification of leprosy control activities everywhere. This led WHO to recognize that there was a historic opportunity to aim at the elimination of leprosy as public health problem with a deadline of the year 2000. (5)

WHO defined “elimination” as reducing prevalence of the disease to less than one case per 10,000 population. This is not to be confused with “eradication” of the disease aiming at reaching zero prevalence and zero transmission. The idea was that when leprosy prevalence reached a level below one case per 10,000 population, the disease would die out over a period of time, provided anti-leprosy measures, including MDT, continued to be available (2). The goal set by WHO enabled development of strong political commitment everywhere and effective and widespread leprosy control programs in all endemic countries.

During the last two decades, many innovations, several of them developed by WHO, have been introduced from time to time for strengthening the NLEP in India. (7) The important ones include: case definition; simplified procedure for leprosy case diagnosis, classification and reporting; change in the duration of treatment of MB cases; delivery of MDT drugs in blister packs; introduction of accompanied MDT for patients who cannot collect monthly drugs from health centres till completion of the course; contribution of state and district leprosy societies to ensure that funds earmarked for leprosy are spent for leprosy elimination activities only; improved supervision/guidance by creating posts of NLEP consultants, district leprosy consultants and district technical support teams.

Impact of MDT in prevalence:

As a result of these decisions, the Prevalence rate (PR) during pre-MDT for the country as a whole, which was 57.4-cases/10000 populations, with a PR of over 100/10000 in several states/districts, plummeted to 1.3/10000 by the end of March 2005. (8) The decline in prevalence has been most dramatic in India during the last three years, from 4.2/10,000 in 2002 to 1.23/10,000 as of June 2005. 24 out of the country’s 35 states/Union Territories have now achieved the elimination goal. Seven states did not reach the goal: 7 states – Bihar, Chattisgarh, Jharkand, Maharashtra, Orissa, Uttar Pradesh and West Bengal and 4 UTs – Chandigarh, Dadra Nagar Haveli, Delhi and Goa. Except for 2 or 3 states, the rest are expected to reach the elimination goal by the end of 2005, should the progress continue at the same level as in 2004-05. (8, 9)

In several high endemic states such as Bihar, the decline in prevalence is dramatic. Deliberate under-detection of cases during the year 2003-04 by the over-zealous staff due to pressure at all levels to achieve elimination by 2005 could have contributed to the steep decline in the PR. In fact, there was a report from a reputed NGO with credible leadership that several new cases in an endemic district under its support were not reported during the first quarter of 2005. (10)

Impact of MDT on Incidence:

Incidence rate for a chronic, insidious disease is rather difficult to measure, and hence the New Case-Detection rate is used as a proxy, which can be reasonably close to the true incidence, if case detection methods are standardized, systematic and regularly adopted. In the NLEP of the Government of India, the use of incidence rates or even the New Case Detection Rates for measure elimination of leprosy was summarily rejected as impractical, and instead the Prevalence rate was adopted. (6)
Globally, the reduction in new case detection is only 32% (5, 8). This is mainly due to the nature of the disease: a good proportion of currently occurring new cases are probably due to infections acquired several years earlier, and even prior to the introduction of MDT. Therefore, reductions in new case detection will be relatively slower, but the declining trend is clearly visible in most parts of the world. The political commitment continues to be sustained in all countries and all countries are implementing critical and focussed activities to further reduce the disease burden. (11).

The impact of MDT administered to every leprosy patient should be seen clearly in the transmission of the disease from the affected to the uninfected. Studies on contacts developing leprosy especially from an index case within household have shown a manifold increase in incidence rates (12, 13) as compared to the general public. Under the vertical system, annual contact surveys used to yield new cases. With integration of leprosy services with the general health system, these surveys are discontinued. Instead, modified leprosy elimination campaigns (MLEC) are carried for the same purpose.

In India new case-detection rates (NCDRs) were stationary or had increased after the introduction of MDT. The increase in NCDR could be due to extension of MDT to new areas and special activities for detecting new cases (14). Given the large terrain of our country, and several inaccessible areas, MDT coverage has not been fully satisfactory, and the treatment with MDT has not always been prompt or regular. No wonder, the incidence rates are yet to decline significantly. (10, 15). While some corrective actions were taken, more efforts were made and fresh directives given to minimize ‘operational factors’ such as wrong diagnosis, re-registration of cases, delayed treatment completion, over-treatment etc; As a result, New case detection declined from 57.5/100,000 population in 2002 to 23.40/100,000 as of March 2005. (8)

Present Status:

The National Health Policy 2002 set the goal for elimination of leprosy, i.e. reduction of leprosy cases in the country to <1/10,000 population, by December 2005. (9, 14) At the time of writing, the Government of India just announced that it had reached the target of reducing prevalence nationally to less than 1 per 10,000 population on 31 December 2005. Efforts will now be directed to reach elimination at the sub-national levels. A Focused Leprosy Elimination Plan (FLEP – 2005) has been drawn up and is being implemented in those identified districts and blocks, where the PR is still more than 3/10,000 (9). It has been already decided to keep the programme activities at a high priority, after stoppage of support by the World Bank, during the next 2 years also, i.e. till the end of the tenth five-year plan in March 2007. All costs towards this end will be from the public sector. However, the programme will continue to receive additional support as at present from partners such as the World Health Organization and the International Federation of Anti-Leprosy Associations (ILEP).

The WHO has encouraged and supported Special Action Programmes for Elimination of Leprosy (SAPEL), and several Modified Leprosy Elimination Campaigns (MLEC), which have helped in dispelling ignorance and changing attitudes, as well as providing access to MDT. (7) More such campaigns are required, especially in specific high endemic areas of our country. Thus, while we might have run 90% of the marathon to eliminate and eventually eradicate leprosy, the final 10% requires a burst of energy to win the race in the form of more innovative and flexible approaches to ensure full and satisfactory coverage of MDT, which is the best therapy available so far. (5) At the same time, the programme administrators and researchers should prepare themselves with second line drugs or alternative therapies, in case of possible MDT-resistances. (11, 16)
Conclusions:

Leprosy is a chronic disease, with an unknown incubation period, and requires generally a long period of treatment, before one could pronounce, “cure”. (1) As yet, there are no clinical or laboratory tools to detect infection or subclinical disease, and hence prompt detection of clinical disease at the earliest and treatment with MDT will hold the key for eradication of this disease. Due to prevailing negative perceptions of leprosy and social stigma, persons suspecting leprosy delay seeking effective treatment till irreversible symptoms such as anesthesia or paralysis due to nerve function impairments develop. By then, the disease would have spread within the body and would also have been transmitted to contacts. While one acknowledges the superiority of MDT over monotherapy in its bactericidal action, it is obvious that drugs alone can never solve a public health problem, such as leprosy, due to public attitudes and health behavior conditioned by massive prejudices, inadequate knowledge & several socioeconomic factors in accessing MDT or anti-reactional drugs, etc. (17, 18)

It is well known that the Prevalence rate, is more an operational index, subjected to a number of non-epidemiological factors such as changing definitions of what is a case of leprosy, changing and diminishing duration of treatment with MDT, excluding those still requiring MDT beyond the fixed duration due to high bacillary load, or wrong classification, etc., etc. While these manipulations succeed in bringing the prevalence rate down to the required level of less than 1 per 10,000 population to reach the elimination target, it is difficult to confidently predict that we are well on the road to eradicate leprosy. Only time will tell if the disease will stage a comeback, as it has happened for Tuberculosis or Malaria or truly decline. Given the slow growing mycobacterium, it may take a longer time to detect relapses or drug resistances, by which time; it may not be easy to take rapid remedial actions. (19)

Epidemiologists have formulated a relationship between the Prevalence Rate (P), the Incidence Rate (I) and the duration of the disease (D) as follows:

\[ P = I \times D \]

In the case of a chronic disease, the Prevalence will always be greater than the Incidence.

The situation in India has become paradoxical, because the original meanings of P, D and I have been changed to:

- \( P = \) Cases of leprosy needing MDT for the first time per 10,000 population
- \( I = \) New Case Detection rate
- \( D = \) Duration of MDT

The current situation has thus created an “epidemiological paradox” where prevalence has become less than incidence for a chronic disease! As durations of MDT got reduced from life-long treatment, to 10 years to 2 years to 1 year, and now being planned for only 6 months, the prevalence rate will reflect largely this diminishing factor, with the programme managers busy “cleaning registers”, releasing large numbers of patients no longer requiring MDT. (20)

Some lessons to be learnt:

The lessons for a good program manager from these experiences are obvious: Use a proper indicator for measuring impacts, even if relatively difficult to measure, use sample surveys to monitor quality and veracity of the statistics generated, introduce necessary laboratory tools to check on presumptions and assumptions and lastly be prepared to supplement routine programs with innovative and effective activities. Never steam-roller or suppress genuine concerns or lone voices however unpleasant, but examine and analyse these situations. In the name of “public health approach”, one should not ignore danger signals such as appearance of drug resistances, noncompliances or reporting biases. A good manager is always prepared for possible emergencies, based on earlier experiences with leprosy.

We hope that the day will not be far off when India will truly declare victory over the physical and social evils of leprosy.
REFERENCES


