A Plea to Revive Skin Smear Examination

TO THE EDITOR:

Leprosy is one of the oldest diseases known to mankind, but an effective treatment for it could only be made available a couple of decades ago. The credit mostly goes to the World Health Organization (WHO) which mobilized the expertise globally, designed the multidrug therapy (MDT) and recommended its use in 1981. It has further convinced the member countries in which the disease posed a problem to adopt the new strategy. India also readily responded to this call for a combined attack on the disease. The magnitude of the leprosy problem in India at the time MDT was begun was considerably high. Its estimated caseload was around 4 million, which constituted almost one third of the global problem. Befittingly, the country started implementing MDT through one of the largest and best organized programs in the world. More than one and a half decades of the Indian National Leprosy Program (NLEP) in the country have generated voluminous information on the MDT operation, and the cumulative data have helped in modifying the WHO guidelines from time to time. It is not wrong to say that the Indian experience is more or less representative of the entire MDT operation in terms of achievements and failures.

The most glaring achievement of MDT in India has been the drastic reduction of the prevalence rate (PR). A PR of 57/10,000 population in the year 1983 had decreased to 5.2/10,000 by the year 2000 ([5]). A spectacular PR reduction is not confined to India. It was shared by many countries. This success led the 44th World Health Assembly to urge its member states to eliminate the disease as a public health problem by 2000 A.D. This was historic, because it announced a target year and laid emphasis on the event of elimination. But setting a target had both virtues and vices. While it whipped the program toward optimal activities, it also compelled the adoption of several compromises in the elimination strategy. The important ones are:

Concept of elimination. The 81st Dhalem Workshop on The Eradication of Infectious Diseases held in Berlin, Germany, in 1997 defined four stages of medical intervention in a disease. The stages are: control, elimination, eradication and extinction. Elimination is the state of zero incidence of a disease at some part of the world at a given point in time. Eradication is permanent zero incidence globally, and extinction means total disappearance of the causative organism. Judged with these criteria, the elimination strategy practiced in leprosy appears to suffer from two inadequacies: a) The presumption of achieving a zero incidence is indirect. The program heavily depends upon the reduction of the prevalence rate (PR) in place of the incidence rate (IR), also with the objective of achieving a PR of less than 1/10,000 and not a PR of zero. It may also be noted here that initially when elimination was defined in terms of the reduction in PR, dissenting voices heard scientists, program managers and nongovernmental organizations who suggested the IR in place of the PR ([9]). The views for inclusion of the IR or its proxy, new case detection rate (NCDR), are often forthcoming even today. Unfortunately, the calculation of the NCDR is another difficult task in leprosy due to the very insidious nature of clinical symptoms, the tendency of self-healing in a high proportion of cases, and the lingering problem of backlog cases. As per the information available, the NCDR has continued at a fairly high level over the last few years, and this is a question mark on the claim of progress toward elimination.

b) Ascertaining the state of cure: There is no second opinion that the MDT is robust. The problem lies generally in deciding the point of cure and the cut-off point of treatment. The natural expectation of any patient is complete relief of clinical symptoms. Leprosy is such a disease that, even in the days of MDT, an unambiguous cure cannot be assured to the patient. Even if he takes regular treatment his skin and nerve lesions take a rather long time to subside, which

leads to an important dilemma. If the patient is treated until complete disappearance of lesions, the regularity of treatment is difficult to sustain. At the same time, a shorter course of treatment is regarded as incomplete, especially if his clinical problem continues. When the MDT program was launched, the recommendation was to treat the cases until the lesions become inactive or the smear becomes negative (MB patients). Although this was itself a compromise, it has some rationale. Then the criteria of cure changed rapidly as the year 2000 approached and, successively, there followed the introduction of fixed-duration treatment (FDT), shorter FDT (12 doses), and single-dose therapy. Added to this, the practices of active surveillance and skin-smear examination were made optional, which otherwise should have been strengthened in the post-FDT scenario. The changing criteria on cure adopted from time to time have points both in favor and against, although there is no consensus on the issue ([1, 3, 4, 7, 8] to cite only a few). Although the elimination slogan greatly charged the patients and workers with renewed enthusiasm, in the technical sense the strategy followed fits more to leprosy control than leprosy elimination. The problem with a disease under control is that once there is relaxation in the intervention efforts, there often is a risk of the disease returning with added complications, such as drug resistance.

The drastic reduction in the PR has resulted in a proportional decrease in the workload. This is the right time to divert manpower and resources in measuring and monitoring the results. Well-equipped surveillance units can be set up at least on an experimental basis in selected areas, perhaps for one district in each state, to see that the simplified approaches are yielding the expected results. It may be mentioned here that the Workshop on Impact of MDT on the Trend of Leprosy held in 1993 proposed a few sentinel centers to keep watch on the disease trend ([6]). Well standardized leprosy information systems are also being organized by endemic countries which have either eliminated the disease or are very near elimination. This step is appropriate and timely although some difficult, yet important, indicators have not been included The indicators presently included are: 1) prevalence rate, 2) case detection rate, 3) percentage coverage of MDT, 4) cure rate, and 5) disability rate ([9]) Of these, indicators 2, 3, and 4 are related. Since presently almost 100% of registered cases are receiving MDT in a program ([9]) and all are taken as cured after FDT, indicators 3 and 4 are repetitions of the same success story. Hence, in place of them other more important and informative indicators can be included. Probably the smear-positivity rate is a well-deserved candidate. We may recollect here that in the rush for early elimination this important aspect of the program was compromised first.

In spite of the numerous achievements of MDT, the issue that makes everyone uneasy is the static or slightly increasing NCDR ([9]). The reasons often cited are: 1) incubating cases surfacing as clinical disease, 2) detection of hidden cases, 3) increased voluntary reporting due to increased awareness, etc. Such reasons may be true for the Indian states of Uttar Pradesh and Bihar, but not for Tamil Nadu, Andhra Pradesh, Maharastra and Orissa where the MDT program was well organized for a long time and was often appreciated in the past ([5, 6]). The detection of a large number of cases with a high MB rate, high child rate, and low disability (grade 2) in these states during the modified leprosy elimination campaigns (MLECs) ([9]) makes one uneasy in terms of NCDR. Although from time to time concern has been shown for this aspect, the possibility of a reservoir of infection and continuing transmission failed to draw due attention.

In a microbial disease, if the NCDR is not coming down and there is a high child case rate looking for or ruling out the role of a causative agent appears more relevant. But, due to reasons to be enumerated later, skin-smear examination–the only affordable laboratory test to detect *Mycobacterium leprae*–has gradually been made optional in the programs. When a difficult procedure is made optional it amounts to near deletion, and today there is no adequate information on this issue. To include again an indicator on smear positivity now needs the revival of smear laboratories, a possibility if this procedure is made more rational and re-

alistic. A few modification in the test are as follows:

1. The grading system probably needs to be dropped. Almost all infectious diseases manage with a positive or negative report, and this is also possible in the management of leprosy. The smear grading system was the most cumbersome exercise, involving averaging at two stages. Even if smears are collected from three sites, as per the guidelines, 100 fields are to be screened if the organisms are scanty and 25 fields if they are numerous. Averaging all the fields gives the bacterial index (BI) of the field, and an average of the three fields gives the BI of the patient. When there is only one drug regimen for a positive case, whether 100 fields show 1–10 bacilli (grade 1) or one field shows more than 1000 bacilli (grade 6, Ridley scale), burdening the technician with such arithmetic computations seems unwarranted. Since isolation of a highly bacillated patient is not required, there is probably no need to know the degree of positivity. Hence, a reliable positive or negative report will be adequate.

2. There is evidence that tuberculoid (TT) and indeterminate leprosy cases are almost always smear negative. If the clinical diagnosis is dependable, these cases do not require smear examination.

3. The number of sites needs to be limited to 3. If the field worker/clinician is good at selecting the most active site, even one site is adequate to give the required information. Examination may be repeated at the interval of 6 months, and it may be from the one site which had the highest BI in the initial examination.

4. In the NLEP set up in India, PMW and NMS belong exclusively to the leprosy cadre. They have no other option than to give their best performance in leprosy. But the technicians, at least in the MDT districts, are mostly from the general health service laboratories. Working in a general laboratory is more attractive and rewarding than doing monotonous smear reporting. Hence, laboratory technicians posted to smear labs generally manage a transfer at the earliest opportunity. This is also sometimes reflected in the independent evaluation team reports. Hence, it would be ideal if the PMW/NMS who are trained in smear reporting were posted to the surveillance units. Another alternative would be their temporary employment by contract.

5. Past experience shows that most of the leprosy programs failed to attract technicians; therefore this area deserves some incentive. In addition, there is also a need to provide good working conditions in the form of a well-lighted room, good binocular microscope and quality reagents. Smear reporting is probably the most difficult test due to the varied morphology of *M. leprae*. A pink rod, a fragment and a granule, anything can be a bacillus. A good binocular microscope reduces eye strain considerably.

6. Other issues which complicate and devalue smear examination are: a) the varied forms of the organism as stated above, b) relating living and death status to morphological forms, c) dead bacilli lying in the tissue for a long time due to the body's ineffective macrophage disposal machinery and resulting smear positivity, d) smear negativity in as much as 80% of leprosy cases (smear negativity does not exclude leprosy) and, lastly, e) the availability of easily countable skin lesions (alternate way of classification). All probably added to the argument for making this examination optional; but then these are the biologic characteristics of *M. leprae* and we have to deal with them. It is a bit odd to think the surveillance/monitoring of an infectious disease, without ascertaining the status of the causative agent, even for public health consideration.

7. *M. leprae* and *M. tuberculosis* share similarities in susceptibility of rifampin, tendency to develop resistance to monotherapy, and manifesting in MB and PB forms ([1]). Hence, MDT for leprosy is designed more or less on the basis of a strategy already in use for the control of tuberculosis, which is a comparable public health problem. The directly observed treatment (DOT) schedule followed in tuberculosis control heavily depends on the result of three consecutive sputum reports ([2]). Compared to *M. tuberculosis*, *M. leprae* is more problematic a bacterium. It has so far defied culture in artificial media, and this prevented the development of a vaccine against it. Its principal host tissue is the nerve–a structure risky for invasive techniques. In short, the biology of *M. leprae* is less explored and its long-term behavior de-

serves to be carefully watched. Hence, the affordable skin-smear examination needs to be included in the surveillance system.

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