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Editorial

EVALUATION OF A MULTIDRUG THERAPY PROGRAMME OF LEPROSY CONTROL

Introduction

Multidrug therapy (MDT) as recommended by the World Health Organisation (WHO)[1] has now been in use for 12 years. However, the availability of MDT alone does not constitute an adequate leprosy control programme. Other essential components are early case-finding and the diagnosis of relapse; equally important are the detection of reactional states and adequate activities for the prevention of disability (POD). Much credit has been given to MDT for the dramatic reduction in the prevalence of leprosy worldwide,[2] but this is mainly due to the shortening of the duration of treatment and the 'register-cleaning' that has accompanied its introduction. It is changes in incidence rather than prevalence that provide evidence that the transmission of the disease is being interrupted.[3]

Evaluation is defined in a variety of ways when applied to programme management. It may be interpreted only as the comparison of the achievements of a programme with pre-set objectives;[4] here we will use it to include 'situation analysis', and for any activity that assesses the effectiveness of a leprosy programme. At the outset of a discussion on evaluation, it is therefore important to define the two basic objectives of MDT programmes of leprosy control:

to control leprosy in populations by interrupting transmission; and
to control leprosy in individual patients by arresting the disease process and preventing disabilities.

Programmes, and components of programmes, should be evaluated on the basis of both these objectives. Effective evaluation of the different parts of the programme will require different approaches. Epidemiological indicators of transmission are needed, but may react slowly to changes and be difficult to measure. Operational indicators are important, and those that are useful now are very different from those advised in the pre-MDT era.[5] Indicators of quality may be difficult to standardize when the diversity of programme contexts is considered; the establishment of 'benchmarks' to encourage self-evaluation may be a better aim. Indicators should ideally be complete, to allow comprehensive evaluation; relevant to the matter to be evaluated; repeatable between

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different observers and different conditions; readily available, so that the results are promptly available for action; simple, neither too complicated nor too costly; and in general use, so there is no controversy about the value or definition of the indicator.[6]

Two levels of evaluation can be considered: first the review of routinely produced programme statistics; and then the detailed evaluation undertaken by independent review, which includes going to see the programme in action. The first is inexpensive and should be done on a continuous basis by the programme manager and by the programme purchaser (whether government or a nongovernmental organization). This is possible, for example, by review of the ILEP 'B' returns over a number of years. Review of a single years' data can be very misleading: trends in indicators are much more useful. Such evaluation of data should be done annually, whereas site visits need only be done periodically (e.g. 3–5 yearly) or when indicated by trends in routine statistics. Pragmatic evaluation, by a site visit and an interview, is also valid and useful for the review of operational and administrative aspects of programmes; though it is more time-consuming and expensive, and needs some structure to gain maximum value, it may reveal much about a programme that is not obvious simply from statistics.

Evaluation of the control of leprosy in populations

The evaluation of leprosy programmes using epidemiological indicators has been comprehensively surveyed.[7] Lechat *et al.* mention the use of 25 different markers. Since then more limited lists have been proposed.[8–10] However, almost all current indicators have drawbacks as indicators of outcome because they all largely reflect programme activities.

Prevalence. This indicator of the number of cases of the disease at a given time has become increasingly invalid in recent years. Defined as the incidence multiplied by the duration of the disease, the indicator reflects the treatment duration rather than giving specific information about disease transmission. Prevalence depends on the case definition in use: at present this is a patient needing chemotherapy.[11] Prevalence therefore also depends on the duration of treatment. Already, many PB patients never appear in prevalence figures, especially if they complete treatment in only 6 months, as they are treated and released from control before the year-end report is drawn up. The situation will become more complex in future as shorter and shorter regimes are introduced. The ultimate state would be reached if there were ever a single-dose treatment, administered on diagnosis—the prevalence of the disease would then be zero, even though there was a continuing incidence. However, the WHO goal of elimination is based on prevalence, and this indicator will continue to be used.

Incidence. This is a difficult indicator in leprosy but is the most useful in evaluating the effect of MDT on transmission. It is defined as the number of new cases occurring in a set period (usually 1 year). However, it has long been recognized that it is very difficult to measure as it would require annual population surveys, which are expensive, as well as complete accuracy in the diagnosis of early leprosy, which needs great skill.

As a proxy for incidence, case detection rate is often used. However, this has a major disadvantage when used for programme evaluation—it is highly programme-dependent as well as disease-dependent. Examination of the records of many programmes shows that case detection varies considerably from year to year. Enquiry will often reveal a

relationship between these variations and changes in the programme: case detection goes down when a crucial staff member is on leave, or goes up when a new detection strategy or health education programme is initiated. The situation can sometimes be made clearer by the consolidation of the results from different programmes in the same area. Local influences are then cancelled out, though national or regional policy changes may still be reflected. Case detection methods and diagnostic practices must remain constant for case detection to be a good reflection of incidence. Case detection rate, therefore, needs careful interpretation, as do two other programme-dependent indicators, child rate and mode of detection.

Child rate. The proportion of children aged 0–14 years among newly detected patients is highly dependent on the programme's strategy for dealing with indeterminate (especially single macular) lesions, and on the use of school surveys—a change in the priority or periodicity of school surveys can cause wild fluctuations in the trend of child rate.

Mode of detection. This is also often recorded, and high rates of self-reporting (voluntary reporting) are regarded as evidence of good community knowledge about leprosy.[12] The point has to be made, however, that any case detected through self-reporting might have been detected at an earlier stage by some active case-finding method, and this indicator is not a sufficient marker by itself of programme efficiency. Cessation of all active methods of case detection leads to high proportions of new cases detected by self-reporting and a drop in the absolute numbers of new cases.

Other epidemiological markers often reported are the gender ratio, and the lepromatous rate.

Gender ratio. This varies in new cases between programmes and countries and this variation may be biological or cultural. In many leprosy-endemic countries, women are less able to obtain health care, and/or are less likely to accept adequate examination by a male health worker. Recruiting of female health staff to redress this imbalance is now frequently undertaken. The imbalance remains, however, in situations widely differing in terms of health care access and the acceptability of examination, and also between those where women stay mainly at home (protected from exposure to *Mycobacterium leprae*), and those where they take a full part in community life. It seems likely that the difference is multifactorial, but this matter is becoming more difficult to research, as many programmes do not now report cases by gender.

Lepromatous rate. In new cases, intrinsically variable by race, lepromatous rate is also thought to change as leprosy transmission stops.[13] This is assumed to be because the incubation period of lepromatous leprosy is longer than that of tuberculoid, and cases therefore continue to appear for some time after interruption of the transmission of the disease and the reduction in the number of tuberculoid cases.

Disability rate at detection. This is another indicator which represents a useful indicator for evaluation. This index, normally taken as the percentage of new cases with WHO Grade 2 disability, gives a double insight into the effectiveness of control activities. It monitors both the promptness and the completeness of case detection—promptness as early case detection should occur before disabilities have had the chance to occur, and completeness on the assumption that all patients with leprosy disabilities will eventually come to the notice of the programme. Disability rate is a useful marker, both by itself, and in association with others mentioned above. For example, if the mode of detection proportions suggest that the programme is mostly relying on self-reporting,

the rate of disability at detection may indicate delay between the onset of disease and case detection. Equally, if the case detection rate is falling, but disability at detection is rising, it suggests incompleteness of case detection rather than a genuine fall in incidence. Disability rate may prove to be the most useful outcome indicator of case detection activities.

Evaluation of the control of leprosy in individuals

It is assumed that MDT is effective in killing *M. leprae* in humans and in stopping the disease process. Similarly it is assumed that prevention of disability activities, such as treatment of reactions[14] and use of appropriate footwear,[15] are effective. Evaluation of an MDT programme is therefore assessing effectiveness in treating patients using MDT, and in preventing disabilities.

Effectiveness in treating patients with MDT

The two most useful measures of the programme's effectiveness in treating patients with MDT are the MDT coverage and MDT completion rates.

MDT coverage. Among new patients and among registered patients, this is commonly used. However, coverage alone is an inadequate indicator, as a single dose of MDT followed by default achieves coverage, even though it is clearly unsatisfactory management. Coverage is usually presented as a percentage which is dependent on the denominator, and patients may be inappropriately deregistered in order to achieve a higher MDT coverage statistic.

MDT completion rates. As used by ILEP in their 'B' form, these give a better indicator of genuine achievement in MDT programmes, and are calculated on a cohort of patients who began treatment during the year up to 9 months before the reporting date (PB) and during the year up to 3 years before the reporting date (MB). These groups are the most recent which can be assessed within the current WHO completion criteria (6 doses in 9 months or 24 doses in 36 months), but in fast-developing programmes, this information may already be out of date, and judgments of 'quality' based on them may therefore also be anachronous. MB completion rates will reflect previous performance rather than current work. Completion rates, even though more complex to calculate, should be the most reliable indices of the effectiveness of programmes in treating patients adequately with MDT, though they are a new indicator for some programmes, and record systems that permit their calculation may take time to develop.

Effectiveness in preventing disabilities

The difficulty of monitoring POD activities associated with MDT programmes is shown by the numerous methods proposed to assess nerve function. While controversy about filaments and ball-pens rages among the experts, most patients do not have access to even the most basic neurological supervision. Monitoring nerve function using WHO grading is a very coarse tool, as much deterioration can happen within grade 2, and therefore not be recorded as change: a slight clawing at detection places the patient in that grade, and even the grossest deterioration thereafter is not recorded as change.

However, there is no other system that could easily replace WHO grading, and the worsening from no disability (Gr. 0) to anaesthesia (Gr. 1) or to visible deformity (Gr. 2) is certainly significant. WHO disability grading is therefore useful in establishing the level of disability but is of less use in assessing change. WHO grading is often done at diagnosis, but less frequently at the completion of treatment to monitor change during the course. More complex methods of assessment are not suitable for use under field conditions but are useful for research purposes. Careful monitoring of sensory and motor nerve function is possible in some centres; it is more difficult to train staff to take action based on any changes recorded. The reproducibility of the tests used may not be high, and variations between assessments may lead to overdiagnosis of 'silent neuritis' and overuse of steroids. Scoring of disability records to get a measure of the situation within a programme has been recommended as a management tool.[16]

Sole wounds (ulcers and cracks) are the most characteristic deformity of leprosy, and the 'doctrine of the first ulcer'[17] has long been a strategy in dealing with patients. Trends in wound counts within the population covered by a leprosy control programme may be a useful and highly reproducible method for evaluating the programme's effectiveness in treating and preventing plantar ulcers, both by self-care and footwear.[18] It may also reflect the effectiveness of other POD activities.

Evaluation of leprosy control programmes by site visit

Site visits are essential for a full evaluation of a programme, whether to develop an overview of the work ('situation analysis'), or to undertake formal evaluation against preset targets. In addition to physical checking of the registers to confirm data previously presented (and to see the quality of the registers and records) site visits allow particular information to be gathered on programme context, methods, and management; and on staff attitudes to their work, to each other, and to their patients. Programmes and organizations often have their own checklists of items to be covered in such visits, but the following areas should be included.

It is essential to know the context of the leprosy control programme for any evaluation to be valid. Programmes may be 'vertical', joint (with TB or dermatology, for example), fully integrated into primary health care (PHC), or integrated with 'vertical' supervision. Additionally they may be running within a Government health service or independently (NGO or private). Programme managers may be defensive of their own position—the more so as the falling prevalence of leprosy is seen to threaten jobs—but should understand the different models, and be open to any modifications that may be appropriate. The programme methods—case finding, case holding, surveillance, prevention of deformity, rehabilitation—may be set by national or organizational policy, and be outside the control of the local manager. However, managers who have an understanding of the benefits and limitations of the strategies used will be better able to maximize their effectiveness. A further essential aspect of management to be assessed is the ability of managers to interpret information that is received (from staff, or by feedback from their own superiors), and to take appropriate action based on it. Managers will also be able to indicate problems within the programme in areas such as the reliability of drug supply, the quality of the staff, the regularity of financial remittances, the availability of transport, and the level of community support.

From the staff it is important to determine their own feelings on matters such as the adequacy of their training (was it appropriate for the job they are doing?), and whether they feel confident and interested in their work. A general enquiry, such as asking about anything that would help them give a better service to the patients, will give an insight into their own attitudes to the work, as well as identifying programme constraints that may not have seemed relevant to the management.

The supervision of the programme is an important area for organizational evaluation. Do the supervisors have a regular timetable, or do they make spot checks? Do they have a supervision checklist? Do they encourage their junior staff or only criticize them? Perhaps the most important point, especially in integrated programmes with specialist supervision, is to determine whether the supervisors really supervise, or whether they simply take over the leprosy clinics that they attend. The supervisory hierarchy must also be determined, to see that supervisors are themselves responsible to someone else; and it should be established whether the supervisors have had specific training in supervision/management, or have simply achieved seniority through long service in leprosy work.

Operational aspects of the programme also need to be examined. In particular, details of the current case-finding strategy, and the confidence and competence of the staff in diagnosing leprosy are both important. In looking at the treatment component, an overlooked problem may be the dropping-out of patients between detection and treatment. Particular note must be taken of any 'noncompliance' which is actually the fault of the programme: due to failures of manpower, transport, or drug supplies. Case notes may be reviewed for specific operational indicators (such as the regularity of disability grading records, or the correct implementation of release-from-treatment criteria) or for completeness of treatment delivery records.

The regularity of attendance can be checked from registers, and the acceptability of this compared with local criteria. By talking to staff and patients, it may be possible to identify the constraints—lack of motivation, lack of opportunity or lack of understanding—that lead to poor compliance. If possible, new and old patients should be reviewed during clinic or drug delivery sessions.

Prevention of deformity activities are particularly appropriate for site visit evaluation. The commitment of the staff to the whole concept of POD can best be elicited person to person. Technical questions about the content of health education, the use of prednisolone and the advice given to patients can be asked, and an assessment of the clinical skills of the staff can also be made.

Attitudes and relationships are important in any programme. On-site evaluation allows the complex relationships among the staff, between staff and patients, and between the programme and the local community, to be assessed. Staff who have a good relationship with patients will be well motivated to give a high quality service, and will also be better able to communicate with their patients.

Summary

MDT programmes for leprosy control have two objectives, controlling leprosy in populations and controlling leprosy in individuals. Evaluation of such programmes needs to address both objectives and this can be done by a review of the trends in key indicators and by site visits. Site visits are more expensive and should be done less

frequently, but they can reveal issues not apparent in routinely produced statistics. Evaluation on an annual basis is the responsibility of programme managers and programme funders. Evaluation by programme staff themselves should be encouraged and supported.

Evaluation of an MDT programme's effectiveness in controlling leprosy in a population should be by analysis of case detection as a proxy for incidence. Prevalence rates will continue to be monitored because of the WHO elimination goal, but these do not reflect disease transmission. Case detection is a proxy measure of incidence and depends on consistency in case detection activities. Case detection data by age, gender, mode of detection, disability ratio and lepromatous (MB) rate need to be analysed over at least 5 years and preferably 10 years to give an indication of trends in incidence. Caution is needed, however, as the pattern seen when case detection deteriorates may resemble the pattern expected when transmission is reduced. The site visit is important in this situation in allowing examination of the case detection activities, as well as in looking for new, undetected cases in the population.

Evaluation of the MDT programme's effectiveness in controlling leprosy in patients should be by analysis of both the effectiveness of MDT delivery and the changes in disability. For drug delivery, MDT coverage of new and registered patients is used, but this only reflects the basic minimum of treatment, that each patient has started MDT. MDT completion rates are the best indicators, with PB rates reflecting the situation in the previous year, and MB rates the longer-term position. In monitoring disability, WHO gradings are of limited use in assessing change, and are not always recorded. If they were available for the start and end of each patient's treatment it would give a crude indicator of the programme's effectiveness in preventing disabilities. Better methods have not yet been proved to be either adequately reproducible or simple enough for PHC-based programmes. More research is urgently needed in this field. It may be that simple counts of sole wounds will prove to be the most suitable indicator of effectiveness in the prevention and treatment of disabilities. A site visit will help to reveal what is actually going on in the area of prevention of disabilities as well as in treatment delivery. Remember that it is always worthwhile speaking to the patients and not only to the staff!

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