Leprosy Elimination Monitoring (LEM)

Guidelines for monitors

2000

World Health Organization
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Introduction

Background
Multi-drug Therapy (MDT) is recognised as a major technological improvement in leprosy control. It enables leprosy control to have a tremendous impact on disease prevalence and consequently on the disease burden and workload. This impact has led to the concept of eliminating leprosy as a public health problem with the assumption that, below a given level of prevalence, disease transmission will be partially or totally interrupted.

Leprosy control strategies based on MDT and the resolution of the 44th World Health Assembly in 1991 to eliminate leprosy as a public health problem was an impetus for greater priority to be given to leprosy by governments and for strengthened political commitment for leprosy elimination. The cost-effectiveness of MDT and its impact has resulted in increased resources for leprosy control activities, including those from bilateral and international agencies, as well as NGOs, both national and international, in a number of countries where leprosy is a public health problem.

Although it is relatively easy to monitor the prevalence of leprosy, evaluation of its transmission trends is extremely difficult because of the epidemiological characteristics. The general impression among experts is that there were considerable changes in the epidemiological pattern of the disease during the past decade. These changes are reflected by clinical profile of newly detected cases; an increasing proportion of patients diagnosed with few lesions; variations in the proportion of MB patients; and decreasing proportion of patients with irreversible (Grade 2) disabilities. In addition, there are visible changes in the prognosis of the disease during treatment and significant reduction in the risk of becoming disabled. All these changes could be explained by a combination of factors, e.g. the historical trend of the disease; the impact of interventions; the efficacy of chemotherapy and the role of improved health services.

The most obvious impact of MDT is the reduction of the risk of transmission from an infected person to others. It is generally believed that a single dose of MDT kills enough bacilli to make both PB and MB patients non-infectious. Leprosy control, based on MDT, is believed to improve the effectiveness of case detection and, in so doing, gives a clearer picture of the overall leprosy problem. The use of standardised and tested procedures to correct detection rates ( according to programme coverage), the duration of the programme, indirect indicators (proportion of cases with disabilities among new cases), standardisation according to age and sex and overall cohort analysis, would give valuable information in assessing the level of transmission within the community.

In many programmes, MDT implementation has improved the quality of case-finding and case-holding by improving community awareness and by increasing patients’ confidence in health services. However, geographic coverage with MDT services is still very low and many cases are diagnosed very late, or not diagnosed at all. The interval between the onset of the disease and diagnosis are still far too long in many parts of endemic countries, increasing the risk of transmission and the risk of disability.

Purpose of LEM
Assessment of interventions becomes particularly important when considering the leprosy elimination goal. The purpose of monitoring is to assist decision makers and programme managers to assess the progress towards leprosy elimination, to make a plan of action, to implement it and to measure its impact. Monitoring a minimum set of indicators that
describes the MDT services will serve the purpose.

The selection of indicators to be monitored needs to be made carefully, in the light of the epidemiological characteristics of leprosy and the large number of grey areas in our understanding of the disease. Incidence is the most relevant but probably the most difficult indicator. Prevalence varies not only with the level of disease burden but also with the operational component of intervention. The uneven distribution of leprosy, as well as the role of various local factors, calls for caution when extrapolating the results from one place to another.

Monitoring methods should be quick and cost-effective. Routine information system is the principal and essential component in monitoring leprosy situation. It needs to be programme oriented, simple and speedy. Too many indicators to be put on the information flow of routine systems will cause paralysis, and therefore some of the indicators among 'a set of minimum indicators' cannot be collected from routine systems. A monitoring exercise that complements routine information systems is needed to measure specific aspects of leprosy elimination programmes and methods for reviewing elimination programmes.

The techniques for collecting indicators are implemented in a standardised way by monitors, in collaboration with national programmes and WHO. Monitors collect information which will complement routine leprosy information systems to address specific issues, such as more detailed information on the trend of transmission, cure rates, impact of interventions and changing patterns of leprosy. It is becoming increasingly important to differentiate areas where substantial numbers of backlog cases are included in newly-detected cases from areas where newly-detected cases may be largely made up of single lesion cases. Information on the number of lesions per case, age and sex specific detection, smear positivity, if available and the delay between onset and diagnosis help in better describing indicators used for monitoring leprosy elimination. It is equally important to validate key indicators, such as prevalence and detection, mainly by applying internationally recommended definitions. Wherever possible, trend analysis over the last 5 years will be used to assess the impact of leprosy elimination activities.

Besides all these technical aspects of LEM, past experiences in LEM have shown that it had highly positive effect on field workers and programme managers, who were strongly motivated through discussions on the epidemiological and clinical situations of their areas.

**Overview**

Indicators collected through LEM exercises are well standardised, have been in use for several years in many countries and are well known to programme managers. All the required information has to be collected from existing patient records, leprosy registers, reporting forms and stock bin cards in selected health facilities as well as interviews of patients. The selected health facilities should reflect the situation prevailing in a specific geographical or administrative area at a given point in time and therefore selection of sample and sample size are essential for extrapolating the findings.

The monitoring will have to be repeated in order to assess the impact of interventions and changes over time. These studies are carried out by independent monitors, responsible for visiting selected units to collect information through standardised methods, and for reporting their findings on compiled data to the national programme managers and the WHO.

The monitoring should be time-limited and the complete cycle (from design to report) should not exceed four weeks. Selected health facilities should be informed in advance of the monitors’ visit so that they have time to prepare to get patients available.
Indicators and methodologies described in this document will be adapted/reviewed as and when needed.

**Contents of the guidelines**

There are two sections in the guidelines.

- The first section explains what to monitor through LEM.
- The second section describes how to monitor.
- Annex provides forms for collecting information, which will also help in understanding the details of information to be collected.

**What to monitor**

This section describes the procedures for measuring the three groups of indicators. After a brief introduction, prerequisites and details for the calculation of each indicator are outlined for each group and an example is presented of how the indicators are interpreted. Forms shown in annex will be helpful in better understanding the indicators.
## Summary table of key indicators

<table>
<thead>
<tr>
<th>Indicator group</th>
<th>Key indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group I: Elimination indicators</strong></td>
<td></td>
</tr>
<tr>
<td>Internal validity of information on prevalence and detection (crude and specific) and analysis of trends. This will be based on the analysis of existing information and review/updating of leprosy registers.</td>
<td>1. <strong>Case finding activities</strong></td>
</tr>
<tr>
<td></td>
<td>1.1 Proportion of new cases with disabilities</td>
</tr>
<tr>
<td></td>
<td>1.2 Average delay in diagnosis</td>
</tr>
<tr>
<td></td>
<td>1.3 Proportion of children among new cases (or age specific detection)</td>
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<td></td>
<td>1.4 Proportion of MB cases among new cases</td>
</tr>
<tr>
<td></td>
<td>1.5 Proportion of single lesion among new cases</td>
</tr>
<tr>
<td></td>
<td>1.6 Proportion of female among new cases (or sex specific detection)</td>
</tr>
<tr>
<td></td>
<td><strong>2. Prevalence: absolute numbers and rate</strong></td>
</tr>
<tr>
<td></td>
<td>2.1 Reported prevalence</td>
</tr>
<tr>
<td></td>
<td>2.2 Prevalence after applying standard definitions (case, cure and defaulters)</td>
</tr>
<tr>
<td></td>
<td>2.3 Prevalence trend over the last 5 years</td>
</tr>
<tr>
<td></td>
<td><strong>3. Detection trend: absolute numbers and rate</strong></td>
</tr>
<tr>
<td></td>
<td>3.1 Detection trend over the last 5 years</td>
</tr>
<tr>
<td></td>
<td>3.2 MB detection trend</td>
</tr>
<tr>
<td></td>
<td>3.3 Child detection trend</td>
</tr>
<tr>
<td><strong>Group II: Integration of MDT services within General Health Services</strong></td>
<td></td>
</tr>
<tr>
<td>Availability of MDT blister-packs and geographic coverage of MDT services. This will be based on a cross-sectional survey of randomly selected health facilities and interviews of patients.</td>
<td>1. <strong>Proportion of existing health facilities providing MDT</strong></td>
</tr>
<tr>
<td></td>
<td><strong>2. Accessibility to MDT</strong></td>
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<tr>
<td></td>
<td>2.1 Average distance</td>
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<td>2.2 Estimated costs for the patients</td>
</tr>
<tr>
<td></td>
<td>2.3 Flexibility in delivering MDT</td>
</tr>
<tr>
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<td><strong>3. Availability of MDT drugs</strong></td>
</tr>
<tr>
<td><strong>Group III: Quality of MDT services:</strong></td>
<td></td>
</tr>
<tr>
<td>Diagnosis, case-holding and information. This will be based on a review of individual records, leprosy registers, and interviews of individuals in communities. The quality of MDT services will be reviewed on the basis of cohort analysis.</td>
<td>1. <strong>Proportion of patients treated with MDT</strong></td>
</tr>
<tr>
<td></td>
<td><strong>2. Case holding</strong></td>
</tr>
<tr>
<td></td>
<td>2.1 Cure rate</td>
</tr>
<tr>
<td></td>
<td>2.2 Defaulter rate</td>
</tr>
<tr>
<td></td>
<td>2.3 Proportion of patients continuing treatment after completing MDT standard regimen</td>
</tr>
<tr>
<td></td>
<td><strong>3. Quality of MDT blister-packs</strong></td>
</tr>
</tbody>
</table>
**Group I : Elimination indicators**

**Group I : 1. Case finding activities**

Internal validity of information on prevalence and detection (crude and specific) and analysis of trends. This will be based on the analysis of existing information and review/updating of leprosy registers.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>To assess the effectiveness of case-finding activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Case-finding activities will be evaluated through a set of 6 indicators, describing the status of a sample of patients <em>diagnosed during one year and who have never been treated for leprosy</em>. One year can be defined as during the past one year from the time of the visit. Should information be unavailable, this can be modified provided it is discussed and agreed before the start of exercise.</td>
</tr>
</tbody>
</table>

**1.1 Proportion of newly detected cases with grade 2 disabilities:**
The number of patients newly diagnosed with disability grade 2 (see definitions below) divided by the number of newly detected patients *for whom disability status is recorded*. (Minimum sample size 100)

**1.2 Average time between recognition of the disease and diagnosis**
Based on individual records and/or interviews of a sample of patients, this is the average time (in months) between the first recognition of symptoms and the date of diagnosis. (Minimum sample size 50)

**1.3 Proportion of children (age specific detection)**
The number of newly diagnosed patients below the age of 15 divided by the number of newly detected patients *for whom age is recorded*. (Minimum sample size 100)

**1.4 Proportion of MB cases**

a) *Clinical classification:* The number of newly diagnosed patients classified as MB patients divided by the number of newly detected patients *for whom classification is recorded*. (Minimum sample size 100)

b) *Bacteriological classification:* Wherever possible: the number of newly diagnosed patients showing a positive skin smear examination divided by the number of newly detected patients *for whom skin smear examination results are recorded*.

**1.5 Proportion of single lesion**
The number of newly diagnosed patients showing a single patch at the time of detection divided by the number of newly detected patients *for whom the number of lesions and/or classification of MB/PB/SSL is recorded*.

**1.6 Proportion of female (sex specific detection)**
The number of newly diagnosed female patients divided by the number of newly detected patients *for whom gender is recorded*.

**Pre-requisites**
Checking leprosy registers and individual records. Whenever necessary, by interviewing a sample of patients.

**Calculation**
All the data and calculations can be recorded on forms 1.1 and 1.2.

**Interpretation**
This set of indicators will only give some indications on the quality and delay for diagnosis. It is not intended to give epidemiological information (detection rate, incidence rate, the intensity of transmission).

**Difficulties and potential biases**
Information might be difficult to collect in programmes having a poor recording system. Considering that the required sample size is significant, monitors may have to collect information in several places, including visits to patients.
Definitions of disability Grade 0 1 2:

**Hands and feet:**
- Grade 0: No anaesthesia, no visible deformity or damage
- Grade 1: Anaesthesia but no visible deformity or damage
- Grade 2: Visible deformity or damage present

**Eyes:**
- Grade 0: No eye problems due to leprosy; no evidence of visual loss
- Grade 1: Eye problem due to leprosy present, but vision not severely affected as a result (vision 6/60 or better; can count fingers at six metres).
- Grade 2: Severe visual impairment (vision worse than 6/60; inability to count fingers at six meters), lagophthalmos, iridocyclitis and corneal opacities.

### Group I: 2. Prevalence

<table>
<thead>
<tr>
<th>Purpose</th>
<th>To measure progress towards the elimination of leprosy at the national and sub-national levels (form 1.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Although the definition of prevalence is very well known, many programme managers are using different definitions, even within the same country. This makes comparisons difficult. Monitors will have to report on information as reported by programmes and 're-analyse' prevalence indicators after applying standard definitions. The main issues are: the definition of a case of leprosy, the definition of defaulters and the definition of cure. For the purpose of the study, monitors will adhere to the following definitions:</td>
</tr>
</tbody>
</table>

Calculation of prevalence indicators **at a given point in time:**

**A case of leprosy** is a person presenting clinical signs of leprosy (with or without bacteriological examination) who has **yet to complete a full course of treatment**.

A patient who has completed a full course of fixed duration MDT (6 doses for PB and 12 doses for MB) is **cured**.

A patient who has not collected treatment for more than 12 consecutive months is **a defaulter** and should be removed from the prevalence.

Monitors will collect information on the following 3 prevalence indicators:

2.1 Reported prevalence: absolute number and rates
2.2 Prevalence after applying standard definitions
2.3 Prevalence trend over the last 5 years

<table>
<thead>
<tr>
<th>Pre-requisites:</th>
<th>Compiling national and sub-national reports, checking leprosy registers at health centre level, and discussions with national programme managers.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calculation</strong></td>
<td>All the data and calculations can be recorded on form 1.3.</td>
</tr>
<tr>
<td><strong>Difficulties and potential biases</strong></td>
<td>The main difficulty will be to collect information on denominators (population by sub-national levels over the last 5 years)</td>
</tr>
</tbody>
</table>
Group I: 3. Detection

<table>
<thead>
<tr>
<th>Purpose:</th>
<th>To evaluate the leprosy situation changes over time (form 1.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition:</strong></td>
<td>Monitors will collect information on these 3 detection indicators at the national and sub-national levels:</td>
</tr>
<tr>
<td>3.1</td>
<td>Detection trend over the last 5 years</td>
</tr>
<tr>
<td>3.2</td>
<td>MB detection trend</td>
</tr>
<tr>
<td>3.3</td>
<td>Child detection trend</td>
</tr>
<tr>
<td>Forms 1.5 to 1.9 are given for more detailed information, including detection by age, sex, mode of detection, skin smear positivity, number of skin lesions, type of leprosy, and disability grading, if available. These are optional and will be useful in analysing transmission trend over time. The decisions should be made beforehand.</td>
<td></td>
</tr>
<tr>
<td><strong>Pre-requisites:</strong></td>
<td>Compiling national and sub-national reports, checking leprosy registers at health centre level and discussions with national programme managers.</td>
</tr>
<tr>
<td><strong>Calculation</strong></td>
<td>All the data and calculations can be recorded on forms 1.4 to 1.9.</td>
</tr>
<tr>
<td><strong>Difficulties and potential biases</strong></td>
<td>The main difficulty will be to collect information on denominators (population by sub-national levels over the last 5 years).</td>
</tr>
</tbody>
</table>

Group II Integration indicators

The availability of MDT blister-packs and geographic coverage of MDT services. This will be based on a cross-sectional survey of randomly selected health facilities and interviews of patients.

‘MDT services’ refers to comprehensive health activities, including: diagnosis, classification, prescription of treatment, delivery of MDT, case-holding, cure of leprosy patients and patient counselling. Quantitative aspect of MDT services are monitored through these indicators. (See Group III).
Group II 1. Proportion of existing health facilities providing MDT

<table>
<thead>
<tr>
<th>Purpose</th>
<th>To estimate the geographic coverage of MDT services (forms 2.1, 2.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Proportion of health facilities where MDT is available among all existing health facilities in a given area. Definition of health facilities should be given beforehand with the relevant authorities in the light of integration plan.</td>
</tr>
</tbody>
</table>
| **Pre-requisites** | a) Obtaining lists of all existing health facilities and those providing MDT from national and/or regional authorities.  
   b) Visiting a selection of health facilities to check whether or not they have stocks of MDT. |
| **Calculation** | a) Proportion calculated by dividing the number of health facilities having stocks of MDT by the total number of health facilities in the area.  
   b) Proportion calculated by dividing the number of health facilities having stocks of MDT by the total number of health facilities visited. |
| **Example** | a) Based on administrative information, 20 out of the 200 existing health centres (10%) have stocks of MDT in the district of Bamako, Mali.  
   b) Out of 5 health centres, only 4 had available stocks of MDT (80%) when visited by monitors. |
| **Interpretation** | A low geographic coverage can reflect a combination of factors, such as: national policy of providing MDT only to specialised centres; lack of MDT and personnel; delayed process of integration. |
| **Difficulties and potential biases** | Data collected from health authorities could be out-of-date. Some MDT services, such as NGOs projects or MDT clinics organised from the regional level, might not be included in the calculation. One of the main difficulties would be that MDT are unavailable in some health centres due to the fact that no leprosy patient had been registered for treatment. The monitors will have to analyse the situation carefully in order to give an accurate estimate of the geographic coverage. |
### Group II 2. Accessibility to MDT

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To evaluate the extent to which patients have easy access (geographical, financial and technical) to MDT services.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Accessibility will be estimated through a set of 3 indicators collected in a sample of patients <em>diagnosed and treated during the year</em>.</td>
</tr>
<tr>
<td><strong>2.1 Average distance to collect monthly dose of MDT (form 2.3)</strong></td>
<td>Based on individual records and/or interviews of a sample of patients, this is the average distance (in kilometres) patients are actually travelling monthly to receive their treatment (Minimum sample size 50).</td>
</tr>
<tr>
<td><strong>2.2 Estimated costs for patients (form 2.1)</strong></td>
<td>Based on interviews of a sample of patients, ascertain whether there are any costs incurred for the service.</td>
</tr>
<tr>
<td><strong>2.3 Flexibility in delivering MDT (form 2.4)</strong></td>
<td>Based on discussions with health workers and patients, the monitors ascertain whether the health centre:</td>
</tr>
<tr>
<td></td>
<td>• provides treatment only on a fixed day of the month or on several days of the month (specify number of days)</td>
</tr>
<tr>
<td></td>
<td>• offers to patients that more than one month treatment can be given if needed (accompained MDT)</td>
</tr>
<tr>
<td></td>
<td>• can manage complications (reactions, disabilities)</td>
</tr>
<tr>
<td></td>
<td>• is a specialised or integrated centre</td>
</tr>
<tr>
<td></td>
<td>• stocks and uses steroids</td>
</tr>
<tr>
<td><strong>Difficulties and potential bias</strong></td>
<td>In analysing information gained through interviews of patients, it should be noted that there is a built-in bias to those with better access to health centres.</td>
</tr>
</tbody>
</table>
### Group II 3. Availability of MDT drugs

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To identify potential surplus stocks or shortage of MDT supply at the health centre, or district and regional stores. (form 2.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Availability of MDT blister packs and loose drugs at time of visit, expressed in terms of months supply, for the given patient caseload.</td>
</tr>
<tr>
<td><strong>Pre-requisites</strong></td>
<td>Checking of MDT stocks and/or stock records, discounting any expired drugs</td>
</tr>
<tr>
<td><strong>Calculation</strong></td>
<td>1) Availability of blister packs in months is simply the number of blister packs of each category in stock, divided by the number of registered cases for each category;</td>
</tr>
<tr>
<td></td>
<td>2) If loose drugs⁵ are still being used, they need to be converted into equivalent blister packs by using the spreadsheet example provided in the annex. Add these results to calculation 1 to obtain the total stock availability in months.</td>
</tr>
<tr>
<td><strong>Example</strong></td>
<td>See form 2.5.</td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>The basic calculation above estimates the stock availability in months for the current caseload. By substituting figures for the anticipated caseload it is possible to indicate the stock availability in months if the caseload rises or falls. The actual stock availability in months will lie somewhere between these two.</td>
</tr>
<tr>
<td></td>
<td><strong>As a basic principle, it is advisable to maintain a minimum MDT stock of three months at all levels.</strong></td>
</tr>
</tbody>
</table>
**Group III: Quality of MDT services**

Diagnosis, case-holding and information. This will be based on a review of individual records, leprosy registers, and interviews of individuals in communities. The quality of MDT services will be reviewed on the basis of cohort analysis.

MDT services refers to comprehensive health activities, including: diagnosis, classification, prescription of treatment, delivery of MDT, case-holding, cure of leprosy patients and patient counselling. Some of these are monitored by Group II indicators.

**Group III: 1. Proportion of patients treated with MDT**

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To measure the extent to which MDT is given to leprosy patients (form 3.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Proportion of leprosy patients treated with MDT among all patients registered for treatment <em>at a given point in time</em></td>
</tr>
<tr>
<td><strong>Pre-requisites</strong></td>
<td>Checking treatment registers and patient records and the need to apply standard definitions. The denominator should be 200 or more to be meaningful.</td>
</tr>
<tr>
<td><strong>Calculation</strong></td>
<td>Proportion calculated by dividing the number of patients registered as treated with MDT by the total number of patients registered for treatment at the time of the visit. If the sample of health facilities is representative, this indicator could be given with confidence limit for the whole region/country.</td>
</tr>
</tbody>
</table>

**Group III: 2. Case holding**

Fixed duration of MDT should lead to the cure of leprosy patients in a relatively short period of time. It is essential to collect reliable information on the outcome of the treatment. The role of monitors will be to evaluate treatment outcome indicators through the analysis of cohorts of sample patients.
### Group III 2. Case holding

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To measure the outcome of case-holding activities (form 3.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Treatment outcome will be evaluated through a set of 3 indicators that can be collected by analysing cohorts of patients having started treatment during a given year.</td>
</tr>
</tbody>
</table>

#### 2.1 Cure rate: proportion of patients cured
The number of patients cured divided by the number of patients *supposed to have been cured* in the same cohort. (PB and MB).

#### 2.2 Defaulter rate:
The number of patients who have not taken treatment for 12 consecutive months divided by the number of patients *supposed to have been cured* in the same cohort. (PB and MB).

#### 2.3 Proportion of patients continuing treatment after having completed treatment
The number of patients continuing treatment after having completed fixed duration treatment of MDT, 6 doses for PB and 12 doses for MB, divided by the number of patients *supposed to have been cured*.

<table>
<thead>
<tr>
<th><strong>Pre-requisites</strong></th>
<th>Checking treatment registers and individual records. Monitors will have to collect information on:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Cohorts of MB patients defined as patients having started MB MDT 18 months before the date of the monitoring exercise or monitor’s visit;</td>
</tr>
<tr>
<td></td>
<td>• Cohorts of PB patients defined as patients having started PB MDT at least 12 months before the date of the monitoring exercise or monitor’s visit.</td>
</tr>
<tr>
<td></td>
<td>The size of each cohort should be at least 100. For each patient belonging to a particular cohort, the monitor will note the status of the patient 18 months (MB) or 12 months (PB) later: cured, defaulter, still on treatment or other. Then the 3 indicators will be calculated using as a denominator the total number of patients (PB or MB) included in each cohort.</td>
</tr>
</tbody>
</table>

| **Example** | In Nepal, treatment outcome of the 1999 MB cohort was: cured 57%, treatment continued 17%, defaulter 8%, other 18%. For 2000, the PB cohort was: cured 78%, treatment continued 3%, defaulter 4%, other 15% |

| **Interpretation** | This set of indicators is very useful to evaluate the performance of the programme and the appropriate use of MDT. It will also help in better estimating drug requirements at various levels. |

| **Difficulties and potential biases** | Information might be difficult to collect in programmes having a poor recording system. The process of compiling many registers or individual records might be time consuming. |
### Group III: 3. Quality of MDT blister-packs

<table>
<thead>
<tr>
<th><strong>Purpose</strong></th>
<th>To identify potential problems in drug supply management(form3.4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Proportion of blister packs showing acceptable physical condition out of a total number of blister packs checked by the monitor.</td>
</tr>
<tr>
<td><strong>Pre-requisites</strong></td>
<td>Examination of existing blister packs to check expiry dates, shape of package and blister and aspect of drugs (especially Clofazimine).</td>
</tr>
<tr>
<td><strong>Example</strong></td>
<td>In a given health centre, 95% of the blister packs were of acceptable quality.</td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>A low quality will indicate failure in supply, transport and/or storage of the drugs. In this case, monitors will collect and return samples of suspect packs to WHO for further testing.</td>
</tr>
</tbody>
</table>
How to monitor

Design of a monitoring exercise

The design of a study will depend on many factors including specific objectives, various components of national programmes, national health infrastructure, health systems, and population and geographical size of the country. Only the practical aspects are discussed below as it is not possible to give a ‘universal’ outline. Key issues are the size and the selection of samples. All suggestions made in this document are based on some statistical theories, but most of them are empirical. The selection of samples should be made in collaboration with national programme managers, experts and WHO consultants and be based on all existing information.

Steps taken by LEM monitors

In order to produce results that are reliable and comparable across studies and countries, the indicators should be measured in a standardised way. The following list outlines the sequence of steps to be carried out by MDT monitors in collaboration with the national programme manager:

- Specify monitoring objectives;
- Discuss methods for measuring indicators;
- Select a sample of health facilities;
- Implement field work;
- Record data for indicators;
- Prepare summary tables;
- Report to participating facilities, national authorities and WHO;
- Follow-up.

Qualifications of LEM monitors

Monitors should have some background in public health and leprosy control and preferably be fluent in the language of the area or region in which they will be visiting. They should be independent of the national programme so that they can be objective and constructive in assessing the leprosy situation in the country.

Inventory of data sources

Considering that monitoring will be only retrospective, the most important step is to identify at what levels sources of data can be found. In most countries, information on leprosy can be found at:

- patient level: individual records, examination and interviews of patients
- community level: interviews
• treatment level: this will vary from one country to another: health centres, leprosy clinics, specialised institutions, district hospitals
• management level: leprosy registers and reports are usually kept at district, state/region and national levels.

**Defining the sample size**

It is assumed that the sample units for this study will be *leprosy patients*. As discussed in the previous section, it is suggested to collect information on at least:

- 200 patient records for indicators on prevalence and case finding activities;
- 200 patients taken out of treatment registers and/or individual records for accessibility of MDT and case holding;
- Interviews from 50 patients for delay in diagnosis and accessibility of MDT;
- Interviews from 50 individuals in communities for IEC;
- All national and sub-national reports of the 5 previous years trends.

**Selecting the sample units**

This is the most difficult step which will need preparation and discussions with national authorities. While the sample units are patients, the sampling has to be done in several steps, in order to take into account geographical, demographic and health infrastructure differences within the same country. The following method is suggested:

1. Select arbitrarily two or three geographic areas if it appears that there are important differences in terms of population, health systems or prevalence of the disease. In many countries for example, it is possible to grossly differentiate between Northern and Southern parts.

2. For each of the geographic areas selected, prepare a list of >districts<, including population and number of registered leprosy patients.

3. Randomly select 2 districts in each geographic area proportionally to the size of the population and/or the number of leprosy patients.

4. For each district selected, prepare a list of health facilities, including the number of registered patients.

5. Randomly select 3 health facilities proportionally to their number of leprosy patients in order to get the appropriate sample size.
Example: In country X, the population is distributed as follows:

<table>
<thead>
<tr>
<th>Northern Region</th>
<th>Southern Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>District</td>
<td>Population</td>
</tr>
<tr>
<td>A</td>
<td>100 000</td>
</tr>
<tr>
<td>B</td>
<td>500 000</td>
</tr>
<tr>
<td>C</td>
<td>200 000</td>
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<tr>
<td>D</td>
<td>50 000</td>
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<td>E</td>
<td>250 000</td>
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</tbody>
</table>

Sampling interval is 550 000. From the third column of the table, the closest number to 550 000 and 550 000 x 2 = 1 100 000 is 600 000 and 1 100 000 respectively, and therefore B and E are selected.

In the selected districts, the list of health facilities and the number of registered patients are as follows:

<table>
<thead>
<tr>
<th>Districts B and E</th>
<th>Districts H and L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health centres</td>
<td>Patients</td>
</tr>
<tr>
<td>1</td>
<td>70</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
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<tr>
<td>3</td>
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<td>6</td>
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</table>

Sampling interval is 500. In the third column, the closest to 500, 1 000 and 1 500 are 990, 1 440 and 1 500 respectively. Therefore 4, 5 and 6 are selected.

Biases should be minimal considering that leprosy activities are consistent between health workers, that differences between health facilities cannot be taken into account, that the aim of the study is to give proxy indicators on national performance and that the study should be conducted in a short period of time. If more accurate and reliable information has to be obtained in a particular area or from health facilities, national programme managers should
organise supervisory visits or in-depth evaluations.

**Planning and carrying out the study**

Organising such a study in the field is a complex process which will require technical and administrative planning. This has to be done in close collaboration with authorities at all levels, especially those at the national and sub-national levels, WHO and, wherever necessary, NGOs. This section will outline the most important steps in organising a study and will highlight steps that must be standardised. It will also indicate requirements and resources needed for implementing the study.

**Planning the monitoring**

1. The study should be initiated by national programme managers and be part of their national plan of action. WHO will be responsible for introducing the concept to leprosy programme managers.

2. The objectives of the study and information to be collected will be discussed with national authorities.

3. The outline of the study will be the responsibility of WHO, in collaboration with national programme managers, WHO national consultants and Regional Advisors.

**Selecting areas to be visited**

This very important step could be organised in two different ways:

- For countries where sufficient information is already available, selection of districts and health facilities can be made by WHO and proposed to the national authorities for approval.

- For other countries, monitors will have to make the selection after collecting all relevant information at the central level.

In any case, national programme managers and monitors will have to organise details of the study, including the plan of work and time-table.

**Requirements**

1. Personnel: Indicators and methods indicated in this document have been designed to minimise the workload. It is assumed that monitors can carry out most of the tasks involved in the process with the assistance and collaboration of health managers and health workers from the area being studied.

2. Transport and logistics: Such a study implies that monitors will have to travel to various places from the central level to the most peripheral health centres. Appropriate support should be provided by the national authorities and/or WHO.
3. All the necessary forms for data collection will be provided by WHO

**Preparations of field visits**

Before starting field visits, organisers should ensure that:

- The objectives of the study and the list of data to be collected are clearly defined and accepted;
- The sample sites to be visited have been selected and all concerned authorities and health facilities are informed and will be available;
- The plan of work and time schedule for the study is defined;
- Required resources and logistics are available.

**Data collection in the field**

- Attitude: monitors should involve local health workers in the process after having explained objectives of the exercise and the procedures to be followed. The attitude of monitors will be very important and they should clearly express that they are not supervisors or inspectors. Monitors should always give positive comments, even if they are facing difficulties in obtaining information they need to collect.
- Monitors will list all available leprosy documents with local workers and compile them for collecting relevant information. At each step, monitors should explain what they are doing and for what purpose.
- Whenever necessary, monitors will select a sample of leprosy patients to be visited, in consultation with local workers.
- At the end of the visit, monitors will prepare a descriptive summary form, describing the key indicators as calculated in the selected health facilities. Feedback will be given to local workers during a debriefing meeting. At this stage, no conclusion nor recommendations should be given. Results will be circulated and participants will be asked for comments. Monitors will highlight the positive aspects and ask how the situation can be improved when discussing the weak points.

**Analysis and reporting**

Analysis and reporting will be done at the health facility and at a higher level of administration. Final reports, including summary tables and graphics, will be discussed and finalised with the national programme manager. Information collected in the field will be consolidated with information available at the central level.
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### Form 1.1  Case finding activities : Summary Form

**Location:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Indicator</th>
<th>Sample size</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td>1.1</td>
<td>Proportion of new cases with Grade 2 disabilities</td>
<td>Number of new cases with G2 disabilities</td>
<td>Proportion %</td>
</tr>
<tr>
<td>1.2</td>
<td>Average delay in diagnosis (Form 1.2)</td>
<td></td>
<td>Months</td>
</tr>
<tr>
<td>1.3</td>
<td>Proportion of children among new cases</td>
<td>Number of children</td>
<td>Proportion %</td>
</tr>
<tr>
<td>1.4</td>
<td>Proportion of MB cases among new cases</td>
<td>Number of MB patients</td>
<td>Proportion %</td>
</tr>
<tr>
<td>1.5</td>
<td>Proportion of single lesion among new cases</td>
<td>Number of single lesion</td>
<td>Proportion %</td>
</tr>
<tr>
<td>1.6</td>
<td>Proportion of female among new cases</td>
<td>Number of female</td>
<td>Proportion %</td>
</tr>
</tbody>
</table>
GROUP I : ELIMINATION INDICATORS
Form 1.2 Case finding activities : Average delay of diagnosis

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<th>Location:</th>
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<tr>
<th></th>
<th>Number</th>
<th>Delay in diagnosis (months)</th>
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<th>Delay in diagnosis (months)</th>
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**Total**

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<tr>
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<th>Months</th>
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<th>Months</th>
<th>Months</th>
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</thead>
</table>

A: Total number of patients
B. Total delay in diagnosis

Average delay in diagnosis = \( \frac{B}{A} \) = \( \text{months} \)
Form 1.3 Prevalence: Absolute number and rates: (Any level)

<table>
<thead>
<tr>
<th>Location:</th>
<th>As reported</th>
<th>After applying standard definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
<td></td>
<td></td>
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<tr>
<td>SSL</td>
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<td>PB</td>
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<tr>
<td>MB</td>
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<tr>
<td>UK</td>
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<tr>
<td>Total</td>
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<tr>
<td>Population</td>
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</table>

SSL: single skin lesion; PB: paucibacillary; MB: multibacillary; UK: unknown
### Form 1.4 Detection: Absolute numbers and rate

<table>
<thead>
<tr>
<th>Location:</th>
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<table>
<thead>
<tr>
<th>YEAR</th>
<th>PB</th>
<th>MB</th>
<th>SSL</th>
<th>UK</th>
<th>Total</th>
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<tbody>
<tr>
<td><strong>Number of new cases</strong></td>
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<tr>
<td>PB</td>
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<table>
<thead>
<tr>
<th><strong>Number of new cases below 15 years old</strong></th>
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<tbody>
<tr>
<td>PB</td>
</tr>
<tr>
<td>MB</td>
</tr>
<tr>
<td>SSL</td>
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<tr>
<td>UK</td>
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<tr>
<td>Total</td>
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<table>
<thead>
<tr>
<th><strong>Population</strong></th>
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## Form 1.5 Detection (Optional)

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<thead>
<tr>
<th>YEAR</th>
<th>Number of cases clinically diagnosed as MB</th>
<th>Skin smear negative</th>
<th>Skin smear positive</th>
<th>Unknown</th>
<th>Total</th>
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</tbody>
</table>
### Form 1.6 Detection according to age, sex and mode of detection (Optional)

<table>
<thead>
<tr>
<th>Type of health facility:</th>
<th>9 Specialised</th>
<th>9 Integrated</th>
</tr>
</thead>
</table>

**Location:**

**Total population:**

<table>
<thead>
<tr>
<th>Age</th>
<th>Year</th>
<th>Mode of detection</th>
<th>M</th>
<th>F</th>
<th>Population</th>
<th>M</th>
<th>F</th>
<th>Population</th>
<th>M</th>
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Population: Number examined for modes of detection 1, 2 and 3
Form 1.7 Detection according to age, sex and number of skin lesions (optional)
Location: Total population:

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0. Unknown 1. One lesion 2. Two to five lesions 3. More than five lesions
Form 1.8 Detection according to age, sex and type of leprosy(Optional)

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### Form 1.9 Detection according to age, sex and disability grading (Optional)

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# Form 2.1 Integration of MDT services within general health services: summary form

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<th>Sample size</th>
<th>Results</th>
<th>Proportion</th>
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<tr>
<td><strong>1. Proportion of existing health facilities providing MDT</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>a) list of health facilities</td>
<td></td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>b) visited health facilities</td>
<td></td>
<td></td>
<td>%</td>
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<tr>
<td><strong>2. Accessibility to MDT</strong></td>
<td></td>
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<tr>
<td>2.1 Average distance</td>
<td>Km</td>
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<tr>
<td>2.2 Estimated costs for patients</td>
<td></td>
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<tr>
<td>2.3 Flexibility in delivering MDT</td>
<td></td>
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</tr>
<tr>
<td>Open days</td>
<td>%</td>
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<tr>
<td>AMDT</td>
<td>%</td>
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<tr>
<td>Can manage reactions</td>
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<td>Can manage disabilities</td>
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<tr>
<td>Integrated within GHS</td>
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<tr>
<td>Have steroid stocks</td>
<td>%</td>
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<tr>
<td>Uses steroid</td>
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<td><strong>3. Availability of MDT drugs</strong></td>
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<tr>
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</table>
Form 2.2 Proportion of existing health facilities providing MDT

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<th>Have stocks of MDT?</th>
<th>Health facilities visited</th>
<th>Have stocks of MDT?</th>
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</table>

Total

Total number of health facilities visited = A
Total number of health facilities having stocks of MDT = B

Proportion of health facilities having MDT stocks = B/A =
Form 2.3 Average distance: calculation sheet

<table>
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<th>Number</th>
<th>Distance (Km)</th>
<th>Number</th>
<th>Distance (Km)</th>
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</table>

A: Total number of patients  
B: Total distance  

Average distance = B/A = KM  

(Distance from residence to the nearest health centre can be obtained either through interviews of patients or from the address on the register, if available.)
## Form 2.4 Flexibility of delivering MDT

**Location:**

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<th>District</th>
<th>Health facility</th>
<th>Open days/month</th>
<th>AMDT</th>
<th>Can manage reactions</th>
<th>Can manage disabilities</th>
<th>Integrated to GHS</th>
<th>Steroid stock</th>
<th>Steroid use</th>
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* Total number of health facilities open on all working days
## Form 2.5 Availability of MDT drugs

<table>
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<th>Region</th>
<th>District</th>
<th>Health facility</th>
<th>Current case load</th>
<th>Current stocks in units and months' supply</th>
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<td>Units Months</td>
<td>Units Months</td>
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</tbody>
</table>

**Current case load:** the number of cases registered at the time of visit

**Units:** number of blister packs

**Months:** Units/Current case load: it is recommended to keep this level around three.

MBA: MB Adult; MBC: MB Child; PBA: PB Adult; PBC: PB Child
### Form 3.1 Quality of MDT services: summary form

<table>
<thead>
<tr>
<th>Location</th>
<th>Proportion of patients treated with MDT</th>
<th>Cure rate (%)</th>
<th>Quality (%)</th>
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### Form 3.2 Proportion of patients treated with MDT

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</table>

<table>
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<th>Type (Integrated/ Specialised)</th>
<th>Number of patients registered for treatment at the time of visit</th>
<th>Number of patients having received at least one dose of MDT during the 12 months preceding the visit</th>
<th>Proportion of patients treated with MDT (%)</th>
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**Total**
Form 3.3 Case holding

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<thead>
<tr>
<th>PB COHORT YEAR( )</th>
<th>Number of patients having started MDT between (       ) and (       )</th>
<th>Status 12 months later (between                 and                )</th>
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<tbody>
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<td></td>
<td>Cured</td>
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<th>MB COHORT YEAR( )</th>
<th>Number of patients having started MDT between(       ) and(       )</th>
<th>Status 18 months later (between                 and                )</th>
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</thead>
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Example of bar charts showing results of cohort analysis

**Treatment outcome**

PB&MB Cohorts

- **Cured**
- **TTT continued**
- **Defaulter**
- **Other**

![Bar chart](image)

Legend:
- MB92
- PB94
Form 3.4  Quality of blister-packs

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<table>
<thead>
<tr>
<th>District</th>
<th>Health facility</th>
<th>No. of blister-packs examined</th>
<th>No. of packs in acceptable condition</th>
<th>Quality (%)</th>
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<tbody>
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</tbody>
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| Total     | MBA             | MBC                          | PBA                                 | PBC         |