Global Leprosy Strategy 2016–2020

Accelerating towards a leprosy-free world

Monitoring and Evaluation Guide

World Health Organization

Global Leprosy Strategy
2016–2020

Accelerating towards a leprosy-free world

Monitoring and Evaluation Guide

World Health
Organization

Global Leprosy Strategy 2016–2020. Accelerating towards a leprosy-free world. Monitoring and Evaluation Guide

ISBN: 978-92-9022-549-2

© World Health Organization 2017

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization..

Suggested citation. Global Leprosy Strategy 2016–2020. Accelerating towards a leprosy-free world. Monitoring and Evaluation Guide. New Delhi: World Health Organization, Regional Office for South-East Asia; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Photos courtesy of The Leprosy Mission England and Wales; Institute Lauro De Souza Lima, WHO collaborating centre; Bauru-SP, Brazil; Damien Foundation Belgium; and Ed Hanley – photographer and videographer, Toronto, Canada.

Contents

List of Contributors iv

Abbreviations v

Executive summary vii

Global Leprosy Strategy at a glance viii

1. M&E Guide scope and target audience 1

2. Introduction to the elements needed to assess programme performance 2
    2.1 Definitions of activities aimed at assessing programme performances 2
    2.2 Tools to assess programme performance 7

3. New tools to monitor programmes 12
    3.1 Definitions 12
    3.2 Recording and reporting tools 14
    3.3 Targets and monitoring indicators of the Global Leprosy Strategy 2016–2020 15
    3.4 Overview of monitoring indicators for programmatic review 54
    3.5 Leprosy programme review 56
    3.6 Active screening activities/case-detection campaigns and their effect on leprosy monitoring indicators 59

4. References 63

Annexes

1. Patient card 64

2. Annexes 64

3. Leprosy register 70

4. Disability register 71

5. Contact register 73

6. Drug resistance register 74

7. Critical incident investigation 75

8. Checklists for supervision 79

9. Programme evaluation process checklist 87

10. Participatory scale 88

11. Five-point scale for stigma assessment 90

List of Contributors

Dr Yasin Al-Qubati
Ms Kerstin Beise
Dr Rosa Castalia
Professor Emmanuelle Cambau
Dr Bertrand Cauchoix
Dr Erwin Cooreman
Dr Rita Djupuri
Dr Osman El Tayeb
Dr Albis Francesco Gabrielli
Mr Pete Garrat
Dr Laura Gillini
Professor Mohan Gupte
Ms Deanna Hagge
Mr Tesfaye Tadesse Haile
Professor Eliane Ignotti
Dr Herman-Joseph Kawuma
Dr Padebettu Krishnamurthy
Dr Pim Kuipers
Dr Jean Norbert Mputu
Dr Uzoma Nwankwo
Dr Basudev Pandey
Dr Vijay Kumar Pannikar
Dr V.R.R. Pemmaraju
Professor Jan Hendrik Richardus
Dr Paul Saunderson
Professor W. Cairns Smith
Ms Hiroe Soyagimi
Dr Nayani Suriyarachchi
Dr Wim van Brakel
Ms Vivian Velema-Andyka
Professor Mitchell Weiss

Abbreviations

A-MDT	Accompanied MDT
CBO	Community-based Organization
CBR	Community-based Rehabilitation
CII	Critical Incident Investigation
DOT	Directly Observed Treatment
DSS	Decision Support System
EHF score	Eye Hand Feet score
G1D	Grade 1 Disability
G2D	Grade 2 Disability
GIS	Geographic Information System
GP	General Practitioner
GPS	Global Positioning System
HF	Health Facility
HIS	Health Information System
IEC	Information Education Communication
LEC	Leprosy Elimination Campaign
LEM	Leprosy Elimination Monitoring
MB	Multi Bacillary
MDT	Multidrug Therapy
M&E	Monitoring and Evaluation
NCDR	New Case-Detection Rate
NGO	Nongovernmental Organization
NTD	Neglected Tropical Disease
PB	Pauci Bacillary
PC	Personal Computer
PD ratio	Prevalence/Detection Ratio

PHC	Primary Health Care
QA	Quality Assurance
RCS	Reconstructive Surgery
RFT	Release from Treatment
SAPEL	Special Action Project for Elimination of Leprosy
SHG	Self Help Group
SOAP	Subjective Objective Assessment Plan
TB	Tuberculosis
WER	Weekly Epidemiological Record
WHO	World Health Organization

Executive summary

There has been considerable progress in leprosy control ever since multidrug therapy (MDT) was introduced more than three decades ago. Strong political commitment, sound strategies and robust partnerships have contributed to a significant impact in terms of reduction in leprosy burden. While this represents good news for leprosy workers, the public and policy-makers, what is of common concern, is the slow decline in the new case detection in the last 10 years. Besides, the global target of one-third reduction in new cases with grade-2 disability (G2D) set by the Enhanced Global Strategy for Further Reducing the Diseases Burden due to Leprosy, 2011–2015 has missed the timeline, prompting the launch by the World Health Organization (WHO) of a more comprehensive strategy which is the Global Leprosy Strategy 2016–2020 "Accelerating towards a leprosy-free world". This strategy was developed around three pillars that address governance, medical and social aspects of leprosy.

The ultimate vision of the strategy is to have a world without leprosy but its immediate goal is to further reduce the leprosy burden at global and local levels. Its targets are: (1) zero disability among new child cases; (2) reduction of G2D among new cases to less than 1 per million population; and (3) zero countries with legislation allowing discrimination on the basis of leprosy. These will have to be achieved by 2020. To assess the implementation of such a wide and comprehensive agenda, a stronger system must be put in place counting on new tools. To help countries to adopt the new tools and to have a common understanding on the means and procedures to measure the extent and direction of progress, this guide has been developed. The main tool that allows monitoring is a good information system. This requires major changes to allow capturing of the needed information either under leprosy systems or within wider communicable disease health information systems. The changes into the recording and reporting tools are defined in details and the new forms are provided as annexes to this guide so that countries can use them as reference for adaptation according to their context. Changes of definitions have also been included along with clear formulas on how to calculate new indicators under each strategic pillar. Ultimately the Monitoring and Evaluation (M&E) Guide aims to guide programmes on how to monitor progress and to identify problems, while the Operational Manual, released in August 2016, was developed to guide on actions with a positive impact on leprosy control. While the Strategy deals with conceptual framework and the Operational Manual with procedures on how to bring about change, this M&E Guide deals with procedures to measure progress and guides also in pointing out needs for improvement. Therefore, the three documents shall be seen as "One" to allow a more effective fight against leprosy at all levels.

Global Leprosy Strategy at a glance

2016-2020
GLOBAL LEPROSY STRATEGY

- ⦿ Zero disease
- ⦿ Zero transmission of leprosy infection
- ⦿ Zero disability due to leprosy
- ⦿ Zero stigma and discrimination

Further reduce the global and local leprosy burden

INDICATORS	2020 target
Number of children diagnosed with leprosy and visible deformities	0
Rate of newly diagnosed leprosy patients with visible deformities	<1 per million
Number of countries with legislation allowing discrimination on basis of leprosy	0

PILLARS AND COMPONENTS

1. Strengthen government ownership, coordination and partnership

- Ensuring political commitment and adequate resources for leprosy programmes.
- Contributing to universal health coverage with a special focus on children, women and underserved populations including migrants and displaced people.
- Promoting partnerships with state and non-state actors and promote intersectoral collaboration and partnerships at the international level and within countries.
- Facilitating and conducting basic and operational research in all aspects of leprosy and maximize the evidence base to inform policies, strategies and activities.
- Strengthening surveillance and health information systems for programme monitoring and evaluation (including geographical information systems)

2. Stop leprosy and its complications

- Strengthening patient and community awareness on leprosy.
- Promoting early case detection through active case-finding (e.g. campaigns) in areas of higher endemicity and contact management.
- Ensuring prompt start and adherence to treatment, including working towards improved treatment regimens.
- Improving prevention and management of disabilities.
- Strengthening surveillance for antimicrobial resistance including laboratory network.
- Promoting innovative approaches for training, referrals and sustaining expertise in leprosy such as eHealth.
- Promoting interventions for the prevention of infection and disease.

3. Stop discrimination and promote inclusion

- Promoting societal inclusion through addressing all forms of discrimination and stigma.
- Empowering persons affected by leprosy and strengthen their capacity to participate actively in leprosy services.
- Involving communities in actions for improvement of leprosy services.
- Promoting coalition-building among persons affected by leprosy and encourage the integration of these coalitions and or their members with other community-based organizations.
- Promoting access to social and financial support services, e.g. to facilitate income generation, for persons affected by leprosy and their families.
- Supporting community-based rehabilitation for people with leprosy-related disabilities.
- Working towards abolishing discriminatory laws and promote policies facilitating inclusion of persons affected by leprosy.

M&E Guide scope and target audience

1

The scope of the M&E Guide is to provide tools for national leprosy programmes (NLPs) to allow monitoring of progress towards the Global Leprosy Strategy 2016–2020 targets. It aims to guide them on remedial actions to be taken if the monitoring indicators point out problems with regard to an effective implementation of the strategy.

The target audience of this third document related to the Global Leprosy Strategy is again the national and regional/state/provincial level manager of leprosy programmes. The Guide contains the new recording and reporting forms for leprosy so that NLPs could adapt them for use in countries. Some parts of the M&E Guide could be used also by national and subnational supervisors, though a simpler document will be developed for field level staff. The Guide is also useful for consultants who support countries as technical assistance providers or as monitors of leprosy programmes and projects.

2

Introduction to the elements needed to assess programme performance

Assessing the quality of a programme requires proper planning and carrying out of multiple activities. They are different in nature but they all contribute to supporting the generation of evidence on which to base an assessment of a public health programme, in our case a leprosy programme. The collection of that evidence and its analysis for decision-making also requires the use of several "tools". Hence, this introductory chapter has two subchapters: one on definitions to clarify the terminology related to activities put in place for assessing programme performances and another on tools that allow monitoring such as the health information system and the monitoring indicators. At the end of the introduction, the audience is expected to a have a clearer understanding of the basic elements to be put in place to allow a routine and ad-hoc assessment of their programme performance.

2.1 Definitions of activities aimed at assessing programme performances

2.1.1 Monitoring, evaluation and programmatic reviews

Monitoring, evaluation and programmatic reviews are means to ascertain the nature, quality, extent and significance of the progress towards a public health goal. Monitoring and evaluation is used to generate best evidence on how well the programme is working and translate that evidence into implementation improvements and/or redefining policy recommendations. While monitoring is internal and looks at programme performance in terms of activities carried out against those scheduled, evaluation is usually intended as an independent external assessment of the ongoing activities to determine their efficacy in achieving the stated public health objectives. The whole process of M&E helps in looking at the targets and milestones with the help of indicators to measure progress and achievements.

Specifically, **monitoring** is the constitutive part of every public health programme. Routine monitoring is the principal and essential component in routine assessing of public health programmes. It consists of continuous flow of information up and down in the programme chain and through progress reports to other units and beyond. It relies on a set of indicators that are identified based on national plan targets, and also based on relevance, objectivity and ease of collection. The information that is generated through monitoring is used at every management level (national and subnational) to assess programme status, identify deviations and institute remedial measures. The recording and reporting system that forms the basis of the information needs to align with the monitoring plans; it needs to include a system to ensure the quality and safety of records.

Monitoring implies analysis of a set of indicators over time and between areas.

Evaluation and programmatic reviews are usually specific, directed at a particular programme thematic component (e.g. patient care or a specific project) or broad-based, covering the major domains of the programme as a single point in time event organized around questions that usually fall into six categories: (i) Is the programme achieving the intended objectives and targets? (ii) Are the activities implemented as planned? (iii) Are the activities being implemented with the appropriate use of resources? (iv) Does the benefit accrued exceed the cost? (v) Can the achievement be attributed to the programme or any other factor? (vi) Are there any unexpected positive or negative side-effects from programme implementation?

As a result of assessing programmes according to those six questions, programmatic reviews help in improving results, increasing efficiency, augmenting accountability and ownership, strengthening partnerships and mobilizing resources. The evaluation can be carried out annually (internal, looks at implementation using routine data); mid-term or end-of-term (at the middle or end of the programme planning cycle) and look at both implementation and results. Reviewers in such case typically are both internal and external. Evaluating a single project or focus the review on a single aspect of the programme, usually also is done by reviewers who are usually external.

The WHO-led programme reviews are special activities with specific procedures, a team of external and internal monitors and a budget that can allow to supplement routine monitoring information by in-depth information to answer a range of questions about the programme as a whole using quantitative and qualitative data.

The review framework includes a statement of objectives, formulation of terms of reference, constitution of a steering committee, definition of methods, development of data collection tools, identification of background documents to be reviewed (plans, strategies, operational guidelines, budgetary allocation, information system procedures, progress reports, other reports, records and registers at health facilities, research initiatives), set up of a list of key persons to be interviewed and their sites/locations (government, service providers, service users, interest groups, partners). Therefore the programme review sets clear timelines and requires logistics and resources.

Table 1: *Summary of main characteristics of monitoring versus evaluation*

Management variable	Programme monitoring	Programme evaluation
Output (service, activities, reach)	How many areas were reached by IEC? As per plan?	How adequate was the reach? Was it enough? Was it right?
Process (implementation)	How was it implemented? In accordance with plan?	How well was it implemented?
Outcome (results)	What has changed?	Were the outcomes worth it?
	Deals with input, process and immediate results	Deals with long-term results including impact
	Looks at relationship between what is planned and what is accomplished	Looks at relationship between output and outcome
	Routine	Special
	Internal	External, internal
	Objective – programme objective	Objective – specific evaluation question
	Immediate relevance to implementers	Immediate relevance to policy-makers and stakeholders

Source: Global leprosy programme (GLP)

Both programme monitoring and evaluation help with:

- Knowing whether the activities are implemented as planned;
- Determining whether the results of the activities are achieved at a reasonable cost;
- Guiding, improving decision-making, policy and strategy reformulation, and improving management procedures;
- Establishing the impact of programme activities in terms of public health benefits;
- Establishing favourable linkages with overall development plans and strategies; and
- Ensuring the development of monitoring skills.

Mechanisms for feedback and dissemination of experiences as well as best practices should be developed since well-planned and conducted programme reviews can give impetus for programme staff to improve quality in service delivery.

2.1.2 Supervision

Supervision is an important management tool for ensuring quality of service delivery. Supportive supervision encourages an improvement in performance through a spirit of collaboration by setting uniform standards, identifying and solving problems, identifying needs and providing opportunities for development. It involves looking at health-care facilities, administrative units, activities and personnel through visits, and collecting information on checklists to assess and provide feedback, based on which improve performance. Supervision has three functions – administrative, educational and supportive. The aim of supervision ultimately is to promote a culture of learning for better performance. It can be done by staff from an administrative unit at a higher level, by staff from other facilities or administrative units (external supervision), by colleagues from the same facility (peer supervision) or by community members or partners (joint supervision which often results in increased demands for quality). One can think of integrated or multipurpose supervision (leprosy and tuberculosis (TB), leprosy and NTD, leprosy disability with other disabilities) that facilitates shared logistics and finances. Multipurpose supervision can also cover part of a leprosy programme only (e.g. drug management, laboratory, recording, outreach activities). Supervision should be continuous – through field visits, during meetings and during routine work.

A supervisor assesses quality of services through observation, identification of good practices and problems, and discussions. Quality facilitation is through interactive problem solving, coaching, training, feedback including supportive feedback to encourage good practices and follow-up on previously identified problems. It is imperative that a supervision system is involved with the supervision of supervisors to ensure that all supervisors are equipped with necessary knowledge and skills. They should have authority and they need to be provided financial and logistic support besides being properly trained as supportive supervisors. Key elements of effective supervision are: commitment to supervision; availability of clear standards of performance; good planning; involvement of major stakeholders (nongovernmental organizations (NGOs), associations of persons affected by leprosy); counting on standardized tools for supervision; proper documentation of activities carried out; and availability of funding.

Supervision also utilizes tools that are checklists, questionnaires, job charts, job descriptions, standards of performance, guidelines, activity plans and reports (programme reports or supervision reports). The focus of supervision is on minimization of inappropriate variations in health practice.

Supervision reports provide complementary evidence on programme performance monitoring. If collected and disseminated properly, they can become an important source for performance measurement that provides corroborative evidence on programme results. To establish an effective supervision system that can complement the monitoring of programmes by managers, all levels of care need to contribute. Table 2 identifies roles and responsibilities to succeed with this important programmatic task.

Table 2: *Responsibilities for supervision at various levels*

Administrative level	Responsibilities
Health facility level	Self-assessment and peer review
	Effective use of checklists
	Promote and maintain good standards of work
	Training needs assessment and technical support
	Local problem solving
District and regional/state/ provincial level	Team work and continuous support
	Integrated supervision
	Develop capacity of supervisors – knowledge, skills, commitment
	Coaching, training to upgrade skills and enable adherence to procedure
	Problem solving
	Strengthen logistics and attention to mobility
	Appropriateness and speed of follow-up actions
	Improve internal supervision
	Reward quality
National level	Provide tools and key information
	Set and enforce technical standards
	Plan and implement supervision guidelines including checklists for different levels
	Develop supervision plan for supervision visits
	Provide necessary resources – funds, mobility
	Create opportunities for training
	Compilation of data and analysis
	Feedback
	Reward quality
	Disseminate information on best supervision practices

Source: Dr Padebettu Krishnamurthy

2.1.3 Research initiatives and surveys

Research can provide valuable information on programme components, which the routine monitoring or evaluation cannot. Research can provide fresh insights and innovative solutions to implementation problems. Research generates an evidence base that could be used to arouse debate and raise public consciousness on social issues. Field research can look at associations and effects and provide information to a variety of audiences. For example, one can try to address through research the challenge of getting valid data on the perception on participation of persons affected or the nature and extent of discrimination and bias in the community against persons affected. Of course, the purpose of research is different from supervision and from monitoring & evaluation. "Research seeks to prove; evaluation seeks to improve". It would be important for national authorities to sponsor research in collaboration with experts and academic institutions from a wider professional base.

2.2 Tools to assess programme performance

2.2.1 The health information system

The health information system is an essential tool providing information to guide decision-making at all levels. It includes a set of interrelated activities that collect, integrate, analyse, interpret, store and disseminate data and information to allow monitoring of progresses towards a public health target. It has three elements: input, process and output. Input is data, process converts data into useful information and output consists of information that is produced in the form of reports. Data consist of raw facts that, when processed, become meaningful; this is called "information" and when it is used to explain the context of a problem or situation, it becomes "knowledge" (referred to as Data Information Knowledge hierarchy). The data flow may be continuous, periodic, or one-time. It may consist of routine data, of data from critical incidents and/or of data from supervision activities, from an evaluation mission or from research. The whole purpose of the health information system is to make available 'the right information, for the right use, to the right people, at the right time'.

Resources are the inputs required to manage the information system efficiently and effectively. Designated people collect the required data and process it into information and disseminate it to required destinations through a set of standard criteria, protocols and procedures. Involving a broader range of professionals including behavioural and data scientists in the information system (designing, monitoring) may be beneficial since the system shall ideally allow the collection of also qualitative data that might help to assess more in detail the facts.

There should be a regulatory and planning framework for managing the information system as an integral part of the overall health system management. It should deal with accountability and credibility issues; collaboration arrangements with partners; needs and rights of the patients who are the end-users; organizational rules for workforce, financial allocations, stock management; and use of new technology. Standard procedures and protocols should be defined for the entire process of collection, dissemination, processing and use of data and information.

It is essential to understand the capacity of the programme at different levels for synthesis, analysis and validation of data and supervision reports are usually key tool that helps greatly with this.

Data collection procedures should be standardized and adapted to health workers. The context of integration into general health or other programmes (TB/skin/NTD) should be kept in mind. There should be clear delineation of responsibility – who collects patient data: a professional who manages the patient or a designated worker? A dictionary of definitions for every item in the patient record/register should be available. Data entering can be paper-based or electronic. Data are usually generated at the health facility level and flow up from health facility to first administrative level, from there to second administrative level (region, state or province), and from there to the national level. It may be automatically sent at specified times or it could be submitted upon a specific request of a manager (for example, additional information on a specific activity). The periodicity or frequency (the relevant reference period) – monthly, quarterly, annual – depends on needs of analysis for decision-making and on the ease of collection.

At every level, a **quality assurance** system needs to be established to ensure that data are of good quality (valid, reliable, precise, integer and timely). Data variations could occur because of people, machines, methods or procedures and measurements. Quality assurance aims to make sure that errors do not occur and that there is safeguard against deliberate manipulation. The following measures facilitate in assuring data quality:

- Standardized definition of data and the procedure for collection, processing, dissemination and use
- Adequate staff capacity
- Supervision

There should be a system of random verification for completeness, correctness, accuracy and consistency of data. Some of the procedures include: looking for data element range (completeness) and consistency; dual data entry; review of a sample of records or three consecutive reports; site visit interviews to understand the data capturing process and local data quality efforts; and immediate resolution of discrepancies. Review of records, registers and reports could be internal or external, continuous or periodic, regular or special and total (all records and reports/total content of record and report) or partial (sample of records and reports/specific part of the content of records and reports). It is also important to look at the entire information trail – what happens at each level and who does what. For each quality variable (completeness, accuracy, correctness, consistency, timeliness, use), standards can be established (excellent, good, average, poor) to measure quality or one can set a threshold (90% of records or reports) for each element.

Data processing mechanisms could be paper-based or electronic. The report is used as a source for calculating monitoring indicators, including targets. In a semi-electronic system, a patient card is used to record information at health facility level while some of those information is entered periodically in an electronic database, from where reports are automatically generated. There are different possibilities of digitization: only indicators or reports and indicators. Also the level of electronic data entry might vary with some countries having electronic reporting including at health facility level. It will vary depending on management needs and available Using newer technology in any case is usually more beneficial in terms of generating accurate, timely reports, for their analysis and for their analysis and dissemination. There is a changing expectation of health-care providers regarding the use of technology in health-care settings.

There are several advantages in shifting data collection and storage from paper to digital database. Electronic health records allow greater coordination and better data sharing. Another advantage is easy accessibility. Records are stored in a database that is secure and at any time any specific data on a variable of interest can be picked up by persons who have been given access rights to that variable and data can be transmitted to the destination and target audience of interest quickly and securely. Data analysis through a standard software package allows instant production of reports and generation of indicators. Case based-records whenever possible shall be preferred since they could avoid duplication of records and they are usually more accurate and precise than aggregated data systems. There is considerable enhancement in the quality with built-in quality assurance mechanism to also include safety and confidentiality of data stored.

Data dissemination is for awareness, for understanding and for taking action. It should respect established management channels of the health system and be responsive to the needs at various levels. It can be between different levels within the programme or outside the programme. Sometimes the report can be in a summarized, convenient and easily understandable form for policy-makers, for example. New technology may improve quality of information; however, even if nicely produced and summarized, no information will have an impact if not used adequately and appropriately.

Using the information for decision-making is the purpose of the information system. Proper use of information at every level including well-established feedback mechanism and innovative approaches in data presentation will result in improvement in patient care and in leprosy care services management at different levels. One of the means to improve the use of information system is to introduce a decision support system (DSS). It is a computerized application that allows health managers to visualize indicators collected by the information system in graphical and geographical presentation. A geographic information system (GIS) can be used for spatial comparison (by health facility, by district, by region. Other comparisons are also possible: temporal (trends by month, year), by indicator, by threshold of achievement. It helps in health intelligence – to discover significant patterns such as sequences, clusters, correlations, with which decisions can be made. Often data managers encounter challenges in interpretation of data. DSS is certainly useful at major administrative levels where there is no data scientist to help in the analysis. It allows rapid analysis and use. Some principles to improve the use of information and to introduce ‘information culture’ are:

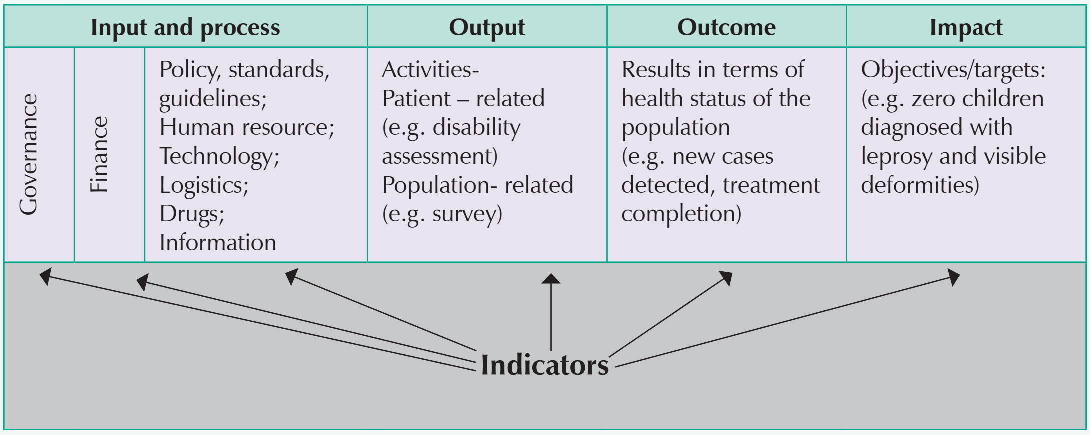
- Active participation of data users and data scientists (analysis and interpretation) in system design to promote ownership and to understand the relevance of information;
- Quality and timely information;
- Performance-based programme management system;
- Communication channel between data collectors and data users; and
- Innovative and adaptable data presentation and dissemination.

An ideal information system for leprosy should be case-based and should allow reporting by all service providers, including private, and be able to disaggregate data by geographic area, sex, age, country of origin, living area (city/village). It should also allow an analysis of risk factors for leprosy to identify vulnerable groups. It should preferably be based on a central data repository with aggregation and regular exchange at all levels. It should be supported by a quality assurance mechanism to minimize errors and ensure quality data and should provide summarized and well-presented information easy to interpret for decision-making and easy to disseminate and share.

2.2.2 Monitoring indicators

Monitoring relies on the use of a well-developed set of indicators. Indicators are variables that measure change. They provide the basis to look at change and sustainability of change, and describe the effects (positive or negative) of programme interventions, expected or unexpected. The most important role of monitoring is to provide a solid basis to managers for assessing their programmes and taking action accordingly. As for most evidence, it is information for action.

Figure 1: *Scope of indicators within the monitoring framework*



Input and process			Output	Outcome	Impact
Governance	Finance	Policy, standards, guidelines; Human resource; Technology; Logistics; Drugs; Information	Activities- Patient – related (e.g. disability assessment) Population- related (e.g. survey)	Results in terms of health status of the population (e.g. new cases detected, treatment completion)	Objectives/targets: (e.g. zero children diagnosed with leprosy and visible deformities)

Source: Dr Padebettu Krishnamurthy

Inputs/resources are necessary to accomplish activities. If resources are used, then these planned activities will occur. If the activities are carried out, then the products or services (outputs) are expected to be delivered. If the outputs are accomplished, then the programme is expected to have the results (outcome) on the target population. If the intended outcomes occur, then changes in population might occur (impact).

Impact indicators express the extent of realization of public health objective(s).

Outcome indicators express the results obtained due to activities (e.g.s number of new cases detected, number of cases cured).

Output indicators express how well the activities that are planned are implemented (proportion of contacts examined).

Process indicators express an activity that is put into action, as for a plan (for example, availability of a web-based information system).

Some indicators are rule-based indicators (bimodal indicators). They are more often the process indicators and, therefore, they are related to expected procedures or practices that are set in place. For example: "existence of an alliance with associations of persons affected by leprosy" to which the answer can be either "yes" or "no" only.

3

New tools to monitor programmes

This chapter refers specifically to monitoring leprosy programmes taking into account the full extent of the Global Leprosy Strategy 2016–2020. At the end of this chapter, the target audience shall have a clearer understanding of what information to collect and how to be able to review their programmes under routine monitoring or under ad hoc monitoring and evaluation activity. Chapter 3 has several subchapters in the following topics: updated definitions, new recoding and reporting tools, leprosy monitoring indicators, indicators' relevance, leprosy programme reviews and the effect of active screening/case-detection campaigns on routine monitoring indicators.

3.1 Definitions

3.1.1 Type of patient definitions

In light of the Global Leprosy Strategy 2016–2020 and keeping in mind the need to enhance activities for drug surveillance for which it is fundamental to understand if a patient is naive to treatment or has been exposed to anti-leprosy drugs already, it was felt that the focus on new cases and relapses only would "exclude" other retreatment cases from programmatic analysis. Additionally the definition of relapse was developed before recommending leprosy diagnosis to be made on clinical grounds. Therefore, the definition has been updated to be more in line with ground reality practices. The new case definitions, expected to be adopted by NLPs are listed below:

> A **case of leprosy** is a patient having one or more of the following:
>
> (1) Hypo-pigmented skin lesions with loss of sensation;
>
> (2) Impairment or involvement of the peripheral nerves as demonstrated by a) definite loss of sensation or b) weakness of hands/feet or face or c) autonomic function disorders such as anhidrosis (dry skin)
>
> (3) Presence of visible deformities
>
> (4) Signs of the disease with demonstrated presence of bacilli in skin smear or histopathological confirmation
>
> AND
>
> in need of leprosy treatment as decided by a clinician.

Among the leprosy cases, they can be further defined as below:

New case (of leprosy): a patient diagnosed with leprosy who has never been treated for the disease;

Retreatment case (of leprosy)**:** a patient diagnosed with leprosy who has already received treatment for the disease in the past. Retreatment cases shall be further classified into the following groups:

Retreatment after loss to follow-up: a patient diagnosed with leprosy who have abandoned treatment before its completion and return to the health facility to complete treatment beyond 3 months for pauci-bacillary (PB) cases and beyond 6 months for multi-bacillary (MB) cases;

Relapse: a patient who has completed a full treatment course for leprosy in the past and who returns with signs and symptoms of the disease that are not deemed due to a reaction according to the clinician;

Transferred in: a patient who has started treatment in one facility and reports to another facility to continue treatment;

Other retreatments: any leprosy case that does not fall in any of the above categories and requires treatment.

Both new and retreatment cases can be further classified in:

PB case: a case of leprosy with 1 to 5 skin lesions and without demonstrated presence of bacilli at a skin smear;

MB case: a case of leprosy with >5 skin lesions; or with nerve involvement (pure neuritis or any number of skin lesions and neuritis); or with demonstrated presence of bacilli in a slit skin smear irrespectively from the number of skin lesions.

3.1.2 Outcomes definitions

The outcomes assigned to patients after antibiotic treatment have been modified to better fit management field realities and to guide declassification of retreatment cases. National programmes are expected to adopt the new definitions and to modify their recording and reporting forms accordingly. The following outcomes are defined:

Treatment completed within standard duration: new patients who have been treated for leprosy with a full course of MDT (6 pulses within 9 months for PB cases or 12 pulses within 18 months for MB cases);

Lost to follow-up: patients who have interrupted treatment for a total of 3 or more months (if PB) or a total of 6 or more months (if MB). This was previously defined as “default” but it has been changed to “lost to follow-up” to use a non-derogatory language towards persons affected by leprosy;

Transferred out: patients diagnosed with leprosy who started treatment in one health facility that recorded them and then have been transferred to another health facility (as much as possible such patients shall be assigned a treatment outcome enquiring with the referral health facility);

Died: patients who have been diagnosed with leprosy and died due to any cause during the course of treatment;

Insufficient/unsatisfactory clinical response to treatment: patients who despite adequate treatment do no respond clinically;

Treatment completed beyond standard duration/Still on treatment beyond standard duration: patients who have been diagnosed and treated for leprosy with a full course of MDT (6 months for PB and 12 months for MB) for whom the clinician has decided that the treatment needs to be extended beyond the standard duration (due to adverse effects to MDT so they are following other/longer regimens or due to detection of resistance strain and had to follow a longer regimen).

3.2 Recording and reporting tools

In correlation with some modifications of the patient card and leprosy register to incorporate the updated case and outcomes definitions whose examples can be found in Annexes 1 and 2 respectively, this M&E Guide also introduces three additional registers. Information to be recorded into the registers in relation to disabilities, contact screening and drug resistance testing will be all part of the annual global data collection of WHO to NLPs starting in April 2017.

3.2.1 Disability register

The disability register provides space for registration of all leprosy affected persons detected with disability of any grade and the related services provided. This has been deemed important for ensuring a periodical assessment of the needs to facilitate service provision. The format of the disability register can be found in Annex 3.

3.2.2 Contact register

The contact register provides a record of the total number of contacts (defined according to national policies as household contacts only or also social contacts) of the leprosy cases registered in a given year and the outcomes of their screening. This register has been deemed important in light of the push of the Global Leprosy Strategy 2016–2020 on early detection, which is also based on active screening of high-risk groups starting from contacts. It might also be used to record pilot activities such as provision of chemoprophylaxis after screening and/or results of follow-up screenings for programmes that include active screening over time for contacts. An example of contact register can be found in Annex 4.

3.2.3 Register of the cases tested for drug resistance

Drug resistance testing has a relevant place in the Global Leprosy Strategy 2016–2020. Therefore the need of a register to record cases tested for drug resistance, the correspondent results and their clinical outcomes as seen in Annex 5.

3.3 Targets and monitoring indicators of the Global Leprosy Strategy 2016–2020

This M&E Guide includes a compendium of indicators to be constructed from well-established data source (patients' records, registers and reports) to monitor the implementation of the three-pillar Global Leprosy Strategy 2016–2020. They can be grouped under three categories – essential (mandatory), desirable (worth having) and useful (advantageous to have). At least annually, all 22 priority countries as defined in the Operational Manual should collect all the indicators listed.

- Each indicator in leprosy control is a summary measure that is designed to describe a particular aspect of the leprosy strategy (under its three pillars) and from the perspective of patient, health-care providers or programme management.
- Indicators in leprosy control listed below are expressed as an absolute number, rate or proportion. Some indicators are rule-based where the response is expected to be Yes /No. A rate or proportion is usually better than an absolute number for comparison.

- It is important to be very specific on what constitutes both the numerator and denominator and the source of information. The data source could be internal to the programme (patient record, register, supervision reports, evaluation reports, census) or external (from NGO centres, private practitioners, reports from associations of persons affected by leprosy). For each indicator, numerator, denominator and source of information have been specified.
- For all the indicators, a performance standard or threshold or target has been defined to help assessing the level of performance expected to define success/positive change. At what level the target should be set has been determined by the epidemiological knowledge on the variable of interest and insight into intervention efficacy. It could be a minimum or acceptable level (e.g. treatment completion of 85%) or routine 'better than before' (e.g. reduction in G2D by 5% compared with the previous year). The target could be descriptive (yes/no) or numerical (zero disability among new child cases).
- For each indicator, the frequency and level of measurement (health facility/district/region/province/country) has been defined.
- Actions are suggested in case the indicator does not meet desired standards, and cross reference for action to be taken is made to the operational guidelines to facilitate the implementation of the strategy.
- Most of the leprosy indicators listed look at results (outcome of activities) and therefore they are outcome indicators. However, from a management point of view, it is essential to also assess and periodically process output indicators that measure activities carried out against those scheduled or planned.

Below, Figure 2 includes all the monitoring indicators that could be used to monitor the Implementation of the Global Leprosy Strategy 2016–2020 at a glance. The first group of indicators listed are the targets of the strategy that are either impact or outcome indicators. The other indicators are listed under each correspondent pillar. The indicators under Pillar 2 are further subgrouped as indicators that reflect the quality of the case finding and indicators that express the quality of the case holding. Although an annex on monitoring indicators is included in the Operational Manual, this M&E Guide should be considered the reference document for leprosy programme monitoring since it has been developed through extensive consultation with relevant stakeholders.

Figure 2: Overview of the Global Leprosy Strategy 2016–2020 monitoring indicators

INDICATORS	
Target indicators	1. Number of children diagnosed with leprosy and visible deformities (G2D) 2. Rate of newly diagnosed leprosy patients with visible deformities (G2D) 3. Legislation allowing discrimination on basis of leprosy
Pillar I	• Availability of a costed national plan for leprosy (per se or integrated) • Number of subnational jurisdictions with a formal alliance between government programme and other stakeholders • Availability of web-based, case-based reporting system allowing disaggregation by age, sex, place of residence and other relevant criteria
Pillar II	**Case finding** • New case-detection (number and rate) • Prevalence (number and rate) • Proportion of G2D cases among total new cases detected • Proportion of child cases among total new cases detected (or child new case rate) • Proportion of female cases among total new cases detected • Proportion of foreign-born cases among total new cases detected • Proportion of MB cases among total new cases detected • Proportion of contacts screened **Case holding** • Number and proportion of retreatment cases over the total leprosy notified cases • MDT completion for PB • MDT completion for MB • Proportion of patients assessed for disability status at least both at beginning and at end of treatment • Proportion of patients who have developed new disabilities during the course of treatment • Number of cases with leprosy reactions during treatment • Proportion of new patients with disability (G1D and G2D) that have received self-care training • Proportion of leprosy drug-resistant cases among new and retreatment cases
Pillar III	• Number of formal alliances between association of persons affected by leprosy and the government leprosy programme • Existence of norms and/or regulations facilitating inclusion of persons affected by leprosy and their communities • Number subnational jurisdictions where persons affected by leprosy are involved in leprosy services • Availability of information on prevalence of social stigma and discrimination • Use by the programme of participation scale to assess the social participation of persons affected by leprosy

3.3.1 Description of Targets and Indicators

(a) Number of children diagnosed with leprosy and visible deformities (G2D)

Definition: Number of children (below 15 years of age) with newly diagnosed leprosy (never treated before) presenting with G2D at diagnosis reported during the reporting year.

Formula: Number

Target: Zero at the end of 2020

Source of information: Leprosy register

Reporting level: Every level

Frequency: Immediate/quarterly, annually

Importance: This is an impact indicator. It indicates quality of case detection, quality of leprosy care services and reflects awareness in the community. The target is set at the geographical (global, regional, national and subnational) and at the aggregation level (health facility and above). For those responsible for managing implementation, the range of success in achieving the target and its final realization should be a major impetus. Even though the target appears a bit ambitious, it is essential and relevant. A child with leprosy and related G2D indicates delay in case detection and continuous transmission of infection in the community. Countries that have already achieved this target could shift their focus to "zero children with leprosy".

Suggested action: The action to be taken is to start a critical incident investigation to find out causes that lead to delay in diagnosis and to investigate the household contacts and the wider community around the diagnosed child. A checklist to guide the critical incident investigation is found in Annex 6 of this guide.

(b) Number of children diagnosed with leprosy

Definition: Number of children (under 15 years of age) with newly diagnosed (never treated before) leprosy.

Formula: Number

Target: Zero by the end of 2020 in low-burden countries; desired threshold in high-burden countries is a reducing trend

Source of information: Patient record, leprosy register, progress report

Reporting level: Every level

Frequency: Immediate/quarterly/annually

Importance: Leprosy among children represents recent transmission. It also indicates efficacy of detection and diagnosis.

Factors affecting: It is important to ensure that variations in the number are not due to underreporting. Also overreporting is possible since leprosy diagnosis among children might prove difficult.

Suggested action in both settings if the number is above the threshold. Detection of a child with G2D due to leprosy or a child with leprosy in low-burden countries should trigger a **Critical Incident Investigation** (CII) (see Annex 9 for details including checklist). This approach is used to review the management of patients or health service delivery in an area when something goes wrong (a child with disability is identified) and the unit of analysis is the health facility covering the area where the child resides. Whenever a new child case is reported, relevant data are collected from the child's family, community and the health centre, on existing practices, data are analysed, areas for concern (with respect to the community and health-care providers) are identified, recommendations are made and actions taken for quality improvement. The focus is on the child patient, on the systems and processes, on measurement, on team work, on reconfiguration of programme management. There should be clear guidelines on who would do this (an individual or a team) with clear delineation of responsibility, data collection method, instruments, reporting form and dissemination.

Another action that could be resorted to is survey of contacts of household, social contacts and neighbouring households (peri-focal survey) around (radius of five households) of the new child cases for identifying hidden cases because child case reflects recent transmission. This can be done by enquiry with leprosy photo card (pictures of different manifestations of leprosy) or clinical screening of individuals. Focused IEC, advocacy through village health committees, training of the local staff are some of the measures that could be introduced.

(c) Rate of new leprosy cases with G2D

Definition: Number of new cases with G2D detected among the new cases (never treated before) in a defined population in a year expressed as rate per 1 million population.

Formula:

$$\frac{\text{Number of new cases detected with G2D}}{\text{Midyear population (reporting year)}} \text{ X 1 000 000}$$

Target: Less than 1 case with G2D per million population by the end of 2020

Source of information: Leprosy register

Reporting level: Every level (through patient records (peripheral level) or registers (intermediate level)

Frequency: Annually

Importance: This is an impact indicator. It reflects delay in diagnosis. It is applicable at global, national and subnational levels with more than 1 million population.

Factors affecting: Standardized criteria and guidelines are needed to get comparable data. Underreporting or overreporting of G2D should be verified on a regular basis. To avoid errors in disability grading, it is important to build the institutional capacity at a level higher than the health facility (district) through identification of skilled staff for disability assessment and other important tasks related to patient care. Disabilities not related to leprosy could lead to overreporting.

Definitions of disability:

@ 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 6 metres), lagophthalmos, iridocyclitits, corneal opacities

If history from a patient is not elicited properly, an individual who has been treated and cured may be wrongly diagnosed as a new case. This will increase the number of new cases with G2D reported. In a programme that resorts to active case-finding, the disability proportion could be low and when the majority of cases are detected through self-reporting, it may be high. It is often useful to look at disability proportion along with MB proportion. High proportion of disability and low MB proportion could mean there is wrong classification. Similarly low disability proportion and high MB could reflect wrong classification (PB as MB) or underreporting of disability while if the two indicators are concordant, meaning they are both high, it reflects consistent delay in diagnosis.

Suggested action if above the threshold: It can be reduced with efficient early case detection including focused case-detection campaigns or other enhanced case-detection efforts including screening of contacts and follow-up examination of contacts. Campaigns may result in initial increase in case detection including for cases with disabilities in the initial stage. There will, however, be progressive reduction in the number later. Other interventions could be focused IEC campaigns targeted at high-endemic areas, vulnerable groups and training of key staff. In underserved populations, it is important to collaborate with agencies already involved to identify local volunteers for suspecting and referral of cases and their treatment and follow-up, establish mobile services as part of integrated mobile outreach health service and introduce focused IEC activity on days when people congregate in one place (temple, mosque, church, market place, festivals, etc).

(d) Legislation allowing discrimination of persons affected and/or their family members on the basis of leprosy

Definition: Number of countries or subnational jurisdictions (district/state/province/region) where discriminations (prejudice based on disease) against persons affected by leprosy and/or their families is allowed legally on the basis of existing legislations, laws and officially accepted practices, procedures and policies

Formula: Number

Target: Zero

Source of information: National publications; gazettes; circulars; legislations; employment regulations; judgments on cases of discrimination.

Reporting level: District/region/country

Frequency: Annually

Importance: This is a rule-based indicator (procedure or practice, yes/no). It indicates level of discrimination in the community and disparities in access to opportunities faced by persons affected by leprosy. It also indirectly reflects the extent of political and legislative support for removing exclusionary practices (accountability of policy-makers and programme managers). Removing such discriminatory regulations from legal practice should be an integral part of good health governance. Absence of such legislation does not necessarily mean there is no discrimination in society. Legal provision may not eliminate social practices. Yet, it is one of the important steps to remove discrimination and facilitate access to services and diagnosis.

Factors influencing: Existence of such legislation may be due to lack of awareness, lack of policy responses, lack of advocacy, lack of information sharing between health and legal departments, and lack of partnership with associations of persons affected by leprosy.

Suggested action if above threshold: Redressal could be through establishing a task force whose responsibility is to collect discriminatory legislations and bring them under legislative and judiciary review for repeal. The task force should also advocate for introducing affirmative laws to facilitate social support and inclusion. Leprosy should become an integral chapter of human rights. There should be clear delineation of policy guidelines directed at health-care providers, the public and persons affected, and enhanced political commitment through advocacy and partnership with associations of persons affected by leprosy. In India, for example, there are several discriminatory laws against persons affected by leprosy. One of the oldest laws (The Lepers Act of 1898) was repealed only in May 2016. The Law commission of India in its report has asked the government to remove all the existing laws that promote discrimination against persons affected by leprosy. (For further information refer to Chapter 5.1 of the Operational Manual)

3.3.2 Monitoring indicators – Pillar I

The concepts of governance, coordination and partnership are the core of Pillar I. This necessitates appropriate leadership and funding, effective organizational structures and processes that are crucial and conducive to participation. The indicators listed facilitate in measuring progress in initiating collaborative approaches for improved management.

(a) Availability of a costed national plan for leprosy (or for NTD including leprosy or for TB and leprosy)

Definition: Existence of a funded national plan for leprosy per se or as part of a plan for communicable diseases (NTD/TB) aligned with the Global Leprosy Strategy 2016–2020 main components.

Formula: Yes/No

Threshold desired: Yes

Source of information: Administrative records at national level

Level of reporting: National level

Frequency: Depends upon duration of national plan. Annually to WHO

Importance: This is an output indicator, rule-based (yes/no). Efforts should be made to bring together government, international agencies, civil society and the private sector to develop a sound and operational plan for leprosy either per se or as part of developing a plan for other communicable diseases The plan should have a budget and should show contributions demonstrating governmental commitment towards leprosy control. The plan being a national plan should be developed according to the national context; however, it shall incorporate attention to the core areas of interventions as defined by the Global Leprosy Strategy 2016–2020. Contribution to the plan should be made by all stakeholders including persons affected by leprosy.

Factors influencing: It assumes that there is sufficient capacity and interest in developing a national plan tackling leprosy per se or within other communicable diseases.

Suggested action: At global and regional levels: sustain and support the development of national plans. At country level: establish a working group to assess weakness and define strategies to improve leprosy control. Calculate funds needed for the defined activities and seek contributions from all stakeholders. For more on suggested actions, see Operational Manual, Chapter 3.

(b) Number of subnational jurisdictions (district/state/province/region) with a formal alliance between government programme and other stakeholders

Definition: Existence of alliance (partnership, coalition, group...) between the NLP and other stakeholders including NGOs, private sectors, community-based organizations, private practitioners including traditional healers for key activities such as case detection, treatment and social support

(Alliance: a collaborative effort with a common objective where key stakeholders work together through formal or informal relationships to plan and implement leprosy-related services that prioritize local needs and pool resources. It is also helpful in furthering gender equity as a constituent element of quality leprosy care services)

Formula: Number of units with partnerships

The following checklist could be used at every major health administrative level to keep track of progress.

- NGO – Yes/No
- Other government programmes – Yes/No
- Private sector (corporate) – Yes/No
- Private informal sector/traditional healers – Yes/No
- Community-based organizations – Yes/No
- Private practitioners – Yes/No
- Organizations of persons affected by leprosy- Yes/No

At every level, the number of heath administrative units with such partnerships should be reported.

Threshold desired: Yes with all, increasing number of alliance over time

Source of information: Administrative records at each level

Level of reporting: District level and above

Frequency: Annually (through review)

Importance: This is an output indicator, rule-based (yes/no). Effort should be made to bring together government, international agencies, civil society and private sector into a formal, collaborative relationship dedicated to the pursuit of the goal of the Global leprosy Strategy 2016-2020. Collaboration and formal alliances may foster collective commitment, local ownership, build capital for strengthening programme implementation and mobilize support in operational aspects including outreach, advocacy and financing. They also provide an entry point to expand coverage especially in underserved areas. The steering role of authorities in the health system at national and subnational levels in this is worth overemphasizing.

Factors influencing: It assumes that there are guiding policy principles, and legislative and regulatory framework in definition and procedures in forming alliances in harmony with national priorities. It reflects capacity to initiate and sustain effective involvement with other partners at different levels. It can be at the local, national and global levels. It can be for governance (health committee, steering committee), managerial (financing and control in a small area) or operational (expand access). It can bring in benefits in the form of raising the profile of disease for advocacy, raising the level of programme response to existing challenges and facilitating coordination. The outcome for the programme will be improvement in service delivery – case detection, case holding, promoting efforts at social inclusion and research on innovative practices.

Suggested actions: At global and regional levels: sustain and enhance current partnerships at the global level; set up regional partnerships to provide support wherever needed especially in low-burden countries for various transnational services (training, research, laboratory); and research initiatives to demonstrate successful partnerships. At country level: establish policy and regulatory frameworks on a long-term basis; develop protocols for shared decision-making; mobilize resources and accountability; capacity-building of authorities in partnership efforts; create a common platform for exchange of information on successful partnership initiatives; engage civil society and associations of persons affected in partnership efforts; and establish linkages through a coalition or alliance with other programmes (TB/NTD/Communicable Diseases) for sharing expertise, resources and services. (For further information refer to Chapter 3.3 of the Operational Manual)

(c) Availability of web-based, case-based reporting system allowing disaggregation by age, sex, place of residence and other relevant criteria

Definition: Information system (data entry, analysis, report generation) where data from individual patients are captured and stored electronically through a specified software, and transmitted through communication network (internet portals) to share with multiple users quickly.

Formula: Yes/No

Desired Threshold: Full case-based electronic reporting system

Source of information: Administrative records at each level

Reporting level: District/region/province/national

Frequency: Annually (through review)

Importance: This is a rule-based indicator. Web-based reporting system leads to better quality of data, better data access, reduces workload resulting in better patient care, better programme management and better monitoring of trends. It brings together all relevant partners to ensure that users of information have access to reliable, useable, accurate, understandable and comparative data. It is also relevant to look at the proportion of reporting units moving from paper-based to electronic reporting.

Factors influencing: It presupposes institutional capacity in terms of availability of resources including policy framework, trained human resources, finances and new technology including network coverage.

Suggested action if below threshold: At the global and regional levels WHO supports strengthening of health information system; promote integrated system with NTDs and CDs; and train monitors. At the country level, the challenges should be addressed with appropriate policy guidelines with standard protocols, exploring the possibility of using resources available with other programmes and involving private sector for resources and expertise. (For further information refer to Chapter 3.5 of the Operational Manual)

(d) Other indicators

Additional to those three indicators that monitor the key areas of intervention under Pillar I, there are several other indicators that reflect how a programme is managed and coordinated. They are listed below to guide national and regional managers on how to look at administrative information so as to assess performance. The source for the collection of indicators below is often supervisory visit reports and other administrative records or studies' reports:

- Percentage of regions/districts/health facilities that have had at least one supervisory visit of all the regions/districts/health facilities (HF) in the reporting year
- Proportion of health facilities/districts/regions with no interruption (no stock-outs) in the drug supply in the reference period
- Proportion of HF/district/region with quality maintenance of records
- Availability of information on private providers' role in leprosy care (through surveys or research studies)
- Existence of a communication strategy plan with identified focal areas and annual budget

- Proportion of districts/regions with results-based plans for leprosy
- Proportion of policy documents including guidelines and plans of actions developed with the contribution of persons affected by leprosy
- Proportion of advocacy events on leprosy attended by senior government officials
- Proportion HF/districts/regions where guidelines and standards on leprosy patient management and programme are available
- Proportion of HF/districts/regions that have implemented all the planned activities in time
- Proportion of patients satisfied with care (patient reported process measure – services offered and outcome measure – disease status)
- Having a national plan indicating priorities for research

3.3.3 Monitoring indicators Pillar II

Under Pillar II, there are two groups of indicators. The first monitors the quality of case finding/leprosy diagnosis; the second, the quality of case management/case holding.

Group 1: Quality of case finding/leprosy diagnosis

Early diagnosis and treatment is key to bringing down the leprosy burden. The indicators help in measuring progress towards the envisioned goal in terms of the results achieved through implementation of various community-based and patient-centred activities. The following indicators measure quality of service in case detection. There are three dimensions – what is offered (technical), how it is offered (functional) and what is the result in terms of patient and population health status (outcome). Some can be generated from registers and patient records; some from administrative records including supervision records.

(a) New case detection

Definition: Number of new cases of leprosy (never treated before) detected in a given period.

Formula: Number of new cases

Threshold: The ultimate target is zero new cases. In the intermediate period, case detection should be monitored using a trend over time of a minimum of five consecutive years, and preferably 10 years or more. This indicator should be interpreted along with other indicators of quality of case finding such as G2D rate, G2D proportion and proportion of children among new cases.

Source of information: Leprosy register

Reporting level: All levels, by area

Frequency: Quarterly, annually

Importance: It is an outcome indicator and relates to magnitude of leprosy burden in an area. It is a reflection of the case finding efforts. Under unchanged programme conditions, it is expected to remain stable or show decline between years.

Factors influencing: Sudden increase in new cases could be due to active case detection or overreporting. Sudden decrease may be due to underreporting because of change in the intensity of activity or sudden change in the index of suspicion (lack of skills; retirement of skilled staff). Comparison with other areas with similar socioeconomic status and endemicity should give an insight into the reasons for the change.

Suggested action: Investigation into the reasons for the change and institution of appropriate measures such as focused case finding including campaigns wherever needed, training and strengthening of supervision are some of the possible measures that could be introduced.

(b) New case-detection rate

Definition: Number of new cases detected in a given population in a year expressed as rate/100 000

Formula:

$$\frac{\text{Number of new cases detected in (year)}}{\text{Midyear population (year)}} \text{ X } 100\,000$$

Threshold: Under consistent programme conditions, the new case detection rate is likely to remain stable and may even show decline. It is important in fact to look at age-specific rates to see it there is any shift over time (higher rates among old age groups shall be the norm in low-burden countries and would reflect reduced transmission of the disease). This indicator should be interpreted along with other indicators of quality of case finding such as G2D rate, G2D proportion, proportion of children among new cases and proportion of MB cases.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Annually

Importance: This is an outcome indicator. It is applicable at the country level and subnational level (above 100 000 population). It is the most important indicator reflecting the burden of leprosy in an area. It is used as a proxy for incidence rate because it is almost impossible to measure incidence rate directly. There is usually a gap between incidence and detection – detection can underestimate or overestimate incidence depending on the efficiency of case detection. In the absence of a scientifically valid estimate of the number of new cases occurring in a population in a year, there is no definite means of knowing when case detection approximates incidence. Information obtained from new cases on the duration of disease may give some idea about the extent of backlog cases among the so-called new cases. It is more significant than absolute numbers because it reflects more accurately burden and transmission.

Factors influencing: High transmission of leprosy may result in a higher new case detection. Often, reduction in the levels of transmission could be due to changes in the socioeconomic status of the population (endogenous change). A standardized definition of new cases of leprosy helps in comparability of the data. The epidemiological definition that is used for programme purpose is different from clinical definition. For instance, relapse cannot be considered a new case by epidemiological definition because the patient has been treated before. Or cases that have been treated before if reregistered for treatment as a new case. Errors in case classification may distort the indicator, especially if their number is significant. Making an accurate diagnosis of leprosy is important for both individuals and the programme. Capacity for correct diagnosis of leprosy depends on training status, index of suspicion in the context of endemicity, completeness in eliciting history and examination of the patient and supportive supervision. Often old cases (cases that have been treated before) are registered as new. This is likely to increase the number of new cases detected (see the box). Any of these or all may affect diagnostic efficiency resulting either in over- or underdiagnosis. It is important, therefore, to have a mechanism in place to validate periodically a sample of new cases for correctness in diagnosis.

Change of case detection from passive to active or vice-versa can also influence the indicator. Active case detection increases the number of new cases detected. It may pick up cases that are not reached by the routine system that depends on self-reporting or that otherwise would have self-healed. The number of cases detected is also influenced by the frequency of active detection. More frequent surveys may identify more cases. Subsequently the number would come down because there would be less backlog cases. Frequent surveys tend to pick up cases that otherwise would have self-healed. This is especially so with school surveys.

Coverage is a function of leprosy care service availability, accessibility and utilization. Availability of infrastructure (health facilities), accessibility (geographical, social and financial) and availability of skilled staff have both a direct and indirect effect on case detection. For the same reason, if active search is done in a previously noncovered area, one is likely to get an increase in the number of new cases. Also people may not be willing to utilize the service if quality of service provided is not up to expectation.

The first contact for a significant proportion of people is the ubiquitous private practitioner. Change from active case detection through active search to passive case detection by voluntary reporting, "innocuous" and painless patches or areas, stigma or social factors and other local factors are important areas. Even though there are no data on how many leprosy cases are managed by the private sector, it is clear that these cases are 'missed' by the programme because they are not reported. The number may increase if the programme succeeds in capturing this information.

In the Leprosy Elimination Monitoring (LEM) exercise carried out in India in 2004 under the sponsorship of WHO, recently detected new cases were validated by independent monitors in several States. Of the 1081 cases reported as new cases by the programme, 18.7% were old cases reregistered as new; of the 879 new cases, 9.4% were not cases; and 12.8% of the 793 new cases were wrongly categorized.

The level of community awareness about the disease and the programme can influence the number of cases detected. In endemic situations, the higher the awareness level, the greater is the likelihood of more number of cases getting detected.

It is essential to ensure that the correct source is used for the census and the correct procedure for estimation is used.

This indicator should be interpreted in association with indicators such as new child case-detection rate or child proportion among new cases that also reflects active transmission and G2D that indicates delay in diagnosis. If all the indicators are above the threshold, then there is a need to take measures to improve the quality of case detection.

Suggested action: Active case detection should be considered in areas with higher burden (significantly higher than national average), underserved population groups and contacts of leprosy cases. Incident investigation including screening of extended contacts of a new child case with or without disability is one of the most relevant actions that should be undertaken in both high- and low-burden settings. Awareness campaigns should be targeted at high-burden communities, general public and health-care workers at least once a year. It is relevant to ensure adequate infrastructure and human resource with task-oriented training; establish viable referral system with trained staff; establish linkages with hospitals, medical colleges; and involve general practitioners, association of persons affected and NGOs. It is necessary to put in place procedures to ensure that cases detected are real cases of leprosy. They include validation of a sample of new cases for overdiagnosis and a sample of a number of persons who might have leprosy for underdiagnosis. It should be clear who does this and when. Training, strengthened supervision, careful watch over the trend of disease and avoidance of targets and incentives for case detection are other measures that should be put in place. (For further information refer to Chapter 4.2 of the Operational Manual)

(c) Prevalence

Definition: Number of leprosy cases registered for treatment (at a point of time)

Formula: Number of new and retreatment cases on treatment at one point in time (usually at the end of the reporting year)

Threshold: Under stable programme conditions and with the treatment duration remaining unchanged, prevalence will remain stable or show a slow decline.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Annually

Importance: It is an outcome indicator. It reflects capacity to detect and manage cases indicating the leprosy burden. It is useful for programme management because it helps in calculating drug requirement. Conceptually prevalence is related to incidence by the following formula:

Prevalence = Incidence x average duration of disease

The prevalence that is measured in leprosy is the "registered prevalence", not the real prevalence. It measures the patients registered for treatment and therefore is a reflection of number of cases detected and of average duration of treatment. Registered prevalence refers to cases that are registered for treatment at one point in time.

Since it indicates leprosy burden at a point in time, it is usually lower than new case detection. In fact about 40% of new cases registered in a year are released by the end of the reporting year, the number of cases remaining will be less than the number of cases detected during the year. So when checking on the ratio of prevalent to new cases (P/D ratio), it should be less than 1.

(d) Prevalence rate

Definition: Total number of leprosy cases registered for treatment in a given population at one point in time (usually the end of the reporting year) divided by mid-year population and expressed as rate per 10 000 population.

Formula:

$$\frac{\text{Number of leprosy cases on register at one point in time} \atop \text{(usually at the end of the reporting year)}}{\text{Midyear population}} \times 10\,000$$

Threshold: Under stable programme conditions with unchanged treatment duration, it should show a stable or downward trend over time. It is important to relate it to case detection to look at threshold of operational efficiency.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Annually

Importance: It is an outcome indicator. It is applicable to the national and subnational levels within a population size of 10 000 or more. It refers to actual number of people who are in need of or receiving MDT (registered for treatment) at a point in time (usually at the end of the reporting year). It reflects the capacity of the programme to detect and manage cases until the end of treatment. This indicator has been used to define the target of elimination as public health problem i.e. prevalence rate below 1/10 000. All endemic countries have achieved elimination defined as for the elimination target and are expected to sustain the rate as part of meeting the goal of the Global Leprosy Strategy 2016–2020 of reducing the leprosy burden globally.

Factors influencing: Since prevalence rate is a function of new case detection and average duration of treatment, each can independently influence the indicator. It can increase either because the case detection has increased through change in mode of case detection, increased coverage, and/or because the average duration of treatment has increased. All the factors that affect case detection also affect prevalence rate. The prevalence rate can also change if there is a significant change of the total population. Assuming that incidence or new case detection has not changed significantly over time and the methods of case ascertainment were the same, any reduction in prevalence rate would be mainly due to reduction in the burden of disease. Further shortening of treatment duration would lead to a reduction of prevalence rate. The declining trend of prevalence seen in the last decade is attributable to a large extent to the shortening of duration of treatment. If the default rate or migration is high, then one can expect reduction in prevalence, and if more patients overstay in the register (longer treatment or not discharging after completion of treatment), then the prevalence will increase. Errors in the denominator can also influence the rate.

Table 3: *Example – effect of new case detection and duration of treatment on prevalence*

Trend of prevalence and new case detection in Bihar, India: 1990–1991 to 1995–1996						
	1990–1991	**1991–1992**	**1992–1993**	**1993–1994**	**1994–1995**	**1995–1996**
Prevalence	451 357	352 193	202 829	180 582	149 572	105 368
New case detection	31 481	34 376	86 281	62 992	48 004	55 993

Note: Bihar State in India had a very high prevalence mainly because of poor records management. In the years 1991–1992 and 1992–1993, the Government of India sent a team of experts (about 25) from outside the state to do validation and clean the registers. The team succeeded in removing a large number of cases that had overstayed in the register. At the same time, the team during the field visits also detected a large number of new cases never treated before. The result can be seen in 1992–1993 and 1993–1994 – reduction in prevalence by almost 100 000 cases and almost two-to-three-fold increase in new cases. The reduction in prevalence was significant but it was offset to some extent by the increase in new cases.

Source: Leprosy annual progress reports, Bihar, National Leprosy Eradication program (NLEP), India.

Suggested action: In the absence of rapid fluctuations in new case detection or of the population or of changes in treatment duration in the national guidelines, only the length of stay in the treatment register affects the prevalence rate. It is therefore important to control all factors that can reduce the cure rate. Patient counseling practice, flexibility in MDT delivery, good maintenance of leprosy register, guidelines and training of staff in cohort calculation and adequate stock of MDT are all important to ensure timely completion of treatment. (For further action refer to Chapter 4 of the Operational Manual.)

(e) Proportion of G2D cases among new cases detected

Definition: Percentage of new cases with G2D among the total new cases detected

Formula:

$$\frac{\text{Number of new cases detected with G2D}}{\text{Total number of new cases detected in the reporting period}} \text{ X } 100$$

Threshold: The G2D proportion varies between 1.8% in Federated States of Micronesia to 42.1% in Somalia (WER, 2016). The global average for this indicator is 6.7%. Generally figures above 5% are considered to reflect delayed case detection. Countries reporting less than 5% can work out the threshold based on country average. It is important to observe a declining trend.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: G2D reflects delay in diagnosis. The average indicator for an area may mask variations in the subgroup populations especially in high-burden countries with sizeable numbers to compare. It is therefore useful to look at disability proportion by area. It is also important to disaggregate G2D by age and sex.

Factors influencing: Standardized criteria are needed to get comparable data, in fact underreporting or overreporting can occur depending on completeness and correctness of both patient examination and data recording. It is important to know the proportion of new cases that are screened for disability. The denominator should only count those examined (ideally 100%). This is the most common reason of underestimating the G2D percentage. Only leprosy-related impairments should be graded, otherwise this indicator might be wrongly increased. Delay in diagnosis can be due to low awareness in the community and in the staff, accessibility and social issues (stigma). Re-registering of old cases could raise the number. Low disability proportion could be there in an area where active case detection (see under new case-detection rate) is practiced, or it could be due to underreporting of disability. It is often useful to look at disability proportion along with MB proportion. High proportion of disability and low MB proportion could mean over reporting of disabilities or wrong case classification (MB as PB). Similarly low disability proportion and high MB could reflect wrong classification (PB as MB) or underreporting of disability (see Table 4). If they are both high, it may represent poor quality of detection. This scenario, however, is also seen in very low-endemic situations (imported cases, low herd immunity and low awareness among communities and knowledge of leprosy among health-care workers).

Suggested action: First, ensure that disability assessment is done for all new cases and that a validation of sample of new cases is made to ensure quality of reported data. If delay in diagnosis is suggested by a high threshold training of the staff, case-detection campaigns, contact screening, school surveys and focused area-specific IEC are some of the measures that could be introduced to reduce G2D among new cases as described in correspondent session of the Operational Manual on case detection of leprosy. (For further action refer to Chapter 4 of the Operational Manual)

(f) Proportion of child cases among new cases detected

Definition: Percentage of children (less than 15 years of age) among the total new cases detected

Formula:

$$\frac{\text{Number of new child cases detected}}{\text{Total number of new cases detected in the reporting period}} \text{ X } 100$$

Target for low-burden countries: Zero

Threshold for high-burden countries: Global average is 8.9%. It varies from 0.8% in Niger to 38.1% in Comoros (WER, 2016). Desired is a reduction in trends aiming at 0% indicating zero leprosy transmission.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: It is an outcome indicator reflecting transmission of leprosy. It also indicates the capacity of the programme to identify the disease among children. It is also used to calculate MDT requirement for children. It should be interpreted in conjunction with other indicators such as MB and G2D proportion.

Factors influencing: Increase in the number may be due to low-quality diagnosis (overdiagnosis) or to delay in diagnosis and thus persistent transmission of the disease. Diagnosis of leprosy among children is not easy. The majority of child cases are PB, and eliciting sensory loss in skin lesion in a child is a challenge. There is also the possibility of overdiagnosis in children possibly due to limited skills.. The indicator is affected by the mode of case detection (see under new case-detection rate) and awareness levels in the community and in schools.

Suggested action: In low-burden countries, the detection of a child case should trigger a critical incident investigation. In high-burden settings, in the presence of a high proportion of cases among children especially with an increasing trend should prompt an analysis of the rate among children (since the proportion of children among the total population might be very high in some countries) and if the increasing trend is confirmed, promotion of all activities improving early case detection should be made as outlined in Chapter 4 of the Operational Manual.

(g) Proportion of female cases among new cases detected

Definition: Percentage of female cases among the total new cases (never treated before) detected

Formula:

$$\frac{\text{Number of new female leprosy cases detected}}{\text{Total number of new cases detected during the reporting period}} \text{ X } 100$$

Threshold: Desired at least equal to the global average, which is 38.8% (WER, 2016).

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: It is an outcome indicator. It indicates differential access in terms of the capacity of the programme to reach and the capacity of the female population to avail the services. It also reflects possible physiological differences in susceptibility to disease. It is important to find out variations in leprosy burden between population groups and also to understand whether the variation is due to a variety of social and economic processes such as differential access and opportunities.

Factors affecting: There is a large void in terms of our knowledge about gender gaps in leprosy. Programmes consistently report lower figures for female proportion. If one assumes exposure to be equal among males and females, then the proportion should be closer to 50%, however susceptibility might be different among adults of different sex. While the sex ratio for leprosy is almost equal (1:1) among children, it is about 2:1 among adults. It is not clear if this is due to physiological differences or to differential access to health care or to extended social life among men increasing the likelihood of infection compared with women. It could be low because of accessibility issues such as distance, cultural factors, health systems barriers such as lack of female staff in health services or due to underdiagnosis because of incomplete examination.

Suggested action: Gender perspective should be integrated into health policies, programmes and analysis. Increasing women's participation in defining health priorities, in planning and decision-making, in case-detection activities; targeted, culture sensitive IEC; involving local health committees in planning) may have an effect on the gender-induced gaps. Analysis of leprosy data using this specific indicator (female proportion and gender-specific new case detection rate), dissemination of information on gender at the national level for advocacy for more gender-sensitive policies are some of the essential measures that could be undertaken. There should be efforts at collaborating with programmes (maternal and child health) to widen access to leprosy care services.

(h) Proportion of foreign-born among total new cases detected

Definition: Percentage of foreign-born diagnosed as having leprosy and registered for right outline MDT among the total new cases detected during the reporting year

Formula:

$$\frac{\text{Number of new foreign-born cases detected}}{\text{Total number of new cases detected in the reporting period}} \text{ X } 100$$

Threshold: Within decreased local transmission and reducing burden, cases of leprosy attributable to patients coming from countries with high endemicity are expected to rise over time. Increasing trend is therefore expected.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: Indicates the magnitude of leprosy local transmission in a given area (global, national, state, province, district, village, urban area or health centre). It also reflects the accessibility to leprosy services for foreign-born and indirectly informs about quality of services provided to them as a vulnerable group.

Factors influencing: High proportion could be due to reduced local transmission of leprosy or to significant migration from high-burden countries. Low proportion suggests unchanged epidemiological conditions/leprosy burden or lack of access to care by foreign-born patients might artificially reduce the proportion.

Suggested action: High proportion could be addressed through validation of sample of cases to exclude wrong reporting. It becomes relevant in low-endemic situations to ensure prompt care to foreign-born patients to reduce transmission within also the local communities and in line with the attainment of the Sustainable Development Goals.

(i) Proportion of MB cases among total new cases detected

Definition: The percentage of MB cases among the total new cases detected.

Formula:

$$\frac{\text{Number of new MB cases detected}}{\text{Total number of new cases detected in the reporting period}} \text{ X } 100$$

Threshold: Global average was 60.2% (varies between 94.8% in Senegal to 27.8% in Kiribati, WER, 2016). There is not enough evidence to set a threshold for this indicator. The indicator should always be looked at in conjunction with indicators such as proportion of G2D among tnew cases, and proportion of child cases among the new. In programmes where case detection is effective and timely, there should be an increasing trend of cases diagnosed when they are still PB. In low endemic countries the last few cases detected will all be MB since they tend to have a longer incubation period.

Source of information: Leprosy patient record, leprosy register, leprosy progress reports at different levels

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: It is an outcome indicator reflecting quality of case detection since a higher proportion of MB cases among the new reflects delay in diagnosis leading to higher transmission. It is important to look at this indicator by age and sex to find variations that should compel focused interventions. The indicator also helps in calculating MDT requirement.

Factors influencing: The definition of MB has changed many times in the last three decades. Every change in the definition – from clinical through bacteriologically positive to number of skin lesions (more than 5) – has had an effect on this indicator. The proportion of MB has increased partly because of the extended definition of MB. This makes it difficult to study the epidemiological trend of leprosy using this indicator only. Under unchanged epidemiological conditions and operational definitions, the factor that can have significant influence on the proportion is the knowledge of leprosy among health-care workers, accessibility of health services and awareness about leprosy from the communities.

The high proportion could be due to overdiagnosis (wrong classification), expansion of coverage (case detection in a new previously noncovered area), and lack of awareness among people and staff. A high proportion of MB among new cases detected in a low-endemic situation could be due to immigrant cases that might have difficulties in accessing care. A low proportion could be due to active case detection or to underdiagnosis (misclassification). A small percentage of leprosy cases can be identified only through bacteriological examination. If there is no facility for skin smear examination, some of these cases may be missed.

Suggested action: A high or low proportion could be addressed through validation of the records related to a sample of cases to exclude wrong reporting. A high proportion paired with high proportion of other indicators indicating delay in diagnosis shall prompt training of health care workers, IEC campaigns and ensuring good coverage of diagnostic services including referral center with availability of smear examination facility to allow proper evaluation of doubtful cases.

(j) Proportion of contacts screened

Definition: Percentage of contacts of index cases screened among those registered as contacts (a contact in leprosy usually means a household contact defined as any person living under a common roof and sharing food from the same kitchen for at least six months). The definition could be extended to include social contacts, including neighbors; especially in countries with a low burden, a wider definition is encouraged; however, it should be done keeping ethical implications in mind considering the high level of stigma and the right of patients to confidentiality. Contact examination should only be done with informed consent of the index case.

Formula:

$$\frac{\text{Number of contacts screened for leprosy}}{\text{Total number of contacts registered in the reporting year}} \text{ X } 100$$

Threshold: 85%, increasing trend

Source of information: Contact register

Level of reporting: All levels

Frequency: Quarterly, annually

Importance: This is an output indicator. It indicates the intensity of efforts at case detection and therefore quality of case detection. Since contacts are more at risk of developing the disease than non-contacts, the current strategy recommends the listing of all household contacts of primary cases of leprosy, their screening for leprosy shall be done promptly either at a residence (active) or at a health facility (passive). The number of cases arising from this high risk population (contacts) should be reported and such information will be part of the global WHO report starting in 2017. For low-burden countries, since contacts represent the only known high-risk groups for leprosy, annual follow-up screening of contacts for five years is suggested. The proportion of contacts screened annually during the follow-up can also be monitored in these countries. It should be possible to analyse the indicator by sex to assess the capacity of the programme to provide equity in access. Some countries might decide to use a wider definition of contacts to include also social contacts. For such countries, a lower threshold might be acceptable. Changes in contact definitions/criteria must be noted to be able to interpret variations of this indicator over time.

Factors affecting: Factors such as lack of standardized definition of contact, completeness and correctness in reporting, relative importance given in the programme to contact screening, supervisory support, all can have an effect on the indicator.

Suggested action: Regular review of this activity, supportive supervision and feedback, clear guidelines on contact screening are important to ensure the implementation of this activity. (For further information refer to Chapter 4.2 of the Operational Manual.)

In summary, it is recommended to interpret the indicators under Pillar II – quality of case finding – not as single indicator but comparing multiple indicators. For example, see Table 4 comparing results for new case-detection rate, proportion of MB, proportion of child cases and proportion of G2D cases in a country against expected thresholds.

Table 4: *Interpretation of more than one indicator of quality of case detection/leprosy diagnosis*

NCDR	G2D %	MB %	Child %	Possible reasons	Actions to be taken
High	Low	Low	High	Active case-detection activities including school surveys	Validation check of sample of cases, observe trends over time
High	High	High	High	Case detection in a previously uncovered area, high-burden, low quality of case finding	Keep a watch on the trend, assess quality of diagnosis through supervision, ensure completeness of contact screening, provide training
High	High	Low	High	Wrong classification (MB misdiagnosed as PB) Low quality of case finding	Validation check of sample of cases; Training
High	Low	High	High	Underreporting of disability	Validation check of sample of cases; Training
Low	High	High	Low	Low-endemic situation generating delay in diagnosis due to low awareness and limited training	Focused case detection among high-risk group; Focused IEC Training
Low	Low	High	High	Low quality of case finding Wrong classification of disability	Focused case detection; Focused IEC; Validation of reporting through supervision and through reviewing a sample of cases; Training on disability assessment

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini, GLP

Group 2: Quality of case management/case holding

The listed indicators reflect the quality of case holding: patients' management after diagnosis and start of treatment. As reflected in the Operational Manual, care does not stop at the moment of leprosy diagnosis and provision of MDT since leprosy might still progress through reactions and because patients with disabilities might require lifelong care.

(a) Number of retreatment cases (including relapses)

Definition: Total number of retreatment cases registered over a period (a quarter or a year). They include retreatment after loss to follow-up, transferred-in cases, relapses and other retreatments.

Formula: Number of retreatment cases

Threshold: Stable or decreasing trend

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an outcome indicator. The number of retreatment cases occurring after adequate treatment is usually small. But it is important to monitor since it reflects the capacity of provision of a full course of treatment, which thus correlates with the quality of case holding. The indicator should be viewed in conjunction with case-detection rate and treatment completion rate to find out the relationship with low-quality detection and diagnosis and poor case holding.

Factors influencing: A rising number of retreatment cases could indicate improvement in reporting or it could be due to drug resistance. A low number of retreatment cases could be due to underreporting also due to lack of standardized definitions and or due to lack of infrastructure and resources to investigate suspected relapses. It may sometimes be difficult to distinguish relapse from reaction (another event than can occur post-completion of treatment) without valid diagnostic support, that is why there are several challenges in getting correct information on the indicator. Some of the relapses might be re-infection; it is at that moment not possible to differentiate between the two.

Suggested action: Improvement in the diagnosis of relapse through increased accessibility of referral centres, improved supervision for identifying and correcting reporting mistakes, improved case holding through better follow-up, use of Accompanied MDT (A-MDT) are some of the interventions that should be considered.

(b) Proportion of retreatment cases (including relapses) over the total leprosy notified cases

Definition: Percentage of retreatment cases. They include retreatment after loss to follow up, retreatment after transfer-in, relapses and other retreatment.

Formula:

$$\frac{\text{Number of retreatment cases}}{\text{Total Number of leprosy cases registered (new and retreatment)}} \times 100$$

Threshold: Stable or decreasing trend.

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an outcome indicator. The percentage of retreatment occurring after adequate treatment is usually small. But it is important to monitor since it reflects the capacity of provision of a full course of treatment; therefore it correlates with the quality of case holding. The indicator should be viewed in conjunction with case-detection rate and treatment completion rate to find out the relationship with low-quality detection and diagnosis and poor case holding.

Factors influencing: A rising proportion of retreatment cases could indicate improvement in reporting or it could be due to drug resistance. Underreporting might also occur due to lack of standardized definition as well as poor history taking from patients. Lack of infrastructure and resources to investigate suspected relapses, can also influence this indicator since it may often be difficult to distinguish relapse from reaction (another event than can occur post-completion of treatment) without valid diagnostic support. Some of the relapses might be re-infection; it is at that moment not possible to differentiate between the two.

Suggested action: Improvement in the diagnosis of relapse, accessibility of referral centres, improved supervision for identifying and correcting reporting mistakes, improved case holding through better follow-up and use of A-MDT are some of the interventions that should be considered.

(c) MDT completion for PB within standard duration of treatment

Definition: Percentage of PB leprosy cases who have completed treatment timely among the total cases registered for treatment in a cohort. A standard duration of treatment for PB leprosy is a treatment which is completed within 9 months from the start of treatment.

Formula:

$$\frac{\text{Number of new PB patients who have completed treatment timely among an annual cohort of cases}}{\text{Total number of new PB patients registered for treatment in the same cohort}} \text{ X } 100$$

Cohort of PB patients is defined as patients having started PB MDT at least 12 months before the reporting year.

Example: For the reporting year 2015 (1January–31 December), the PB cohort is 2014 (1 January–31 December). If the total number in the cohort is 100 and 75 have taken 6 pulses in 6 months, 10 have defaulted, 2 have died, 5 have migrated and 8 have continued treatment beyond standard duration (within 9 months). (PB) completion is 75% (75/100), default is 10%, died is 2%, migrated is 5% and continued beyond is 8%.

PB patients are sometimes reclassified as MB following observation during treatment due to appearance of new patches during treatment; the reclassification is their end-point as PB patients and their outcome shall be insufficient/unsatisfactory clinical response to treatment. This represents a "progression of the disease" despite treatment and since treatment completion is defined as a proxy of cure they should NOT be included among the patients who completed treatment. If the reclassification is due to a wrong classification at the beginning of the treatment, the patient should be erased from the PB cohort and examined/reported under the MB cohort two years after treatment.

Note: if A-MDT is used, the date of completion of treatment should be the date on which the patient is expected to complete the treatment.

Threshold: 85%, increasing trend desirable

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: It is an outcome indicator. This along with a cure rate for MB is the most important indicator informing on quality of case holding. Every patient that is given MDT treatment should complete the treatment on time. Incomplete treatment may have adverse consequence to the patients and sustain transmission in the community. With the flexibility in delivering MDT to patients (such as accompanied A-MDT or Directly Observed Treatment (DOT) for selected patients), obtaining a high completion rate should not be a serious challenge. For getting valid information, numerator and denominator data are required at every level.

Factors influencing: There could be mistakes in reporting which could lead to under- or overestimation. If a large number of patients do not complete treatment on time due to being seasonal migrants or due to irregular employment, the proportion of patients that completed treatment is likely to be lower. Stigma – fear of being 'found out' – is also a major factor in treatment adherence. Also lack of access to MDT and/or flexibility of health services with facilitating treatment for children in school or adults with a job are likely to impact on this indicator. With lack of proper counseling, the treatment completion would be lower. If A-MDT is used, the date of release for treatment (RFT) should be the date on which the patient is expected to complete the prescribed number of pulse doses. Otherwise, it may artificially raise the treatment completion.

Suggested action: Flexibility in MDT delivery, patient counseling, quality maintenance of records and registers, adequate stock of MDT, all measures that improve treatment adherence including A-MDT and DOT for selected patients (children, low compliance patients, others).

(d) MDT completion for MB within standard duration of treatment

Definition: Percentage of new MB patients that have completed treatment timely. A standard duration of treatment for MB leprosy is a treatment which is completed within 18 months from the start of treatment.

Formula:

$$\frac{\text{Number of new MB patients who have completed treatment timely among an annual cohort}}{\text{Total Number of new MB patients in the same cohort in the same cohort}} \text{ X 100}$$

Cohort of MB patients is defined as patients having started MB MDT at least 24 months before the reporting year.

Example: for the reporting year 2015 (1 January–31 December), the new MB cohort is 2013 (1 January–31 December). The total number in the cohort is 100 and 75 have taken 12 pulses in 12 months, 10 have been lost to follow up, 2 have died, 5 have been transferred out to another facility and 8 have continued treatment beyond standard duration (within 18 months). Treatment completion within standard duration is 75% (75/100), lost to follow up is 10%, died is 2%, transferred out is 5%, still on treatment/completed treatment beyond standard duration is 8%.

Threshold: 85%, increasing trend desirable

Source of information: Leprosy register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: It is an outcome indicator. This, along with completion rate for PB, is the most important indicator informing on quality of case holding. Every patient who is given MDT treatment should complete the treatment on time. Incomplete treatment may have adverse consequence to the patients and sustain transmission in the community. With the flexibility in delivering MDT to patients (such as A-MDT or DOT for selected patients), obtaining a high completion rate should not be a serious challenge. For getting valid information numerator and denominator, data are required at every level.

Factors influencing: There could be mistakes in reporting which could lead to both under- or overestimation. If a large number of patients do not complete treatment on time due to being seasonal migrants or due to irregular employment the proportion of patients that completed treatment is likely to lower. Stigma – fear of being ‘found out’ – is also a major factor in treatment adherence; Also lack of access to MDT and/or flexibility of health services with facilitating treatment for children in school or adults with a job are likely to impact on this indicator. With lack of proper counseling, the treatment completion would be lower. If A-MDT is used, the date of treatment completion should be the date on which the patient is expected to complete the treatment, otherwise it may artificially raise the treatment completion.

Suggested action: Flexibility in MDT delivery, patient counseling, quality maintenance of records and registers, adequate stock of MDT, good patient follow-up are all measures that improve treatment completion. DOT for selected patients (children, low compliance patients, others). (For further information refer to Chapter 4.3 of the Operational Manual)

(e) Proportion of patients assessed for disability status at least both at beginning and at end of treatment

Definition: Percentage of persons with leprosy who are assessed for the presence of disability as per the WHO grading scale and graded either 1 or 2 both at the time of diagnosis and at the end of the treatment among the new cases detected during the reporting year.

Formula:

$$\frac{\text{Number of new cases assessed for disability at the time of diagnosis and at the time of treatment completion}}{\text{Number of new cases detected during the reporting year}} \text{ X } 100$$

Threshold: >85%, increasing trend

Source of information: Leprosy patient record

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an output indicator. It is important to ensure that all new cases are adequately followed during treatment. It reflects quality of case holding meaning patient management.

Factors affecting: Lack of clarity in understanding of the definition and criteria due to lack of training, wrong reporting can affect the indicator.

Suggested action: If the percentage is less than 85%, investigation as to the reasons and introduction of remedial measures including supportive guidance and training with case demonstration may be done. Programmes should make sure that guidelines are available at each point of patient care. A focal person could be identified for checking the quality of disability assessment could be identified. This health care worker could be at the referral centre or attached to the district administrative unit. She/he should be able to visit the peripheral health facilities on designated days to provide the additional patient care services needed including assessment for disability. (For further information refer to Chapter 4.4 of the Operational Manual)

(f) Proportion of patients who have developed new disabilities during the course of treatment

Definition: Percentage of patients under treatment developing new disabilities during the course of treatment measured as a change in the EHF score (= total disability score for both eyes, both hands and feet) between examination findings at the time of diagnosis and at the completion of treatment/ or when the patient received the last dose of treatment within the annual cohort of patients. It ha to be calculated among PB and among MB cases separately.

Formula:

$$\frac{\text{Number of patients under treatment developing new disability among an annual cohort of patients}}{\text{Total number of cases in the same cohort who completed treatment}} \text{ X } 100$$

Calculation: Calculation is made using the cohort approach as for treatment completion. For example, for the reporting year 2015, the MB cohort is cases registered in 2013. If 5 cases developed a new disability (based on change in EHF score) out of the 75 that completed treatment, the proportion is 6.6% (5/75 x 100). For PB, the cohort for the reporting year 2015 is cases registered in 2014. The denominator is cases completing treatment (75). If 1 PB case has developed disability from the treatment completed cohort, then the proportion is 1.3% (1/75 x 100).

Threshold: 1%. Desired declining trend over time.

Source of information: Leprosy register, leprosy disability register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an outcome indicator. It reflects the quality of care (case holding) provided to patients during the period of MDT treatment. High proportion could mean lack of follow-up of patients and in adequate management of reactions.

There should be at least two assessments for all cases – one at the time of diagnosis and the other at the end of treatment for this indicator to be calculated. This indicator needs to be looked at in conjunction with treatment completion.

Factors affecting: Errors in recoding and reporting can affect this indicator. Lack of disability assessment at the time of diagnosis or at the end of treatment can influence the indicator. Insufficient health education and low adherence to treatment also can influence this indicator. Low proportion could mean efficient patient management or underdiagnosis/ underreporting.

Suggested action: Programmes should make sure that periodic disability assessment is done and the health-care providers are trained in disability assessment and recording. Steroids should be available at all points where patients with reaction are managed. Some of the intervention measures could include random validity checks during supervision visits, patient counseling (someone in the facility should be given the responsibility – i.e. a person affected by leprosy is an excellent choice for this), availability of guidelines and anti-reaction drugs and a nodal person in the district identified for specific patient care activities including disability assessment and treatment of reactions.

(g) Number of cases with leprosy reactions during treatment

Definition: Number of cases identified with leprosy reaction, type 1 or 2 with or without neuritis, any time in the course of leprosy treatment. It can be related to the number of total cases detected as a percentage or total number of cases treated as a percentage. It is the number of individuals not episodes that is considered.

Leprosy reaction: Acute inflammatory episode manifesting with the skin lesions becoming erythematous, increasing in number or size. Or there could be erythematous, evanescent nodules, painful and tender with or without systemic symptoms such as fever. There may be associated nerve thickening and tenderness (neuritis) with or without sensory and motor nerve dysfunction.

Formula: Number

Threshold: It is difficult to know what percentage of the cases treated in a year may have reactions. It is on average 10–30% depending on the population. But then, it is prudent to get the threshold by studying the reported number in a good programme setting.

Source of information: Leprosy patient card

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an output indicator. It is also useful to calculate the requirement of steroids. It reflects quality in patient records and proper identification of a reaction. Reaction is an emergency. If not managed adequately, the patient may develop a disability. It is good to correlate the number of reactions with the number of relapses reported.

Factors affecting: There could be underreporting or an overreporting of the number due to lack of completeness of records. Often patients may think that reaction is not related to the disease and may therefore seek treatment elsewhere or may not report it when seen at follow-up visits. Or patients may be referred to referral centres and data may not be captured. It may be high because of efficiency in identification or due to wrong diagnosis. If very low, it may indicate underdiagnosis (some of the reactions are wrongly diagnosed as relapses).

Suggested action: Good counseling of patients so they report when a reaction occurs, training of health care workers on identification of reaction, establishing a referral system in each district/region, validation during supervision visits with case demonstration is important to ensure that all cases of reaction are identified early and adequately managed so that there is no adverse consequence to the patient (disability). Validation checks of records, training on recording and reporting should be thought of. (For further information refer to Chapter 4.4 of the Operational Manual)

(h) Proportion of patients with disabilities that have received self-care training

Definition: Percentage of new patients with disabilities (grade 1 and 2) in self-care that have received self-care training among the total registered for treatment in a cohort

Self-care is self-help carried out by persons affected to deal with their disease/disability physically and emotionally so that they develop the capacity to take control of their own life. Only patients with leprosy-related disability shall be counted for calculating this indicator.

Formula:

$$\frac{\text{Number of patients with G1D and G2D trained on self-care}}{\begin{array}{c}\text{Number of patients with G1D and G2D leprosy-related disabilities}\\ \text{identified in the reporting year}\end{array}} \text{ X } 100$$

Threshold: 100%. Increasing trend, desirable, if below the threshold

Source of information: disability register

Level of reporting: All levels

Frequency: Quarterly and annually

Importance: This is an output indicator. Patient care does not end with prescribing MDT. Persons affected by leprosy with disabilities need to be trained to take care of themselves some time for a lifetime. Individuals may receive support either individually or in groups. The indicator measures the intensity of participation of the health-care services in rehabilitation and prevention of further disabilities.

Factors affecting: Availability of human resources, their capacity for the intervention, level and intensity of partnership with associations of persons affected, NGO centres and the social welfare department are some of the determinants that can influence the indicator.

Suggested action: Identification of a person or team responsible for this activity, integration with NTD, developing partnership with association of persons affected and NGOs and department of social welfare are some of the interventions that could be considered. In addition, provision should be made for supply of aids and appliances to patients who are in need of them. The health-care person involved in training for self-care support should be trained in counseling. It is important to involve the persons' affected family and village committee in supporting the patients. It is important to identify a reconstructive surgery service centre where persons with a disability can undergo corrective surgery. See Operational Manual Pillars II and III suggested activities.

(i) Proportion of leprosy drug-resistant cases among retreatment cases

Definition: Percentage of retreatment cases with drug resistance among those retreatment cases that have been tested

Formula:

$$\frac{\text{Number of retreatment cases with drug resistance}}{\text{Number of retreatment cases tested for drug resistance}} \text{ X } 100$$

Threshold: Stable or declining trend

Source of information: Drug-resistance register

Level of reporting: Regional or national or external reference laboratory

Frequency: Annually

Importance: It is an outcome indicator. This indicator reflects quality of care and must be assessed together with PB and MB completion. It is important to keep a watch on the trend of drug resistance even though the number of reported cases of drug resistance is small. It is also important to scale up surveillance for drug resistance; otherwise this indicator is not meaningful. All retreatments and a proportion of new cases should be tested for resistance in the reference laboratory either within the country or abroad.

Factors affecting: The challenge is to identify and record all retreatment cases and ensure that they are tested for drug resistance. This indicator is largely influenced by the total number of cases tested.

Suggested action: Countries should have centres that refer all the retreatment cases for sample collection and ensure that samples are sent to a national or reference laboratory for testing. Training of staff at least in all referral centres should be undertaken and guidelines on definitions and procedures for investigating retreatments should be made available in the referral centres. (See Chapter 4 of the Operational Manual, Pillar II.)

(j) Proportion of leprosy drug-resistant cases among new cases

Definition: Percentage of new cases with drug resistance among the total new leprosy cases tested

Formula: *Number/proportion*

$$\frac{\text{Number of new cases with drug resistance}}{\text{Number of new cases tested for drug resistance}} \times 100$$

Threshold: Stable or declining trend

Source of information: Drug resistance register

Level of reporting: National or from external reference laboratory

Frequency: Annually

Importance: It is an outcome indicator. This indicator reflects quality of care and shall be assessed together with PB and MB completion.

It is important to keep a watch on the trend of drug resistance even though the number of reported cases of drug resistance is small. It is also important to scale up surveillance for drug resistance; otherwise this indicator is not meaningful. All retreatment and a proportion of new cases should be tested for resistance in the reference laboratory either within the country or abroad.

Factors affecting: The challenge is to collect samples from an adequate number of new cases to allow proper surveillance of resistance. Having access to drug resistance surveillance is not enough if it is not used.

Suggested action: Countries should have sentinel surveillance centres that can investigate new cases. There should be training of staff at least in referral centres and guidelines on definitions, and procedures for testing new cases should be made available in the referral centres.

3.3.4 Monitoring indicators Pillar III

(a) Having a formal alliance between associations of persons affected by leprosy and the NLP

Definition: Existence of partnership with associations of persons affected by leprosy

Formula: Partnership with associations of persons affected = Yes/No. It reflects the existence at least at the national level of a formal alliance with association of persons affected by leprosy. For big, endemic countries, it can also be calculated as percentage of states/provinces/regions where alliance exists with association of persons affected as part of a national policy framework and guidelines.

Threshold: Yes. Desired trend: alliances in all subnational jurisdictions in high-burden countries

Source of data: Government notification/legal notification/leprosy progress reports

Level of reporting: District/region/nation

Frequency: Annually

Importance: This is an output indicator, rule-based (yes/no). The indicator reflects patient-centred programme orientation (responsive to the aspirations and needs of the persons affected).

Such partnerships are important because they promote inclusivity and have the change potential; they help in generating political support, promoting demands for quality service, and help in responding to special needs of people. It helps build convergence between the needs of persons affected and the interests and priorities of the programme. It indicates a shift in emphasis on persons affected by leprosy from passive recipients to active participants. The alliance should not be 'loose'. It should be based on mutual respect for the autonomy of the partnership.

Factors influencing: Presence of policies and regulatory frameworks to allow generation of partnerships. The non-availability of associations of persons affected may affect the indicator.

Suggested action: There should be policy and regulatory framework as part of common guidelines for forming alliances; health-care staff and social workers should be trained to develop the capacity for forming partnerships; association of persons affected by leprosy should be regarded as the major stakeholder; promotion of collaboration persons affected by leprosy and the NLPs is important to increase the demand for quality in leprosy care services and raising advocacy issues with authorities. (For further information refer to Chapter 3 of the Operational Manual)

(b) Existence of norms and/or regulations facilitating inclusion of persons affected by leprosy and their communities

Definition: At the national level at least, there should be supportive laws and policies for facilitating inclusion of persons affected by leprosy per se or as part of persons with disabilities

Formula: Yes/No

Threshold: Yes

Source of data: Government notification, gazette, legal notifications

Level of reporting: Region/country

Frequency: Annually

Importance: This is an output indicator, rules-based (yes/no). It assesses destigmatizing initiatives that go one step further than removing archaic laws that promote discrimination. It indicates commitment to addressing the societal challenges faced by persons affected. Norms and regulations should be able to create an enabling environment for people affected by leprosy that facilitates access to social and livelihood support and work through policy guidelines on how to promote community-based rehabilitation for them and through a regulatory framework for opening up access to job opportunities. Existence of supportive laws does not mean that there is change in the perception and attitude towards persons affected. Combating stigma and social exclusion should be thought of as both legal rights and moral rights issues. Even if there are laws promoting social inclusion, equity cannot be guaranteed without a supportive social framework.

Factors affecting: The presence of commitment towards removing the social consequences of leprosy might generate the definition of regulatory frameworks and policy documents such as national guidelines and policies for inclusion of leprosy-affected persons within ministries.

Suggested action: This needs the support of legislative frameworks and policies on a long-term basis; introduction of equity perspective into policies, programmes and analysis; and partnerships with NGOs and associations of persons affected by leprosy who can provide support in promoting enforcing laws. (For further information refer to Chapter 5 of the Operational Manual)

(c) Involvement of persons affected by leprosy in leprosy services

Definition: Extent of involvement of persons affected by leprosy in leprosy services.

Formula: Yes/No. For high-endemic countries, they could have a percentage of subnational jurisdictions where persons affected by leprosy have a role in leprosy services

Threshold: Yes. Desirable trend, up to 100% of subnational jurisdictions

Source of data: Leprosy progress report/report from Association of persons affected/NGOs

Level of reporting: Country/region

Frequency: Annually

Importance: This is an output indicator, rules-based (yes/no). The prerequisite for this is the level and intensity of relationship between the programme providers and association of persons affected. They may participate in health governance (health committees) or health system input level. The latter leads possibly to identification, training and involvement of persons affected in certain patient-related activities such as counseling, treatment, case identification and referral, self-care support, advocacy, etc. This indicates willingness and commitment to empowering persons affected. In view of the vital importance in the process of participation, it is important to encourage their involvement because they can bring a depth of expertise to the programme. This contributes to patient-centred approach.

Factors influencing: The driving principle for this is centred on the concept of equity. Lack of capacity, lack of willingness on the part of health-care providers to involve, lack of regulatory support, lack of empowered individuals or associations of persons affected by leprosy, stigma limiting their will to contribute, can affect the indicator.

Suggested action: It is necessary to produce training and other materials to facilitate implementation of the global "guidelines on involvement of people affected by leprosy in service delivery". Measures to improve include policy framework at the national level with allocation of budget and regulatory guidelines for involving persons affected, training programme for building the capacity of health-care providers, training programme for building the capacity of persons affected who have been identified to provide a service, partnerships with association of persons affected and NGOs, facilitating operational research to demonstrate best practices, and creating a platform for sharing of information on best practices. (For further information refer to Chapter 5 of the Operational Manual)

(d) Availability of information on prevalence of social stigma and discrimination

Definition: Having information on the extent of negative attitudes and discriminatory practices directed at persons affected by leprosy obtained through a survey, research studies carried out in the recent past (up to five years)

Formula: Yes/No

Threshold: Yes

Source of information: Survey and/or research initiative

Level of reporting: National/Subnational

Frequency: Annually

Importance: This is an output indicator, rule-based (yes/no). Programmes have an obligation to promote health and human rights. It is therefore important to measure the prevalence of prejudicial attitudes and discriminatory behaviours towards persons affected by leprosy to provide evidence for advocacy in collaboration with partners and define and prioritize action likely to reduce stigma and discrimination. Conducting periodic surveys would allow assessment of impact of interventions to reduce stigma.

Factors affecting: With available tools, it is not difficult to measure stigma and discrimination. Prevalence of stigma is influenced by various other factors including educational level, cultural background, economic status, and knowledge, attitudes and practices in regard to leprosy in the population.

Suggested action: Professional advice is needed to measure stigma. However, easy-to-use questionnaires are available and have been used in many countries for research studies. Research on stigma should become an integral part of policy framework with appropriate resource allocation. It is also possible to get a quick insight into the issue by asking a few questions from the public during supervisory visits (supervision interview), e.g. using the 5-question stigma indicators (see Annex 10). (For further information refer to Chapter 5 of the Operational Manual)

(e) Use of participation scale to assess the social participation of persons affected by leprosy

Definition: The scale is used routinely or through special surveys by NLPs to measure client-perceived participation among persons affected by leprosy.

Formula: Yes/No

Threshold: Yes. Desired trend – from research initiative/survey approach to routine use of at least the referral level

Source of information: Research study or survey report or patient card

Reporting level: National/regional

Frequency: Annually

Importance: This is an output indicator, rule-based (yes/no). One needs resources to measure social participation and the impact of interventions directed at reducing discrimination and facilitating inclusion. This could be one step in the right direction to address the participation levels of persons affected by leprosy. Availability of data on participation and participation restrictions could start the much needed conversation on the issue of social inclusion and used to evaluate the impact of community-based rehabilitation (CBR) initiatives.

Factors influencing: Lack of resources to carry out survey/research initiatives, lack of collaboration with behavioural science experts, lack of interest in social aspects of leprosy could affect the use of the instrument.

Suggested action: There could be a common platform for sharing information on best practices between government and NGOs working on social rehabilitation. This could become the basis for reporting at the national level. An example of participation scale that can be used can be found at: ILEP, Infolep: participation scale and user manual v.6.0, www.leprosy-information.org/keytopic/participation-scale. (For further information refer to Chapter 5 of the Operational Manual)

3.4 Overview of monitoring indicators for programmatic review

Though ideally each programme should collect and analyse all the information available to monitor quality in programme management, Table 5 identifies priorities and other desirable indicators to be used, including the target indicators.

Table 5: *List of leprosy indicators to be collected, analysed and interpreted*

Essential	Desirable	Useful
Number of children diagnosed with leprosy and visible deformities (G2D)	Number of cases with leprosy reactions during treatment	Proportion of regions/districts/ health facilities that have had at least one supervisory visit of all the districts in the reporting year
Number of new child leprosy cases*	Proportion of patients assessed for disability status at least both at beginning and at end of treatment	Existence of a communication strategy plan with identified focal areas and annual budget
Rate of newly diagnosed leprosy patients with visible deformities (G2D)	Availability of a costed national plan for leprosy (per se or integrated)	Proportion of health facilities visited that have good quality patient records
Legislation allowing discrimination on basis of leprosy	Number subnational jurisdictions where persons affected by leprosy are involved in leprosy services	Proportion of districts/regions with results-based plans for leprosy
New case-detection (number and rate)	Number of subnational jurisdictions with a formal alliance between government programme and other stakeholders	Proportion of budget utilized out of disbursed to health facilities/ district/region
Prevalence (number and rate)	Availability of web-based, case-based reporting system allowing disaggregation by age, sex, place of residence and other relevant criteria	Availability of information on private providers role in leprosy care (through surveys or research studies)
Proportion of G2D cases among total new cases detected	Availability of information on prevalence of social stigma and discrimination	Availability of a national list of prioritized research areas
Proportion of child cases among total new cases detected (or child new case rate)	Proportion of health facilities/ districts/regions with no interruption (no stock-outs) in the drug supply in the reference period	Proportion of health facilities/ districts/regions that have implemented all the planned activities in time
Proportion of female cases among total new cases detected	Proportion of new patients with disability (G1D and G2D) that have received self-care training	Use by the programme of participation scale to assess the social participation of persons affected by leprosy

Essential	Desirable	Useful
Proportion of foreign-born cases among total new cases detected	Number of formal alliances between association of persons affected by leprosy and the government leprosy programme	Proportion of policy documents including guidelines and plans of actions developed with the contribution of persons affected by leprosy
Proportion of MB cases among total new cases detected		Proportion of patients satisfied with the services provided
Proportion of contacts screened		Proportion of advocacy events on leprosy attended by senior Governmental officials
MDT completion for PB		Proportion health facilities/ districts/regions where guidelines and standards on leprosy patient management and programme are available
MDT completion for MB		
Proportion of patients who have developed new disabilities during the course of treatment		
Proportion of leprosy drug-resistant cases among new and retreatment cases		
Number and proportion of retreatment cases over the total leprosy notified cases		
Existence of norms and/or regulations facilitating inclusion of persons affected by leprosy and their communities		

** The target as it applies to low burden countries.*

Source: Dr Padebettu Krishnamurthy,Dr Laura Gillini and Dr VRR Pemmaraju, GLP.

All high-burden countries[1] will report on essential and desirable indicators and, during programmatic reviews, also on useful indicators. Other countries will use only essential indicators while desirable and useful indicators will be used and assessed only during annual internal or external reviews since most or all of the useful indicators are derived from supervision reports or special research initiatives.

---

[1] Angola, Bangladesh, Brazil, Comoros, Côte d'Ivoire, Democratic Republic of Congo, Egypt, Ethiopia, Federated States of Micronesia, India, Indonesia, Kiribati, Madagascar, Mozambique, Myanmar, Nepal, Nigeria, Philippines, South Sudan, Sri Lanka, Sudan, United Republic of Tanzania

3.5 Leprosy programme review

There have been several WHO documents published regarding programmatic review. The first was an Independent Evaluation that was introduced in the mid-1980s. The second was Leprosy Elimination Monitoring (LEM) introduced in the late-1990s. It guided, with a constituent set of indicators, programme managers to measure progress in implementation, institutional change and impact in terms of reaching the target of elimination of leprosy as public health problem defined as having less than 1 leprosy case under treatment per 10 000 population at a specified point of time. It was used extensively with local adaptation and the concepts and practices became well established. LEM was a selective exercise with global dimensions. It also helped in organizational and developmental learning and in building the capacity of the health system. Under the Global Leprosy Strategy 2016–2020, programme monitoring and evaluation required the review of more indicators according to a more comprehensive framework. To guide interpreting the indicators as a whole, the subchapter below shows how to monitor the implementation of programmes for leprosy under the Global Leprosy Strategy 2016–2020.

3.5.1 Interpretation of monitoring indicators for programme review

Progress towards the predefined targets under the current Global Leprosy Strategy should be assessed by all programmes. Given below are the summarized target indicators.

Table 6: *Summarized target indicators – an overview*

Indicator	Threshold	Importance
Number of children diagnosed with leprosy and visible deformities (G2D)	Zero by 2020	Impact indicator. Denotes quality of case detection, awareness in the community, quality of leprosy services
Number of new child leprosy cases*	Zero by 2020	Impact indicator. Represents recent transmission. Also denotes quality of case detection
Rate of newly diagnosed leprosy patients with visible deformities (G2D)	Less than 1 per million by 2020	Impact indicator. Reflects delay in diagnosis.
Legislation allowing discrimination on basis of leprosy	Zero	Rule-based indicator. Indicates burden of disparities in access to opportunities

** The target as it applies to low burden countries.*

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini

The tables below contain indicators grouped under the three Pillars. For Pillar II, two summary tables have been developed to facilitate assessing quality of case detection and case holding. The tables, as well as the targets, also include suggestions on remedial action in case of variations.

Table 7: *Summarized indicators for strategy Pillar I – an overview*

Indicator	Threshold	Importance
Availability of a costed national plan for leprosy (per se or integrated)	Yes	Rule-based output indicator Important to indicate governmental commitment
Number of subnational jurisdictions with a formal alliance between government programme and other stakeholders	Yes	Rule-based output indicator Important to assess coordination role of government programmes
Availability of web-based, case-based reporting system allowing disaggregation by age, sex, place of residence and other relevant criteria	Yes	Rule-based output indicator. Important to assess the quality of the health imformation system (HIS)

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini

Table 8: *Summarized indicators for strategy Pillar II, quality of case detection – an overview*

Indicator	Threshold	Importance
New case-detection (number and rate)	Declining trend (unless active screening new policy in place)	This is an outcome indicator. It is the most important indicator reflecting the burden of leprosy as it is a proxy for incidence rate
Prevalence (number and rate)	Declining trend (unless active screening new policy in place);	It is an outcome indicator. It reflects the capacity of the programme to detect and manage cases till the end of treatment. It reflects the leprosy burden and the treatment duration
Proportion of G2D cases among total new cases detected	≤ 5%, desired declining trend	G2D reflects delay in diagnosis
Proportion of child cases among total new cases detected (or child new case rate)	Decreasing trend in high-burden countries Zero for low-burden countries	It is an outcome indicator reflecting transmission of leprosy. It also indicates the capacity of the programme to identify the disease among children
Proportion of female cases among total new cases detected	Not below global average (39%)	It is an outcome indicator. It might indicate differential access to care by men versus women
Proportion of foreign-born cases among total new cases detected	Increasing trend	It is an outcome indicator. Indicates the magnitude of leprosy local transmission in a given area; also reflects access to care by migrants

Indicator	Threshold	Importance
Proportion of MB cases among total new cases detected	Decreasing trend	It is an outcome indicator. It reflects quality of case detection since a higher number of MB cases among the new, might suggest delay in diagnosis
Proportion of contacts screened	85%, increasing trend If wider definition of contacts maybe a lower threshold might be acceptable, within an increasing trend	This is an output indicator. It indicates the intensity of efforts for early case detection and therefore quality of case detection

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini

Table 9: *Summarized indicators for strategy Pillar II, quality of case holding – an overview*

Indicator	Threshold	Importance
Number and proportion of retreatment cases over the total leprosy notified cases	Declining trend	It is an outcome indicator. Reflects the quality of case holding (loss at follow-up); it might relate with transmission and with drug-resistance
MDT completion for PB	85%, increasing trend desirable	Outcome indicator. Along with treatment completion for MB it constitutes most important indicator reflecting quality of case holding
MDT completion for MB	85%, increasing trend desirable	Outcome indicator. Along with treatment completion for PB it constitutes most important indicator reflecting quality of case holding
Proportion of patients assessed for disability status at least both at beginning and at end of treatment	85%, increasing trend desirable	Output indicator. Reflects quality of patient care
Proportion of patients who have developed new disabilities during the course of treatment	1%, declining trend desirable	Outcome indicator. Reflects quality of patient care
Number of cases with leprosy reactions during treatment	It is on average 10%. Cannot have a threshold. It is prudent to get the threshold by studying the reported number in a good programme setting	Outcome indicator. It reflects quality in patient management. It is used for calculate the requirement of steroids
Proportion of new patients with disability (G1D and G2D) that have received self-care training	100%. Increasing trend desirable, if below threshold	Output indicator. Reflects quality of patient care
Proportion of leprosy drug-resistant cases among new and retreatment cases	Stable or declining trend	Outcome indicator. It reflects quality of case holding and leprosy transmission

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini, GLP.

Table 10: *Summarized indicators for strategy Pillar III – an overview*

Indicator	Threshold	Importance
Number of formal alliances between association of persons affected by leprosy and the government leprosy programme	Yes. Desired trend: alliance in all subnational jurisdictions	Output indicator, rule-based. Important because such partnerships promote inclusivity and reduce stigma and discrimination
Existence of norms and/or regulations facilitating inclusion of persons affected by leprosy and their communities	Yes	Output indicator, rule-based Important to ensure impact on stigma and discrimination
Number subnational jurisdictions where persons affected by leprosy are involved in leprosy services	Yes. Desirable trend, up to 100% of all subnational jurisdictions	Output indicator, rule-based. Important for patient-centred care and quality of case holding in programme implementation
Availability of information on prevalence of social stigma and discrimination	Yes	Output indicator, rule-based. It is important to get an insight to frame improved policy interventions.
Use by the programme of participation scale to assess the social participation of persons affected by leprosy	Yes	Output indicator, rule-based. Done with standard instrument could facilitate identification of policy on social inclusion. It can be used to evaluate the impact of CBR initiatives

Source: Dr Padebettu Krishnamurthy and Dr Laura Gillini

3.6 Active screening activities/case-detection campaigns and their effect on leprosy monitoring indicators

The introduction of LEM was preceded by the launch in the late 1990s of Leprosy Elimination Campaigns (LECs) with the purpose of clearing the backlog of cases that had accumulated over time in endemic countries. It was mass case-detection campaign covering large geographical areas (regional/national) with clear procedures. A series of such LECs were conducted in several countries that resulted in detection of a large number of cases and gave a much-needed boost to the image of the leprosy programme. Once elimination was achieved and the leprosy programme was integrated, LECs were signed off. Nearly two decades later, there is realization that the LEC needs to be revisited taking into consideration the small decline in new case detection witnessed in the past 8 years. The current Global Leprosy Strategy proposes a focused campaign approach in endemic countries and/or in endemic areas or among hard-to-reach populations. It is important that if programmes undertake focused case-detection campaigns, that they monitor them.

The monitoring of LEC requires specific tools. The first tool would be a checklist for campaign preparation (Table 11 below provides an example of such a list):

Table 11: *Example of a checklist for campaign preparation*

Planning phase
Data from the routine reports and supervision reports is collected
Problem analysis is done
Geographical areas/ population groups to be covered is identified based on predefined criteria – endemic (high case detection, high G2D and/or high MB), underserved population groups
Purpose of the campaign – to inform (IEC) or to detect cases – is clearly stated
Major stakeholders are involved in the planning (health-care workers, person affected by leprosy, NGO, government publicity department)
Methodology to be followed is defined (could be national guideline, if available, with modification if needed)
List of activities is prepared
Resources needed are identified • Human resources – Medical officers, supervisors, health workers, volunteers, staff from other departments, staff from NGOs, staff from CBO and from association of persons affected, and others (bench staff in case of emergency) • Mobility support for field visits • Allowance for personnel • Records, reports*
Responsibility chart (who is responsible for what) is prepared
Preparatory phase
Publicity about the campaign – involving volunteers, publicity department, health workers, NGO staff
Separate training by training teams to health workers and other staff, and for medical officers and supervisors
Identification of personnel for different tasks – survey, supervision, diagnosis, follow-up of absentee suspects, data collation, analysis, dissemination
Preparation of circuit map for the mobility of supervisor, internal from same facility or district or external from another health facility or district (responsible for supervision during implementation)
Getting sufficient number of data collection instruments, reporting forms
Getting enough MDT/ steroid stock (based on expected number of new cases)
Campaign phase
Adherence to guidelines by the survey staff (sample of staff)
Preidentified staff are there at different locations as per plan
Survey instruments are filled properly
Suspects identified are given referral slips
Summary reports are prepared every day at the health facility and sent to district
Suspects not visiting health facility are followed within one week of the campaign
Sample of confirmed cases are validated

Post-campaign phase
Suspects not reporting to the health facility are followed
Cases detected from among the suspects reporting to health facility following the campaign are added to the list of cases of campaign origin
Consolidated report is prepared and disseminated
Profile of cases detected in the campaign is compared with the routinely detected cases (last one year)
The results of the campaign are presented to the stakeholder group
System for sustainability of case detection and patient management is set in place

Source: Dr Padebettu Krishnamurthy.

The effect of campaigns over routine monitoring indicators should be known and looked for. The examples below explain the most common "effect" of leprosy active detection campaigns over indicators that monitor the quality of case finding.

Table12: *Example - mode of case detection and G2D*

Comparative profile of new cases detected by special action and routine in Assam and Tamil Nadu, India (2013–2014)*

State	Special case detection	Routine
Assam		
Total new	61	3810
MB	44 (72%)	2040 (75.3%)
Child	4 (6.5%)	349 (9.25%)
G2D	2 (3.3%)	164 (7.6%)
Tamil Nadu		
Total new	229	1048
MB	83 (36%)	789 (52.35%)
Child	16 (6.9%)	97 (12.7%)
G2D	9 (3.9%)	80 (5.2%)

Note: Active case detection tends to pick up early cases and therefore the disability proportion and MB proportion among new cases would be low (Tamil Nadu). It is prudent to look at disability in conjunction with MB. In Assam, the special action picked up predominantly MB cases but the disability proportion is low. There could be the possibility of underreporting of disability.

Source: Data from National Eradication Leprosy Programme, Ministry of Health, India.

Table 13: *Example – gender difference in new case detection in routine programme and special case-detection activities*

Profile of new cases detected through special surveys and routine activities in Uttar Pradesh and Haryana States (2009–2010) and Nellore district of Andhra Pradesh State (2013)

State	Population covered	New cases detected	Female cases	MB cases	Child cases
Uttar Pradesh(S)*	400 000	269	136 (51%)	64 (24%)	57 (21%)
Uttar Pradesh (R)			32.3%	39.4%	6.1%
Haryana (S)*	400 000	73	36 (49.3%)	22 (30%)	27 (37%)
Haryana (R)			11.2%	79.7%	0.9%
Nellore (S)**	47 000	70	35 (50%)	32 (45.7%)	19 (27%)
Nellore (R)			50%	45.7%	27%

Note: As one can see from Table 13, gender difference in new case detection that is apparent in the routine programme situation fades away with active case detection.

***Santhosh Kumar M, et al (2015).*

Source: data from National Eradication Leprosy Programme, Ministry of Health, India.

Table 14: *Example – effect of campaigns on new case detection*

Trend of new case detection in Bihar, India: 1995–1996 to 2002–2003*

	1995–1996	1996–1997	1997–1998	1998–1999	1999–2000	2000–2001	2001–2002	2002–2003	2003–2004
New case detection	55993	99526	111743	**282081**	**172449**	**137361**	**120080**	**94561**	65019
				↑	↑	↑	↑	↑	
				Case-detection Campaigns					

Note: Active case detection (surveys) was scaled up in 1996. In 1998, a leprosy elimination campaign as part of a nation-wide exercise was carried out. It was repeated three years consecutively. In 2002-2003, surveys were replaced by IEC campaign. Campaigns were not continued beyond 2002-2003.

**Source: data from National Eradication Leprosy Programme, Ministry of Health, India.*

Knowing the effect of active detection on indicators related to the target and to pillar 2, can indeed help managers to interpret the indicators of their programmes and to understand the reasons behind variances between years/periods and regions/districts in the light of the different detection strategies.

References

(1) World Health Organization, Regional Office for South-East Asia. Global leprosy strategy: 2016-2020: accelerating towards a leprosy-free world. New Delhi, 2016.

(2) World Health Organization, Regional Office for South-East Asia. Global leprosy strategy 2016–2020: accelerating towards a leprosy-free world – 2016 operational manual. New Delhi, 2016.

(3) World Health Organization. Weekly epidemiological record, 2 September 2016, vol. 91, 35 (pp. 405–420)

(4) World Health Organization, Regional Office for South-East Asia. Guidelines for strengthening the participation of persons affected by leprosy in leprosy services. New Delhi, 2011.

(5) International Federation of Anti-leprosy Associations (ILEP). Infolep. Participatory scale and users manual v.6.0.

(6) Kadushin A. Supervision in social work, 3rd edn. New York: Columbia University Press, 1992.

(7) Campbell SM, Roland MO, Buetow SA. Defining quality of care. Soc Sci Med. 2000;51;1611-25.

(8) Keeble G. Monitoring and evaluation in the public health sector, the purpose of monitoring and evaluation.

(9) Kumar A, Hussain S. The burden of new leprosy cases in India: a population based survey in two states. ISRN Tropical Medicine.2013, article id 329283.

(10) Kumar MS, Padmavathi S, Shivakumar M, Charles U, Appalanaidu M, Perumal R, et al. Hidden leprosy cases in tribal population groups and how to reach them through a collaborative effort. Leprosy review. 2015 Dec;86(4):328-34.

(11) van Brakel WH, Anderson AM, Mutatkar RK, Bakirtzief Z, Nicholls PG, Raju MS, et al. The participation scale: measuring a key concept in public health. Disabil Rehabil. 2006;28(4):193-203.

(12) Stevelink SA, Hoekstra T, Nardi SM, van der Zee CH, Banstola N, Premkumar R, e al. Development and structural validation of a shortened version of the Participation Scale. Disabil Rehabil. 2012;34(19):1596-1607.

Annexes

Annex 1

Patient card

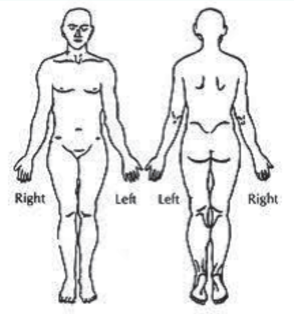
Part -1. General information				
Registration Number		Date of registration		
Health facility		District		
Region/Province/ State				
Patient name			Age:	Sex: Male/ Female
			Date of birth:	/ /
Place of birth:		Marital status:	Married/Unmarried/Single/ Divorced/NA	
Religion/Ethnicity:		Occupation:	Phone number:	
Present address				
Permanent address				
Name, address & phone no. of contact person:				

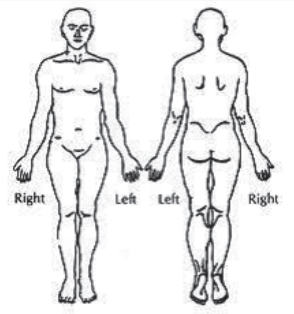
Part-2. Disease status			
Presenting signs/ symptoms		Duration of symptoms in months	
Past history (of similar symptoms and treatment)			
Relevant family history			
Mode of detection	General survey/ Contact screening/School survey/ Voluntary/ Referral / Others (sp)		
General examination			
Patient Type	☐ New case ☐ Retreatment case (☐ relapse, ☐ treatment after loss to follow up, ☐ transferred in, ☐ other retreatment)		
Skin examination: Total anesthetic Patches: (No.)		Skin infiltration: Yes/No	
Skin anhydrosis: Yes/No			

Nerve examination	Ulnar		Median		Radial		LPN		PT	
	R	L	R	L	R	R	L	R	L	R
Thickened										
Tender										

Date of skin smear	Date:	Date:	Date:	Date:
Results: +/-, BI if +.				
Reaction at the time of diagnosis	Yes / No (If yes →)	Type 1 [Yes/No]	Type 2 [Yes/No]	Neuritis [Yes/No]

Disability status at the time of diagnosis	Hand:		Feet:		Eyes:	
	R- 0/1/2	L- 0/1/2	R- 0/1/2	L- 0/1/2	R- 0/1/2	L- 0/1/2
Diagnosis	PB leprosy MB leprosy					





Name &
Registration number

Part- 3. Treatment status												
Type of treatment (MDT)	MB adult/MB child/PB adult/ PB child							Date of first dose treatment: / /				
Remaining pulses	2	3	4	5	6	7	8	9	10	11	12	Outcome with date / /
Subsequent treatment dates												Treatment completed within standard duration/Lost to follow-up/ Died/ Transferred out/ Still on treatment/ insufficient clinical response to treatment
Clinical status at the end of treatment: (if still on treatment , give reason and specify regimen)												

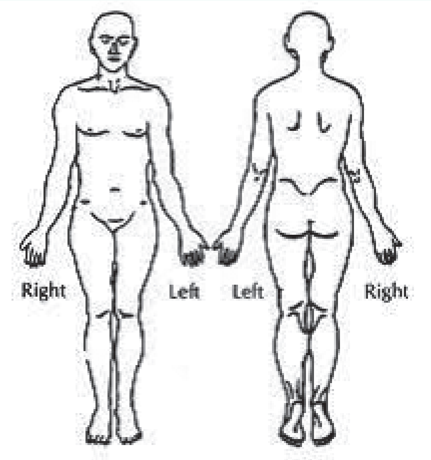
Part-4. Management of Leprosy reaction/ other events treatment			
Date	Symptoms and signs	Diagnosis	Drugs, dose, duration of treatment

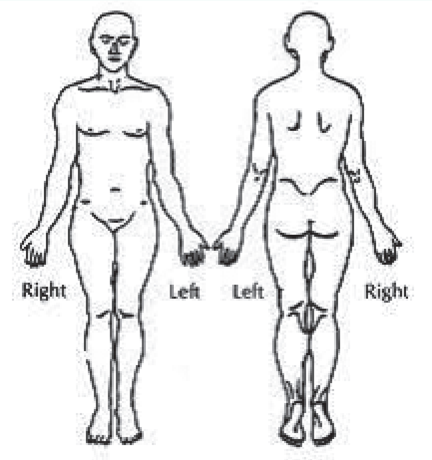
Part-5. Medical and social rehabilitation						
Provided livelihood support: yes/no (If Yes →)	Education/ Self-employment / new house / Renovation house / other(specify): Month/year of support: /					
	date	date	date	date	date	date
Self-care kit support						
Self-care training						
Footwear Eligible: Yes/No (If Yes →)						
Aids/Appliances: Yes/No (If Yes →)						
Eligible for RCS: Yes/No	Date of surgery ; H/F/E		Date of surgery ; H/F/E		Date of surgery ; H/F/E	

Hand		Foot		Eye	
R	L	R	L	R	L

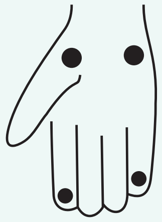
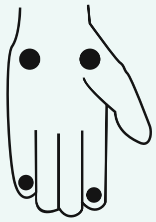
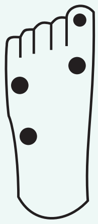
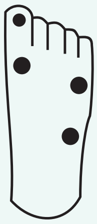
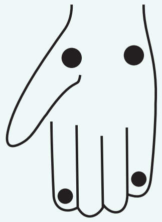
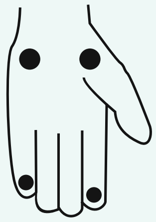
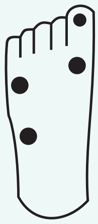
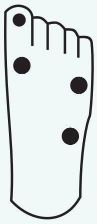
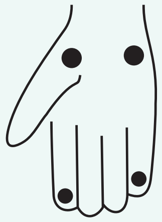
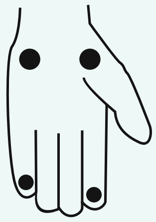
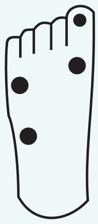
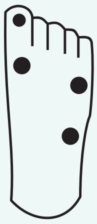
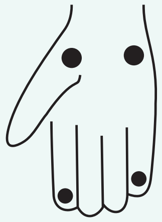
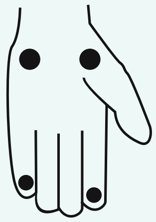
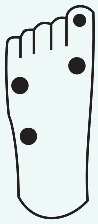
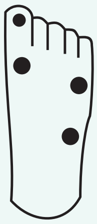
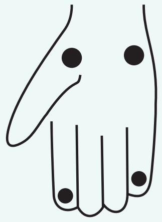
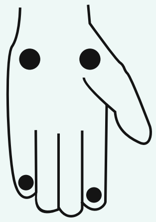
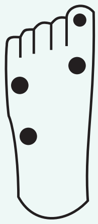
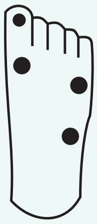
Name &
Registration number

Part-6. Patient follow-up:			
Date	Event	Findings- clinical and laboratory	Treatment given





Name &
Registration number

Part-8. Assessment of disability and Nerve function					
Date / / Assessor:					Comments
Date / / Assessor:					
Date / / Assessor:					
Date / / Assessor:					
Date / / Assessor:					

Key : (Put these marks/icons on the site where lesion is seen)

Sensation Present within 3 cm √   Contracture S   Scar/Callus ⬭

Anaesthesia X   Wound ⊗   Shortening level ✚   Crack ╤

Name &
Registration number

Part-9. Voluntary muscle test

Right							Left					
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
						Vision*						
						Lid gap in mm						
						Blink- present(Yes /No)						
						Little finger out						
						Thumbs up						
						Wrist extension (UP)						
						Foot up(UP)						
						Disability grade hands						
						Disability grade feet						
						Disability grade eyes						

Date						
Max WHO Grade						
Signature						

Muscle power:

S = Strong

W = Weak

P = Paralysis

*** Score of vision: counting fingers at 6 metres**

0 = Normal

1 = Blurring vision

2 = Unable to count fingers

Annex 2

Leprosy register

Serial no.	**Registration no.**	Name of patient	**Date of birth**	**Sex (M/F)**	**Country of birth**	**Marital status**	**Occupation**	**Address**	**Type (MB/PB)**	**Leprosy diagnosis (New/retreatment)**	**Mode of detection**	**Initial skin smear with date and result**	**Leprosy reaction Type 1/2**	**Date of reaction**	**Drugs given for treating reaction**	**Date of completing treatment with outcome**	**Disability at diagnosis (0/1/2)**	**Disability at the end of treatment within standard duration**

Date of start of MDT MB/PB	2 Date	3 Date	4 Date	5 Date	6 Date	7 Date	8 Date	9 Date	10 Date	11 Date	12 Date	Outcome Treatment completed within standard duration/ Lost to follow-up /Died/ Transferred out/Insufficient clinical response to treatment//Still on treatment	Remarks

Annex 3

Disability register

Serial no.	Registration no.	Name	Address	Date of birth	Sex (M/F)	Marital status	Leprosy diagnosis Type and date	Date of end of treatment and outcome		Eye (Tick appropriate item)				Hand (Tick appropriate item)					Foot (Tick appropriate item)				
							i.e.new MB			CA	LP	CO	VA	A	UC	MC	AB	Other	PA	FD	UL	AB	O
1									R														
									L														
2									R														
									L														
3									R														
									L														

Serial number	Medical Service provided Tick appropriate item and write date						Socioeconomic support Tick appropriate item and write date					Involved in leprosy service (sp)	Follow-up			Remarks
	Counseling	Self-care training	Physiotherapy	MCR Footwear	Aids & Appliance	RCS	Disability pension	Self-employment	Educational support	Housing	Others - specify		Date with status & service provided	Date with status & service provided	Date with status & service provided	
1																
2																
3																

Legend for Disability register

Eye	
CA	Corneal anaesthesia
LP	Lagaphthalmos
CO	Corneal opacity
VA	Visual acuity (partial loss/Total loss)
Hand	
A	Palmar anaesthesia
UC	Ulnar contraction
MC	Median contracture
AB	Absorption
Other	Specify
Foot	
PA	Plantar anaesthesia
Foot drop	Foot drop
Ulcer	Ulcer in the sole of the foot
AB	Absorption
Other	Specify

Annex 4

Contact register

Name of Health Facility:

District/Region/Province

Serial no.	Registration no.	Patient name	Patient type	Date of birth	Sex (M/F)	Address with phone number	MB/PB	Date of start of treatment	Contact details					
									Name	Date of birth	Sex M/F	Examination Done (date)	Status (L/NL) MDT reg number if Leprosy	Remarks
1														
2														

Annex 5

Drug resistance register

Name	Surname	Leprosy register number	Type of patient (new/ retreatment)	Type of retreatment	Date of start of MDT treatment	Name & location Treating Facility	Date of sample collection	Name & Location Facility collecting the sample	Skin site of sample collection	BI index skin slit smear in National Lab	Results of nationalLab	Results PCR of national Lab	Results PCR reference Lab	Results seq Rif national Lab	Results Seq Rif reference Lab	Results seq Dapsone National Lab	Results Seq Dapsone Reference Lab	Results Seq Ofloxacine National Lab	Results Seq Ofloxacine Reference Lab	Treatment regimen (for drug resistant cases)	Start of treatment (for drug-resistant cases)	End of treatment (for drug resistant cases)	Treatment Outcomes	Remarks

Annex 6

Critical incident investigation

1. **Critical incident-Identification of a child with leprosy and associated disability**
2. **Purpose of Critical incident investigation:**
    - To verify the incident;
    - To identify factors contributing to the incident and gain a better understanding of circumstances leading to the incident; and
    - To provide a means for identifying preventive measures or procedural changes that need to be made in order to prevent such incidents
3. **Timeline**- investigation should be carried out within one week of reporting of the incident
4. A **team** is identified for this purpose. The team consists of individuals from the district programme management, NGO, association of persons affected by leprosy, from the health facility responsible for the area from which the incident was reported and from the health committee (if it exists).
5. **Resource support**- finances, checklist, mobility
6. **Visit** to the patient's residence, health facility, village/area
7. **Collecting information** using checklist from the patient/parents, medical officer/ health worker in charge of the health facility/community
    - Verify the event
    - Analyse – cause and effect
    - Identify root causes
    - Support each root cause with evidence
    - Identify and select the best way of addressing the problem
    - Develop recommendations
    - Write and present the report

Checklist for Critical Incident Investigation

Name of the patient		
Age		
Sex		
Father's name		
Address		
School going		
Disease status		Leprosy MB/ Leprosy PB/ Not leprosy
Disability status	Hands	
	Eyes	
	Feet	
Any other case in the family		
What was the first manifestation		
When was it noticed		
Who noticed it		
What was done about it		
Nothing, why		
Took him to a private doctor, when and why		
What was the treatment given		
How much money was spent		
What was the response to Treatment		
Why the child was not taken to Government health facility		
Took him to Government Health Facility, when and why		
What was the treatment given		
How much money was spent		
What was the response to treatment		
When was the disability noticed		
What was done about it		
Nothing, why		
Took him to a private doctor, when and why		
What was the treatment given		
How much money was spent		
What was the response to Treatment		
Why the child was not taken to Government health facility		
Took him to Government Health Facility, when and why		
What was the treatment given		
How much money was spent		
What was the response to treatment		

What do you think is the disease the child is suffering from? (ask the parent)	
What do you think is the cause of the disability? (ask the parent)	
How was the child identified	During consultation visit to HF/ By health worker during routine visit/ By health worker during General survey/ By health worker during campaign/ By village nurse/ By health worker during school survey/ Others (specify)
Health facility	
Accessibility of health facility to the place of residence of child	Easily accessible/difficult to access Distance in km
Means of transport available	Yes/No
MDT services are available on all days at HF	Yes/On specified days/No
Who diagnoses and manages leprosy at HF	
Capacity to manage	
Training status	
How many cases of leprosy have been identified in the last one year	
How many of them with disability	
How many child cases have been identified in the last one year	
How many of them with disability	
Records and reports are available	
MDT drug stock is available	
Steroids are available	
Health education materials are available	
Leprosy patient management guidelines are available	
Any IEC activity in the village/area of interest in the last 6 months/one year?	
Any supervisory visit by the district level supervisor in the last one year?	
Is there any school in the area?	
Has there been any school survey conducted in the last one year?	
Has there been any other case detection activity conducted in the area?	
What is the main mode of leprosy case detection in the area	
In case of doubt where is the patient referred for management	
Community	

Awareness about leprosy in the community (Interview of a few people in the village/area)	
From where do people seek treatment when sick, why	
What do they feel about the services offered at the Government HF	
Problems identified with evidence	
Actions suggested	
Names, designations and signatures of team members	

Annex 7

Checklists for supervision

(A) Checklist for supervision plan

Supervision plan	
Prepare a visit schedule	
Develop a visit plan	Purpose
	Activity and tasks to be supervised
	Tools- checklist, job chart, previous report, standards of performance, activity plan
	Resource
	Schedule
Visit health facility/Administrative unit/field and meet person(s) to	Collect information- direct observation, interviews, desk review and inspection of facility
	Assess problems
	Assess working condition
	Possible solution
	Provide guidelines (written/published) if needed
	Coaching, on the job training
Problem solving	Supportive/Corrective feedback with discussion
Debriefing to supervisor	
Report, feedback and follow-up	

(B) Checklist for supervision at health facility level

Activity Variable	Yes/No/with remarks/Not applicable/ Not assessed
General	
Microplan available	
Leprosy programme guidelines available	
Supervision guidelines available	
Information system guidelines available	
Map of the catchment area available and displayed properly	
Has the demographic information, village –wise population by age and sex and ethnicity	
List of underserved population areas available	
Health education materials available	
Programme management	
The facility participated in the development of district plan	
Health facility has developed the plan on its own	
Activities are implemented as per the plan	
Any problem identified since the last visit	
Action taken	
MDT services are available all days of week	
Endemic pockets in the area covered	
If yes, Special activity undertaken & when	
Any IEC activity carried out in the last quarter, where and when	
IEC plan (result based) is available	
Personnel management	
Availability of Key staff (medical officer, health worker designated for leprosy, field staff including field supervisor)	
Trained in leprosy (at least once in the past 3 years)	
Awareness about who is doing what for leprosy	
Mobility support	
Supervision checklist available	
Supervision checklist used	
Number of field visits made in the last one month by the field supervisor	
Monthly meetings are held (how many in the last 3 months)	
Performance in leprosy is assessed during the meeting (minutes of the meeting)	
Capacity for diagnosis of leprosy	

Activity Variable	Yes/No/with remarks/Not applicable/ Not assessed
Patients are counseled	
Capacity for managing reactions	
Capacity for managing disabilities	
Knows where to send patients with complications	
Awareness about the leprosy situation in the area covered	
Capacity to analyse and interpret reports	
Prevention of disability/rehabilitation	
Percentage of patients assessed for disabilities	
Number of persons with leprosy disabilities in the area	
G1D	
G2D	
Number eligible for support	
Number provided support (footwear/ aids/ self-care training/ RCS)	
Number provided livelihood support	
Any participation of person affected by leprosy in patient care	
Percentage of patients satisfied with service (client satisfaction survey)(number interviewed/Number satisfied)	
There is suggestion box for clients	
Community health committee exists	
If yes, number of times it has met in the last 6 months	
Prevalence of stigma in the community	
Patient record/Registers	
Adequate no of blank records are available	
Percentage of the cards which are complete	
No of patient cards verified	
Number of cards which are up to date	
Number of cards which are consistent (Diagnosis is consistent with clinical findings; treatment is consistent with diagnosis)	
Cards are preserved well	
Leprosy register is available	
Leprosy register is maintained well (up to date)	
Disability register is available	
Disability register is maintained well	
Contact register is available	

Activity Variable	Yes/No/with remarks/Not applicable/ Not assessed
Contact register is maintained well	
The last 3 months reports have been sent in time	
The report is up-to-date	
It is clear	
It tallies with the data in patient record/register	
It is consistent	
The person preparing the report is aware of the definition and criteria for each item and how to extract them from the record and register	
Drug stock	
MDT drugs are available	
MDT drugs are adequate	
Quality of MDT is good	
Has there been any nil stock in the last 3 months	
Has any drug expired	
Steroids are available	
Coordination	
Coordination committee involving partners exists	
If yes, Persons affected by leprosy are members of the committee	
If yes to 1, Number of meetings held in the last 6 months	
Problems identified (with causes):	
Suggested action, who is responsible and timeline	
Actions suggested during the last visit and extent of realization:	
Name, designation and signature of the supervisor with date	

(C) Checklist for supervision at the district/regional/provincial levels

Variables	Yes/No (with reasons)/Not Applicable/ Not Assessed
Planning	
Plan is available	
Funding available for leprosy (and/or NTD)	
It is not prescriptive (dictated by national programme)	
Major stakeholders participated in developing the plan including persons affected by the disease?	
It is result based?	
Analysis of the prevailing situation	
SMART objective in consonance with the national objective	
Intermediate results expected	
Risks and assumptions	
Activities with timeline	
Resources needed- human resources, logistics, Budget	
IEC plan as part of general plan prepared	
Training needs assessment done	
Training plan** prepared	
General	
Leprosy programme guidelines are available	
Supervision guidelines available	
Information system guidelines available	
Map of the catchment area with health facilities available	
Has the demographic information, urban and rural: town, city, village –wise population by age and sex and ethnicity	
List of underserved population areas available	
Health education materials available	
Programme management	
Any Critical Incident Analysis done when a new child with leprosy with disability is identified?	
What other actions are undertaken (when new child with leprosy disability is identified)	
Activities are implemented as per the plan	
Activities not carried out	
Reason	
Any problem identified since the last visit	

Variables	Yes/No (with reasons)/Not Applicable/ Not Assessed
Action taken	
Any endemic pockets in the area covered	
If yes, Special activity undertaken, where, when	
Any IEC activity carried out in the last quarter, if yes where, when	
Referral system exists*	
No of trainings carried out	
No of persons affected by leprosy involved in the programme	
Partnership with Association of persons affected by leprosy	
Number of NGO/CBO and other organizations with which there is partnership agreement	
There are discriminatory laws against persons affected by leprosy	
Stigma is measured and some information is available	
Information system management	
Information system- paper-based or web-based	
Indicators are calculated	
Analysis is done	
How are the reports used	
The last 3 months reports have been sent in time	
The report is up-to-date	
It is clear	
Reports are consistent	
Feedback – how many facilities have been given feedback in the last 3 months	
Problems identified	
Action taken	
Appropriateness of action	
Speed of action	
Has the unit received feedback from the higher level any time in the last 3 months	
Number of HF from which the unit is expected to receive reports	
Number from which reports for the last three months received	
The person preparing the report is aware of the definition and criteria for each item and how to extract them from the record and register	

Variables	Yes/No (with reasons)/Not Applicable/ Not Assessed
Drug supply management	
MDT drugs are available	
MDT drugs are adequate	
Quality of MDT is good	
Has there been any nil stock in the last 3 months	
Has any drug expired	
Steroids are available	
Stock register is available	
Stock register is well maintained	
Personnel management	
Availability of Key staff (Programme manager, field supervisor, data entry operator)	
Trained in leprosy (at least once in the past 3 years)	
Mobility support	
Supervision checklist available	
Supervision checklist used	
Number of health facilities	
Number of health facilities visited at least once in the last one year	
Monthly meetings are held	
Performance in leprosy is assessed during the meeting (minutes of the meeting)	
Number of trainings organized in the last one year	
Finance management	
Percentage of the budget received from higher level from the amount requested	
Percentage of the budget that is utilized from the amount received	
Coordination and partnership	
Coordination committee involving partners exists	
If yes, Persons affected by leprosy are members of the committee	
If yes to 1, Number of meetings held in the last 6 months	
Problems identified: (with causes)	

Variables	Yes/No (with reasons)/Not Applicable/ Not Assessed
Suggested action, who is responsible, timelines	
Actions suggested during the last visit and extent of realization	
Name, designation and signature of the supervisor with date	

For items with negative connotations (e.g., records available- “NO”) reasons should be mentioned)

- Referral system- Directory of referral centres with services, teams in the centres, coordinator or nodal person, guidelines for initiating centres and receiving centres, referral forms, feedback reports, support to patients for travel, means of communication
- Training plan- Who needs? Who are the trainers? Method? Learning modules? Training guide? Follow-up plan?

Annex 8

Programme evaluation process checklist

Preparation
Form a team
Identify coordinator
Identify and engage key stakeholders (funding agency, persons affected, NGO, programme staff, experts, etc.)
Steering committee, if required
Administrative
Develop an evaluation charter (Goals, objectives, stakeholders and users, assumptions, risks, roles and responsibilities)
Human resource
Budget
Tasks and timelines
Evaluation plan
Programme profile
Background and context
Programme components and procedures, manuals, guidelines
Inputs, activities, output, outcomes
Identify the intended users
Identify the intended use- improve programme or its component, make judgment about its worth or merit
Evaluation questions – one or more or all- implementation[1], relevance[2], success[3], adequacy[4], effectiveness[5], efficiency[6], learning[7]- depends on age of programme, resources, consensus
Evaluation methodology
Data collection- identifying indicators, procedure for their calculation • Qualitative (observation, conversation, interview, surveys with open-ended questions, focus groups, documents, supervision reports, research findings; • Quantitative-rating scales, administrative data, progress reports, Determine the balance of qualitative and quantitative Triangulation of data collection source and methods Training, ethical considerations
Design- descriptive, sampling
Data analysis plan- statistical methods, planned vs actual comparison, demographic and geographic comparison, thematic comparison
Communication plan
Conduct evaluation
Report findings, conclusions, recommendations, action
Use findings

1-Implementation- activities carried out as planned? Delivered as planned? 2. Relevance- are the goals as per the needs? 3. Success- is the programme achieving the intended outcome within budget and without unwanted outcome? 4. Adequacy- were the outcomes enough? 5. Effectiveness- extent to which the outcomes were achieved – can the outcome be attributed to the programme? Is the programme achieving the goals it was intended to realize? 6. Efficiency- is the maximum possible outcome accomplished from a set of resource inputs? 7. Learning- has the programme established best practices?

Annex 9

Participatory scale

Serial no.	Participation Scale 6.0	Not specified, not answered	Yes	Sometimes	No	Irrelevant, I don't want to, don't have to	NO problem	Small	Medium	Large	SCORE
1	Do you have equal opportunity as your peers to find work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
2	Do you work as hard as your peers do? (same hours, type of work etc.)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
3	Do you contribute to the household economically in a similar way to your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
4	Do you make visits outside your village/ neighbourhood as much as your peers do? (except for treatment) e.g., bazaars, markets		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
5	Do you take part in major festivals and rituals as your peers do? (e.g., weddings, funerals, religious festivals)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
6	Do you take as much part in casual recreational/social activities as do your peers? (e.g., sports, chat, meetings)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
7	Are you as socially active as your peers are? (e.g., in religious/community affairs)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
8	Do you have the same respect in the community as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
9	Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
10	Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Serial no.	Participation Scale 6.0	Not specified, not answered	Yes	Sometimes	No	Irrelevant, I don't want to, don't have to	NO problem	Small	Medium	Large	SCORE
11	Do you visit other people in the community as often as other people do?		0			0					
	[if sometimes or no] How big a problem is it for you?						1	2	3	5	
12	Do you move around inside and outside the house and around the village/neighbourhood just as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
13	In your village / neighbourhood, do you visit public places as often as other people do? (e.g., schools, shops, offices, market and tea/coffee shops)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
14	In your home, do you do household work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
15	In family discussions, does your opinion count?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
16	Do you help other people (e.g., neighbours, friends or relatives)?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
17	Are you comfortable meeting new people?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
18	Do you feel confident to try to learn new things?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

TOTAL	

Name: ____

Age: ____ Gender: ______

Interviewer: ________________________________ Date of interview: ___ / ___ / ____

Grades of participation restriction

No significant restriction	Mild restriction	Moderate restriction	Severe restriction	Extreme restriction
0 – 12	13 – 22	23 – 32	33 – 52	53 – 90

Disclaimer: The Participation Scale is the intellectual property of the Participation Scale Development Team. Neither the Team nor its sponsors can be held responsible for any consequences of the use of the Participation Scale.

Annex 10

Five-point scale for stigma assessment

For the community:

In your community or neighbourhood:	**Never**	**Some-times**	**Often/ usually**	**Don't know**
1. Would having (had) leprosy cause problems for a person to find work or keep his or her job?	0	1	2	0
2. Would someone with leprosy be worried about others knowing this?	0	1	2	0
3. Does having leprosy cause shame to the person affected?	0	1	2	0
4. Would leprosy cause a problem to get married or in an existing marriage?	0	1	2	0
5. Would people try to avoid someone with leprosy?	0	1	2	0

5-QSI-CS indicator score: 0-10

For the affected persons: year:

In the past year:	**Never**	**Some-times**	**Often/ usually**	**Don't know**
1. Have you experienced problems in finding or keeping work because you have (had) leprosy?	0	1	2	0
2. Have you been worried about others finding out you have (had) leprosy?	0	1	2	0
3. Have you felt ashamed because of your condition?	0	1	2	0
4. Have you had problems getting married / in your marriage because of leprosy?	0	1	2	0
5. Have people tried to avoid because you have (had) leprosy?	0	1	2	0

5-QSI-CS indicator score: 0-10

This Monitoring & Evaluation Guide is the third document on the Global Leprosy Strategy 2016–2020 "Accelerating towards a leprosy-free world" and follows closely the August 2016 publication of the Operational Manual. To monitor progress towards the Global Leprosy Strategy 2016–2020 targets and to assess the implementation of such a wide and comprehensive umbrella, a stronger system must be put in place, counting on new tools. To help countries to adopt these new tools and to have a common understanding on the means and procedures to measure the extent and direction of progress, the Guide has been developed by the Global Leprosy Programme with inputs from several partners and core stakeholders, including leprosy programme managers. Its audience comprises national and regional/state level managers of leprosy programmes as well as consultants that support countries as technical assistant providers and as monitors of programmes and projects on leprosy.

World Health Organization
Regional Office for South-East Asia
World Health House
Indraprastha Estate
Mahatma Gandhi Marg
New Delhi-110002, India

ISBN 978-92-9022-549-2