Validation of Leprosy Diagnosis in India 2004

Government of India, WHO, NIHFW

in collaboration with

ILEP
International Federation
of Anti-Leprosy Associations

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Foreword

Under the second phase of World Bank supported National Leprosy Elimination Project due emphasis was laid on regular monitoring of the progress of the programme implementation. Subsequent to the start of the project in 2001-02, the Programme has redesigned an inbuilt Simplified Information System to concurrently monitor the progress in implementation and initiate timely corrective measures at all levels of implementation.

Different Surveys carried out have shown that there are instances of over diagnosis or under diagnosis in different states, which needs to be understood better. The programme therefore felt the need for a properly designed study for new case validation alongwith the LEM – 2003 and thereafter. WHO with the help of ILEP and Govt. of India agreed to carry out validation studies separately but simultaneously with LEM 2003, 2004 and 2005. The current Validation – 2004 was conducted between 17th June and 3rd July 2004.

We are sure that the observations of the Validation – 2004, like in the case of the previous study will immensely benefit the Programme Managers to take suitable action as needed, so that only correctly diagnosed leprosy cases are recorded and put under treatment.

(DR. G.P.S. DHILLON)

PREFACE

The Government of India introduced Multi Drug Therapy (MDT) in 1983 and renamed ongoing control programme as National Leprosy Eradication Programme (NLEP). With the sustained efforts, the National Level Prevalence Rate for leprosy has declined from 57.6/10,000 in 1983 to 2.4/10,000 in March 2004. With the integration of NLEP programme and decentralization of decision making with the general health care services in the country, larger section of the society stands to benefit from the leprosy elimination services. As envisaged in the programme, the country is determined to eliminate Leprosy by 2005.

Several independent evaluations of the diagnosis of the diseases have been conducted in the past years in India, either on routine detection or just after special activities (MLECs). Results varied from 3 to 12% of wrong diagnosis and from 5 to 22% of re-registration of cases. Similar studies in other countries showed varied results but making comparison difficult due to different methodologies adopted. In order to get a clear picture of the quality of diagnosis of leprosy, Validation of Leprosy exercise was carried out in a standardized way in the endemic States of country. NIHFW in collaboration with WHO, GOI and ILEP carried out Validation Study for the first time in 2003. Using the same methodology, it was carried in 2004 again. Prof A.K. Sood was the Nodal Officer at NIHFW. It is hoped that the outcome will be useful for programme managers and appropriate actions will be taken for improvement of the programme.

Dr. N.K. Sethi
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All the validators and district facilitators (list in annexure) who made their services available for the Validation exercise deserve a special mention, without their contribution it would not have been possible to carry out such a nation wide exercise. The facilities and support provided by the state governments, district authorities, WHO coordinators, members of ILEP agencies and Regional Leprosy Training Institutes is highly appreciated.

The contribution of Dr. Sandeep Sachdeva (Epidemiologist, LEM Project) and staff members of Department of Education and Training is duly acknowledged. The data entry and typing work was done by Mr. Shiv Kumar, Mrs.Varsha Mudgal and Mr. Vikas Kulhan, I.T. Officer. The cover design was made by Shri Ashok Chaudhary. The contribution of Post graduate students of NIHFW Dr. L. Swasthicharan, Dr. Ritu Beri, Dr. Veenu Goel, Dr. Shivani and Dr. Mithila, is highly appreciated. The administrative support from DD(A), Dean's office, Accounts Section, Stores Section, WMO Section, Reprography and Hostel of NIHFW is also acknowledge.

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Abbreviations

ANM	Auxiliary Nurse Midwife
CI	Confidence Interval
CMO	Chief Medical Officer
DFIT	Damien Foundation India Trust
DLO	District Leprosy Officer
DTST	District Technical Support Team
ILEP	International Federation of Anti Leprosy Association
GOI	Government of India
LEM	Leprosy Elimination Monitoring
MB	Multi Bacillary
MDT	Multi Drug Therapy
MLEC	Modified Leprosy Elimination Campaign
MO	Medical Officer
MOHFW	Ministry of Health Family and Welfare
NCDR	New Case Detection Rate
NE	Non Existent (Fake cases)
NIHFW	National Institute of Health and Family Welfare
NLEP	National Leprosy Eradication Programme
NLR	Netherlands Leprosy Relief
NMS	Non Medical Supervisor
PB	Pauci Bacillary
P/D ratio	Prevalence / Detection ratio
PHC	Primary Health Centre
PR	Prevalence Rate
RR	Re-Registered (cases)
SLO	State Leprosy Officer
TLM	The Leprosy Mission
TNA	Traced but Not Available (cases)
WHO	World Health Organization

EXECUTIVE SUMMARY

Since 1985, leprosy prevalence has steadily decreased in India to 2.4/10 000 in March 2004. More than 10 million leprosy cases have been cured in India over the past 20 years. From 1991 to 2002, the detection rate remained stagnant. It has substantially declined in the recent years. Nevertheless, leprosy detection rates in India are among the highest in the world. Among factors that could contribute to this phenomenon, the quality of diagnosis was identified as a potential component, which could influence the detection rate. Several small scale independent evaluations of the accuracy of leprosy diagnosis have been conducted in India and in the South-East Asia Region, during the previous years. Results showed substantial proportions of wrong diagnosis and re-registration of old cases. But the methodologies used were not standardised, making difficult comparison of results.

In order to get a better picture of the quality of leprosy diagnosis in India, a validation of diagnosis study, supported by WHO, was conducted in 12 priority states, from 17th June to 3rd July 2004 in 10 states, and from 1st to 15th September 2004 in Jharkhand and Orissa, due to the delay in completing the fifth MLEC. In each state, one district was randomly selected. All recently detected cases (in the past one month for PB and the past two months for MB cases) in the selected districts were eligible for being double-checked by a team of two validators per district.

Twelve teams of 2 validators conducted the study, after a two-day standardization workshop at NIHFW, where most of the NLEP partners participated. Newly detected cases were re-examined independently by the validators, without sharing any of their findings. Information was collected separately in a validation form, and was send to NIHFW, which ensured the data entry on the Epi-Info software.

After data cleaning, data analysis was done by matching the two records per patient, including the findings of both validators. The analysis of wrong diagnosis and wrong grouping was conducted on patients whom agreement by both validators was found. Validators findings were compared to the diagnosis and grouping made by the health workers involved in the leprosy programme. When a disagreement occurred among validators, the concerned cases were excluded from the analysis. Each indicator of wrong diagnosis, wrong grouping and re-registration was calculated globally (for both PB and MB cases), as well as for PB and MB cases separately.

The results of the validation study were as follows:

- *Among the twelve states included in the study, 1510 cases were listed by the routine programme health workers, as newly detected during the reference period.*
- *Out of 1510 listed cases, attempt was made by the validators to contact 1461 of them (97%).*
- *Among the 1461 cases, 1081 (74%) were seen by both validators. The others were represented by patients traced but not available or non-existent (fake) cases.*
- *Among the 1081 cases seen by the validators, 879 were examined by both of them. The remaining 202 cases (18.7%) had taken previous MDT treatment, and therefore were identified as re-registered cases.*
- *Among the 879 cases examined, the validators agreed on diagnosis (case of leprosy or not a case) in 822 of them. The remaining 57 cases, with disagreement on diagnosis, were excluded from the analysis.*
- *Overall, the agreement between validators was 93.5% on diagnosis, 92.3% on grouping, 92.0% for anaesthetic skin lesion, and 78.7% on nerve involvement.*

<u>Re-registration of old cases as new cases</u>

- *Among the 1081 cases seen by the validators, 202 (18.7%, [with 95% CI: 16.4%-21.0%]) had taken MDT in the past and therefore were considered as re-registered cases.*
- *The proportion of re-registration was extremely high in Tamil Nadu (45.5%), Delhi (36.2%), Orissa (32.6%), and West Bengal (28.8%).*
- *Low proportion of re-registration was found in Madhya Pradesh (4.3%), Jharkhand (8.3%), and Chhattisgarh (8.3%).*
- *The overall proportion of re-registration of MB cases was 25.5% [95% CI: 22.1%-28.9%], significantly higher than 8.8% [95% CI: 6.2%-11.4%] for PB cases.*
- *The re-registration of MB cases was extremely high in Tamil Nadu (78.9%), Delhi (42.9%), and Orissa (41.7%).*
- *The re-registration of PB cases ranged from 0% in Karnataka and West Bengal to 26.3% in Delhi.*

Wrong diagnosis

- *Among the cases, for whom validators agreed on diagnosis, 9.4% of them [95% confidence interval [CI] 7.4%-11.4%] were found wrongly diagnosed (not leprosy).*
  The proportion of wrong diagnosis varied widely among states. The states reporting high proportion of wrong diagnosis were Madhya Pradesh: 19.0% [95% CI: 7.1%-30.9%], Orissa: 17.2% [95% CI: 8.0%-26.4%], Andhra Pradesh: 15.4% [95% CI: 4.1%-26.7%], and Maharashtra: 12.4% [95% CI: 6.3%-18.5%].
- *High endemic states like Chhattisgarh, Bihar, and Jharkhand had low proportion of wrong diagnosis, 3.7%, 4.6% and 6.7% respectively.*
- *The overall proportion of wrong diagnosis of PB cases was 11.1% [95% CI: 7.9%-14.3%], higher than 8.0% [95% CI: 5.5%-10.5%] for MB cases.*
- *The wrong diagnosis of PB cases was especially high in Madhya Pradesh (27.3%), Uttar Pradesh (22.7%), Andhra Pradesh (20.8%), and Maharashtra (18.2%).*
- *The wrong diagnosis of MB cases was high in Orissa (28.6%0, Madhya Pradesh (16.1%),and West Bengal (12.5%).*

Wrong grouping

- *Among the 688 cases confirmed as leprosy, for whom the validators agreed on grouping as PB or MB, 12.8% [95% CI: 10.3%-15.3%] of cases were wrongly classified by the health staff involved in NLEP.*
- *The proportion of wrong grouping was high in West Bengal (40.6%), Madhya Pradesh (39.4%), Karnataka (15.2%), Uttar Pradesh (14.3%), Bihar (12.6%), Orissa (11.5%), and Delhi (11.1%).*
- *The wrong grouping was low in Tamil Nadu (0%), Andhra Pradesh (3.3%), and Maharashtra (4.4%).*
- *The wrong grouping of MB cases – which were in fact true PB cases – was significantly higher with 17.8% [95% CI: 14.0%-21.6%] than the wrong grouping of PB cases: 6.6% [95% CI: 3.8%-9.4%].*
- *Wrong grouping of MB cases was extremely high in West Bengal (56.5%), Madhya Pradesh (52.0%).*

Non-Existent cases

- *Overall, the proportion of non-existent (fake) cases was 5.2%. It was high in Delhi (38.7%), and lower in Bihar (5.7%) and Uttar Pradesh (3.8%).*

Summary of over-reporting

- *The causes of over-reporting were wrong diagnosis, re-registration and non-existent cases. Using as denominator the number of cases where attempt was made by the validators to contact those (1461) minus the 277 existent cases but not available, it appears that overall the number of newly detected cases was over reported by* ***at least 30%.***
- *Over-reporting is artificially inflating the prevalence and detection rates, which are essential indicators used by programme managers to monitor the programme. Quality of diagnosis is therefore an important component of the programme, which needs to be substantially improved.*

Recommendations

1. *All health workers involved in the diagnosis of leprosy should apply the standard definitions of a new case of leprosy and its classification as PB or MB case.*
2. *All health workers involved in the diagnosis of leprosy should perform the clinical examination by applying standard criteria and procedures for testing the sensory deficit of a skin lesion (Annexure-I) and looking for nerve involvement (Annexure-II).*
3. *Special attention should be paid for the diagnosis of PB cases, in order to avoid wrong diagnosis.*
4. *All health workers involved in the diagnosis of leprosy should systematically ask the patient, at the time of diagnosis, about history of previous MDT taken by the patient, in order to avoid re-registration.*
5. *Special attention should be paid to MB cases, in order to avoid re-registration.*
6. *Each block or district should be set up a feasible system for routinely validate the newly detected cases. District Technical Support Teams and reference Medical Officer from the district should be actively involved in this process.*
7. *On-the-job training should be conducted in areas where high proportion of wrong diagnosis, wrong grouping or re-registration had been identified.*
8. *For cases found wrongly diagnosed, their MDT treatment should be stopped and their name removed from the leprosy register.*
9. *For patients found wrongly classified as PB or MB, the treatment should be adjusted (shortened or extended). Treatment register and patient's card should be updated accordingly.*
10. *Non-existent patients should be removed from the leprosy register.*

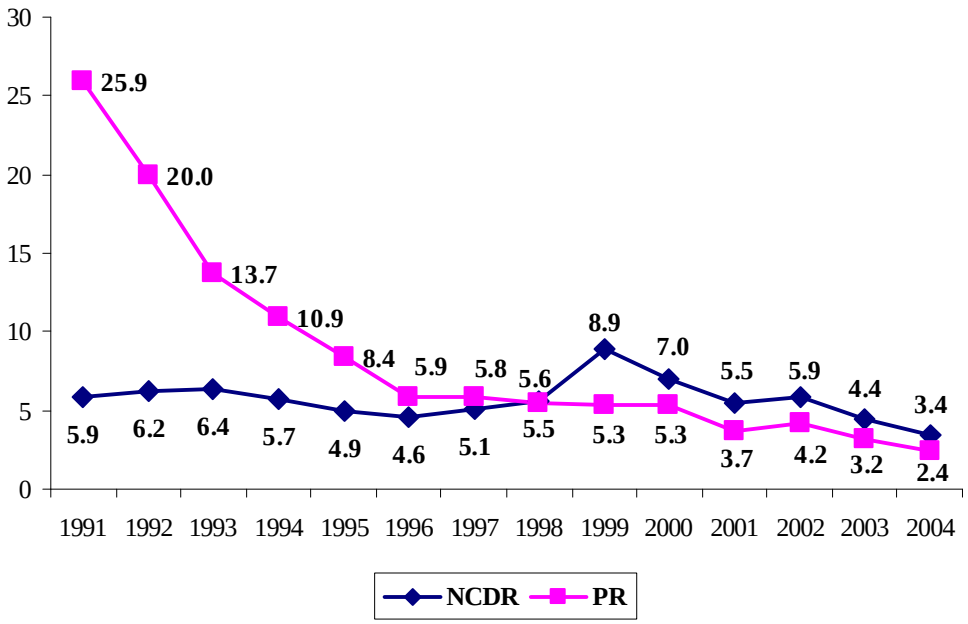
VALIDATION OF LEPROSY DIAGNOSIS IN INDIA, 2004

INTRODUCTION

Prevalence of leprosy in India has steadily decreased since 1985, when Multi-Drug Therapy (MDT) was introduced in phases, falling by 94% in the period up to March 2004 (Figure 1). From 1998 to 2004, the prevalence showed a declining trend with a small increase in March 2002, due to a higher number of cases detected during that year.

Trends of detection increased in 1999 mostly due to the first Modified Leprosy Elimination Campaign (MLEC), which was also carried out in 2000. In 2001, there was no MLEC conducted in India, explaining the sharp drop in detection. The third, fourth MLECs were carried out in 2002 and 2003 respectively. During the year 2003-2004, a fifth MLEC was conducted in 6 priority states, while two other states (Jharkhand & Orissa) carried it out after March 2004, end of the fiscal year.

Figure 1: Trends of Leprosy Prevalence and Detection Rates per 10 000, India, 1991 - 2004



From 1991 to 2002, the detection trend was stagnant. The increase in 1999 and 2000 can partly be explained by intensified activities, such as MLECs as well as a significant increase in the geographical coverage of MDT services due to the phased integration of the leprosy programme into the general health care system.

If data are analysed from 1999, year of the first MLEC, it showed a steady decline in detection, taking into account that no MLEC was carried out in 2001. The decline in

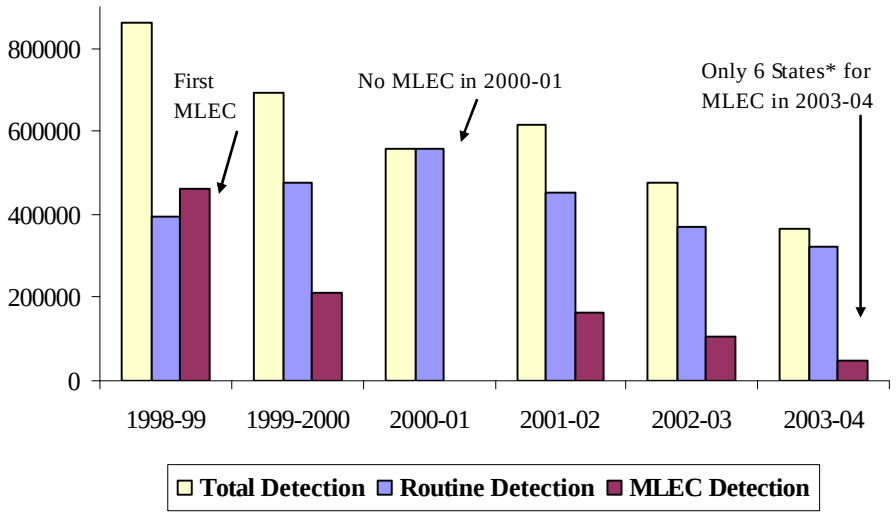
detection has accelerated during the last two years. From March 2002 (617 993 cases detected during the year) to March 2003 (476 000 cases), the decline in detection was 23%. Similarly, from March 2003 to March 2004 (367 143 cases detected), a 23% decline in detection was also observed. Nevertheless, the leprosy detection rates in India are among the highest in the world. During the past five years, between 367 000 and 700 000 cases were detected each year.

Despite the significant decline of cases detected through consecutive MLECs overtime, the number of cases annually detected through routine leprosy services remained high (Figure 2).

This paradoxical situation could be due to a combination of factors: 1) lack of sufficient efficiency of the MLECs supposed to clear most of the backlog cases, 2) increased community awareness and improved leprosy services coverage through integration, 3) operational factors such as fulfilling annual detection targets, over-diagnosis and re-registration of old cases, and 4) high transmission in various areas.

It was noted that since April 2003, for the first time in India, no detection targets have been set-up by the Central Leprosy Division, Government of India.

Figure 2: New leprosy cases detected through routine and MLEC, India, 1998 – 2004



(*): Two states, - Jharkhand & Orissa -, conducted MLEC after March 2004; therefore the cases detected during MLEC-5 in these 2 states will be included in the March 2005 report.

As opposed to other diseases, a gold standard laboratory test does not exist for the diagnosis of leprosy. The skin smear test used for leprosy is positive for cases with a high bacteriological index of *Mycobacterium leprae*, mostly MB cases. The sensitivity of the skin smear is low. Therefore, the only way to validate the diagnosis of leprosy is by using standard procedures during clinical examination.

Several independent evaluations of the diagnosis accuracy have been conducted in the past years in India, either on routine detection or just after MLECs. Results varied from 3 to 12% of wrong diagnosis and from 5 to 22% of re-registration of cases. In other countries of the region, quality of diagnosis after leprosy elimination campaigns was assessed, showing between 10 and 20% of wrong diagnosis and between 10 and 25% of re-registration among newly detected cases. It was noted that the various studies used different methodologies, making difficult to compare results.

As on March 2004 in India, twelve endemic States represent 93.6% of the total prevalence of the country. They are Andhra Pradesh, Bihar, Chhattisgarh, Delhi, Jharkhand, Karnataka, Madhya Pradesh, Maharastra, Orissa, Tamil Nadu, Uttar Pradesh and West Bengal. As on March 2004, these twelve states represented 94.0% of the newly detected cases, during the previous 12 months.

In order to get a better picture of the quality of leprosy diagnosis in the country, a validation of diagnosis study, supported by WHO, was carried out in the twelve priority states. For 10 of them the study was carried out from 17th June to 3rd July 2004, and for Jharkhand & Orissa from 1st to 15 September 2004. This delay was due to late completion of the fifth MLEC, as the Validation of diagnosis study is based on cases detected by the routine programme, outside the MLEC, known for a higher proportion of wrong diagnosis.

The study used uniform, standardized criteria and procedures for diagnosis, as described below. The study was co-ordinated by the National Institute of Health and Family Welfare (NIHFW). This study involved most of the partners of the National Leprosy Eradication Programme (NLEP), such as GoI, WHO, ILEP agencies and NIHFW. The information of such a study would be useful to quantify the extent of over-diagnosis and re-registration, and be helpful for improving the quality of programme implementation.

The 2004 Validation of Leprosy Diagnosis study was a follow-up of a similar study, which was conducted for the first time in India, in 2003.

The design of the study and the methodology was worked out to set up standards for validation of leprosy diagnosis, which could be used elsewhere, thus making it easier comparison of results.

OBJECTIVE

The objective the study was to assess the accuracy of the diagnosis among recently detected new cases of leprosy, in 12 States of India.

Specific objectives

Among the newly detected cases by the routine programme:

1. To assess the proportion of wrongly diagnosed cases;
2. To assess the proportion of re-registered cases;
3. To assess the proportion of wrong grouping of leprosy cases;
4. To assess the proportion of non-existent cases.

METHODOLOGY

In order to achieve a high quality study, a core group was set up. It comprised members representing the Government of India, WHO, NIHFW, DFIT, NLR, TLM and the State Leprosy Officer of Delhi. The objective of the core group was to ensure a quality control mechanism at each stage of the study, from the protocol to the final report.

The study was carried out in 10 states from 17th June to 3rd July, and from 1-15th September 2004 in Jharkhand and Orissa. For each state, two validators were identified. The study was conducted by 12 teams of two validators each. Validators were Medical Officers, with at least ten years of field experience in leprosy, coming from various institutions and organisations, both from Government and Non-Government set-up. Validator teams were assigned to States in which they were not involved, in order to avoid potential bias.

Sampling of districts

In each of the 12 states, a list of districts was prepared in the descending order of number of new cases detected during 2003 (from 1st April 2003 to 31st March 2004). This was to ensure the probability of selecting the districts that would yield enough number of

cases for the study. For sample size purposes, the goal was to get at least 100 new cases per district.

From among the top five districts detecting reasonably large number of cases, one was selected by simple random method. The selected districts were: Chittor (Andhra Pradesh), Gaya (Bihar), Durg (Chhattisgarh), West Singhbhum (Jharkhand), Bangalore urban (Karnataka), Shahdol (Madhya Pradesh), Jalgaon (Maharashtra), Mayurbhanj (Orissa), Thiruvannamalai (Tamil Nadu), Allahabad (Uttar Pradesh), Murshidabad (West Bengal) and North West district in Delhi.

Criteria for inclusion

All recently detected cases by the routine programme during the following recall period: in the past one month for PB and in the past two months for MB cases, were included in the study (PB cases detected from 1st to 31st May and MB cases detected from 1st April to 31st May 2004). For Jharkhand and Orissa the included cases were detected from 1st to 31st August (PB cases), and from 1st July to 31st August (MB cases).

The patients with generalised infiltration of skin/nodules only (without skin patches) were excluded from the study.

Standardisation workshop

Despite the commensurable experience of the selected validators, it was felt by the core group members that a 2-day standardisation workshop was mandatory. It took place at NIHFW, just before the field work (15-16 June 2004), with 24 validators as participants and 5 facilitators from GoI, WHO, NIHFW, DFIT and TLM. Responsibilities of each facilitator were determined in advance. Meeting for preparation of the technical and logistical aspects was held prior to the workshop.

The main objective of the workshop was to reach at least 90% of agreement between the participants for diagnosis and grouping (classification) of leprosy cases.

The first day was a dedicated to technical subject, with emphasis on demonstration, including:

- Objectives of the workshop and the presentation of the study,
- Diagnosis of cardinal signs,
- Standardised procedures for sensory testing, (Annexure – I),

- Standardised procedures for examination of ulnar and lateral popliteal nerves (Annexure – II),
- Criteria used to define a new case, old case, not a case of leprosy (Annexure– III),
- Criteria used for grouping/classifying leprosy cases as PB or MB,
- Introduction to the forms used during the study,
- Practical aspects of field work.

The second day way almost entirely dedicated to practice the concepts and demonstrations explained on Day one. A sample of 15 leprosy patients recently detected, PB and MB cases, as well as patients with dermatological conditions but not leprosy cases, participated in the workshop. Patients were all volunteers and received Rs. 100 as incentive. Four small groups of six validators were set-up. Each validator independently examined at least five patients of various types (2 PB, 2 MB, 1 with nerve involvement, 1 not leprosy) and filled the validation form. At the end of the practice, validation forms were compared. When there was a disagreement (on diagnosis or grouping) between validators, the clinical examination and standard procedures were reviewed and patients re-examined, until an agreement was reached. This exercise was repeated several times.

The last session of the workshop was for logistics and administrative aspects. A checklist on practical aspects at the patient screening point was distributed to the validators (Annexure – IV). Maps of the selected districts were made available to the validators. The validators went to their respective field work the next day.

The “district facilitators” (see below) also attended the 2-day workshop. During the second day, emphasis was on their role during the data collection phase.

Operational aspects

Lessons were learnt for last year experience. In 2003, out of the 2541 cases listed by the NLEP during the reference period, 1737 cases were seen by the validators, representing an attrition of 32%. This was attributed to gaps in the preparation phase during which screening points were identified, day-to-day route chart was prepared, and patients were informed to come to the screening points on a specific day. In addition, last year data suggested that some validator teams did not fully follow the required protocol, some of them sharing their findings during the data collection phase. In order to reduce the attrition rate

and to avoid potential bias during the data collection, the core group decided to standardise the preparation and the data collection phases by adding one “district facilitator” per state.

The district facilitators were given the responsibility of being the focal point for the preparatory phase of the study. In liaison with the District Leprosy Officer (DLO) and the Medical Officers In-Charge (MO/IC) of the PHCs, they were responsible to coordinate the listing of cases detected during the reference period, to map these cases, to identify the most suitable screening points, to prepare a realistic day-to-day route chart for the Validators, and to ensure that patients were informed in advance.

In addition, the district facilitators were responsible during the data collection phase to assist the validator teams by: 1) coordinating logistics aspects at the screening points, 2) ensuring that patients were examined by both validators without communicating findings, and 3) helping for tracing patients at home, when necessary. A detailed job description of district facilitators is presented in Annexure – V.

Most of the district facilitators involved in the study were Non-Medical Supervisors from the District Technical Support Teams of ILEP agencies. They were familiar with the selected districts, so that their knowledge of the area would be helpful for both the preparatory and data collection phases.

In order to standardise the methodology, a one-day workshop was organised at NIHFW on 28 May 2004, about 6 weeks before the field work data collection.

About two months before the start of the study, the respective states were informed by a letter from the Central Leprosy Division (GoI), that a validation of diagnosis study was going to be conducted. Two weeks before the start of the study, District Leprosy Officers (DLOs) of selected districts were asked to list all the new detected cases during the reference period, with the support of the district facilitators.

The Medical Officers (MOs) of blocks Primary Health Centres (PHC, covering an average of 100 000 population) prepared a list of recently detected patients. Information included: district name, block PHC name, patient name & address, sex, age, MB/PB, date of detection. Depending on the convenience of the patient and the density and geographical distribution of the cases, the MOs and district facilitators identified screening points and prepared a day-by-day route chart with dates and time (Annexure – VI). Screening points could be either a PHC, a health sub-centre, a hospital or a dispensary.

District Medical Officers, with the support of the district facilitators, were responsible for coordinating the information to the patients to meet at their respective screening points. The information was passed to the patients by either block PHC Medical Officer, auxiliary nurse midwife (ANM), non medical supervisor (NMS), District Technical Support Teams (DTST), or WHO/NLEP coordinator.

For each recently detected patient listed by the routine programme, a validation form was filled by each validator. Either the patient was present at the screening point and seen on the spot by the validator team, or he/she was absent. In case of absence, the validators made an attempt to contact the patient at home, with the help of people familiar with the area. If the patient was met at home, the validators conducted the procedure in the same way that at the screening point. If the patient was absent from home and was not available for examination, he/she was considered “traced but non available”. If the patient was unknown at the listed address by any of the neighbours, he/she was considered “non existent”, and therefore classified as a fake case.

Travel arrangement for the validators to the respective states and districts were prepared in advance by NIHFW and GoI. Local logistic arrangements (vehicle, accommodation) were prepared in advance by the district authorities.

Patient examination and data collection

At the screening points, all the cases were seen independently by both validators who recorded their observations in the validation form (Annexure – VII), without sharing any information on their respective findings. Two validation forms, corresponding to the same patient, were filled independently by the validators, and collected on the spot by the district facilitator who checked the forms for completeness.

Each validator started the patient examination by asking question about previous leprosy treatment taken by the patient. If the answer was positive, the case was labelled as “re-registered” and no further clinical examination was performed. If the answer was negative, the validator went through a standard procedure: a) examined the patient to locate the skin lesions, b) did the sensory test with Reynold’s ball pen for eliciting sensory deficit,

c) examined the ulnar and lateral popliteal nerves, d) categorised the clinical condition as leprosy or not leprosy, and e) classified the disease as PB or MB if leprosy.

During the field work, the validators were assisted by the district facilitator to ensure that the implementation was made according to the protocol. His responsibility was to assign a serial number to each case and transfer the relevant information from the patient card to two validation forms and hand them over to the validators. He ensured that all the cases were examined by both validators and verified the completeness of the forms. Each pair of forms, corresponding to the same patient, was stapled together. At the end of each screening point' session, forms were put into a sealed envelope by the district facilitator. At the end of the field work, all sealed envelops were handed over to the validators to be brought back to NIHFW, Delhi.

A debriefing session with the validator teams was conducted on 5th July 2004 at NIHFW (16th September for Jharkhand & Orissa teams). Validation forms were double-checked for completeness and consistency. Forms were then handed over to NIHFW who was responsible for data entry.

Ethical issues

It was decided by the core group members that for patients found to be wrongly diagnosed (not leprosy) by both validators, their treatment should be stopped and their name removed from the leprosy register. Similarly, for patients found to be wrongly classified as PB or MB, their treatment should be re-adapted (shortened or extended) according to the validators grouping and the leprosy register and patient card updated. These measures were the responsibility of the Medical Officer in-charge, after being informed of the results of the study.

Data entry and analysis

Data were entered at NIHFW by two data entry operators, by using the Epi-Info software (Version 3.2.2 Windows). Each validation form was entered as a single record, including the findings of both validators. An in-depth data cleaning process was conducted to ensure a high quality data set.

The analysis of wrong diagnosis and wrong grouping was conducted on patients in whom agreement by both validators was found. When a disagreement occurred among validators, the concerned cases were excluded from the analysis, as there was no way to determine who was right or wrong. The numbers and proportions of disagreement for diagnosis and grouping were quantified.

Each indicator of wrong diagnosis, wrong grouping and re-registration was calculated globally (for both PB and MB cases), as well as for PB and MB cases separately (Annexure – VIII).

To assess the performance of the validator teams (Annexure – IX), analysis on agreement of sensory deficit and nerve involvement was also performed. For analysis purposes, “total” and “partial” sensory deficit were combined in one category.

Main criteria for validation of leprosy diagnosis study

In order to contribute to a standardised method for the validation of leprosy diagnosis, the following cardinal points were identified as key elements of the present study:

- Recall period: 1 month for PB cases, 2 months for MB cases,
- Standardisation workshop for validators: of 2 days, with one day of clinical practice, at the end of which at least 90% of agreement on diagnosis and grouping among validators was reached,
- Two validators per team, independently examining the patients, without sharing findings,
- Analysis of data based on agreement between the validators, for diagnosis and grouping; cases with disagreement were excluded from the analysis.

RESULTS

1. Description of the sample

According to the methodology presented above, the validation of diagnosis study covered the following:

Table 1: Description of the sample

Parameter	Andhra Pradesh	Bihar	Chhattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Cases listed by NLEP (1)	55	235	202	106	129	73	56	207	110	46	222	69	**1510**
Cases where attempt was made to contact them	55	229	202	106	128	73	56	181	108	46	208	69	**1461**
Cases seen by validators (2)	54	158	121	47	109	59	46	152	95	44	130	66	**1081**
Cases examined by validators (3)	45	134	111	30	100	51	44	133	64	24	96	47	**879**
PB cases examined	30	84	45	14	43	16	12	78	29	20	22	11	**404**
MB cases examined	15	50	66	16	57	35	32	55	35	4	74	36	**475**

Source: Validation teams

(1): All newly detected PB cases in the past 1 month and MB cases in the past 2 months, by the routine NLEP;
(2): Cases seen by validators were cases physically present at the validation screening places or at home;
(3): Cases examined were all cases seen by validators, minus the Re-registered cases.

Among the twelve states, 1510 cases were listed by the NLEP, as newly detected during the reference period. It ranged from 46 cases in Tamil Nadu to 235 in Bihar.

The overall proportion of cases where attempt was made to contact them was 96.8% (1461/1510) of listed cases. No attempt was made to contact some cases when accessibility was very difficult (floods, etc.) or when address of cases was missing.

A total of 1081 cases were seen by the validators. The overall proportion of cases seen by the validators was 71.6% (1081/1510) of listed cases. It varied from 44.3% in Delhi and 59.9% in Chhattisgarh to 98.2% in Andhra Pradesh. The cases that were not seen were represented by: a) cases where attempt to contact them was not made, b) cases traced by validators but not available, and c) cases traced but non existent (fake cases).

Among the 1081 cases seen by the validators, 879 cases (81.3%) were examined by both validators. The difference of 202 is represented by cases that had taken previous MDT treatment, and therefore identified as re-registered cases. The overall proportion of cases examined by the validators was 58.2% (879/1510) of the total of listed cases. It varied from 28.3% in Delhi to 81.8% in Andhra Pradesh.

Table 2: Description of the sample, Cases examined by age group and sex

Parameter	Andhra Pradesh	Bihar	Chhattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Cases examined by validators	45	134	111	30	100	51	44	133	64	24	96	47	**879**
Adults	38	97	97	29	79	46	38	105	54	20	84	43	**730**
% Adults	84.4	72.4	87.4	96.6	79.0	90.2	86.4	79.0	84.4	83.3	87.5	91.5	**83.0**
Children	7	37	14	1	21	5	6	28	10	4	12	4	**149**
Male	23	81	65	20	55	27	26	75	40	16	53	20	**501**
% Male	51.1	60.4	58.6	66.7	55.0	52.9	59.1	56.4	62.5	66.7	55.2	42.6	**57.0**
Female	22	53	46	10	45	24	18	58	24	8	43	27	**378**
Adult Male	18	60	58	20	46	26	22	61	35	13	45	19	**423**
Adult Female	20	37	39	9	33	20	16	44	19	7	39	24	**307**

Source: Validation teams

Overall, among 879 cases examined, 730 (83%) were adults and 149 (17%) children. The adult proportion varied from 72.4% in Bihar to 91.5%% in West Bengal (96.6% in Delhi but small sample).

Overall, among cases examined, 501 (57%) were male and 378 (43%) female. The male proportion varied from 42.6% in West Bengal to 62.5% in Orissa (66.7% in Delhi and Tamil Nadu, but small samples). Among adult cases, 423 (58%) were male and 307 (42%) female. Among children cases, 78 (52.3%) were male and 71 (47.7%) female.

Among the 879 cases examined, agreement on diagnosis (leprosy or not leprosy) between validators was reached for 822 of them (93.5%). The remaining 57 cases with disagreement were excluded from the analysis (see flow chart, next page).

Similarly, among 745 cases diagnosed as leprosy by both validators, agreement on grouping was reached for 688 of them (92.3%). The remaining 57 cases were excluded from the analysis of wrong grouping.

In addition, 27 cases with infiltration only (without skin patches), were excluded from the analysis, as they did not meet the inclusion criteria (page 5).

Flow Chart

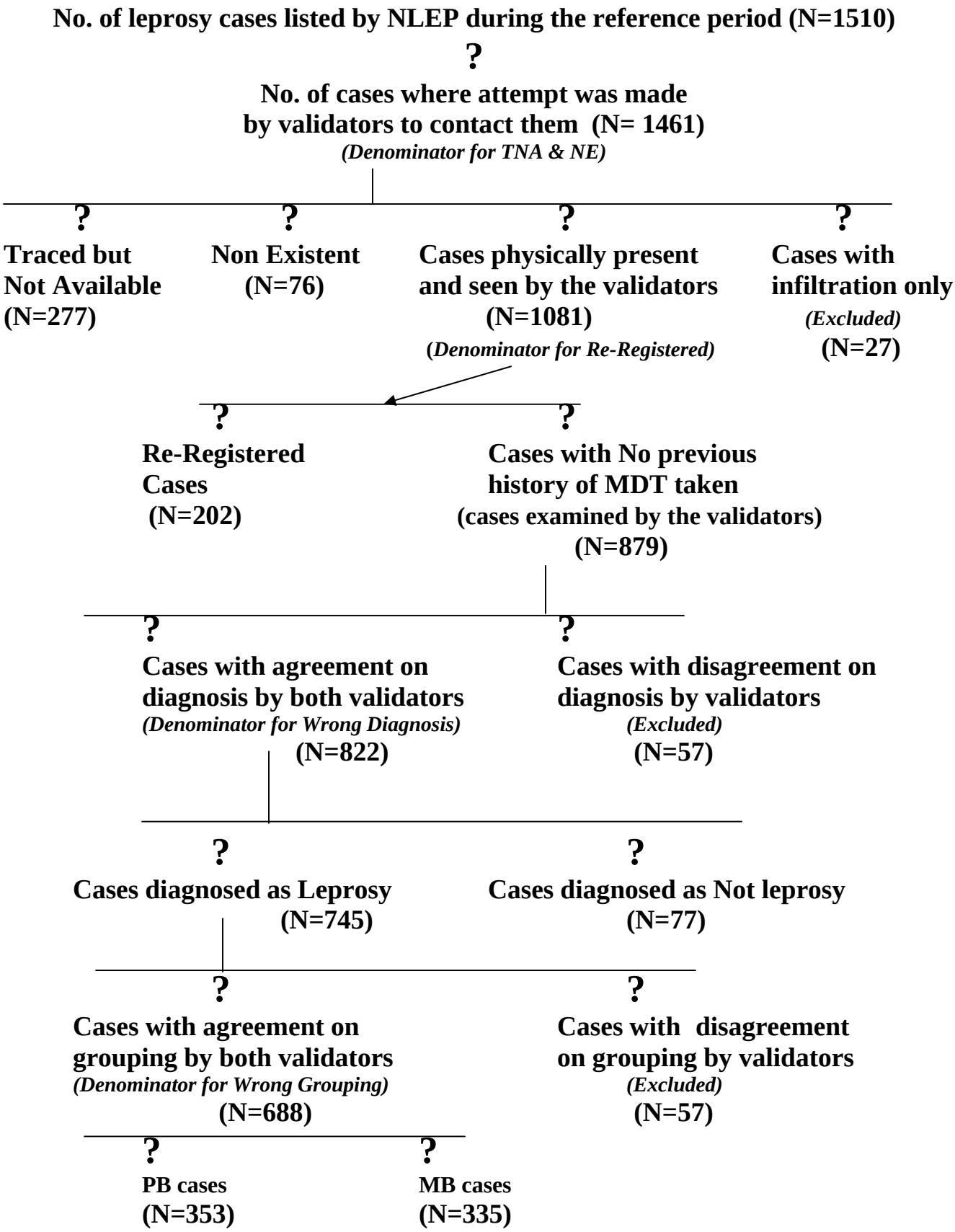

No. of leprosy cases listed by NLEP during the reference period (N=1510)
No. of cases where attempt was made by validators to contact them (N= 1461)
(Denominator for TNA & NE)
Traced but Not Available (N=277)
Non Existent (N=76)
Cases physically present and seen by the validators (N=1081)
(Denominator for Re-Registered)
Cases with infiltration only (Excluded) (N=27)
Re-Registered Cases (N=202)
Cases with No previous history of MDT taken (cases examined by the validators) (N=879)
Cases with agreement on diagnosis by both validators (Denominator for Wrong Diagnosis) (N=822)
Cases with disagreement on diagnosis by validators (Excluded) (N=57)
Cases diagnosed as Leprosy (N=745)
Cases diagnosed as Not leprosy (N=77)
Cases with agreement on grouping by both validators (Denominator for Wrong Grouping) (N=688)
Cases with disagreement on grouping by validators (Excluded) (N=57)
PB cases (N=353)
MB cases (N=335)

Table 3: Proportion of Wrong Diagnosis of leprosy cases

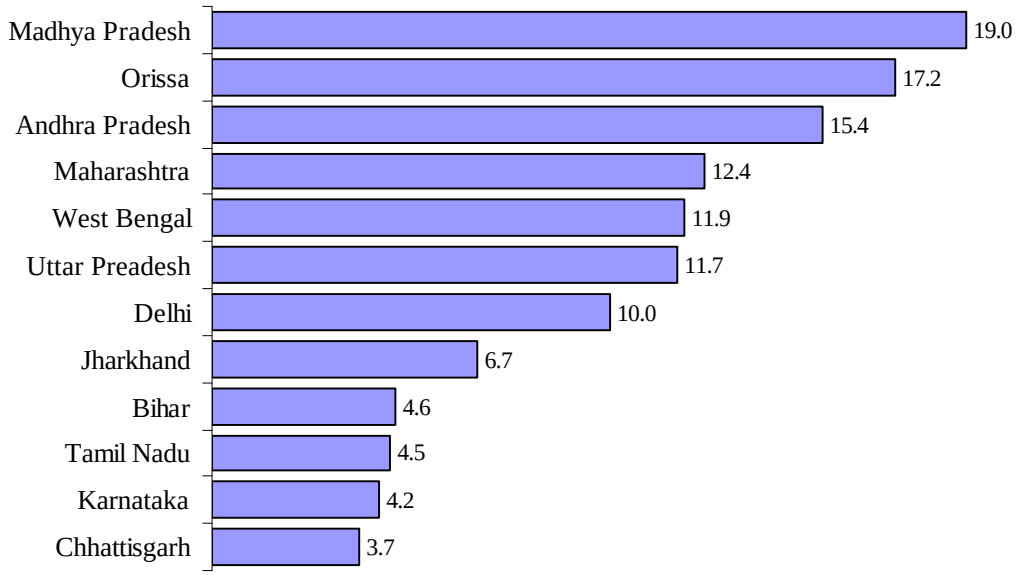
States	Both PB & MB cases	95% C.I. * (PB & MB)	PB cases	95% C.I. * (PB cases)	MB cases	95% C.I. * (MB cases)
Andhra Pradesh	15.4%	4.1% - 26.7%	20.8%	4.6% - 37.0%	6.7%	0% - 19.4%
Bihar	4.6%	1.0% - 8.2%	4.9%	0.2% - 9.6%	4.0%	0% - 9.4%
Chhattisgarh	3.7%	0.1% - 7.3%	9.5%	0.6% - 18.4%	0%	0%
Delhi	10.0%	0% - 20.7%	14.3%	0% - 32.6%	6.3%	0% - 18.2%
Jharkhand	6.7%	1.5% - 11.9%	2.7%	0% - 7.9%	9.4%	1.5% - 17.3%
Karnataka	4.2%	0% - 9.9%	14.3%	0% - 32.6%	0%	0%
Madhya Pradesh	19.0%	7.1% - 30.9%	27.3%	1.0% - 53.6%	16.1%	3.2% - 29.0%
Maharashtra	12.4%	6.3% - 18.5%	18.2%	8.9% - 27.5%	4.3%	0% - 10.1%
Orissa	17.2%	8.0% - 26.4%	3.4%	0% - 10.0%	28.6%	13.6% - 43.6%
Tamil Nadu	4.5%	0% - 12.8%	5.3%	0% - 15.4%	0%	0%
Uttar Pradesh	11.7%	5.2% - 18.2%	22.7%	5.2% - 40.2%	8.3%	1.9% - 14.7%
West Bengal	11.9%	2.1% - 21.7%	10.0%	0% - 28.6%	12.5%	1.0% - 24.0%
Total	**9.4%**	**7.4% - 11.4%**	**11.1%**	**7.9% - 14.3%**	**8.0%**	**5.5% - 10.5%**

Source: Clinical Examination and Observation of Validation teams
*: 95% C.I.: 95% Confidence Interval

Overall, the proportion of wrong diagnosis was 9.4% (with 95% confidence interval [CI]: 7.4%-11.4%). The states reporting high proportion of wrong diagnosis were Madhya Pradesh: 19.0% [95% CI: 7.1%-30.9%], Orissa: 17.2% [95% CI: 8.0%-26.4%], Andhra Pradesh: 15.4% [95% CI: 4.1%-26.7], Maharashtra: 12.4% [95% CI: 6.3%-18.5%].

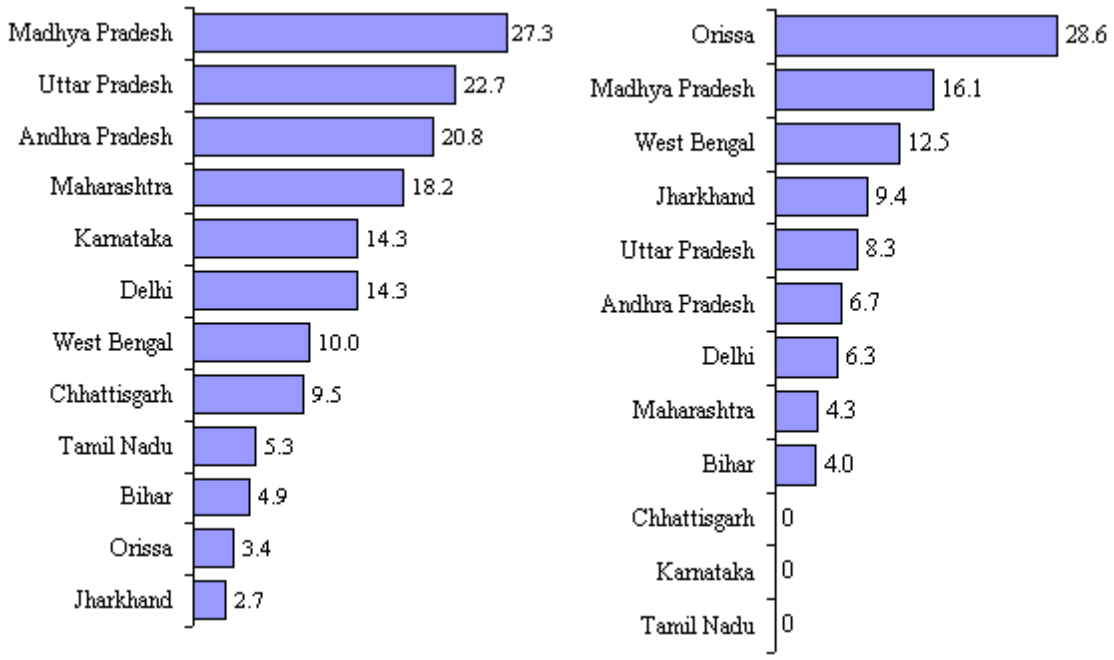
High endemic states like Chhattisgarh, Bihar and Jharkhand had very low proportion of wrong diagnosis, as well as Karnataka and Tamil Nadu (small sample).

Figure 1: Proportion of Wrong Diagnosis (both PB & MB cases), India 2004



The overall proportion of wrong diagnosis of PB cases was 11.1% [95% CI: 7.9%-14.3%], and 8.0% [95% CI: 5.5%-10.5%] for MB cases. All the states had higher proportion of wrong diagnosis of PB cases than of MB cases, except Jharkhand, Orissa, and West Bengal, in which it was reverse. However, the difference was significant in Orissa only.

Figure 2: Proportion of Wrong Diagnosis of PB and MB cases respectively



The wrong diagnosis of PB cases was especially high in Madhya Pradesh (27.3%), in Uttar Pradesh (22.7%), in Andhra Pradesh (20.8%), and in Maharashtra (18.2%).

The wrong diagnosis of MB cases was high in Orissa (28.6%), Madhya Pradesh (16.1%), and West Bengal (12.5%).

Among the 77 wrongly diagnosed cases, 23.4% were children, higher but not statistically different from the 17% of children included in the global sample (p value= 0.2). Similarly, 46.8% were female, higher but not statistically different than the 43% of female included in the global sample and examined by the validators (p value = 0.6).

Therefore, it can be stated that to be a child or a female was not a higher risk for wrong diagnosis, in the 2004 Validation study.

Wrong diagnosis has individual consequences for the patients, having to take a long-term treatment for a disease which they don't have. Wrong diagnosis also has public health consequences, by artificially inflating the prevalence and new case detection rates.

Table 4: Proportion of Re-registered leprosy cases

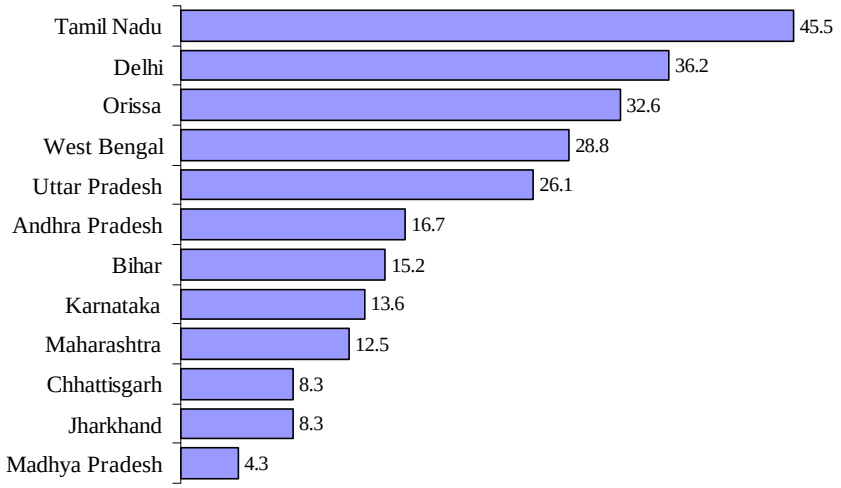
States	Both PB & MB cases	95% C.I. * (PB & MB)	PB cases	95% C.I. * (PB cases)	MB cases	95% C.I. * (MB cases)
Andhra Pradesh	16.7%	6.8% - 26.6%	6.3%	0% - 14.7%	31.8%	12.3% - 51.3%
Bihar	15.2%	9.6% - 20.8%	11.6%	5.2% - 18.0%	20.6%	10.6% - 30.6%
Chhattisgarh	8.3%	3.4% - 13.2%	2.2%	0% - 6.4%	12.0%	4.6% - 19.4%
Delhi	36.2%	22.5% - 49.9%	26.3%	6.5% - 46.1%	42.9%	24.6% - 61.2%
Jharkhand	8.3%	3.1% - 13.5%	6.5%	0% - 13.6%	9.5%	2.3% - 16.7%
Karnataka	13.6%	4.9% - 22.3%	0%	0%	18.6%	7.0% - 30.2%
Madhya Pradesh	4.3%	0% - 10.2%	7.7%	0% - 22.2%	3.0%	0% - 8.8%
Maharashtra	12.5%	7.2% - 17.8%	3.7%	0% - 7.8%	22.5%	12.8% - 32.2%
Orissa	32.6%	23.2% - 42.0%	17.1%	4.6% - 29.6%	41.7%	29.2% - 54.2%
Tamil Nadu	45.5%	30.8% - 60.2%	20.0%	4.3% - 35.7%	78.9%	60.6% - 97.2%
Uttar Pradesh	26.1%	18.6% - 33.6%	8.3%	0% - 19.3%	30.2%	21.5% - 38.9%
West Bengal	28.8%	17.9% - 39.7%	0%	0%	34.5%	21.9% - 47.1%
Total	**18.7%**	**16.4% - 21.0%**	**8.8%**	**6.2% - 11.4%**	**25.5%**	**22.1% - 28.9%**

Source: Observation of Validation teams, *: 95% C.I.: 95% Confidence Interval

All cases included in the study were cases diagnosed as new cases by the NLEP routine programme. A leprosy case was defined as re-registered if MDT had been taken by the patient in the past, anywhere.

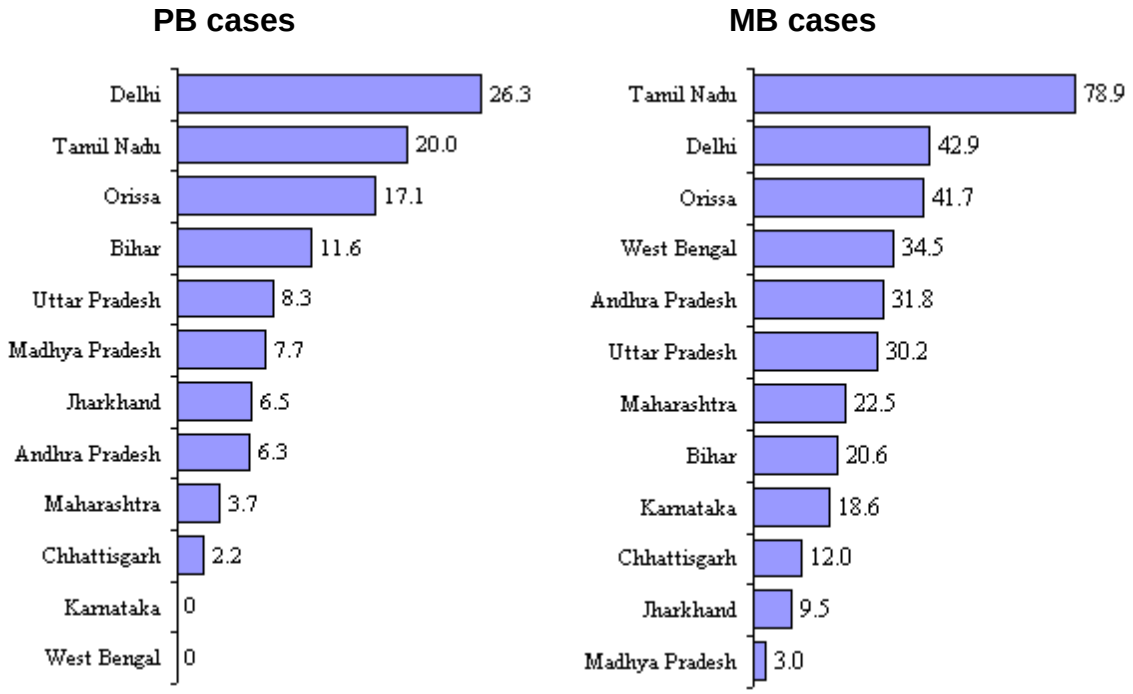
Overall, out of 1081 cases seen by the validators, 18.7% were re-registered cases, (with 95% confidence interval [CI]: 16.4%-21.0%). Three states, Tamil Nadu, Delhi and Orissa were found with extremely high proportion of re-registered cases, with 45.5%, 36.2% and 32.6% respectively. Two states had also high proportion of re-registered cases, West Bengal (28.8%) and Uttar Pradesh (26.6%). The states with low proportion of re-registration were Madhya Pradesh (4.3%), Chhattisgarh (8.3%) and Jharkhand (8.3%).

Figure 3: Proportion of Re-registered cases (both PB & MB), India 2004



The overall proportion of re-registration of MB cases was 25.5% [95% CI: 22.1%-28.9%], significantly higher than 8.8% [95% CI: 6.2%-11.4%] for PB cases.

Figure 4: Proportion of Re-registered PB and MB cases respectively



Three states, Delhi, Tamil Nadu and Orissa topped the 12 states for re-registration of PB and MB cases respectively. But samples were small (< 50) in Delhi and Tamil Nadu. The states of Bihar and Uttar Pradesh also contributed substantially to re-registration, to a lesser extent though.

The re-registration of PB cases ranged from 0% in Karnataka and West Bengal to 26.3% in Delhi. It was less than 10% in all the states, except in Delhi, Tamil Nadu, Orissa and Bihar.

As expected, the re-registration was higher for MB cases than for PB cases. In Tamil Nadu, almost 79% of the MB cases were re-registered, but the sample was small, as well as in Delhi (about 43%). Re-registration of MB cases was less than 10% in Jharkhand, and Madhya Pradesh only (small sample in Madhya Pradesh).

Re-registration is the consequence of health staff who do not ask systematically the question “have you taken MDT in the past, anywhere?” at the time of diagnosis. Therefore, a same patient can be registered twice or more, at any time he/she goes to a new health facility. Consequently, the new case detection rate is artificially inflated.

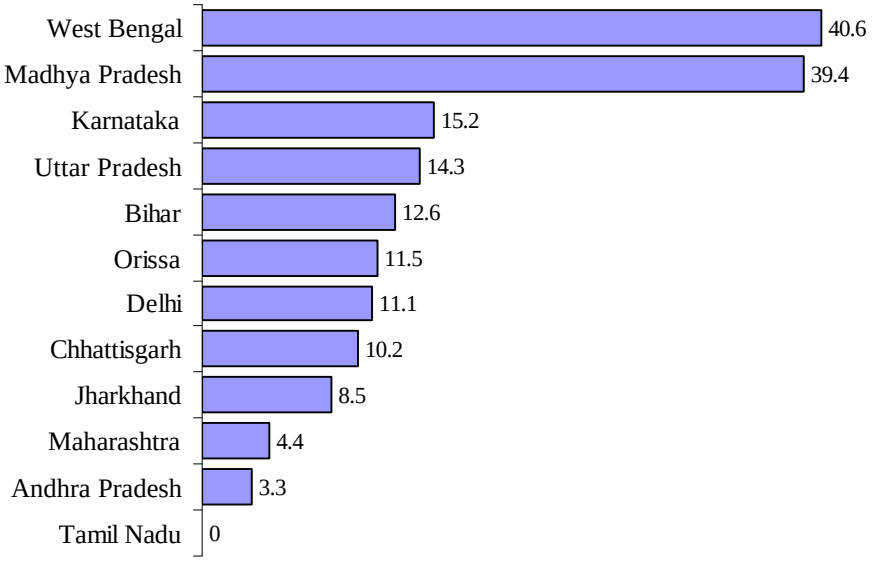
Table 5: Proportion of Wrong Grouping of leprosy cases

States	Both PB & MB cases	95% C.I. * (PB & MB)	PB cases	95% C.I. * (PB cases)	MB cases	95% C.I. * (MB cases)
Andhra Pradesh	3.3%	0% - 9.7%	0%	0%	9.1%	0% - 26.1%
Bihar	12.6%	6.4% - 18.8%	16.7%	7.7% - 25.7%	6.7%	0% - 14.0%
Chhattisgarh	10.2%	4.2% - 16.2%	2.8%	0% - 8.2%	14.5%	5.7% - 23.3%
Delhi	11.1%	0% - 22.9%	0%	0%	20.0%	0% - 40.2%
Jharkhand	8.5%	2.0% - 15.0%	6.7%	0% - 15.6%	9.8%	0.7% - 18.9%
Karnataka	15.2%	4.8% - 25.6%	8.3%	0% - 23.9%	17.6%	4.8% - 30.4%
Madhya Pradesh	39.4%	22.7% - 56.1%	0%	0%	52.0%	34.2% - 71.6%
Maharashtra	4.4%	0.2% - 8.6%	2.0%	0% - 5.8%	7.5%	0% - 15.7%
Orissa	11.5%	2.8% - 20.2%	0%	0%	25.0%	7.7% - 42.3%
Tamil Nadu	0%	0%	0%	0%	0%	0%
Uttar Pradesh	14.3%	6.5% - 22.1%	25.0%	3.8% - 46.2%	11.5%	3.5% - 19.5%
West Bengal	40.6%	23.6% - 57.6%	0%	0%	56.5%	36.2% - 76.8%
Total	**12.8%**	**10.3% - 15.3%**	**6.6%**	**3.8% - 9.4%**	**17.8%**	**14.0% - 21.6%**

Source: Clinical Examination and Observation of Validation teams
*: 95% C.I.: 95% Confidence Interval

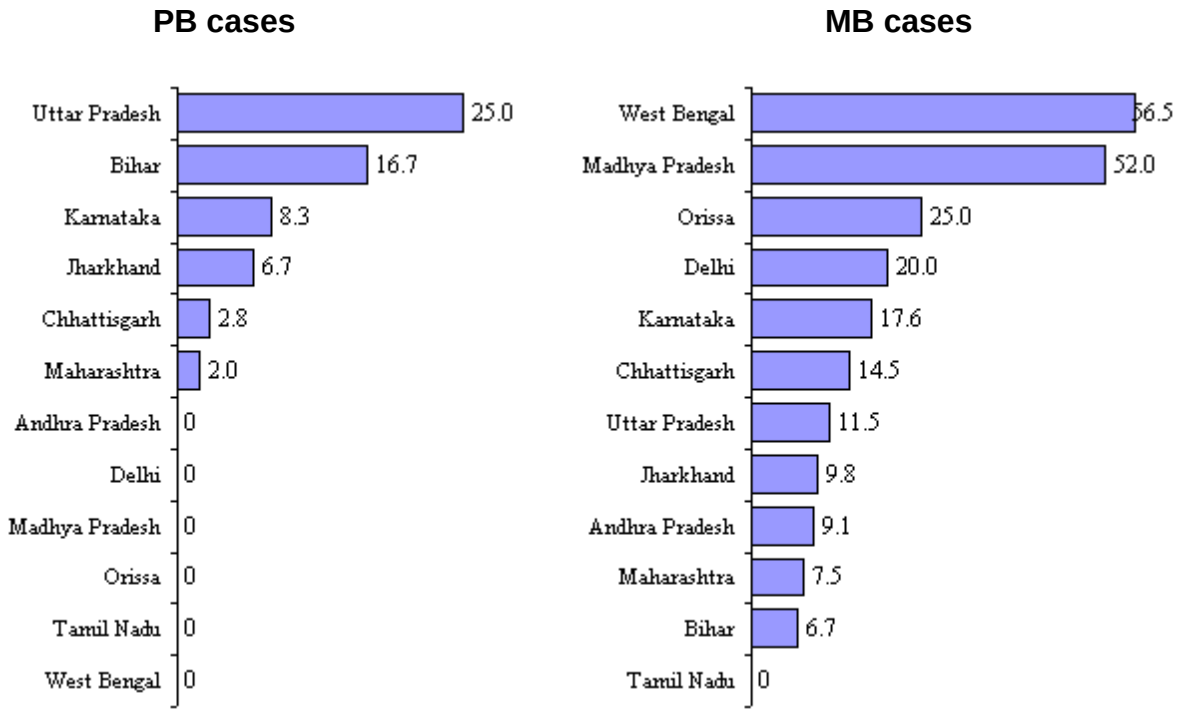
Overall, the proportion of wrong grouping, for both PB and MB cases, was 12.8% (with 95% confidence interval [CI]: 10.3%-15.3%). The states where wrong grouping was the most prevalent were West Bengal: 40.6% [CI: 23.6%-57.6%], Madhya Pradesh: 39.4% [CI: 22.7%-56.1%], Karnataka: 15.2% [CI: 4.8%-25.6%], Uttar Pradesh: 14.3% [CI: 6.5%-22.1%], and Bihar: 12.6% [CI: 6.4%-18.8%]. Low proportion of wrong grouping was found in Tamil Nadu (0%), Andhra Pradesh (3.3%), and Maharashtra (4.4%).

Figure 5: Proportion of Wrong Grouping (both PB & MB cases), India 2004



The wrong classification was mostly attributed to wrong grouping of MB cases: 17.8% [95% CI: 14.0%-21.6%], significantly higher than wrong grouping of PB cases of 6.6% [95% CI: 3.8%-9.4%].

Figure 6: Proportion of Wrong Grouping of PB and MB cases respectively



All states, except Bihar, and Uttar Pradesh, reported higher proportion of wrong grouping of MB cases than wrong grouping of PB cases.

The wrong grouping of MB cases was extremely high in West Bengal (56.5%), and Madhya Pradesh (52.0%). In these two states, it means that more than half of the MB cases, detected by the routine NLEP programme staff, were in fact true PB cases.

The wrong grouping of MB cases has individual consequence for the patients, having to take 12 months of MDT instead of 6. It also has consequence on the prevalence rate, by retaining patients under treatment for a period longer than required.

Table 6: Proportion of cases Traced but not Available and Non-Existent cases

Parameter	Andhra Pradesh	Bihar	Chhattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Proportion of:													
Cases Traced but Not Available	1.8	25.3	29.2	17.0	7.8	19.2	17.9	14.4	12.0	4.3	30.3	4.3	19.0
Non Existent cases	0	5.7	3.5	38.7	3.1	0	0	1.7	0	0	3.8	0	5.2

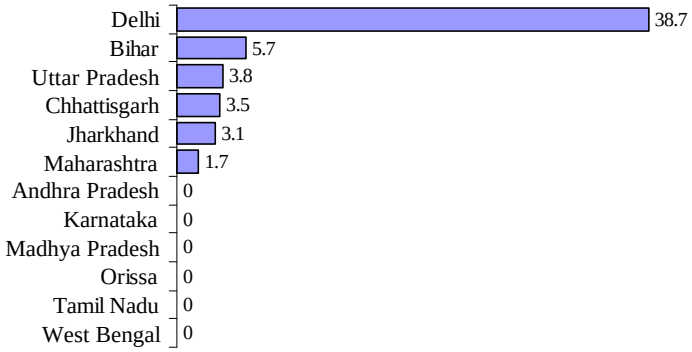
Source: Observation of validation teams

The definition used for "cases traced but not available" was cases for whom the validators went to the patient' address as recorded by the NLEP, but the patient was not at home, though he/she was "existing".

Overall, the proportion of cases which were traced by the validators but not available was 19.0%. It ranged from 1.8% in Andhra Pradesh to 30.3% in Uttar Pradesh. The proportion of cases traced but not available was also high in Chhattisgarh (29.2%), Bihar (25.3%), and Karnataka (19.2%).

The meaning of "non-existent" cases was cases listed by the NLEP, for whom validators went to the patient address; not only the patient was not present at home, but nobody in the neighbourhoods heard about the patient. Therefore, non-existent patients were considered as fake cases.

Figure 7: Proportion of Non-Existent cases, India 2004



Overall, the proportion of non-existent leprosy cases was 5.2%. It ranged from 0% in Andhra Pradesh, Karnataka, Madhya Pradesh, Orissa, Tamil Nadu and West Bengal to 38.7% in Delhi. Interpretation of the Delhi finding should consider the migration factor.

Table 7: Summary of Over-reporting (%) of leprosy cases, India 2004 (*)

Indicator	Andhra Pradesh	Bihar	Chattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Source of over-reporting (%):													
Wrong Diagnosis	15.4	4.6	3.7	10.0	6.7	4.2	19.0	12.4	17.2	4.5	11.7	11.9	9.4
Re-registration	16.7	15.2	8.3	36.2	8.3	13.6	4.3	12.5	32.6	45.5	26.1	28.8	18.7
Non-Existent cases	0	5.7	3.5	38.7	3.1	0	0	1.7	0	0	3.8	0	5.2

Source: Validation teams

(*): The proportion of each cause of over-reporting cannot be added, as the denominators for wrong diagnosis, re-registration, and non-existent cases are different, as explained on page 13 (flow chart).

As a summary, the causes of over-reporting were wrong diagnosis, re-registration, or non-existent cases, with re-registration being the major factor.

Using as denominator the number of cases for who attempt was made to contact them (1461), minus the 277 cases traced but not available, it appears that the number of newly detected cases was over reported by **at least 30%**.

The causes of over-reporting varied from state to state. In Delhi and Uttar Pradesh, it was the combination of the three causes, especially high re-registration (and non-existent cases in Delhi). In Andhra Pradesh, Maharashtra, Orissa, and West Bengal, it was mainly due to re-registration and wrong diagnosis. In Bihar, it was mostly due to re-registration and non-existent cases. In Tamil Nadu and Karnataka, it was mainly re-registration only. In Madhya Pradesh, it was mainly wrong diagnosis only.

Finally, it can be considered that two states, namely Chhattisgarh and Jharkhand, had relatively low proportions in all components of over-reporting.

The global figures of over-reporting are a real concern. When applied to the entire country, it represents a large number of cases, as well as MDT supply.

Table 8: Agreement between Validators on diagnosis

Indicator	Andhra Pradesh	Bihar	Chattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Agreement (%) between Validators on:													
Diagnosis (both PB&MB)	86.7	97.8	96.4	100	90.0	94.1	95.5	85.0	100	91.7	97.9	89.4	93.5
Diagnosis Of PB cases	80.0	96.4	93.3	100	86.0	87.5	91.7	84.6	100	95.0	100	90.9	91.3
Diagnosis Of MB cases	100	100	98.5	100	93.0	97.1	96.9	85.5	100	75.0	97.3	88.9	95.4
Sensory deficit of skin lesion	84.4	95.5	97.3	93.3	88.0	94.1	95.5	83.5	100	91.7	94.8	87.2	92.0
Nerve involvement	84.4	82.8	75.7	90.0	69.0	92.2	81.8	69.2	84.4	91.7	81.3	72.3	78.7

Source: Validation teams

Overall, the agreement on diagnosis (both PB & MB cases) between the validators was 93.5%. It ranged from 85% in Maharashtra to 100% in Orissa (and Delhi with a small sample). The agreement on diagnosis was above the original cut-of point of 90%, set up during the standardization workshop, in all states except in Andhra Pradesh (86.7%), and Maharashtra (85.0%). The 6.5% of disagreement on diagnosis represented 57 cases, out of the 879 examined by both validators. These 57 cases were excluded from the analysis.

The agreement between validators was higher for diagnosis of MB cases (95.4%) than for diagnosis of PB cases (91.3%).

The agreement on sensory deficit of skin lesion was overall 92%. It ranged from 83.5% in Maharashtra to 100% in Orissa. It was below 90% in Andhra Pradesh (84.4%), Jharkhand (88%), Maharashtra (83.5%), and West Bengal (87.2%).

The agreement on nerve involvement was overall 78.7%. It ranged from 69% in Jharkhand to 92.2% in Karnataka. It was below 90% in all states, except Delhi (90%), Karnataka (92.2%) and Tamil Nadu (91.7%).

These findings reflected the performance and the overall good quality of the validation teams, who had vast clinical leprosy experience and went through a 2-day standardisation workshop.

It showed that the clinical examination of nerve involvement is the most difficult to be standardised, with a subjective component. It also highlighted that the sensory deficit examination was not homogeneous, even among experienced health workers.

Table 8: Agreement between Validators on Grouping

Indicator	Andhra Pradesh	Bihar	Chattisgarh	Delhi	Jharkhand	Karnataka	Madhya Pradesh	Maharashtra	Orissa	Tamil Nadu	Uttar Pradesh	West Bengal	Total
Agreement (%) between Validators on:													
Grouping (both PB&MB)	90.9	88.8	95.1	100	84.5	100	97.1	91.9	98.1	95.2	92.8	86.5	92.3
Grouping of PB cases	100	85.7	94.7	100	83.3	100	100	94.4	100	100	94.1	100	93.0
Grouping of MB cases	78.6	93.8	95.4	100	85.4	100	96.1	88.9	96.0	66.7	92.4	82.1	91.9

Source: Validation teams

Overall, the agreement on grouping cases as PB or MB by the validators was 92.3%, ranging from 84.5% in Jharkhand to 100% in Delhi and Karnataka. It was above 90% in all states, except in Bihar (88.8%), Jharkhand (84.5%), and West Bengal (86.5%).

The 7.7% of disagreement on grouping represented 57 cases out of the 745 cases for which both validators had mutually agreed on their leprosy status. These 57 cases were excluded for the analysis of wrong grouping.

The overall agreement on grouping PB cases was 93%, above 90% in all states, except Bihar and Jharkhand. It was higher than the agreement on grouping MB cases, which was 91.9% overall, ranging from 66.7% in Tamil Nadu (but small sample) to 100% in Delhi and Orissa.

Given the simplicity of the method for classifying leprosy cases into the categories of PB or MB, these findings were considered relatively poor. The reasons why validators, who had agreed on diagnosis, would differ in grouping the cases, was mostly due to the disagreement on nerve involvement.

COMPARISON BETWEEN 2003 AND 2004 VALIDATION FINDINGS

Gaining from last year experience, the 2004 Validation of leprosy diagnosis study was conducted with the same methodology as in 2003. Some adjustments were made during the preparatory phase (adding district facilitators) and the field data collection in order to further improve the quality of the study.

The aim of this chapter is to highlight the changes between 2003 and 2004, as well as to start a trend analysis, which should be continued in 2005, and therefore provide more in-depth interpretation to the Validation of diagnosis results.

Table 9: Comparison of samples

Parameter	2003	2004
Cases listed by NLEP during the reference period	2541	1510
Cases seen by the validators, (%) *	1737 (68%)	1081 (72%)
Cases examined by the validators, (%) *	1503 (59%)	879 (58%)
Number of PB cases examined, (%) **	773 (51%)	404 (46%)
Number of MB cases examined, (%) **	730 (49%)	475 (54%)

(*): Denominator = cases listed, (**): Denominator = cases examined

The 2004 sample of cases listed by the NLEP, in the selected districts during the reference period, was much smaller (-41%) than in 2003. This was attributed to: 1) a significant decline in detection during the last year, and 2) a sampling effect.

In 2003, 68% of patients listed by the NLEP were seen by the validators; thus representing an attrition of 32%. In 2004, 72% of listed patients were seen (28% of attrition), This small decline in attrition, although disappointing, was attributed to the role played by the district facilitators in better implementation of the preparatory phase of the study. However, it is considered that this attrition is still too high (are the patients not seen by the validators different than those seen?), and all efforts should be made in the subsequent studies to reduce this attrition.

Among the cases examined by the validators, in 2003 the number of PB cases was slightly higher than the number of MB cases, 51% and 49% respectively. In 2004, this ratio was inversed (46% and 54%). The reason is not clear. It can be mentioned that the proportion of MB cases detected in India during the year 2003-2004 was up to 39%, from 35% during the previous year of 2002-2003.

Table 10: Comparison of results (global sample)

Parameter	2003	2004
Proportion of:		
Wrong diagnosis, [95% C.I.]	**9.4%**, [7.9%-10.9%]	**9.4%**, [7.4%-11.4%]
Re-registration, [95% C.I.]	**13.5%**, [11.9%-15.1%]	**18.7%**, [16.4%-21.0%]
Wrong grouping, [95% C.I.]	**11.2%**, [9.4%-13.0%]	**12.8%**, [10.3%-15.3%]

Wrong diagnosis: The proportion of wrong diagnosis was exactly the same (9.4%) in 2003 and 2004, with a slightly wider confidence interval in 2004, due to the smaller number of cases examined by the validators. At the state level, the 2004 results of wrong diagnosis are consistent with those of 2003.

In 2003, the four states with the lowest performance in quality of diagnosis were: Madhya Pradesh, Maharashtra, Orissa, and Andhra Pradesh. It was the same four states in 2004 that showed the lowest performance. Similarly, the three states with the best performance in 2003 were Bihar, Jharkhand and Chhattisgarh (excluding Delhi due to small sample). In 2004, the same three states were among the top 5 performing states. The major differences were in Karnataka which reduced by 3 times the proportion of wrong diagnosis in 2004 compared to 2003 (4.2% and 12.5% respectively), and in Tamil Nadu which reduction was about 2 times (4.5% and 8.9%); but the 2003 and 2004 confidence intervals overlapped, and therefore these trends need to be confirmed in 2005 for a better interpretation.

Re-registration: The 2004 proportion of re-registration was significantly higher (18.7%) than in 2003 (13.5%), with no overlapping of confidence intervals. Does it mean that getting closer to the elimination threshold, the risk of re-registration increases? Next year' results will probably provide some clarification on this hypothesis. At the state level, the 2004 results rarely matched the 2003 findings, with the exception of Delhi and West Bengal for which consistent high re-registration was found during both years.

On the contrary, states with high proportion of re-registration (Karnataka) or low re-registration (Andhra Pradesh) in 2003, showed large variations in 2004.

Wrong grouping: The 2004 proportion of wrong grouping (12.8%) was higher than in 2003 (11.2%), but the difference was not statistically significant. As for wrong diagnosis, state level results showed consistency between the 2003 and 2004 results. The two states of Madhya Pradesh and West Bengal had much higher proportion of wrong grouping during

the two consecutive studies than the other states. Similarly, states with low proportion of wrong grouping in 2003 were the same in 2004 (Tamil Nadu, Andhra Pradesh).

Table 11: Comparison of agreement between validators (global sample)

Parameter	2003	2004
Proportion of agreement between validators on:		
Diagnosis (both PB & MB)	90.7%	93.5%
Grouping (both PB & MB)	92.9%	92.3%
Sensory deficit of skin lesion	89.2%	92.0%
Nerve involvement	79.2%	78.7%

The agreement between validators on clinical examination's findings is an important component of the Validation study, as data analysis was based on cases for whom an agreement between validators (on diagnosis & grouping) was found. Globally, the 2004 results were very close to the 2003 results, with a minor increase on agreement for diagnosis and sensory deficit, and a slight decrease in nerve involvement' agreement. None of the differences was statistically significant.

Table 12: Comparison of risk for child or female to be wrongly diagnosed

Parameter	2003		2004	
	Among global sample of examined (n=1503)	Among wrongly diagnosed cases (n=128)	Among global sample of examined (n=879)	Among wrongly diagnosed cases (n=77)
Proportion of:				
Children	15.2%	19.5%	17.0%	23.4%
p value for children	0.2 (No statistical difference)		0.2 (No statistical difference)	
Female	41.4%	51.6%	43.0%	46.8%
p value for female	0.03 (**Statistically different**)		0.6 (No statistical difference)	

p value from Chi-square (Yates corrected)

Children: Both in 2003 and 2004, the proportion of children was higher among the wrongly diagnosed cases than among the global sample of patients examined by the validators. But, no statistical difference was found in either year (p value = 0.2 in both years). The results are consistent in the two consecutive studies. Therefore, based on existing findings and samples, it can be stated that a child has no more risk of being wrongly diagnosed than an adult.

Female: Both in 2003 and 2004, the proportion of female was found higher among the wrongly diagnosed cases than among the global sample of patients examined by the validators. In the 2003 study, the difference (41.4% versus 51.6%) was found statistically significant (p value = 0.03), but in the 2004 study no statistical difference was found between 43.0% and 46.8% (p value = 0.6). Therefore, no strong statement can be made on a higher risk for women to be wrongly diagnosed. This parameter should be followed during the 2005 validation study.

DISCUSSION

The main goal of the Validation Study was to quantify the problem of over-reporting of new leprosy cases, and to sensitise decision makers and health workers on this issue, hoping that it will contribute to better quality of programme implementation in the future. The Study does not underestimate the issue of undetected cases that remain in areas poorly covered by MDT services. Since last year's validation study, questions were raised on how to assess and quantify the number of undetected cases. The SAPEL and LEC are tools available and can be used to answer this question, provided that the detected cases are truly new cases.

The 2004 results for wrong diagnosis and wrong grouping, both at the national level (global sample), and at state level (state sample) are consistent with the 2003 results. However, re-registration results are higher in 2004 than in 2003, with only a few states showing consistent findings on high or low re-registration during both years. These variations among consecutive years could be attributed to: 1) the smaller sample of 2004, 2) the sampling effect (different districts were selected), or 3) to an improvement/deterioration of the quality of registration over time. Is the increase in re-registration in 2004, only due to the above factors or to a tendency of some health workers to contribute to a higher re-registration when prevalence and detection are decreasing, therefore artificially maintaining a certain level of prevalence and detection? Follow-up validation studies should provide a response to this question.

The limitations of the study were mainly threefold: 1) the representativeness of results at state level, 2) the limited sample size of cases listed by the NLEP in some states, and 3) the attrition between cases listed and cases seen by the validators.

As opposed to the Leprosy Elimination Monitoring (LEM) exercise, which included a large number of districts per state (proportional to the size of the population and the number of cases), the validation study included only one randomly selected district per state. Obviously, it would be preferable to include more than one district per state, but the validation study is much more difficult to set up than the LEM exercise, by involving recently detected patients to be examined and traced individually. Logistics factors, time, availability of adequate validators, and budget are all constraints that should be taken into consideration for the study design.

Results are presented for the global sample as well as state-wise. The sampling methodology used for the study allows such presentation of results (as opposed to a cluster sampling method). However, state-wise results might lead to a caricatured interpretation for states with a small sample. Due to the attrition between cases listed by the NLEP during the reference period and cases seen by the validators on one hand, and the level of re-registered cases on the other hand, the number of examined cases was small in some states (especially Delhi and Tamil Nadu). Therefore, results of wrong diagnosis and wrong grouping for states with small sample should be interpreted with caution, taking into account the confidence intervals. As the trends in detection have been steadily decreasing over the past years, it is most probable that it will continue in the coming years. The consequence will be a smaller sample size, both at global and state levels, for future validation studies, leading to the above limitations on a wider scale. Hence, it might be useful to adapt the sampling methodology for future studies. One possibility, which will need further investigation by the core group, would be to include in the study two districts for low/moderate endemic states, therefore increasing the sample sizes at state and global levels. The criteria could be to get at least 100 listed cases in the reference period.

The attrition between cases listed by the NLEP and cases seen by the validators is an issue. Was the status of cases not seen by the validators similar to the cases seen? This limitation was identified after the 2003 study and led to the recruitment and training of the district facilitators in 2004. Despite a slight improvement in lowering this attrition in 2004 (28% compared to 32% in 2003), this proportion still remains too high. All efforts should be made in 2005 to further decrease the attrition between cases listed and seen, by further improving the quality of the preparatory phase of the validation study.

Nevertheless, even with the above mentioned limitations, consistency of results in many states, during two consecutive years, makes the results stronger. Trends will be important to follow in the coming years.

According to the statistical tests (Chi-square, Yates corrected), there is no higher risk of being wrongly diagnosed for a child than for an adult, despite higher proportions of children among the wrongly diagnosed group than among the global sample of examined cases. On the other hand, a difference was found in 2003 for women having a higher risk

than men of being wrongly diagnosed; but this difference was not found significant in 2004. This could be attributed to several factors: a) too small sample size of women examined, or b) the sampling effect; for example in the 2003 selected districts the risk for women to be wrongly diagnosed was higher than in the 2004 selected districts, attributed to various reasons, especially the proportion of female health workers might be different).

The Study‘s strengths is its methodology. Four components were essential:

1) The short recall period, one month for PB cases and two months for MB cases, made the signs/symptoms of leprosy examined by the validators close to the ones examined by the medical officers during the routine programme.

2) The standardisation of procedures for clinical examination by the validators was a must for the quality of the study. This was done despite using experienced validators. The standard clinical procedures were determined and practiced during the two-day standardisation workshop, including one day of clinical practice.

3) Each newly detected patient included in the study was examined independently by two validators, without sharing their findings. Due to the absence of a gold standard laboratory test for the diagnosis of leprosy, it is mandatory for such a study that cases to be double-checked are re-examined by more than one person. Otherwise, doubt on the quality of the validation might occur.

4) The data analysis for wrong diagnosis and wrong grouping was based on the number of cases with agreement of the two validators. This component was essential for solid results. It was assumed that when experienced leprosy medical officers, having gone through the standardisation workshop, agreed that a case was not leprosy, their findings were specific enough. However, when there was a disagreement between validators, one of them saying it was leprosy, and the other it was not, there was no way to know who was right or wrong, therefore these cases had to be excluded from the analysis.

The results presented in this study are conservative for two main reasons: 1) the cases with disagreement were excluded. It can be assumed than among them, some cases were wrongly diagnosed or wrongly grouped; and 2) some wrong diagnosis or grouping might also have occurred among the re-registered cases, who were not examined by the validators, and therefore not accounted for.

CONCLUSION

The objective of the validation of diagnosis study was to quantify the accuracy of diagnosis of newly detected cases, one of the factors that contributed to a high new case detection rate over the past years. As a gold standard laboratory test does not exist for the diagnosis of leprosy, a validation of diagnosis was done by clinical examination.

As a follow-up to the 2003 study, the validation of leprosy diagnosis study was conducted on a large scale in India, in twelve high priority states, with a rigorous standardised methodology and procedures.

The study was conducted in 12 randomly selected districts of each priority states. It included a large sample of leprosy cases, recently diagnosed as new cases by the health staff involved in the NLEP. The validation teams had seen 1081 cases, out of which 879 were clinically examined. The other 202 cases were detected as re-registered, having taken MDT in the past, therefore they were considered as “old” cases.

Wrong diagnosis

Among the 879 cases clinically examined independently by twelve teams of two validators each, in which their diagnosis was similar (leprosy or not leprosy) in 93.5% of the time, 9.4% of the total cases diagnosed by health staff as leprosy were non-leprosy. This proportion was high in Madhya Pradesh (19.0%), Orissa (17.2%), Andhra Pradesh (15.4%), and Maharashtra (12.4%). It was low in Chhattisgarh (3.7%), Karnataka (4.2%), Tamil Nadu (4.5%), Bihar (4.6%), and Jharkhand (6.7%).

In the 2003 study, it was the same four states which had the highest proportion of wrong diagnosis, and the three states of Chhattisgarh, Bihar, Jharkhand which had the lowest proportion of wrong diagnosis. With a few exceptions (Karnataka and Tamil Nadu), there was a consistency of results between the 2003 and 2004 studies.

PB cases detected by the routine NLEP programme were more often wrongly diagnosed (11.1%), than MB cases (8.0%). This finding suggests that wrong diagnosis of PB cases was probably the fact of doubtful cases that were diagnosed as leprosy “in case of doubt”, rather than waiting for more specific leprosy symptoms to develop.

Even if the proportions of female and child cases were found higher among the wrongly diagnosed cases than in the global sample, no statistical difference was found.

Wrong diagnosis has individual consequence for the patients, having to take a long treatment for a disease which they don't have. Wrong diagnosis also has public health consequence by artificially inflating the prevalence and new case detection rates.

Wrong grouping

Among the 688 cases confirmed as leprosy by the validators, in which the validators agreed on grouping (as PB or MB cases), 12.8% of cases were wrongly grouped as MB or PB by the health staff involved in the NLEP. This proportion was very high in Madhya Pradesh (40.6%), and West Bengal (39.4%), and Karnataka (15.2%). It was low in Tamil Nadu (0%), Andhra Pradesh (3.3%), and Maharashtra (4.4%).

The proportion of wrong grouping was higher for MB cases (17.8%) than for PB cases (6.6%). Most of the wrong grouping by the health staff was by classifying MB cases which were in fact PB cases. This proportion was very high in West Bengal (56.5%), Madhya Pradesh (52.0%), and high in Orissa (25.0%), and Delhi (20.0%).

The wrong grouping of MB cases has individual consequence for the patients, having to take 12 months of MDT instead of 6. It also has consequence on the prevalence rate by retaining patients under treatment for a longer period.

Re-registration

Among the 1081 cases seen by the validators, 202 (18.7%) had taken MDT treatment in past and therefore were considered as re-registered by the validation teams. The proportion of re-registered cases was very high in Tamil Nadu (45.5%), Delhi (36.2%), Orissa (32.6%), West Bengal (28.8%), and Uttar Pradesh (26.1%). Obviously, the health staff did not ask systematically, at the time of diagnosis, the question "have you taken MDT in the past anywhere?" Therefore, a same patient can be registered twice or more at any time he/she goes to a new health facility. This phenomenon is probably important among

patients who migrate from one district/state to another, as highlighted by 36.2% of re-registered cases in Delhi.

The proportion of re-registered cases was higher for MB cases (25.5%) than for PB cases (8.8%). The proportion of re-registered MB cases was very high in Tamil Nadu (78.9%), Delhi (42.9%), Orissa (41.7%), West Bengal (34.5%), Andhra Pradesh (31.8%), and Uttar Pradesh (30.2%).

The re-registration of cases could be easily avoided by asking a simple question of patient's history, at the time of diagnosis. Re-registration artificially inflates the new case detection rates.

Overall, the total number of cases which were over-reported by the health staff was **at least 30%** (9.4% wrongly diagnosed, 18.7% re-registered, and 5.2% non-existent). When applied to the entire country, this figure represents a large number of cases, as well as MDT supply.

For the National Leprosy Eradication Programme, prevalence and detection rates are essential indicators. Programme managers, at every level, are monitoring the programme based on these indicators, which both are significantly influenced by the quality of diagnosis.

RECOMMENDATIONS

Given the findings presented in this report, it is urgent to improve the accuracy of leprosy diagnosis in many high priority states of India. In order to get a picture close to the reality, through prevalence and detection rates, the quality of diagnosis is one important component of the National Leprosy Eradication Programme, Therefore, special efforts in this direction are required from all health staff involved in leprosy services.

Based upon the findings of the 2004 validation study, the following recommendations have been formulated:

- The results of the 2004 validation of leprosy diagnosis study should be widely disseminated in the country, especially at the health facility/block level where the diagnosis of leprosy is made. Workshops, meetings, presentations, informal discussions should be organised, focusing on districts and blocks with high detection rates. State and District Leprosy Officers, District Technical Support Teams, and WHO State/Zonal co-ordinators should be involved in disseminating the findings in order to sensitise the health workers and decision makers involved in leprosy.
- All health workers involved in the diagnosis of leprosy should apply the standard definitions of a new case of leprosy and its classification as PB or MB case.
- All health workers involved in the diagnosis of leprosy should perform the clinical examination by applying standard criteria and procedures for testing the sensory deficit of a skin lesion (Annexure-I) and looking for nerve involvement (Annexure-II).
- Special attention should be paid for the diagnosis of PB cases, in order to avoid wrong diagnosis.
- All health workers involved in the diagnosis of leprosy should systematically ask the patient, at the time of diagnosis, about history of previous MDT taken by the patient, in order to avoid re-registration.
- Special attention should be paid to MB cases, in order to avoid re-registration.
- Each block or district should be set up a feasible system for routinely validate the newly detected cases. District Technical Support Teams and reference Medical Officer from the district should be actively involved in this process.

- On-the-job training should be conducted in areas where high proportion of wrong diagnosis, wrong grouping or re-registration had been identified.
- For cases found wrongly diagnosed, their MDT treatment should be stopped and their name removed from the leprosy register.
- For patients found wrongly classified as PB or MB, the treatment should be adjusted (shortened or extended). Treatment register and patient's card should be updated accordingly.
- Non-existent patients should be removed from the leprosy register.

Annexure – I

Sensory Testing of Skin lesions

Skin patch with loss of sensation is the commonly used cardinal sign to diagnose leprosy. Correct diagnosis can be made **only if sensory testing is done correctly**. Important components of sensory testing are:

- Instrument
- Stimulus
- Patient's response
- Steps in doing sensory testing

The right instrument – Ballpoint pen

Ballpoint pen if properly used is a safe and fairly standardized instrument for sensory testing (touch sensation).

Method of using ball pen

- Use of tip of ball pen.
- Place the pen perpendicular to the skin surface being tested.
- Weight of the ball pen is adequate to produce the stimulus. Do not apply pressure.
- Skin of palm and sole are thick. Hence apply gently pressure just adequate to produce a slight depression in the skin.
- Apply uniform pressure in all points tested.
- Allow adequate time between stimuli.
- Start from normal skin & go to affected part (patch.)

SENSORY TESTING FOR DIAGNOSIS OF LEPROSY

Don'ts

- Don't follow a rhythm. (interval between stimuli should not be same)
- Don't apply repeated stimuli at the same point.
- Don't apply too much pressure on the ball pen.
- Don't stroke with pen.
- Don't allow spectators when you perform the test.

The steps in sensory testing

- Explain the procedure to the patient
  Talk slowly & clearly
  Use simple words
- Demonstrate the test with **eyes of patient open**.
- Make sure the patient understood the procedure.
- Perform the actual test with **patient's eyes closed**.

Sensory Testing of Palm and Sole

- If there is "definite" nerve thickening of ulnar or common peroneal (lateral popliteal) nerves, do not perform sensory testing of palm or sole.
- If there is no nerve thickening but evidence of nerve damage due to Leprosy, perform sensory testing of Palm or Sole.
- Palm = 2 Points : 1. MID-Thenar
  2. MID-Subthenar
- Sole = 2 Points : 1 MID-Heel
  2. 1st Metatarsal head (MTH-1)

<u>STRICTLY LIMIT THE TESTING TO THE 4 POINTS</u>

Annexure – II

Examination of nerves for thickening

The following points should be kept in mind while examining peripheral nerves:

- ❖ Correct positioning of the limb and the examiner
- ❖ Locating the correct site for feeling the nerve
- ❖ Trace along the course of the nerve proximally till the nerve disappears into muscle
- ❖ Palpate the nerve across not along its course
- ❖ Use pulp of finger, not tip, for palpating the nerve
- ❖ Examine nerves on each side separately and determine if it is enlarged.

ULNAR NERVE - STEPS FOR EXAMINATION

1. Site – groove above and behind the medial epicondyle at the elbow.
2. Both the examiner and the patient should face each other and both should be comfortable – either standing or sitting.
3. Explain to the patient what you are doing in a clear and simple way.
4. Hold the right arm with your left hand, for support and left arm with your right hand, for support.
5. Ensure that the examined area is free of clothing, arm-bands etc.
6. Keep the arm to be examined away from the body, with elbow at 120%.
7. a) Locate the medial epicondyle
   b) Gently palpate the nerve, with the pulp of two fingers only i.e. index and middle fingers
   c) Just roll the two fingers over the nerve – do not dig and do not apply pressure.
   d) Trace the nerve proximally (towards the shoulder) and decide whether the nerve is thickened
8. Do not compare with the opposite nerve

LATERAL POPLITEAL NERVE – STEPS FOR EXAMINATION

1. Site – back of the knee – just below the knee groove on the lateral side, behind the head of the fibula.

2. Position of the patient – standing with the knee slightly flexed (bent). Position of the examiner – sitting with hands in line with the knee or kneeling with hands in line with the knee.

3. Ensure that the examined area is free of clothing.

4. Locate the head of the fibula, slide two fingers – index and middle fingers behind the head of fibula and gently roll the two fingers across the nerve.

5. Trace the nerve proximally (towards the thigh) as far as possible and decide whether the nerve is thickened.

6. Do not compare the nerve with the opposite nerve.

Annexure - III

Definitions used for the Validation of Leprosy Diagnosis

I. **New case of Leprosy**: Patient with anesthetic patch with definite sensory deficit and /or definite nerve thickening requiring treatment with MDT, who never received any leprosy treatment in the past, anywhere.

II. **Not Leprosy**: Skin patches without definite sensory deficit or no definite nerve thickening

III. **Re-Registered** (RR): A case of leprosy partly or fully treated and registered again as a new case for treatment

IV. **Traced but Not available** (TNA): newly registered patient who could not be examined despite all efforts by the validators to trace him/her.

V. **Not Existent** (NE): newly registered patient who does not exist at the given address, and whom nobody knows about (Fake case)

VI. **Sensory deficit**: Partial =hypoesthesia or Total=anesthesia

VII. **Paucibacillary** (PB): Skin lesions with definite sensory deficit up to 5 or definite thickening of one peripheral nerve.

VIII. **Multibacillary** (MB): Skin lesions with sensory deficit 6 and above or thickening of more than one peripheral nerve.

Annexure – IV

Checklist for validators at the patient screening point

1. Carry sufficient number of validation forms (number should be twice the total number of patient to be screened);
2. Carry with you the list of patients to be screened at each screening point;
3. Carry Reynolds ball pen for doing the sensory test. Don't use the pen to write. Use separate pencil for writing on the Validation form;
4. Introduce yourself to the staff at the screening point;
5. Contact the Identified district facilitator. He will be the point coordinator;
6. The two validators should sit separate (different rooms if possible) while screening patients so that they will not be able to observe each other or privy to the information in each other's record. The two validators should not have any discussion on any case after the screening. The validators should not make any changes in the entries after the form is filled once.
7. Select the spot with good sunlight for the examination;
8. The validators will examine the patients and fill the form. The validator will append at the bottom of the form his/her name and signature. He will circle the serial number of patient in the list. He will sign in the slip, hand it back to the patient and ask him to go back to the patient co-ordinator who will send him to the other validator.
9. The other validator will examine the patient and fill the form. He will sign the slip, hand it back to patient and ask him to hand it to the patient co-ordinator. He will also circle the serial number of patient in the list
10. Those patients in the list who fail to attend the screening could be visited in their house the same day or mobilized by MO/Support team/District Facilitator at the next screening point the following day. Even for the cases not screened (because they are traced but not available or non-existent) the form should be filled.

The District Facilitator will circle the serial number of patient completing examination by both the validators. The patient will be relieved by him after ensuring that he/she has been examined by both the validators. The district facilitator will collect all the filled forms from both the validators making sure that there are completely filled and that there are two forms for each patient. He will then staple two forms per patient. He will subsequently place them into an envelop, seal it and hand it to one of the validators.

11. The validator will collect the patient forms in sealed envelops from all the screening points and bring it to NIHFW during the de-briefing on 5th July 2004.

Annexure-V

Expected roles from District Facilitators

The district facilitators will have an important role to play during the preparatory phase as well as during the field data collection stage.

1) During preparatory phase

The District Facilitator will maintain liaison with DLO and Medical Officers In-charge of the PHCs and will prepare a list of all new leprosy cases detected up to one/two months prior to the teams visit i.e. for MB category (new cases detected between 1st April to 31st May, 2004) and for PB category (new cases detected between 1st May to 31st May, 2004).

Subsequently, he will prepare a mapping of the listed cases. Depending on the geographic distribution and density of the cases in a particular area, he will identify the most appropriate screening points and prepare a day-today Route Chart with dates and time. The route chart should take into consideration: 1) the patients (should be convenient and near by for the patients to attend), 2) the validators (on an average the team can examine 10 to 15 patients a day), and 3) the feasibility in field conditions. The screening point could be a PHC/CHC, sub-centre, school, Panchayat house, anganwadi centre, etc.

The list of new cases in the block should include information on patient's identification (address, age and sex), date of detection, Group, treatment given (see Form-I, Annex 1). He will sensitize MO (I/C) for deputing his staff [ANMs/NMS/Health Worker (M)] for informing and motivating patients to attend screening point on the designated day and time.

ROUTE CHART (for each block)

Block name: _____

Date/Day	Time	Screening point	Number of cases	Name of Patients	Address of patients

In order to prepare an efficient and feasible route chart the district facilitator may get support from an NMS who are the most familiar person of the geographic location.

2) During field data collection

Each district facilitator will:

- Assist the validation team;
- Coordinate the activities at screening points;
- Ensure two separate sitting arrangements for validators, with good light condition;
- Assemble all patients in a group and explain to them what would be done;
- Assign a serial number to each case and transfer information on the validators form;
- Call each patient by his/her name, write his/her name and serial number on a piece of paper and hand it to the patient. The patient would then be asked to go to each validator for examination;
- Ensure that each case is examined by both the validators;
- Encircle the serial number of patient completing examination by both the validators;
- Verify all the forms for completeness;
- Staple all the forms in the sealed manner and hand it over to the validators;
- Help the validators in tracing the cases at home, for those absent at screening point;
- Cross check that all the listed cases has been traced and examined by validators;
- Those patients who fail to attend the screening at the designated point could be seen at their houses or at the next screening point on the following day.

Annexure – VI

Route chart – Validation of Leprosy Diagnosis – (Example)
from 17th June to 3rd July 2004

State: _____

Name of the District: _____ Name of the Block: _____

S. No.	Name & address	Sex M / F	Age (in years)	PB / MB	Date of Detection
	18/6/2004 Roddam PHC Screening point				
1	Radha Address:	F	34	PB	13/5/04
2	Krishna Address:	M	43	MB	7/4/04
3	Mohan Address:	M	12	PB	30/5/04
	Etc.				
	19/6/2004 Durg Hospital Screening point				
4	Madan Address:	M	56	MB	15/5/04
5	Kumar Address:	M	22	PB	02/5/04
6	Raman Address:	M	35	PB	23/5/04
	Etc.				

(Use a separate form for each block)

NLEP VALIDATION FORM

Serial No. ☐

State: (Write) ☐ **District:** (write) ☐ **Block PHC:** (write) ☐

Name: (Write) ☐ **Age in years:** (write) ☐☐ **Sex** (Tick) **M** ☐ **F** ☐

Diagnosis: (Tick) **PB** ☐ **MB** ☐

Previous leprosy treatment? **Yes** ☐ **No** ☐

(Tick) **Reregistered (1)** ☐ **Traced but Not Available (2)** ☐ **Non Existent (3)** ☐

(You need not proceed further if any of the three boxes is ticked)

---

1. Number of skin lesions (0,1,2,3,4,5,6,7,8,9,10,11,12,13,14,15) ☐

(Don't count skin lesions not suggestive of leprosy like PV, PA, Naevus. Write the exact number of lesions)

2. Sensory deficit in skin lesions: **Yes Total** ☐ **Yes Partial** ☐ **No** ☐

(It may be total or partial)

3. Nerve Involvement: **Yes** ☐ **No** ☐ **If Yes, please tick the appropriate box:**

Rt ulnar ☐ **Left ulnar** ☐ **Rt LPN** ☐ **Left LPN** ☐

4. Diagnosis: **Leprosy** ☐ **Not leprosy** ☐

5. If Leprosy, please tick the box for grouping: **PB** ☐ **MB** ☐

(Don't count lesions due to other cause- Naevus, Ptyriasis alba, Ptyriasis versicolor, etc.)

Validator's No.: 1 or 2 ☐

Name & signature of validator:……

…….

Date:…….

1) Reregistered (RR): Old case, who has taken leprosy treatment, anywhere, in the past, but was re-registered as a new case.

(2) Traced but Not Available (TNA): newly registered patient who could not be examined despite all efforts by the validators to trace him/her.

(3) Non Existent (NE): newly registered patient who does not exist at the given address, and whom nobody knows about (Fake case)

Annexure – VIII

List of Indicators

A. Wrong diagnosis:

$$\frac{\text{Number of cases which are diagnosed as not leprosy by both the validators}}{\text{Total number of cases examined by both the validators, with agreement on diagnosis}}$$

B. Wrong grouping: PB as MB:

$$\frac{\text{Number of MB cases which are diagnosed as PB by both the validators}}{\text{Number of MB cases examined by both the validators, with agreement on classification}}$$

C. Wrong grouping: MB as PB:

$$\frac{\text{Number of PB cases which are diagnosed as MB by both the validators}}{\text{Number of PB cases examined by both the validators, with agreement on classification}}$$

D. Re-Registration of PB:

$$\frac{\text{Number of PB cases, partially or fully treated with MDT in the past, and registered as new case, among cases seen by both the validators}}{\text{Number of PB cases seen by both the validators}}$$

E. Re-Registration of MB:

$$\frac{\text{Number of MB cases, partially or fully treated with MDT in the past, and registered as new case, among cases seen by both the validators}}{\text{Number of MB cases seen by both the validators}}$$

F. Agreement between the two validators for anaesthetic skin lesions:

$$\frac{\text{Number of cases with skin lesion(s) examined, in which both validators agree for anaesthesia}}{\text{Number of cases with skin lesion(s) examined by both the validators}}$$

G. Agreement between the two validators for nerve thickening:

$$\frac{\text{Number of cases examined by both validators in which both agree for nerve thickening}}{\text{Number of cases examined by both the validators}}$$

H. Traced but Not Available:

$$\frac{\text{Number of cases which were traced but not available for examination from among cases detected during the reference period}}{\text{Number of cases detected during the reference period, in which attempt was made by the validators to contact them}}$$

I. Not Existent:

$$\frac{\text{Number of cases which do not exist from among cases detected during the reference period}}{\text{Number of cases detected during the reference period, in which attempt was made by the validators to contact them}}$$

Annexure – IX

List of Validation Teams

(1 & 2 = Validators, 3 = District Facilitators)

Andhra Pradesh

1. Dr. M.N. Casabianca
2. Dr. D.C. Mohapatara
3. Mr. John Aruldoss

Bihar

1. Dr. Veera Kumar
2. Dr. Ajay N. Walter
3. Mr. Peter Paul

Chhattisgarh

1. Dr. Raman
2. Dr. R. Nagesh
3. Mr. Appalaswamy

Delhi

1. Dr. V.K. Jain
2. Dr. Vijayshankar
3. Mr. Anil Kumar

Jharkhand

1. Dr. A.K. Mishra
2. Dr. R. Nagesh
3. Mr. Srinivasan

Karnataka

1. Dr. M.V. Bhatt
2. Dr. Sumit Talukdar
3. Mr. Rajesh

Maharashtra

1. Dr. R.K. Mishra
2. Dr. Subash Chandra Reddy
3. Mr. Nemade Rajeev K.

Madhya Pradesh

1. Dr. Shivakumar
2. Dr. Rathore
3. Mr. B.S. Raghuwanshi

Orissa

1. Dr. R.K. Mishra
2. Dr. Durai Venkatesan
3. Mr. V.K. Gochayat

Tamil Nadu

1. Dr. Balasubramanyam
2. Dr. Durai Venkatesan
3. Mr. P.G. Rajendaran

Uttar Pradesh

1. Dr. Sekar
2. Dr. Govida
3. Mr. Amar Kashyap

West Bengal

1. Dr. A.K. Mishra
2. Dr. Parareddy
3. Mr. S. Saha