

WHO-GOI - ILEP-NIHFW

**Protocol
Validation of Leprosy Diagnosis
in India
2004**



**National Institute of Health and Family Welfare
New Delhi**

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I. INTRODUCTION

Prevalence of leprosy in India has come down from 57 per 10,000 in 1983 to around 2.3 per 10,000 in February 2004, but the number of new cases detected or the New Case Detection Rate (NCDR) has not shown any corresponding decline. Every year around 400 000 to 500 000 new cases are detected. Among the several factors that are likely to influence the new case detection, accuracy of leprosy diagnosis is one. How many of the cases detected are really leprosy? Studies conducted in different states indicate that over diagnosis could be between 4% and 18%. Majority of these studies are related to MLEC.

The 2003 Validation of Diagnosis study in India, which was conducted for the first time, on a large scale, with a standardised methodology, has shown that about 25% of newly detected cases by the routine programme (not MLEC), were over-reported. In order to follow-up into the problem of diagnostic validity, it was decided to repeat the same exercise, covering a large number of states with different endemicity levels and case detection patterns, by using uniform, standardised criteria and procedures. The information generated from such a study would be useful to analyse the trends and helpful for fine-tuning the quality of programme implementation. The 2004 Validation of diagnosis study in India will be carried out from 15th June to 5th July, 2004.

II. OBJECTIVE

To assess the validity of diagnosis of leprosy among recently detected new cases, by the routine programme, in 12 endemic states of India.

III. THE LEM CORE GROUP

In order to achieve a high quality Validation of leprosy diagnosis study, a core group has been set up. It comprises members representing GOI, WHO, NIHF, DFIT, NLR, TLM, SLO (Delhi) and Public Health Expert from Indira Gandhi National Open University.

The objective of the core group is to ensure a quality control mechanism at each stage of the Validation of diagnosis exercise.

The core group will:

- Provide technical inputs in reviewing the Validation protocol & tools,
- Review the progress of the project,
- Contribute to field supervision during data collection,
- Contribute towards data analysis & interpretation and thus provide technical inputs in the preliminary report.

IV. METHODOLOGY

The same methodology that was used in 2003 will be implemented in 2004. But in order to increase the quality of the study some important operational components will be modified. In the 2003 study, 68% (1737/2541) of patients, listed by the NLEP during the reference period, were seen by the validators. This represented an attrition of 32%. It is believed that a more careful preparation could reduce this factor. Similarly, despite the qualification of the validators and the standardisation workshop, the performance of the validator teams varied. This protocol will describe in details the modifications for 2004.

1. Validation study area

The study will be carried out in 12 endemic states - Andhra Pradesh, Bihar, Chhattisgarh, Delhi, Jharkhand, Karnataka, Madhya Pradesh, Maharashtra, Orissa, Tamil Nadu, Uttar Pradesh, and West Bengal. One district in each state will be randomly selected.

2. Selection of districts

One district in each state will be selected randomly from the pool of districts with high new case detection. In each of the 12 states, a list of districts with number of new cases detected in 2003-04 (from April 2003 till the latest month in 2004 for which report is available) will be prepared in the descending order for number of cases. This is to ensure the probability of selecting the district that would yield enough number of cases for the study. From among the top five districts detecting reasonably large number of cases, one district would be selected by simple random sampling. The selected districts are: Chittoor (Andhra Pradesh.), Gaya (Bihar), Durg (Chhattisgarh), North West (Delhi), Chaibasa (Jharkhand), Bangalore Urban (Karnataka), Shahdol (Madhya Pradesh), Jalgaon (Maharashtra), Mayurbhanj (Orissa), Thiruvannamalai (Tamil Nadu), Allahabad (Uttar Pradesh), Murshidabad (West Bengal).

3. Selection of patients

All recently detected cases by the routine programme, during a recall period of one month for PB cases and two months for MB cases, will be included in the study. In practice it means for the PB category, all new cases detected from 1st May to 31st May 2004 and for the MB category, all new cases detected from 1st April to 31st May 2004 ¹.

All cases detected during the reference period, will be listed by the NLEP local authorities [DLO/CMHO], (see Annex 1, page 10).

¹ The states of Orissa and Jharkhand are conducting MLEC-5 in April-May 2004. Therefore, the validation study will be carried out at a later period, to avoid including cases detected during MLEC in the validation study.

Exclusion criteria: The patients with generalised infiltration of skin/nodules will be excluded from the validation study.

4. Sample size

For precision purposes, it is required that about 100-150 newly detected patients per district be examined by both validators.

5. Data collection

It will be carried out by pre-identified Medical Officers with ten years field experience in leprosy, from Government or Non-Government Organisations.

For each state, a team of two validators will be identified. For the study, they will be assigned to a state in which they are not involved to avoid potential bias.

All the cases will be seen independently by both the validators who will record their findings in the form provided for the purpose. The district facilitator will assign serial number to each case and transfer the relevant information from the patient card to both the copies of the validation form and hand them over to the validators. He should ensure that all the cases are examined by both the validators and the forms are filled. All the forms will be verified for completeness. Each pair of forms should be stapled together.

From data collected, a list of **indicators** will be computed, as follows:

- Proportion of Wrong Diagnosis, on combined PB & MB cases, on PB cases and MB cases separately;
- Proportion of Re-registered cases, on combined PB & MB cases, on PB cases and MB cases separately;
- Proportion of Wrong Classification (grouping), on combined PB & MB cases, on PB cases and MB cases separately;
- Proportion of cases “Traced but not Available” and “Non-existent cases”.

A definition of the indicators, with numerators and denominators is provided in Annex 2, page 11.

6. Data collection form, data entry and analysis

Data will be collected on a Validation form (see Annex 3, page 13), by each validator independently. Forms will be collected by NIHFW at the end of the field work. Forms will be checked for completeness during the debriefing on 5th July. Forms will be sorted out and given a serial number. A coding of block names will be made prior to data entry. The data will then be

entered into the Epi-Info software by NIHFW. The database will be carefully cleaned prior to analysis.

Data analysis will be based on agreement of both validators, for diagnosis (case or not a case) and classification of cases (PB and MB). Agreed diagnosis and classification will be compared with the diagnosis/classification made by the health workers involved in NLEP. If there is a disagreement – on diagnosis or classification – the records will be excluded from the main analysis.

Data analysis will be conducted and preliminary results shared with the core group members. Major results and interpretation of data, state wise, will be included in the LEM 2004 report. A separate, more detailed, Validation of leprosy diagnosis report 2004, including 95% confidence intervals of results, will be made and distributed to the Central, State and District level authorities, as well as to all the NLEP partners.

V. OPERATIONAL ASPECTS

Lessons learned from the 2003 Validation exercise showed that the quality of the study could be enhanced by a more careful preparatory phase and better field implementation. Therefore, the core group decided to formally add a resource person to each validation team. This individual, called District Facilitator, will play a crucial role, in both the preparatory phase and the data collection stage.

1. Selection of District Facilitator

Each validator team will be assigned a district facilitator. The district facilitator will be a Supervisor from the District Technical Support Teams of the selected district. His role will be crucial to enhance the quality of the outcome, both during the preparatory phase and during the field data collection.

The criteria for selection of district facilitators are: 1) availability during a 5-week period, from 28 May to 3 July 2004, 2) good organisation skills, 3) good geographic knowledge of the selected district, and 4) high level of motivation.

2. Workshop for District Facilitators

The district facilitators will be oriented in a one-day workshop, to be held at NIHFW, New Delhi, on 28 May 2004. The objectives of the workshop are: 1) to describe/train on all the necessary steps to be carried out during the preparatory phase, and 2) to describe all the duties of the district facilitators during the field data collection phase, (see Annex 6).

3. Expected roles from District Facilitator

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

3.1. 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 date(s) 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.

3.2. 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.

4. Selection of Validators

To conduct the Validation study in the twelve selected states, 12 teams of 2 validators are required, (total = 24 validators). Four more will be added to take care of any attrition due to last minute drop out. Each validator team will cover one district. Validators will be assigned to a state in which they are not associated.

Criteria for identification of validators are: 1) at least 10 years of experience in leprosy clinical diagnosis, 2) previous field experience, preferably in field survey, 3) availability for a minimum period of three weeks, from 15th June to 5th July 2004, 4) high level of motivation, and, 5) fluency in the language of the area in which he/she will be visiting.

5. Standardisation workshop

The validators will be oriented to the procedures in a two-day standardisation workshop, which will include one day of practice with newly detected cases from New Delhi. The objectives of the workshop are: 1) to describe the protocol and its operational aspects, and 2) to ensure that all validators will apply the same diagnosis procedures and criteria during the field data collection. The standardisation workshop will be held at NIHFWS in Delhi, on 15-16 June 2004. Five facilitators will be identified from among the Medical Officers working with institutions or organisations with long-standing experience in leprosy, in field surveys, and in facilitating workshops. The goal is to reach at least 90% inter-reliability among the validators (see Annexes 7 & 8).

6. Expected roles from Validators

Each validator will:

- Explain the purpose of visit to the DLO and MO I/C of the PHC/screening point;
- Examine all the newly detected cases (PB/MB), listed for the reference period;
- See/examine all the cases in the field (see Annexes 10 & 11), independently by both the validators, without sharing/discussing their findings;
- Record their findings in the form provided for the purpose;
- Fill the validation form correctly and completely;
- Ensure that the case is 'new' by asking the question to the patient about previous leprosy treatment. If the answer to the question is 'yes' the case is labeled as re-registered and then appropriately entered in the validators form. The particular patient does not need further examination;
- Examine the patients as explained, demonstrated and practiced during the standardization workshop;
- The validators while examining the patient will locate the skin lesions, do the sensory test with Reynolds's ball pen for eliciting sensory deficit, examine the ulnar and lateral popliteal nerve, categorise the clinical condition as leprosy, not leprosy and classify the disease as PB or MB if leprosy;
- The patient who does not attend the designated screening points should be examined at their home or the next screening point on the following day;
- Every attempt should be made by the validators to examine all the listed new cases;
- After completing the field work in the district, the validators would bring the filled forms stapled in pairs to NIHFW (see Annex 12).

7. Advanced notification

Each state will be informed in advance (during May) regarding the selected district, the visit schedule of the team and expected role of the DLO. All new cases detected in the district, during the past one month for PB and the past 2 months for MB cases, prior to the visit of the team, will be selected for validation of diagnosis.

8. Ethical issues

It was decided by the core group members that for patients for to be wrongly diagnosed (not leprosy) by both validators, their treatment should be stopped and their name removed from the treatment 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 validator's classification, and the leprosy register and patient' card updated. After analysis of data, a mechanism will be put in place to inform the district authorities for such patients, and necessary actions.

INDICATORS FOR VALIDATION

A. Wrong diagnosis:

Number of cases which are diagnosed as not leprosy by both the validators

Total number of cases examined by both the validators, with agreement on diagnosis

B. Wrong grouping: PB as MB:

Number of MB cases which are diagnosed as PB by both the validators

Number of MB cases examined by both the validators, with agreement on classification

C. Wrong grouping: MB as PB:

Number of PB cases which are diagnosed as MB by both the validators

Number of PB cases examined by both the validators, with agreement on classification

D. Re-Registration of PB:

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

Number of PB cases seen by both the validators

E. Re-Registration of MB:

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

Number of MB cases seen by both the validators

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

Number of cases with skin lesion(s) examined, in which both validators agree for anaesthesia

Number of cases with skin lesion(s) examined by both the validators

G. Agreement between the two validators for nerve thickening:

Number of cases examined by both validators in which both agree for nerve thickening
Number of cases examined by both the validators

H. Traced but Not Available:

Number of cases which were traced but not available for examination from among cases detected during the reference period

Number of cases detected during the reference period, in which attempt was made by the validators to contact them

I. Not Existent:

Number of cases which do not exist from among cases detected during the reference period

Number of cases detected during the reference period, in which attempt was made by the validators to contact them

FORM – II – DATA COLLECTION FORM

NLEP VALIDATION FORM

Serial No.

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

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

Diagnosis: PB MB
 (Tick)

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

Validator's number 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)

Procedures and criteria for Validation

1. **D**efinitions

- 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.

2. **S**ensory test in skin lesions

Skin patch with loss of sensation is the commonly used cardinal sign of leprosy 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

A. The right instrument?

Variety of instruments is used. Ballpoint pen if properly used is a safe and fairly standardised instrument for sensory testing (touch sensation).

B. How the stimulus is applied using ball pen?

- ❖ Use the tip of ball pen.
- ❖ Place the pen perpendicular to the skin surface being tested.
- ❖ Weight of the ball pen is usually adequate to produce the stimulus.
- ❖ Skin of palm and sole are thick. Hence apply 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).

C. What is the response to stimulus expected from the patient?

Patient is asked to point to the exact spot touched with ball pen. If the patient points to the exact spot touched or within one centimeter then there is no sensory deficit in the lesion. If he points at a spot which is away from the spot touched there is impairment (partial loss of sensation). The other method of identifying impairment is by touching the normal skin and affected area and asking the patient which one he feels better. If he is not

able to point at all, there is anesthesia (total loss of sensation). While testing areas like back or buttock, patient can be asked to count when stimulus is applied.

D. What are the steps in sensory testing?

- ❖ Explain the procedure to the patient.
- ❖ Demonstrate the test with eyes of patient open.
- ❖ Make sure that the patient understood the procedure.
- ❖ Perform the actual test with **patient's eyes closed**.



Do s & 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.

3. 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 then determine whether it is enlarged.

3.1. Ulnar nerve

- ❖ It is in the groove above and behind the medial epicondyle at the elbow.
- ❖ Both the examiner and the patient should sit comfortably facing each other
- ❖ Explain to the patient what you are going to do
- ❖ To examine the right ulnar nerve ask the patient to flex his elbow to 90⁰ (at right angle), hold his right wrist with your left hand (for support) and with your right hand feel the medial epicondyle.
- ❖ Pass behind the elbow and feel the ulnar nerve in the groove
- ❖ Gently palpate the nerve across its course with the pulp of your two fingers (index and middle). Trace the nerve proximally as far as possible to ascertain thickening or swelling, if present.

3.2. Lateral popliteal nerve

- ❖ It is at the back of the knee behind the head of fibula
- ❖ The patient is made to stand with the knees slightly flexed (to unlock the knees)
- ❖ The examiner should squat in front.
- ❖ Palpate both the lateral popliteal nerves simultaneously
- ❖ Identify the head of fibula on the lateral aspect of the knee joint in line with the lower pole of patella.

- ❖ Pass backwards and feel the lateral popliteal nerve just behind the fibular head.
- ❖ Gently palpate with the pulp of your two fingers (index and middle) and feel across the nerve.
- ❖ Trace the nerve proximally as far as possible to ascertain thickening or swelling, if present

4. **N**erve function impairment (sensory test) in hand or foot_____

This will be done only if there is disability of hand or foot and there is no skin lesions with anaesthesia and no nerve enlargement.

Hand:

Two points in the hand are tested- base of thenar and hypothenar eminence. The procedure for sensory test is the same as given under point 2.

Foot:

Two points are tested in the foot- one is the centre of the heel and the second is the second metatarsal head.

Workshop for District Facilitators

1.	Duration	:	One day
2.	Venue	:	NIHFW, New Delhi
3.	No. of participants	:	12
4.	No. of Facilitators	:	3
5.	Date	:	28 th May, 2004

General Objective:

To improve the quality of data collection for the validation exercise, by improving the preparatory phase and the field data collection procedures.

Specific objectives:

At the end of the workshop the participants:

- i. Will be able to list out, in proper sequence, all the activities to be carried out by them during the preparatory phase;
- ii. Will be able to draw the most appropriate Route chart, given the criteria stated during the workshop;
- iii. Will be able to list out, in proper sequence, all the activities to be carried out by them during the field data collection of the validation of diagnosis study.

Standardization Workshop for Validators
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1. Duration	:	Two days
2. Venue	:	NIHFW, New Delhi
3. No. of participants	:	30
4. No. of facilitators	:	5
5. Date	:	15 th -16 th June, 2004

A. Main objective:

The agreement between participants for diagnosis and classification will be 90% and above.

B. Specific objectives:**At the end of the workshop the participants:**

- i. Will be able to list out, in proper sequence, all the activities to be carried out by them during the validation of diagnosis;
- ii. Will recount, in the correct order, the procedure to be followed for sensory test, nerve examination, sensory test in hand and foot, and recording;
- iii. Will fill the validation form correctly; and
- iv. Will mention correctly the criteria used for diagnosis and grouping.

Note: The District Facilitators will also attend the Standardisation workshop. On day 1, they will attend the same sessions with the Validators. On day 2, they will attend a separate session, about their specific role during field data collection.

Workshop schedule for the Validators

Day	Content	Time	Methodology	Outcome
1	Introduction	15minutes	Self-introduction	All the participants become familiar to each other
	Objectives of workshop (Dr. A.K. Sood)	15minutes	Lecture cum discussion	All should be able state the purpose of the workshop when asked
	Work plan (Dr. A.K. Sood)	30 minutes	Presentation cum discussion	All the participants should be able to list out the activities in sequence to be carried out by them during validation
	Diagnosis- cardinal signs (Dr. D. Wilfred)	30minutes	Demonstration & Discussion	When asked all the participants should be able to mention the two clinical signs
	Diagnosis- sensory test Diagnosis- sensory test of palm and sole (Dr. D. Lobo)	30 minutes	Demonstration and discussion	All the participants will be able to list out correctly the steps in sensory test and sensory testing in palm and soles
	Diagnosis-nerve examination (Dr. P. Krishnamurthy)	30 minutes	Demonstration and discussion	All the participants will be able to list out correctly the steps in examination of ulnar and Lateral popliteal nerve
	Diagnosis (Dr. Vijaykumaran)	30 minutes	Discussion	All the participants will be able to list out correctly the criteria used for defining leprosy, not leprosy
	Grouping (Dr. P. Krishnamurthy)	30 minutes	Discussion	All the participants will be able to list out correctly the criteria used for grouping cases as PB and MB
	Introduction to forms and how to complete these forms (Dr. S. Manoncourt)	60 minutes	Demonstration & discussion	All the participants should be able to describe how to fill the various forms for validation
	Practical aspects of field work Dr. P. Krishnamurthy & S. Manoncourt)	30 minutes	Discussion	All the participants should be able to describe what actions are to be taken during field work.

Day	Content	Time	Methodology	Outcome
2 (Validators)	Clinical examination of cases for diagnosis and classification	One day	At least 5 cases are examined by each participant (from a pool of 15 newly detected cases)	Agreement for diagnosis and grouping will be 90% and above. Information in the validation forms of all the participants will be complete, consistent.
2 (District Facilitators)	Roles during field work		Case studies Role plays	All the participants should be able to describe what actions are to be taken during field work.
	Presentation of findings		Discussion	

Implementation plan and Timetable

- 1) Workshop for the District Facilitators at NIHFW: Friday, 28th May, 2004**
- 2) Preparatory phase at district level: 29th May – 14th June, 2004**
- 3) Standardization workshop for Validators at NIHFW: 15th – 16th June, 2004**
- 4) Field work for data collection: 17th June to 3rd July, 2004**
- 5) Debriefing meeting (Validators) at NIHFW: Monday, 5th July, 2004**

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 examining 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 examining 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.

SENSORY TESTING

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)

STRICTLY LIMIT THE TESTING TO THE 4 POINTS

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 envelopes from all the screening points and bring it to NIHFW during the de-briefing on 5th July 2004.