Dear Reader,

The ILEP Technical Commission (ITC), through its eight experts in different areas of leprosy work, provides advice to the Members of the Federation (Members) on technical matters.

In order to provide advice on a particular subject, the ITC often asks one of its members, or an invited expert, to prepare a discussion document to serve as input into ITC discussions on the subject. By posting this discussion document on the ILEP website, it is now possible to reach more people with expertise in and experience on the subject under discussion, and who may be willing to contribute to the ITC advisory process.

These documents do not pretend to be complete; they are documents for discussion purposes only and remain on the website for a limited length of time. They do not constitute official ITC advice.

Any input should be sent to the Secretary to the ITC at susan.lord@ilep.org.uk

Discussion document on ensuring the accuracy of the diagnosis of leprosy in routine control programs

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Introduction

As leprosy becomes less common, health workers will see fewer cases and are therefore more likely to make mistakes in the diagnosis of leprosy. Leprosy may be over-diagnosed when people who do not have the disease are labeled as leprosy cases and are treated with MDT; leprosy may also be under-diagnosed when a new case is not recognized and goes untreated. It is possible to review registered cases to confirm the diagnosis and identify those who have been diagnosed in error. It is much more difficult, however, to deal with the problem of under-diagnosis, as those cases are not registered and followed up; untreated cases may come back later with more obvious
signs of leprosy, such as an ulcer or a deformity, or they may go on living in the community without treatment.

With the assistance of WHO and ILEP, the Government of India has carried out several exercises to validate the diagnosis of leprosy, especially in the most endemic states. The results varied from state to state and although the majority of cases were confirmed as correctly diagnosed, a significant number were found not to be true new cases:

*Just under 10% of registered cases were found not to have leprosy at all.*  
*Over 13% of cases were not true new cases, but had been diagnosed and treated previously.*  
*A further 5% of cases could not be traced and reexamined.*

Apart from inaccurate statistics, overdiagnosis of leprosy causes unnecessary suffering to the person concerned and their family. The accuracy of diagnosis may well be worse in other countries, particularly in Africa, although this has not yet been studied. Leprosy is very variable in its clinical manifestations and some cases are more difficult to diagnose, causing disagreement even amongst experts. Therefore, while overdiagnosis should be minimized through adequate training and supervision, a certain level is unavoidable.

The re-registering of previously diagnosed cases may cause misleadingly high figures for leprosy case detection, but some of these people may need to be treated with MDT if they did not complete the earlier course. Care should be taken to ensure that a past history of treatment for leprosy is identified, so that such patients are not registered as ‘new’ cases.

**Factors leading to inaccuracy in the diagnosis of leprosy**

There are several factors which may be contributing to the problem:

- Inadequate coverage of leprosy in basic training courses
- Lack of experience of leprosy amongst health workers
- Poor knowledge of other skin diseases in the differential diagnosis
- Lack of skin smears, which help to identify difficult multibacillary cases
- Lack of supervision by someone knowledgeable about leprosy
- Delegation of responsibility for leprosy diagnosis to peripheral clinics, or to junior staff who have not had adequate training.

**Objectives of this policy guideline**

- To suggest ways in which the risk of inaccurate diagnosis can be reduced
- To suggest ways in which the level of inaccurate diagnosis can be monitored

**Reducing the risk of inaccurate diagnosis**

- Policy decisions to be made by the National Leprosy Control Program:
  - *Who can make the diagnosis of leprosy?* This will relate to training received and a knowledge of the differential diagnosis. In areas of higher endemcity, at least one
staff member in each peripheral clinic should be able to diagnose straightforward cases of leprosy (those with loss of sensation in a skin patch), while in areas of lower endemicity, such expertise may only be available at a referral center, such as a Health Center or District Hospital.

- **Referral of cases.** Even if no staff member has training in the diagnosis of leprosy, all health workers should know some of the signs suggestive of leprosy and also where to refer such cases for assessment. The National Program must decide whether suspects can be started on MDT while waiting for the diagnosis to be confirmed at the referral center and this will depend on local factors, such as the epidemiology of leprosy in the area and the accessibility of the referral center. In an integrated setting, staff should be comfortable with the idea of dealing with cases they can manage and referring more difficult or complex cases to the next level.

- **Training and supervision**
  - Having decided who should be responsible for diagnosing leprosy, the National Program should take steps to ensure that these people have adequate training in the diagnosis and management of leprosy, as well as the identification and treatment of common skin conditions which may be confused with leprosy.
  - Supervision should include on-the-job training, in order to maintain an appropriate level of knowledge and skill in clinics where leprosy cases are being seen.

- **Skin smears**
  - The skin smear remains the only widely available laboratory test to confirm the diagnosis of multibacillary leprosy. If this test can be done in a local laboratory (it is almost identical to the test for tuberculosis in sputum) its use should be encouraged, in order to improve the level of accuracy in the diagnosis of leprosy.

**Monitoring the accuracy of diagnosis**

It is unrealistic to expect National Programs to arrange for every case of leprosy to be confirmed by a second clinician, especially as the problem is likely to be worst in areas where the program is weakest. Similarly, few countries could mount a monitoring exercise as large and complex as the one reported from India.

It is therefore suggested that monitoring should rely on specific studies of a sample of new cases. For example, a monitoring exercise of one month’s duration could aim to examine all new cases diagnosed within the previous three months in a defined area; the number of staff required for the exercise would be determined by the number of cases to be traced and examined.

- **Protocol**

All new cases to be examined would be listed and arrangements made for them to be examined by an experienced clinician. The complexity of the arrangements will depend, of course, on the number of patients involved.

  - The person checking the diagnosis would place the patient in one of two categories: **a)** leprosy is the correct diagnosis or **b)** not leprosy.
  - The classification would be checked. The classification would be marked as either **c)** correct or **d)** incorrect.
- The registration status of the patient would be checked: either e) a new case or f) a previously treated case (a re-registered or recycled case).

- **Analysis**

  - The number of patients and their proportions in each category [a), b), c), d), e) and f)] will be reported and checked against stated targets.
  - Errors in diagnosis (a high proportion in category b) would indicate the need for either further training, or the reassignment of responsibility for diagnosing leprosy to a more senior level.
  - Errors in classification (a high proportion in category d) would indicate the need for further training.
  - Errors in registration (a high proportion in category f) would indicate the need for more supervision and on-the-job training.

- **Indicators**

  Indicators, with targets, would be:
  
  1. The proportion of the total sample actually examined (>80%)
  2. The proportion of checked cases in which leprosy was the correct diagnosis (>90%)
  3. The proportion of leprosy cases correctly classified as PB or MB (>95%)
  4. The proportion of checked cases correctly registered (>90%)

- **Examination technique**

  For training purposes, a detailed protocol for examining suspects can be approved by each National Program, taking into account local practice. The ILEP Learning Guide on diagnosis can be recommended as a guideline for checking the diagnosis of leprosy.

**References**

3. ILEP Learning Guide One: How to Diagnose and Treat Leprosy (see [www.ilep.org.uk](http://www.ilep.org.uk))