

# Monitoring Grade-2 Disability Rate and Applicability of Chemoprophylaxis in Leprosy Control

*Report of the Informal Consultation  
London, United Kingdom, 12-13 November 2009*



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Printed in India

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## **1. Introduction**

The “Enhanced Global Strategy for further reducing the disease burden due to leprosy 2011-2015” has set a target of reducing the rate of grade-2 disability among new cases by at least 35% from the base line of 2010 by the year 2015. At the Tenth Technical Advisory Group (TAG) meeting on Leprosy Control in New Delhi on 23 April 2009, one of the recommendations was that an in-depth review by experts is needed to see how this indicator could be better monitored and validated at the global level and to explore its association with delay in diagnosis and estimate undetected cases in the community.

In addition, the TAG also recommended that experts should review the past and current data on the use of various anti-leprosy drugs as chemoprophylactic agents with the aim to analyse their effectiveness and applicability in the field, especially in integrated leprosy control programmes. The TAG felt that further research is needed to find a single drug or drug combination for use as a chemoprophylactic agent that takes into consideration the current field conditions in endemic countries and the declining trend of the disease. An informal consultation meeting was held in London on 12-13 November 2009, which was attended by members of the Technical Advisory Group (TAG), experts and WHO Regional Advisors.

## **2. Opening session**

Dr Myo Thet Htoon welcomed the participants on behalf of WHO. Dr H.J.S. Kawuma and Dr P. Krishnamurthy were selected as chairperson and rapporteur respectively for the meeting.

Dr H.J.S. Kawuma in his introductory remarks said that the meeting was a follow-up on the issues identified for detailed deliberations in the last meeting held in April 2009 in New Delhi, India. The two issues on the table were: identifying an appropriate mechanism to monitor the progress towards achieving the target of reduction by 35% of the G2 disability rate among new cases by 2015 compared to the baseline at the beginning of 2010; and looking critically at any new information available on chemoprophylaxis and explore the feasibility of using it in routine programme.

## **3. Objectives of the meeting**

The objectives of the meeting were:

- To review the current trends of grade-2 disabilities among new cases per 100 000 population and to project future scenarios.

- To explore ways to validate the grade-2 disabilities reported from leprosy control programmes.
- To develop models to see the association between grade-2 disabilities and delay in detection and estimate undetected/hidden cases in the community.
- To review past and current studies on the use of anti-leprosy drugs used as chemoprophylaxis agent for prevention.
- To suggest possible areas for research in chemoprophylaxis with the aim to develop an effective drug combination for use as chemoprophylaxis in leprosy control programmes.

## **4. Monitoring grade-2 disability rate**

There were seven presentations covering the following issues: trends of grade-2 disability rate and its association with new cases, current practices in grade-2 disability assessment, requirements for validation, association between hidden cases and disability, between delay and disability and mechanisms to validate grade-2 disability reported from the field.

### **4.1 Trend of grade-2 disabilities among new cases**

Professor Smith reviewed the trends in grade-2 disability among new cases in 17 countries that had reported more than 1000 new cases in 2007 and some other countries (Guinea, Ghana, Tanzania, Thailand and Viet Nam). The three formats of reporting of grade-2 disabilities (absolute number, proportion of grade-2 disabilities among new cases and the rate of new cases with grade 2 disabilities per 100 000 population) were considered. The trend of grade-2 disabilities in all the three formats, both independently and in relation to new cases, was examined.

While grade-2 disabilities as a proportion among new cases was highest in China followed by Myanmar, Ethiopia and Madagascar, the indicator viewed as an absolute number was found to be highest in India followed by Brazil and Indonesia, which is due to the large number of new cases detected annually. The grade-2 disability rate among new cases per 100 000 population, which is the target indicator, was the highest in Brazil followed by Mozambique and the Democratic Republic of Congo. In almost all the countries that were reviewed a reduction in the grade-2 disability rate was seen. However, this was less apparent with the proportion of grade-2 disabilities.

In countries where the control programme was performing consistently well, such as in Thailand and Viet Nam, the new case detection rate and the new cases with grade-2 disability rate are seen to be declining in parallel.

In the ensuing discussions, it was highlighted that the Enhanced Global Strategy has set a target for 2015 for an anticipated 35% reduction in grade-2 disability rate and this is expected to be attained at the global level. Countries are to set similar targets for this

indicator taking into account programme performance and the current trends of new case detection and the grade-2 disabilities rate. A wide variation among countries and even within countries was noted and the importance of analysing the grade-2 disability data at the sub-national level was discussed.

## **4.2 Trend of grade- 2 disabilities in Brazil**

Dr Maria Leide W. Oliveira from Brazil shared the data from 2000 to 2008 on new cases and grade-2 disability from Brazil. It was shown that coverage of new cases assessed for disability was on average 88% in 2008, which was a marked improvement from 1995 when the assessment coverage was only 79%. The grade-2 disability rate in 2008 was 1.39 per 100 000 population. It declined slowly from 1.45 per 100 000 population in 2000 to 1.3 per 100 000 population in 2006. The sudden increase in 2008 (1.39 per 100 000 population) was apparently due to a change in the grading scheme which created some confusion in recording and reporting of this indicator at the peripheral levels.

The variations in the trend of new case detection and grade-2 disabilities among new cases in the different regions in a large country like Brazil were discussed.

## **4.3 Current practices in disability grading and monitoring**

Dr Wim van Brakel in his presentation on current practices in disability grading and monitoring said that most of the national programmes were reporting maximum grade-2 either in eyes, hands and feet. Some projects had started using summary measures by adding the disability score 0, 1 and 2 affecting the eyes, hands and feet in addition to the WHO maximum grade-2 for monitoring. The use of EHF scores to monitor impairment was presented. In comparing WHO grade-2 (maximum grade) with EHF scores at the time of starting treatment and at completing treatment it was found that in 30% of the new cases (n=706) the EHF score was more useful in identifying changes in impairments.

The operational issues relating to collecting grade-2 disability data in the field were presented. Issues regarding coverage (assessing patients at the time of diagnosis and on completing treatment), validity and quality of data (whether grade 0 is reported or assumed, grading criteria, nerve function assessment and practical training needs) and interpretation of indicators in terms of individual impairment status and programme performance were discussed.

It was agreed that countries should make a concerted effort to ensure the quality and validity of grade-2 disability data.

#### **4.4 Requirements for monitoring and validation of grade-2 disabilities**

Dr Paul Saunderson gave an essential list of requirements for monitoring and validation of grade-2 disability. It was suggested that programmes should introduce validation as part of the routine supervisory process and carry out special actions, such as re-examining samples of new patients to validate the data wherever needed and possible. This may be needed when the reported data are very different from what may be expected and from results reported from elsewhere or when some data are missing or if the data are showing large fluctuations from year to year and region to region. Trends in new case detection need to be monitored together with grade-2 disability rates and any sudden changes observed should be reviewed to determine whether this represents successful control efforts or poor case finding activities or incorrect disability grading.

The importance of support from a strong referral system with a built-in validation mechanism was also highlighted.

#### **4.5 Association between grade-2 disability and hidden cases**

Professor W.C.S. Smith discussed the nature of the hidden cases occurring in the community in terms of: increased risk of developing grade-2 disabilities, increased risk of transmission, various reasons for delay in detection due to accessibility, limitation of the health services, self-healing and concealment by self or family due to stigma. The rate of grade-2 disabilities is an indicator of the thoroughness of case finding. The trends in this indicator must be interpreted in light of the case finding efforts and whether case finding efforts have changed over the course of the period for which the trends are documented. Concerted case finding efforts in previous uncovered or un-reached areas are likely to result in a higher grade-2 disability rate initially as a higher proportion of hidden cases will be found, followed by a decline resulting from detection of early cases as the leprosy services and coverage improves.

Reference was made to the attempts by countries in the past to uncover hidden cases through special mechanisms like Leprosy Elimination Campaigns (LECs) and Special Action Projects for Elimination of Leprosy (SAPELs).

In reviewing data from LECs carried out during the late 1990s, Myanmar reported grade-2 disability rate of 3.1 per 100 000 population, Nepal 12.0 per 100 000 population and in India, Chhattisgarh State 1.3, Jharkhand State 1.9 and Bihar State 1.6 per 100 000 population. When repeated LECs were done in India in the same areas, grade-2 disabilities among new cases declined subsequently. It was also noted that a high grade-2 disability was also related to high MB proportion among new cases.

#### **4.6 Association between grade-2 disability and delay in diagnosis**

Dr P. Krishnamurthy presented the data on association between grade-2 disability and delay in diagnosis. He mentioned that results from 11 studies from countries ranging from

Brazil to the United Kingdom, covering patient populations ranging from 28 to 27 928 revealed that registration delay (delay between onset of disease and institution of treatment) was common. Even though different methods and criteria were used in different studies, registration delay ranged from 3 months to 47 months. Another set of 10 studies in seven countries done in the period between 1995 to 2008 clearly pointed out that the delay between onset and registration was a risk factor for impairment; the rate of impairment was higher with longer delay; and presence and severity of impairment were associated with duration of disease.

The conclusion was that there seemed to be a direct association between registration delay and impairments at diagnosis and that timely detection could prevent impairments in a large proportion of patients.

#### **4.7 Mechanism to validate grade-2 disability reported from the field**

Professor Paul E. M. Fine critically reviewed the mechanism to validate grade-2 disability reported from the field. He asserted that it was imperative for the programme managers to have a clear idea of the whole process regarding the flow of information from the time of diagnosis right up to national and then global records. The quality of the disability assessment in the field will also depend upon who does the initial assessment and the programme will need to review this process in terms of the category of health worker (general health workers, specialized leprosy workers, physiotherapists, physicians etc.) and their expertise. Data on the grade-2 disability trend (rate and percentage of new cases) should be interpreted in light of the quality of disability assessments and the percentage of patients assessed at diagnosis, as well as reporting completeness and delays, and consideration of the prevalence of disability due to other causes. One also needs to be aware about the effect (weight) of data from large programmes like Brazil, India and Indonesia contributing to the declining trend of grade-2 disabilities at the global level.

In realistic terms, conducting special surveys to validate these data will not lead to strengthening the routine services and could even lead to manipulation of data. The most appropriate thing to do is for the national programme to insist upon rigorous management in the collection and reporting of these data in the field.

### **5. Applicability of chemoprophylaxis in leprosy control**

The second issue that was discussed at length was the applicability of chemoprophylaxis in leprosy control. Seven presentations looked at the history of chemoprophylaxis, studies on its effectiveness and economics of the intervention.

#### **5.1 History of chemoprophylaxis in leprosy**

Dr Etienne Declercq presented the whole history of chemoprophylaxis. A total of 18 studies carried out in eight countries between 1965 and 1999 were identified in the

scientific literature. These studies differed from each other in terms of using different drugs ranging from dapsone to a combination of rifampicin, ofloxacin and minocycline (ROM), regimens (single to multiple doses), methodology (controlled to uncontrolled), target population (contacts or whole population) and in the criteria for defining contacts.

The inferences drawn from these studies were that:

- chemoprophylaxis was effective in preventing leprosy;
- the overall protective efficacy was 60%;
- problems arose with using dapsone or acetadapsonone as chemoprophylaxis due to the long duration and development of resistance;
- impact was limited if only household contacts were given chemoprophylaxis; and
- the effect seemed to wane over time.

## 5.2 Studies on effectiveness of chemoprophylaxis

### *Studies in the Federated States of Micronesia*

Dr Arturo Cunanan presented the results of a chemoprophylaxis trial carried out in the Federated States of Micronesia with support from WHO. The chemoprophylaxis trial was carried out as part of the routine programme. Two rounds of chemoprophylaxis were given to the whole population in Micronesia with a gap of one year after screening the population for active leprosy. The first round of screening and provision of chemoprophylaxis was carried out during March 1996 to March 1997 and the second round from March 1997 to April 1998. The regimen used was a single dose of rifampicin 600 mg, ofloxacin 400 mg and minocycline 100 mg (ROM) for people above 15 years and children below 15 years of age were given a single dose of rifampicin according to their age.

Out of 105 506 persons recorded in the 1994 census, 75 866 (72%) were screened for leprosy and 73 516 (70%) were given chemoprophylaxis during the first round. In the second round, 77 199 (73%) were screened and 75 865 (72%) were given chemoprophylaxis. In summary, 87% of the population received at least one dose and 54% received two doses.

The trend of new cases detected annually subsequent to the completion of the intervention (1997 onwards) showed an increase with a high proportion of children among the new cases, which led to questions about the efficacy of the intervention. In 1998, 80 new cases were reported and since then the number of new cases reported have steadily increased to 124 in 2008. The MB proportion among new cases was around 60%-70% and the proportion of children was around 30%- 40%.

### ***Studies in Maldives***

On behalf of Dr Kyaw Lwin the report on the chemoprophylaxis trial that was carried out in Maldives with support from WHO was presented by Dr Myo Thet Htoon.

Single-dose rifampicin (20mg per kg) was administered to the population in 34 islands regarded to have high leprosy endemicity compared to others. The population in these 34 islands was screened over a period of four years from 1991 to 1994 and a single dose of rifampicin was given to all above four years of age fulfilling the inclusion criteria (children 0-4 years, pregnant women, breastfeeding women, patients under MDT, TB patients, patients with liver diseases and people above 60 years). Out of a total of 49 735 registered population in these 34 islands, chemoprophylaxis was administered to 33 041 (66%) after screening for active leprosy.

Records of the intervention were not available and therefore follow-up could not be done as was the case with Micronesia. The last available data were from 1996 and 1997 when seven and six new cases were reported from these 34 islands, respectively.

No conclusion can be drawn based on the data presented. It was suggested that retrospective data from these 34 islands should be collected to see the impact of this intervention.

### ***Trials in Indonesia***

Dr Linda Oskam presented the study from Indonesia which was carried out in five islands (population 4739) in the Flores Sea in 2000. Yearly screening was done from 2001-2006. Screening was also done in 2008 and the next screening is planned for in 2010.

The population was divided into three groups, namely, contacts (household, direct neighbours and neighbours of direct neighbours); blanket treatment groups (all eligible individuals in the island); and the control group. Single-dose rifampicin (600 mg for adults and 300 mg for 6-14 year olds) was given to individuals in the contact and blanket treatment groups after active population screening and treatment of new leprosy patients with multidrug therapy (MDT). In the contact group, 18% of the population received rifampicin and in the blanket treatment group 82% received a single dose of rifampicin.

After a follow-up of three years no difference was seen in the cumulative incidence between the contact and control groups. However, a significant difference was observed between blanket treatment and control groups ( $p=0.03$ ). At six years of follow-up, the blanket treatment and control groups were not significantly different. However, at eight years of follow-up, though the incidence of cases increased in the control groups no significant difference was seen between blanket treatment and control groups ( $p=0.09$ ). When looking at groups by intake (supervised and unsupervised rifampicin) it was found that supervised intake of at least one dose of rifampicin gave a significant effectiveness of 66%.

The study concluded that:

- population-based prophylaxis (blanket treatment) was associated with a reduction in leprosy incidence in the first three years;
- after six years no significant difference was observed;
- after eight years a sudden rise in incidence was seen in the control group; and
- supervised provision of prophylaxis seems to be important.

### ***Trials in Bangladesh***

Professor J.H. Richardus presented the results of the study (single centre, cluster randomized, double blind, placebo-controlled) carried out from 2001 to 2009 in two northwest districts in Bangladesh. These two districts had a population of around 4 million, and 1500 to 1800 new leprosy cases were detected annually.

Single-dose rifampicin (300 mg to 600 mg based on age and weight) was given to individuals in the treatment and placebo groups six weeks after the start of multidrug therapy (MDT) treatment of the index patient. The treatment group was made up of 10 857 individuals from 517 contact groups and the placebo group had 10 854 individuals from 520 contact groups. Follow-up after two years was 92% and after four years it was 87%. Contacts were categorized as household contacts, neighbours and social contacts. Analysis was also done based on blood relation and type of index patient.

At two years of follow-up, the treatment group showed an overall reduction of 65.5% (95% CI 32.9-71.9,  $p=0.0002$ ). At four years of follow-up, the overall reduction was 34.9% (CI 9.8-53.0,  $p=0.02$ ). The protective effect was 54% ( $p=0.17$ ) among household contacts, 49% ( $p=0.12$ ) among neighbours and 76% ( $p=0.0003$ ) among social contacts.

The study concluded that:

- rifampicin chemoprophylaxis reduces the incidence of leprosy;
- the protective effect was maintained up to two years and no difference was found between placebo and treatment groups beyond two years;
- the protective effect of single-dose rifampicin was found to be highest in the contacts with lowest a priori risk (contacts further removed from patients, both genetically and physically); and
- a regular contact survey with treatment of newly found cases is an effective intervention in itself.

### 5.3 Economic evaluation of chemoprophylaxis in leprosy: cost effectiveness of chemoprophylaxis

Professor W.C.S. Smith presented the cost effectiveness of chemoprophylaxis based on lessons learned from tuberculosis. A list of criteria to be considered when assessing economic evaluations for cost effectiveness of an intervention was outlined. It was pointed out that various elements of the costs and outcomes should be:

- measured accurately and valued credibly;
- effectiveness of the programme should be well established;
- adjustment made for differential timing;
- competing alternatives should be described; and
- allowance should be made for uncertainty in the estimates of costs.

Future research in the area of cost analysis should be well designed. It is important to ask the right question so as to ensure that evaluation is of high quality and focused on alternative regimens including BCG and chemoprophylaxis.

Professor Jan Hendrik Richardus presented the work on a simulation model based on data obtained from studies in Indonesia and Bangladesh to suggest that the intervention was cost effective. Based on data from a prospective (sero) epidemiological study on contact transmission and chemoprophylaxis in leprosy (COLEP) in Bangladesh (13% MB and 86% PB proportion among new cases), the incremental cost effectiveness ratios (ICER) per case prevented was calculated to be US\$ 252. The assumption made in the cost analysis was that the calculations for the standard programme cost was US\$ 307.13 per patient and that for the intervention (examination of household contacts, relatives, neighbours and social contacts and providing single dose of 600 mg rifampicin) was US\$ 374.84. The additional cost incurred was calculated for the cost of rifampicin only. The cost for active examination of household contacts, relatives, neighbours and social contacts were assumed to be part of the routine programme activities.

Critical application of cost effectiveness of prophylaxis at the national level with realistic input parameters will be important for large-scale implementation. The cost effectiveness model developed is to be reviewed in light of questions raised on the definitions and assumptions used in the analysis in order to have wide applications.

### 5.4 Future directions for research

Ms Elena Vuolo, Regional Adviser, CTD, WHO-EMRO, shared the points raised by the national programme managers when discussing about introduction of chemoprophylaxis during the regional meeting held in July 2009 in Cairo, Egypt. The concerns raised were:

- about the potential of mass chemoprophylaxis programmes to confuse existing health education messages about the low infectivity of leprosy to both the community and health-care workers;

- the danger of increasing stigma and the need to be careful with the health education messages to be given to the general public regarding the introduction of chemoprophylaxis;
- chemoprophylaxis was a low priority compared to other activities and introducing this could distract the programme from more important activities;
- chemoprophylaxis could create complacency in carrying out routine household contact screening by assuming that all contacts are protected; and
- mass approaches were seen to be useful in dealing with foci of leprosy in specific villages or communities.

Dr Kawuma made a presentation on future directions for research. The priority areas could be related to transmission and operational issues regarding chemoprophylaxis.

A field test for identifying infection especially among the household contacts of cases and for identifying those who are likely to progress from infection to disease are urgently required for defining and grading high risk groups and for introducing specific measures for controlling transmission of infection. Greater efforts are needed to study the various aspects of transmission of infection that would be amenable to control.

It is also useful to study the inherent genetic characteristics of island populations (e.g. Micronesia and Maldives) that define those at risk of developing the disease. Finally, pilot studies to address various operational issues involved in implementing chemoprophylaxis under routine programme conditions including cost effectiveness are required. Such pilot studies in different parts of the world would provide critical information for national programmes for large scale implementation.

## **6. Conclusions and recommendations**

- (1) All new cases should be assessed for grade-2 disabilities and the findings recorded and reported in standard formats.
- (2) WHO grade-2 disability grading should be used for collecting data for the population-based indicator as described in the Updated Operational Guidelines for the Enhanced Global Strategy to ensure uniformity.
- (3) Training by national programmes is important to ensure validity and reliability of grade-2 disability assessment, recording and reporting. Validation of data on a sample basis where possible is recommended.
- (4) Pilot projects on implementing chemoprophylaxis under routine programme conditions and using standard definition of “contacts” are recommended to better understand the operational issues. Pilot projects could be conducted in areas where contact examinations are being done successfully with current staff in order for it to be cost effective. Such pilot projects should use robust, standard methods to assess acceptability, cost effectiveness, feasibility and ethical issues.

## Annex 1

# Programme

### Day 1 – Thursday, 12 November 2009

#### Informal consultation on grade-2 disability

09:00 – 09:15 hrs	Opening Session <ul style="list-style-type: none"><li>➤ Opening Remarks by TAG Chairman</li><li>➤ Welcome by <i>Dr Myo Thet Htoon</i></li><li>➤ Selection of chairperson and rapporteur</li><li>➤ Introduction of participants</li></ul>
09:15 – 09:45 hrs	Global trends in grade-2 disabilities ( <i>Professor W.C.S. Smith</i> ) <i>Discussion</i>
09:45 – 10:15 hrs	Trend of grade-2 disability in Brazil ( <i>Dr Maria Leide W. Oliveira</i> ) <i>Discussion</i>
10:15 – 10:45 hrs	Current practices in grade-2 disability assessment and monitoring ( <i>Dr Wim van Brakel</i> ) <i>Discussion</i>
11:15 – 11:45 hrs	Requirements for monitoring and validation ( <i>Dr Paul Saunderson</i> ) <i>Discussion</i>
11:45 – 12:15 hrs	Association between grade-2 disability and hidden cases ( <i>Professor WCS Smith</i> ) <i>Discussion</i>
12:15 – 12:45 hrs	Association between grade-2 disability and delay in diagnosis ( <i>Dr P. Krishnamurthy</i> ) <i>Discussion</i>
14:00 – 14:30 hrs	Mechanism to validate grade-2 disability reported from the field ( <i>Professor Paul E.M. Fine</i> ) <i>Discussion</i>
15:00 – 17:00 hrs	Conclusion and recommendations
17:00 hours	Closing

## Day 2 - Friday, 13 November 2009

### Informal consultation on chemoprophylaxis in leprosy

- 09:00 – 09:30 hrs      General overview: History of chemoprophylaxis in leprosy  
(*Dr Etienne Declercq*)  
*Discussion*
- 09:30 – 10:30 hrs      Studies on effectiveness of chemoprophylaxis in:  
➤ Federated States of Micronesia (*Dr Arturo Cunanan*)  
➤ Maldives (*Dr Kyaw Lwin and Dr Myo Thet Htoon*)
- 11.00-12.30hrs      ➤ Bangladesh (*Prof Jan Hendrik Richardus*)  
➤ Indonesia (*Dr Linda Oskam*)  
*Discussion*
- 14:00-14.30hrs      Economic evaluation of chemoprophylaxis in leprosy.  
Cost effectiveness of chemoprophylaxis  
(*Professor WCS Smith and Professor Jan Hendrik Richardus*)  
*Discussion*
- 14:30 –15:00 hrs      Future directions for research (*Dr HJS Kawuma*)  
*Discussion*
- 15:30–16:00hrs      Conclusions and recommendations
- 16:00 hrs              Closing

## Annex 2

# Participants

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The Informal Consultation on Monitoring Grade-2 Disability Rate and Applicability of Chemoprophylaxis in Leprosy Control was held in London, United Kingdom on 12-13 November 2009. The objectives were to review current trends of Grade-2 disabilities among new cases, to project future scenarios, explore ways to validate reports, and to develop models to see the association between Grade-2 disabilities and delay in detection. In addition, past and current studies on use of anti-leprosy drugs for chemoprophylaxis were to be reviewed and recommendations made on possible areas for research.

The meeting concluded that uniformity in the collection of Grade-2 disability is important and that WHO Grade-2 disability grading is to be used. Pilot projects on implementing chemoprophylaxis under routine programme conditions and using standard definition of "contacts" were recommended to better understand the operational issues.

This report presents the proceedings of the Consultation, including the deliberations and recommendations made.



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SEA-GLP-2010.1