Volume 70, Number 1 (Suppl.)
Printed in the U.S.A.
(ISSN 0148-916X)

Introduction

1. Background and Objectives

Since the seventh meeting of the WHO Expert Committee on Leprosy ([1]), held in 1997, a number of new technical policies aimed at simplifying the diagnosis and treatment of leprosy have been recommended for application in the field ([2,3]). The implications of these new policies for leprosy control have not been systematically examined. In addition, a number of important issues that may have profound impact on leprosy control—e.g., the basic concept of leprosy elimination—require further discussion.

Currently, an appropriate forum in which to review these issues and to prepare recommendations and technical guidelines does not exist. However, the effort to control leprosy cannot afford to await the eighth meeting of the WHO Expert Committee on Leprosy. For this reason, the convening of a technical forum, in which important issues related to leprosy control may be discussed, was urgently needed.

That the International Leprosy Association (ILA) had never organized technical meetings other than international or regional leprosy congresses by no means suggests that it should not or could not take such an initiative. During the past few years, its members have been seriously discussing reform of the ILA, and many have expressed their beliefs that, as a professional association, the ILA should play a more active role in the day-to-day activities of leprosy control. Organizing a technical forum not only conformed perfectly with one of the objectives of ILA—i.e., "*. . . to help in any practicable manner the antileprosy campaign throughout the world*" ([4]), but also marks an important step in its reform.

There are numerous precedents for technical recommendations or guidelines for a number of diseases being issued by professional associations rather than by governmental or inter-governmental organizations. If the ILA has any strength, it is the technical expertise of its members; virtually all of those recognized as experts in leprosy, regardless of affiliation, are members of the ILA, including many who have played leading roles in the major international and regional meetings on leprosy, including those of the WHO Expert Committee on Leprosy. Therefore, the ILA is very favorably situated to convene a high-level technical meeting with participation of the most recognized experts.

The objectives of the technical forum are to:

- review critically the important issues related to leprosy control and the major technical policies being applied in the field;
- produce evidence-based recommendations for leprosy control activities;
- where evidence is lacking, produce recommendations based on best practice; and
- identify those areas requiring further research.

2. Methods

An organizing committee, which met twice during 2001, was charged with the responsibility of preparing a working document, which would form the basis of the discussions of the Forum. The committee developed a set of questions that were considered to represent important areas of change in the field of leprosy. These questions are listed in Annex 1.

In preparing the working document, a systematic search of the literature was carried out by researchers at the University of Aberdeen, working in collaboration with INFOLEP, using the set of questions to define the parameters of the search, and using four health-related bibliographic databases covering the literature from the year 1966 onwards, as well as the bibliographies of papers already identified, searching the "gray literature," and contacting key researchers in the various disciplines. A potential limitation of this approach is the so-called publication bias, as a result of which studies with positive or significant findings are more likely to be published.

Approximately 7000 titles and abstracts were read for relevance. From among these,

837 studies were selected and distributed to the committee members who were responsible for writing the relevant chapters of the working document. Thus, the recommendations contained in the working document are supported by a variety of published papers and studies. These critical studies were examined in order to grade the strength of the evidence supporting each recommendation, based on an objective assessment of the design and quality of each study, and a subjective judgment of the consistency, clinical relevance and external validity of the whole body of evidence ([5]).

The guidelines used in this review are those recommended by SIGN ([6]), having been developed by the U.S. Agency for Health Care Policy and Research ([7]) and employed extensively in systematic reviews. The grading system is explained in more detail in Annex 2; briefly, recommendations graded "A" are based on evidence from randomized controlled trials, those graded "B" involve evidence from other well-designed studies, and those graded "C" are based solely on expert or experienced opinion.

For this report, a systematic review of the literature was carried out for each of the questions posed. The computerized information retrieval systems used to search for relevant information were Medline, Cinahl, EMBASE and Healthstar, covering the period 1966–2001, and restricting the search to studies on humans. The key words used differed for each of the questions posed. Experience in other fields has indicated that searches of the electronic databases identify only about half of the relevant studies ([8]), so this approach was augmented by:

- searching the 'gray literature', the non-significant research findings, which are rarely accepted for publication, and which tend to remain in internal departmental reports;
- searching bibliographies of studies identified from the computer-based searches;
- contacting key researchers in the field;
- hand-searching key publications; and
- exploiting other resources (e.g., speaking with colleagues and other experts).

The abstracts identified by the electronic search were assessed to determine whether each article met predetermined eligibility criteria. All abstracts or titles that appeared to meet the eligibility criteria were retrieved. If, given the information available, it was determined that the abstract definitely did not meet the criteria, it was rejected. If, on the other hand, the title or abstract left room for doubt in the reviewer's mind, the full article was retrieved.

For abstracts that had been identified as potentially eligible, the complete articles were assessed to determine if the inclusion criteria had been met. A relevance form (Annex 2) was used to insure that the criteria had been applied in a standard way, and a data-extraction form was employed to record data from the studies included.

LITERATURE CITED

1. WHO Expert Committee on Leprosy. Seventh report, 1998. WHO Tech. Rep. Ser. no. 874. Geneva: World Health Organization.
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5. Guyatt, G. H., Sackett, D. L., Sinclair, J. C., Haywood, R, Cook, D. J. and Cook, R. J. Users' guides to medical literature. IX. A method for grading health care recommendations. Evidence-based Medicine Working Group. JAMA **274** (1995) 1800–1804.
6. Scottish Intercollegiate Guidelines Network. Methodology Review Group. Report on the Review of the Methods of Grading Guideline Recommendations, 1999. Edinburgh: SIGN.
7. US Department of Health and Human Services. *Agency for Health Care Policy and Research. Acute Pain management: Operative or Medical Procedures and Trauma. Rockville (MD): The Agency; 1993, Clinical Practice Guidelines No.1.* AHCPR Publications No. 92-0023, p. 107.
8. Crombie, I. K. and Davies, H. T. O. *Research in Health Care*, 1996. Chichester, England: J. Wiley & Sons Ltd.

ANNEX 1. QUESTIONS

Diagnosis

1. What are the sensitivity and specificity of the diagnosis of leprosy based solely on skin lesions with loss of sensation?
2. What are the sensitivity and specificity of classification based solely on counting the number of skin lesions, using skin smear positive cases as the gold standard?
3. Can the slit skin smear be replaced for field use by any other tool for the purposes of diagnosis and classification?

Treatment

4. What is the treatment completion rate in patients given unsupervised, accompanied MDT, under different field conditions?
5. What is the risk of new nerve damage in these patients?
6. What are the relapse rates in patients with various initial BI's, after 12 or 24 months of MDT?

Prevention of Disability

7. Is early detection of leprosy cases, with prompt MDT, effective in prevention of impairments?
8. Does early detection and treatment of reactions and new nerve damage prevent impairment? If so, what are the best methods of detection and the thresholds for treatment?
9. Does steroid prophylaxis prevent impairment?
10. How effective are interventions in self-care, footwear provision and socio-economic rehabilitation?

Epidemiology and Control; Organization of Leprosy Services

11. Are untreated MB cases the only significant source of infection?
12. What evidence is there for the effectiveness of interventions to stop or reduce the transmission of leprosy? Consider BCG, MDT, chemoprophylaxis, segregation and increased living standards.
13. What are the best indicators of trends in incidence of leprosy?
14. How can leprosy control activities best be sustained? What place can LEC's play in promoting sustainable services? What can be done where there is no health care infrastructure?
15. What is the evidence that IEC interventions can change the knowledge, attitudes and behavior of the public with regard to leprosy—especially with regard to self-reporting, reduction of stigma and compliance?
16. Which methods are most cost-effective?
17. How can appropriate and effective training be developed for all grades of staff involved in leprosy control?
18. For evaluation purposes, what are the minimum program data that must be recorded in an integrated setting?

THE TABLE. *Numbers of abstracts and complete articles reviewed.*

Question	Database							
	Medline		Embase		Healthstar		Cinahl	
	Abstracts	Complete articles	Abstracts	Complete articles	Abstracts	Complete articles	Abstracts	Complete articles
1–3	234	55	310	41	0	0	0	0
4, 5	476	79	346	43	3	0	3	1
6	255	74	128	40	0	0	1	0
7	37	12	27	2	0	0	0	0
8	16	3	24	11	0	0	0	0
9	106	32	113	27	0	0	0	0
10	448	49	255	27	2	0	0	0
11, 12	142	34	115	14	1	0	1	0
13	597	50	272	22	2	0	1	0
14	362	13	597	44	3	0	0	0
15	57	18	105	21	0	0	1	1
16	4	2	14	5	0	0	1	0
17	382	48	333	49	3	0	4	0
18	807	31	410	19	6	0	7	0
Total	3923	500	3049	365	20	0	19	2

ANNEX 2. DATA EXTRACTION FORM

BIBLIOGRAPHIC DETAILS

Authors:

Journal:

Title:

Year Volume Issue Page Numbers Country of origin

Reviewer 1 Reviewer 2

SECTION: **QUESTION:**

SEARCH DETAILS

MEDLINE EMBASE CINAHL Healthstar OTHERS

Identified from reference checking (which article?)

Refman Database/s ID No.

TYPE OF STUDY

☐ Systematic review with meta-analysis of randomized controlled trials

☐ Randomized control trial

☐ Non-randomized study

☐ Quasi-experimental study

☐ Review article

☐ Comparative study

☐ Cross sectional study

☐ Correlation study (ecological study)

☐ Case-control study

☐ Expert committee reports or opinions

☐ Clinical experiences

☐ Others with details

QUESTION ADDRESSED:

Sample size:

Setting of the study:

Age and sex of the patients:

Methodology:

Results:

Conclusions:

Reviewer's Comments:

GRADE OF RECOMMENDATIONS

Grade A	Ia Evidence obtained from meta-analysis of randomized controlled trial
	Ib Evidence from at least one randomized controlled trial
Grade B	IIa Evidence from at least one well-designed controlled study without randomization
	IIb Evidence from at least one other type of well-designed quasi-experimental study
	III Evidence from well designed non-experimental descriptive studies, such as comparative, correlation and case studies
Grade C	IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities