

to the topics discussed/presented at the pre-congress workshop.

- To organize training in social science methods.

Participants of the Pre-Congress Workshop on Social Science and Leprosy were: Dr. Zoica Bakirtzief, ALM Representative for Brazil; Ms. Zilda Maria Borges, Coordinator IDEA/Morhan; Dr. Wim van Brakel, TLM Research Coordinator; Mr. C. S. Cheriyan, Health Education Officer GLRA & Country Coordinator India, IDEA International; Dr. Denis Byamongo Chitrongota, TLM Coordinator East Congo; Dr. V.V. Dongre, Director, Gandhi Memorial Leprosy Foundation; Dr. Bassy Ebenso, Country Coordinator, TLM—Nigeria; Dr. Ulla-Britt Englebretsson, Research and Evaluation Officer TLP—Nepal; Mr. Tom Frist; Ms. Priscila Fuzikawa, Occupational therapist; Dr. P.K. Gopal, President IDEA International; Dr. Miriam Heynders, Research Fellow; Dr. Kongawi Kinda Jacques, ALM Representa-

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Special Workshop on Repeated and Late Reactions

Prof. Cairns Smith, Chairman

Peter Nicholls, Rapporteur

The INFIR/3 research program brought together authors of published work describing poor outcomes of Type 1 and Type 2 reactions in leprosy. Through a series of Workshops, it established new channels of communication and prompted a comprehensive literature review. A review of recent research findings identified priority areas for research into the treatment of reactions. Discussion also focused on the difficulties experienced in comparing research findings between different treatment centers. This led to the development of a set of definitions recommended for use in research into new and alternative treatment regimens. The definitions are not intended to replace existing operational definitions used in the clinic situation. Rather, they are intended to provide the higher level of definition required to ensure consistency and facilitate comparisons between research findings. With this in mind, the definitions rely on existing, widely understood definitions where possible.

1. Reversal or Type 1 Reactions

A Type 1 Reaction is an immunological complication of leprosy presenting with inflammation at sites of localization of *M. leprae* antigens. It is manifested by erythema and edema of skin lesions and/or neuritis. Edema of hands, feet or face may also be present.

Outcome definition and diagnostic cut-off:

A Type 1 Reaction is diagnosed when a patient has erythema and edema of skin lesions and/or neuritis. There may be accompanying edema of the hands, feet and face.

2. Type 2 Reaction or Erythema Nodosum Leprosum (ENL)

A Type 2 Reaction is an immunological complication of multibacillary leprosy presenting with short-lived and recurrent crops of tender erythematous subcutaneous nodules which may ulcerate. There may be signs of systemic involvement with fever

and malaise, inflammation in lymph nodes, subcutis, nerves, eyes, joints, testes, fingers, toes or other organs.

Outcome definition and diagnostic cut-off:

A Type 2 Reaction is diagnosed when a patient has crops of tender erythematous subcutaneous nodules/skin lesions. There may be accompanying neuritis, iritis, arthritis, orchitis, dactylitis, lymphadenopathy, edema, fever and malaise.

3. Neuropathy

Neuropathy is any functional disturbances and/or pathological changes in the peripheral nervous system. This includes neuritis and sensory, motor or autonomic impairment.

4. Neuritis

Neuritis is inflammation of a nerve presenting with any of the following: spontaneous nerve pain, paraesthesia, tenderness, sensory, motor or autonomic impairment.

Outcome definition and diagnostic cut-off:

Neuritis is diagnosed when a patient has spontaneous nerve pain, tenderness or sensory, motor or autonomic impairment of recent onset. Paraesthesia may accompany any of the above signs.

5. Nerve Function Impairment (NFI)

NFI is defined as any definite reduction in sensory, motor and/or autonomic nerve function.

Diagnostic cut-off:

NFI is determined by any new/additional sensory, motor or autonomic impairment.

6. Motor Impairment

Motor impairment is motor neuropathy resulting in definite weakness of the muscles innervated by a given nerve.

Diagnostic cut-off:

A patient is diagnosed as having motor impairment in any of the following situations: The VMT score for any muscle is less than four on the 0–5 (modified) MRC scale, Weak or Paralyzed on the Strong/Weak/Paralyzed scale or Movement Reduced on the 4-point scale (Strong, Resistance Reduced, Movement Reduced, Paralyzed).

7. Sensory Impairment

Sensory impairment is any sensory neuropathy resulting in definite reduction in the sensory ability of the patient when compared to normal subjects.

Diagnostic cut-off:

A patient is diagnosed as having sensory impairment in any of the following situations: The monofilament threshold is increased by three or more levels (filaments) on any site, or two levels on one site AND at least one level on another site, OR one level on three or more sites for one nerve. If a single monofilament test or the ballpen test is used, the cut off is 'touch stimulus not felt' on two or more test sites for one nerve.

8. Silent Neuropathy

Silent neuropathy is any sensory and/or motor impairment of recent onset (≤ 6 months duration) without spontaneous symptoms of nerve pain or tenderness or signs of a reaction (T1R or T2R).

Outcome definition and diagnostic cut-off:

A patient has silent neuropathy when he/she has sensory and/or motor impairment of recent onset (≤ 6 months duration) without signs of a reaction (T1R or T2R) or nerve pain or tenderness. The neural impairment may be new in a previously normal nerve, or may be superimposed on previous sensory or motor damage.

9. Nerve Tenderness

Tenderness is defined as pain on gentle palpation of a nerve trunk.

10. Mixed Signs Neuritis

Mixed signs neuritis is a combination of signs of mild sensory and/or motor impairment that on their own do not meet the criteria for the diagnosis of sensory or motor impairment and symptoms of neuritis in the same nerve(s), such as paraesthesia or pain.

11. Severity of Sensory Impairment

- **Mild sensory impairment.** Loss of sensation up to the monofilament threshold of 2 gm.
- **Severe sensory impairment.** Monofilament loss in excess of 2 gm may be considered as severe.

12. Duration of Symptoms

- **Acute.** Symptoms of less than one month duration—that is, changes within the last month. Hence:

Acute neuropathy is neuropathy of less than one month duration. Neuropathy of greater than one month duration may have been acute in onset but is no longer acute. Acute Neuritis is neuritis of less than one month duration.

- **Sub-acute.** Symptoms of greater than one month up to six months duration, that is, changes occurring from one to six months previously. Hence:

Sub-acute neuropathy is neuropathy with a duration between 1–6 months.

- **Chronic.** Symptoms of more than six months duration in the presence of a pathological process. Hence:

Chronic neuropathy is neuropathy of longer than 6 months duration.

- **Permanent.** Used to describe fixed neuropathy in the absence of any continuing pathological process.

- **Recent.** The term covers acute and sub-acute symptoms. Hence:

Recent nerve function impairment—Sensory or motor impairment with an onset no more than 6 months previously.

13. Post-treatment Reaction or Neuritis

A reaction or neuritis episode occurring after completion of anti-bacterial treatment.

14. Recurrent Reaction or Neuritis

A reaction or neuritis episode recurring after a symptom-free interval of at least three months since the end of anti-reaction treatment.

15. Chronic Reaction or Neuritis

A reaction or neuritis episode recurring during or within three months after completion of anti-reaction treatment.

16. Bacterial Relapse

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