



WHO MEETING ON THE COMPREHENSIVE APPROACH
 TO LOW BACK PAIN TREATMENT
 Kuala Lumpur, Malaysia
 5-7 December 1994

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1. INTRODUCTION

The meeting was opened by Dr. N. Khaltaev who welcomed participants on behalf of the Director-General of the World Health Organization. Dr. Ehrlich (USA) was elected as the chairman, Dr. Jayson (UK) had been appointed as the Deputy Chairman, and Dr. Gillies (Canada) appointed as the Rapporteur for this meeting. The meeting was called to order by the Chairman Dr. Ehrlich. Dr. N. Khaltaev welcomed two new members to the group from Vietnam: Dr. Tran Ngoc An (President, Vietnam Rheumatology Association) and Dr. Doan Minh Chau, Secretary-General, Vietnam Rheumatology Association).

2. WHO-WORLD BANK DOCUMENT - THE BURDEN OF DISEASE

The WHO and the World Bank will be publishing a book entitled "The Burden of Disease", which urgently needs data regarding back pain. This chapter of the book needs to be written by the end of December i.e. within three weeks. It was raised, in his absence, that Dr. Tugwell (Canada) has been briefed as to how the data need to be presented. Data are available from the following sources: Dr's. Raspe, Jayson, Hadler, Darmawan, Silman. It was emphasised that back pain MUST be represented in this document, despite there being only a few weeks to put the data together. ILAR President Dr. Arinoviche (Chile) emphasised that musculoskeletal disease has not appeared in the WHO top 10 of the diseases listed as causing disability. Dr. Jayson pointed out that musculoskeletal disease represents the first cause of disability, with low back pain (LBP) heading the list of disabling musculoskeletal diseases.

The group discussed in detail how to proceed with this important issue. It was agreed that a letter should be hand delivered to Dr. A. Lopez by Dr. Khaltaev on his return to Geneva, requesting a deferral on the final date for submissions for this document. It was suggested that as far as possible national data be obtained from several of the regions represented and that Dr. Deyo be approached for any USA data. It was agreed that Dr. Ehrlich would compose this letter the next day and have it reviewed and co-signed by Dr. Darmawan, as President of APLAR, and by Dr. Arinoviche, as President of ILAR.

(Letter appended).

3. REVIEW OF OUTCOME MEASURES FOR INTERNATIONAL STUDIES ON LBP

The discussion began with a review of the minutes from the WHO Manchester, U.K. meeting of April 6-9, 1994. After much discussion, it was decided to identify some items as CORE OUTCOME MEASURES and others as OPTIONAL OUTCOME MEASURES.

CORE OUTCOME MEASURES

- a. Visual analogue scales of pain and disability. (There was some discussion regarding the specifics of a visual analogue scale i.e. the benefits of having a line without cross bars, horizontal lines being preferable to vertical lines.
- b. Oswestry disability questionnaire. Dr. Chahade stated that the Portuguese translation of this questionnaire has been validated in Brazil.
- c. Modified Zung and the modified somatic perception questionnaire (MSPQ) -- recognising that there have been some cultural translation problems.
- d. Modified Schober test (15 cm test).

- e. Some CORE work incapacity/RTW measures (to include issues such as housework, availability of compensation) are required that are applicable to both developing and developed countries.
ACTION: details yet to be decided.
- f. Timed walking test.

OPTIONAL OUTCOME MEASURES

- a. Pain grids
- b. Modified Schober test (15 cm test).
- c. Sorenson test for quantifying extensor muscle activity (needs a special examining table).
- d. AIMS anxiety/depression scores
- e. Waddell Physical Impairment Index (revised version) --takes 15 minutes -- Spine 1992;17:617.
- f. Waddell Chronic Disability Index.
- g. "Hightech" assessments of spine function e.g. assessments of paraspinal muscle activity.
- h. Some OPTIONAL work incapacity/RTW measures are required that will be specific to each county.
ACTION: details yet to be decided.
- i. Cultural global score (e.g. patient's individual outcome measure of success) -- would require documentation of time it was achieved.
ACTION: Dr. Gillies (Canada) to formulate.

4. **QUALIFICATIONS FOR A PARTICIPATING CENTRE**

After a long discussion, three types of participation in WHO LBP initiatives were identified:

- a. WHO-RECOMMENDED CENTRES FOR BACK PAIN RESEARCH. It was envisioned that LBP centres with expertise in clinical trials, could be identified as the centre of excellence for back pain research for that country. With this recognition, these centres would be more able to apply for major funding within their country, without requiring WHO funding. These centres could be involved in multi-centre trials, and could assist WHO APPROVED STUDIES (see below).
- b. WHO-APPROVED LOW BACK PAIN STUDY. A centre wishing to undertake a LBP trial using the outcome measures recommended by this meeting would apply to the appropriate WHO-centres for approval of the study design and its completion. This approval would entail a site visit, the site visit paid for by the applying centre.
- c. LBP STUDIES USING WHO-OUTCOME MEASURES, BUT NOT APPLYING TO BE A "WHO-APPROVED LOW BACK PAIN STUDY". These centres would be able to use the WHO-outcome guidelines, but would not receive any endorsement from the WHO.

A Steering Committee was suggested with the following names put forward: Dr. Chahade, Dr. Darmawan, Dr. Ehrlich, Dr. Gillies, Dr. Homma, Dr. Jayson, Dr. Khaltaev. This steering committee would identify the terms of reference of the above outlined centres.

5. COST-EFFECTIVENESS AND THE ECONOMIC ADVANTAGE OF VARIOUS INTERVENTIONS: ECONOMIC OUTCOME MEASURES.

Dr. Khaltaev clearly stated there is a need to address the cost-effectiveness of treatment. A treatment could be very effective, but very expensive. Outcome measures must be linked to costs. Dr. Jayson reported on the great difficulties of estimating the wide ranging costs of back pain, having just completed such a study with the assistance of a health economist. Dr. Gillies suggested that some of these measures could perhaps be simplified without losing the quality of the data.

ACTION: Dr. Jayson to circulate the economic assessment used in his study.

6. THE STUDY DESIGN (NEED THEY BE PURE OR MAY THEY INCORPORATE MORE THAN ONE TREATMENT INTERVENTION).

It was agreed that where appropriate, baseline therapy should be available to patients entering LBP studies. Studies could be carried out with a treatment protocol added to the baseline treatment, but that this treatment protocol would, of course, have to have an appropriate placebo. It was recognised that when these treatment protocols involved "hands-on" therapy such as acupuncture, chiropractic, physiotherapy etc, then the influence of treating health provider becomes an issue. It was recommended that in such situations, these treatments must be carried out at another centre, not the centre which administers the treatment, with an independent observer to ensure that the treatment and placebo were administered in comparable ways. It was recognised that there might still a place for "mono-therapy" trials in certain situations. However, the supplementary treatment approach (i.e. adding the research treatment to the baseline treatment) by-passed the ethical issues of non-treatment of patients suffering LBP while enrolled in a trial.

7. OUTCOME MEASURES FOR BACK PAIN OF KNOWN CAUSE: OSTEOPOROSIS, ANKYLOSING SPONDYLITIS, DIRECT TRAUMA, FIBROMYALGIA

After much discussion, the committee agreed that outcome measures for these specific disorders should be established at a future separate meeting. The initial outcome measures should focus specifically on "non-specific low back pain", the diagnosis coined by Dr. Jayson regarding low back pain where a specific diagnosis has not been established. There may well be overlapping clinical outcome measures from the non-specific low back pain outcome measures and the back pain of specific cause. However, most likely, there would be additional outcome criteria that would be required. In terms of osteoporosis, it was decided that, where possible, osteoporosis should be excluded from studies of non-specific low back pain. Some patients may have mild osteoporosis and inevitably be in the non-specific low back pain group, since, for example, micro-fractures which do not show up on plain X-rays could not be excluded. In addition expensive tests such as bone densitometry to rule out osteoporosis were not thought appropriate. It was decided that clinical judgement should be used to establish whether a patient does or does not have osteoporosis for entry into a non-specific low back pain trial. In terms of fibromyalgia, after much discussion it was agreed that fibromyalgia is a specific diagnosis even if there is controversy as to the exact nature of the disorder. It was thought that fibromyalgia should have separate outcome measures. Dr. Jayson recommended that a special protocol be set up within the low back pain module, adopting the ACR definition. In terms of the spondyloarthropathies exclusion of the specifically named spondyloarthropathies should be undertaken so that these patients not be included in the non specific low back pain trials.

8. ASSESSMENT OF KNOWN LOW BACK PAIN FOR CONSISTENCY IN REPORTING

HISTORY AND PHYSICAL EXAMINATION

It was agreed that a general history and physical examination would be mandatory prior to entry into a low back pain protocol in order for the identification of known causes of low back pain (eg. infectious endocarditis, ankylosing spondylitis, fibromyalgia, psoriatic spondyloarthropathy, inflammatory bowel disease spondyloarthropathy) in order that these diseases be excluded from the entry group. A future protocol specifically addressing clinical trials of known causes of low back pain such as ankylosing spondylitis, will be the focus of future WHO-ILAR initiatives. In terms of the general history patients should be excluded if they have a serious illness, unexplained weight loss, unexplained night sweats, morbid obesity, HIV disease, cancer, psoriasis, ulcerative colitis, Crohn's disease, uveitis, chronic infectious diseases (brucellosis but not inactive TB). In terms of age, it was agreed that there should be no age limit realizing that certain studies might want to limit the age group. In terms of gender, the gender of the patients included in trials should be stated. It was agreed that pregnant women should be excluded from studies on "non-specific low back pain".

INVESTIGATIONS

BLOOD TESTS--Acute phase reactants (ESR, C-reactive protein), alkaline phosphatase, complete/full blood count (WCB, Hgb/ haematocrit, platelet count).

RADIOGRAPHS--Lumbosacral films to include the sacroiliac joints.

9. THE VALUE TO BE PLACED ON: THE TYPE OF WORK (MANUAL, SEDENTARY, DRIVING, WALKING); RECOGNITION OF "SAFETY NET"; CULTURAL DETERMINATES (EG. ACCEPTABILITY OF PAIN REPORTING; AGE, GENDER).

There was a long discussion regarding which measures would be appropriate to evaluate the difficult area of lifestyle elements including work, recreation, and cultural aspects. For example in Vietnam, 80% of the 70 million population are peasants working as agricultural labourers. In terms of cultural and social determinants, Dr. Ehrlich gave the example of three tribes in Nigeria where one tribe is forbidden to talk about pain, the second group have much the same attitude to pain as industrial societies, and the third group are supposed to complain vehemently about pain in order "ward off the gods". Cultural aspects regarding the social acceptability of reporting pain in populations was discussed in detail. Some recording of the social support network (social support system, social "safety net") was thought to be important with regard to clinical outcome measures in low back pain treatment trials. Industrialized nations have a variable degree of social support networks which the developing countries do not have access to. In Indonesia for example one "must work to eat". In Germany low back pain would qualify a patient for a six week treatment program in a rehabilitation center, along with six weeks of holiday and fourteen religious holidays in one year: a strong disincentive to return to premorbid activities, especially work, or to report improvement that would curtail future time allowances. No specific clinical outcomes in these areas were decided upon at this meeting but it was generally agreed that some measures to take into account these social and cultural variables should be undertaken.

10. FUTURE PLAN STUDIES, THE ROLE OF WHO AND ILAR

It is recognized that low back pain is a huge problem worldwide and is being recognized as such. The benefit of a WHO/ILAR collaboration was discussed in detail. Dr. Roberto Arinoviche (Chile),

President ILAR, was very supportive of this collaboration. It was recognized that if ILAR became involved in this WHO initiative, then major funds could be raised for this work, through ILAR. Of note, Dr. Arinoviche has appointed Dr Ehrlich and Dr. Chahade (Brazil) President's delegates functioning as a subcommittee of ILAR addressing soft tissue rheumatism, including back pain. It was also discussed in detail that it would be of great benefit to involve the International Society for the Study of the Lumbar Spine (ISSLS) in this task force. It was agreed that future initiatives of this committee should be to determine clinical outcome measures for specifically named causes of low back pain such as osteoporosis, spondyloarthropathies and direct trauma. In terms of osteoporosis and spondyloarthropathies there could be a reciprocal benefit with ILAR since funding could be linked to the pharmaceutical industry via ILAR.

11. GENERAL DISCUSSION; NEXT MEETING; PROPOSED PUBLICATION; APPROVAL OF THE REPORT

It was agreed that the next meeting of this WHO initiative on the comprehensive approach to low back treatment be undertaken June 18-24, 1995, during the EULAR meeting in Amsterdam. Unfortunately Dr. Jayson will be in Helsinki at the ISSLS meeting of which he is the President. It was suggested that a pilot study from each center be presented at the next meeting in Amsterdam. This would be a pilot study with approximately twenty five patients to measure the effectiveness of the outcome measures recommended. It was agreed that a statistician will be required at the Amsterdam meeting. At the next meeting it was suggested that Dr. Deyo (USA) and Dr. Gillies (Canada) collaborate on a document regarding cost effectiveness that could be incorporated into the clinical outcome measures. Once the report from this committee has been approved, publication in either *Spine* or *The Journal of Rheumatology* was suggested.

12. STEERING COMMITTEE MEETING

The meeting was called to order by the Chairman, Dr. Ehrlich

1. Committee Members:

Dr. G.E. Ehrlich (USA) Chairman
Dr. N. Khaltaev (Switzerland, WHO)
Dr. R. Arinoviche (Chili) President, ILAR
Dr. W.H. Chahade (Brazil)
Dr. J. Darmawan (Indonesia) President, APLAR
Dr. J.H. Gillies (Canada) (Rapporteur)
Dr. M. Homma (Japan)

The steering committee members met to discuss the development of WHO international designated centres in various countries that would eventually would become centres of excellence for low back pain. Prior to becoming a WHO-designated center for low back pain, these centres need to develop their local resources before being able to become WHO Co-ordinating Centres. It was suggested that the following centres become WHO-Coordinating Centers for their respective countries:

WHO-Co-ordinating centres for low back pain:

Australia - Yet to be determined
Brazil - Dr. W.H. Chahade (Sao Paulo)
Canada - Dr. J.H. Gillies (Vancouver)
Germany - Dr. H.H. Raspe (Luebeck)*
Indonesia - Dr. J. Darmawan (Semarang)
Japan - Dr. M. Homma (Yokohama)
Russia - Dr. V. Nassonova (Moscow)
UK - Dr. M.I.V. Jayson (Manchester)
USA - Dr. R. Deyo - (Seattle)

(*Professor Raspe (Luebeck, Germany) was proposed as an outside overseer, but the Center to be involved is the Hochrhein-Institut for Rheumatology and Rehabilitation based in Bad Seckingen, Germany with its other focus in Rheinfelden, Switzerland, and encompassing the Universities and Rehabilitation Centers of Southern Germany, Switzerland, and the Alsace of France, under the direction of Professors W. Mueller and W. Jaeckel. Dr. Ehrlich nominated this collaborative center because of their ambitious Interregio study, a three country cooperative venture on the treatment of low back pain in three different types of health care systems.)

There was detailed discussion on the establishment of these WHO Co-ordinating Centers for each country. It was agreed that these Co-ordinating Centers would not necessarily be charged to undertake the trials themselves. It was envisaged that low back pain trials regarding treatment outcomes would be co-ordinated through each of these centres for each of the countries. It was envisaged that a group wishing to undertake a low back pain trial could use the WHO clinical outcome measures and apply to the Co-ordinating Center of their country for the study to become a "WHO approved" low back pain study. These studies would need to include money within their budget for a site visit from one of the personnel from the Co-ordinating Center to ensure that the study was being undertaken appropriately, such that the label of "WHO approved low back pain study" could be given. It was suggested that there be a pilot study of approximately twenty five patients from each center using the criteria currently established at this Kuala Lumpur meeting, for review at the next meeting in Amsterdam in June 1994. In terms of the international co-ordination of these low back pain centres, there was general agreement that support from Geneva would be essential, along the lines of the WHO co-ordination of diabetes trials. In terms of each centres funding, it was suggested that each individual country try to establish local donors in order to establish the WHO Co-ordinating Center for each country. Each Center will report back on their progress at the next meeting in Amsterdam.

13. LETTER ON LBP BURDEN

WHO MEETING ON THE COMPREHENSIVE APPROACH
TO LOW BACK PAIN TREATMENT

Kuala Lumpur, Malaysia

5-7 December 1994

December 7, 1994

Dr A.D. Lopez
Scientist, HPP/TOH
Building V
WHO CH-1211, Geneva 27
Switzerland

Dear Dr Lopez,

Musculoskeletal diseases (Rheumatic Diseases) comprise the leading causes of disability, in both industrialised and developing nations. Of these, about half the disabling conditions are related to Low Back Pain (LBP). It is all the more surprising, therefore, to find back pain omitted from the listing and chapters in the forthcoming edition of book Burden of Diseases: Global and Regional Estimates. As you are probably aware, a LBP WHO Initiative has been meeting over the past two years to develop strategies for study of LBP globally, including the development of inclusion criteria and outcome measures for comparability of the great variety of interventions currently in use. We have belatedly been informed through Dr Peter Tugwell of the omission and of your offer to include this important subject, providing a chapter conforming to the style and content instructions could be produced by January.

The WHO-LBP Initiative and the International League of Associations of Rheumatology (ILAR), and its component league, The Asian League of Association of Rheumatology (APLAR), hosting the current meeting of the WHO Initiative, earnestly request that consideration be given to including low back pain after all. We have asked several members of the initiative (including Dr M.I.V. Jayson, President of the ISSLS, a member of this initiative) to provide national data from the several regions represented, and we will be prepared to deliver these to you with a short justification, for preliminary inclusion in this edition, because of the emerging recognition of the global magnitude of the problem. Time constraints will obviously not permit providing the full panoply of data and discussion, but clearly an expanded version fulfilling all the requirements can be prepared for the next edition, now that our organizations are aware that you have not previously been provided with the appropriate materials. We would hope that this compromise will be acceptable to you, so that attention will be drawn to LBP and the fully developed justification can be produced for future editions.

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We have asked that Dr N.G. Khaltaev personally deliver this letter, and to apprise us of new deadlines, requirements, and your comments. As you can see the undersigned consider this project of highest priority and great urgency. We are keenly aware that this is a holiday season, and would not intrude upon it if we did not believe that the need of inclusion of LBP is so great.

Yours sincerely,

Dr George E. Ehrlich (USA)
Chairman, WHO Initiative on LBP
ILAR President's delegate on Soft Tissue Rheumatism

Dr John Darmawan (Indonesia)
WHO expert, and President, APLAR

Dr Roberto Arinovich S, (Chile)
President ILAR

WHO MEETING ON THE COMPREHENSIVE APPROACH
TO LOW BACK PAIN TREATMENT

Kuala Lumpur, Malaysia

5-7 December 1994

14. LIST OF PARTICIPANTS

1. Dr M. Alattar, School of Chiropractic, Life College, 1269 Barclay Circle, Marietta, Georgia 30060, USA
2. Dr Tran Ngoc An, President, Vietnam Rheumatology Association, Vietnam
3. Dr R. Arinoviche, Clinica de Rheumatologia, Santiago, Chile
4. Dr A. Burdeiny, Institute of Rheumatology, Moscow, Russian Federation
5. Dr W.H. Chahade, Director, Rheumatology Department, Hospital do Servidor Publico Estadual de Sao Paulo, 4510 Avenue Brig. Luiz Antonio, 01402 Sao Paulo, Brazil
6. Dr Doan Minh Chau, Secretary-General, Vietnam Rheumatology Association, Vietnam
7. Dr J. Darmawan, Asia Pacific League Against Rheumatism (APLAR), Rheumatology Unit, Seroja Arthritis Centre, Jalan Seroja Dalam 7, Semarang 50241, Indonesia
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10. Dr J.-P. Giroud, Department of Pharmacology, Faculté de Médecine Cochin Port-Royal, Paris, France*
11. Dr M. Homma, Pharmaceutical Basic Research Laboratories, Japan Tobacco Inc., 13-2, Fukuura 1-Chome, Kanazawa-ku, Yokohama, Kanagawa 236, Japan
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14. Dr P. Tugwell, Faculty of Medicine, University of Ottawa, Ontario, Canada*
15. Dr S.E. Williams, School of Chiropractic, Life College, 1269 Barclay Circle, Marietta, Georgia 30060, USA

Secretariat

16. Dr N. Khaltaev, World Health Organization, Geneva, Switzerland

* Unable to attend