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THIRD WHO INFORMAL CONSULTATION ON THE COMPREHENSIVE APPROACH TO LOW BACK PAIN TREATMENT

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1. OPENING OF THE MEETING

Dr. N. Khaltaev (Secretariat, WHO) welcomed the members of the committee to the meeting and gave an overview of the current priorities of the WHO in Geneva. The current priorities of infectious diseases, sanitation and birth control were recognised as enormous and very important concerns in the developing countries. However, the huge economic burden and suffering caused by low back pain in both the developed and developing countries are also of great importance given the magnitude of the problem.

2. ELECTION OF THE CHAIRMAN AND RAPPORTEUR

Dr. Ehrlich (USA) was elected as the Chairman, and Dr. Gillies (Canada) as the Rapporteur.

Dr. Ehrlich (USA), as Chairman, reiterated Dr. Khaltaev's concerns regarding low back pain being a major, world-wide cause of pain and suffering at the individual level, and being a huge economic burden at the national and international level. He emphasised that the problem of low back pain is under-appreciated in some countries. For example in countries where there is no available "safety net", the worker is not missed at the job site, since he or she is replaced by a family member; however, in industrialised nations, occupational back pain of the skilled worker is recognised since once the "safety net" is in place, a huge national economic burden ensues.

3. ADOPTION OF THE AGENDA

The agenda for the meeting was adopted without amendments.

4. REVIEW OF ONGOING PILOT STUDIES

CHILE - Dr. R. Arinoviche

Dr. Arinoviche reported that he was delighted that Santiago, under his leadership, had recently been added as a WHO-recommended centre for co-ordinating low back pain trials for Chile. Since Chile was not included as a centre at the Kuala Lumpur December 1994 meeting, a pilot study testing out the proposed outcome measures has not yet been undertaken. Dr. Arinoviche stated Chile would be able to undertake pilot testing of the Spanish translation of the outcome measures.

BRAZIL - Dr. W. Chahade

Dr. Chahade reported that two trials were underway using the a Portuguese translation of the outcome measures, one trial in the out-patient rheumatology clinic and the second trial on an exercise intervention trial of construction labourers.

Recommendations/Comments:

- *Condensing (shortening) the Protocol* - Since it was taking approximately 60 minutes for every evaluation, Dr. Chahade recommended shortening the protocol.
- *Deleting the Modified Zung Questionnaire* - The questionnaire was found to be culturally inappropriate for the many illiterate, unskilled

workers in the lower socio-economic class in Brazil.

- *Difficulty with the short McGill Pain Questionnaire* - This questionnaire was found to be culturally inappropriate for many illiterate, lower socio-economic class workers in Brazil. Dr. Chahade reported the different descriptors for pain were not understood in translation into Portuguese. (Of note, the short McGill Pain Questionnaire, although used frequently in the literature, was not one of the core outcome measures recommended previously by the committee.) Dr. Chahade's findings confirm the committee's reservation about the use of this questionnaire in a multi-national setting.
- *Modified Schober test* - Dr. Chahade reported that the Modified Schober test clinically appeared to be more accurate than the Schober test.
- *Funding* - Dr. Chahade emphasized that funding was required to test out the protocol at other Brazilian centres.

USA, LIFE COLLEGE (Chiropractic) - Dr. M. Alattar

Dr. Alattar reported that Life College has developed a protocol using the following outcome measures in a proposed "randomized controlled clinical trial of specific cervical and lumbar chiropractic care versus drug therapy for sub-acute low back pain", scheduled to begin July 1995:

Oswestry Disability Questionnaire*
Short Form McGill Pain Questionnaire
Present Pain Index
Visual Analogue Pain Scale*
Pain Drawing
Waddell Chronic Disability Index**
Waddell Physical Impairment Index**
Modified Zung Questionnaire*
Modified Somatic Perception Questionnaire*
Modified Schober's Test*
(*outcome measures currently recommended by this committee)
(**optional outcome measures currently recommended by this committee)

Dr. McDuffy (Atlanta) has agreed to be the physician assisting the Chiropractic College in undertaking this research. Dr. McDuffy has also agreed to assist in the trials of chiropractic care that Life College is co-ordinating in Egypt (Cairo) and Russia (Moscow). Patients are recruited into these studies through newspaper advertisements. Difficulties encountered so far in Life College's pilot studies have been attributed to poor reproduction (quality) of the forms used for the questionnaires, and inconsistencies in the verbal instructions. So far, the Oswestry Disability Questionnaire and the Visual Analogue Scale for Pain have proved to be the most satisfactory outcome measures, with the poorest being the Modified Zung Questionnaire and the Waddell Physical Impairment Index. Trials with the Arabic translation of the outcome measures in Cairo are underway.

Recommendations/Comments:

- *Modified Zung Questionnaire* - re-consider the inclusion of this outcome measure.
- *Waddell Physical Impairment Index* - re-consider the inclusion of this outcome measure.
- *Invitation to Dr. McDuffy* - Dr. Darmawan (Indonesia) suggested that it might be helpful to

invite Dr. McDuffy to the next Committee meeting.

- *Protocol review* - Dr. Arinoviche (Chile) suggested that the protocol could be shown to Dr. P. Brooks (Australia) for his comments since Dr. Brooks is on the ILAR Standing Committee on Clinical Trials.

CANADA - Dr. J. Gillies

Dr. Gillies reported that pilot testing was underway using the recommended patient questionnaires, where the patient enters the data directly into the computer, using a touch screen. No computer skills are necessary, but the patient has to be able to read. For those patients where English is their second language, the patient has been accompanied by an English-speaking relative. At present the computer program is only in English, but plans are underway to translate the program into several languages. Since Vancouver has many large communities where English is the second language, future studies comparing the translations of the various forms will be undertaken.

Recommendations/Comments

Advantages of using touch-screen computer questionnaires

- *Printout* - An immediate printout is available.
- *Scoring* - The questionnaires such as the Oswestry questionnaire can be scored automatically, the information being available immediately.
- *Data Entry Cost* - Patient entry decreases the cost since a data entry clerk is not needed.

Disadvantages of using touch-screen computer questionnaires

- *Hardware/software cost* - Cost of the computers and the software.
- *Illiterate patients* - Illiterate patients require a translator. (This is the same for the paper questionnaires.)

In addition, Dr. Gillies reported that the interdisciplinary structure of the Vancouver, Canada's WHO-recommended back pain centre has been established along with a structure for internal funding.

INDONESIA - Dr. J. Darmawan

Dr. Darmawan reported that in Indonesia similar difficulties had been encountered with illiterate patients, the protocol taking between two to three hours, adding the additional concern that some bias is likely encountered when the questions are explained verbally. He reported that the semi-literate patients took a little less time completing the questionnaires, patients with a high school education taking approximately one hour, and university educated patients taking considerable less time. He reported that a number of the questionnaires had been translated into several languages. Cultural differences have been encountered with some of the translations. In the Philippines, a physiatrist in Manila has been using a translation of the outcome measures, with the back translation being forwarded to Dr. Jayson (UK). In India, Dr. P. Pispati a rheumatologist in Bombay has been using the outcome measures for his English-speaking patients (middle class and upper class patients), with plans to use translations of the outcome measures with his non-English speaking patients in the near future. A Chinese version is

being pilot tested (with the back translation being forwarded to Dr. Jayson). Plans are underway to test out the back translation of a Persian translation.

JAPAN - Dr. Homma

Dr. Homma (Japan) reported that the pilot study undertaken was designed to assess whether the Japanese version of the various questionnaires could be easily and correctly understood for the majority of Japanese patients with low back pain. 13 of the 47 patients surveyed had non-specific low back pain. 24 of the 47 patients had specific diagnosis (disc lesions=13, osteoarthritis=6, osteoporosis=3, spondylolysis=2), and in 10 of the 47 patients data relating to the diagnosis was not available. Low back pain patients attending three different departments took part in the study; patients being evaluated in an orthopedic clinic (30/47), patients being evaluated in a rehabilitation clinic (6/47), and patients being evaluated in an internal medicine clinic 11/47). Dr. Homma commented that some of the outcome measures were difficult to score.

Recommendations/Comments:

- *Outcome measurements associated with some problems* - Difficulty was encountered with the following questionnaires or measurements in Japanese-speaking low back pain patients.

    Core outcome measures
    Modified Zung Questionnaire
    Modified Somatic Perception Questionnaire
    Modified Schober test (15cm)
    Incapacity/RTW measures
    Timed walk test
    Optional outcome measures
    Pain grids
    Sorenson test
    AIMS anxiety/depression scores
    Waddell Chronic Disability Index

- *Successful outcome measurements* - The Oswestry Disability Score was relatively easy to administer, the questionnaire revealing differences in the groups assessed (i.e. the majority of patients with non-specific low back pain scored in the 0-20% range, whereas the majority of the "disc" patients scored in the 20%-40% range).

RUSSIA - Dr. V. Nassonova

Dr. Nassonova reported that a pilot study has been carried out at the Institute of Rheumatology, in Moscow. Nineteen patients with low back pain (including patients with ankylosing spondylitis and osteoporosis) had been assessed using the outcome measures. The average Oswestry Disability Score was 34% (range 10%-76%), with the average Waddell score being 2 (range 1-9). Dr. Nassonova reported that difficulty had been encountered with some of the questions on the Waddell questionnaire. However, she reported that overall the outcome measures were found to be useful and very convenient. The Institute plans to continue the study. Financial assistance for extending the study is required. Patients are being enlisted through advertisements in local newspapers and local cable television stations. Computerizing the questionnaires is being considered. The Institute is interested in

conducting studies examining both traditional and non-traditional treatments for low back pain (e.g. physiotherapy, artificial sun).

Recommendations/Comments:

- *Non-specific low back pain* - Dr. Chahade (Brazil) commented that the committee's recommended outcome measures for low back pain studies are for conducting studies in "non-specific low back pain", with future recommendations to come regarding outcome measures for back pain related to specific conditions such as ankylosing spondylitis and osteoporosis.
- *Non-specific low back pain* - Dr. Homma (Japan) commented that in Japan the outcome measures were being tested to clarify whether the questionnaires are useful for patients in general, using non-specific low back pain patients first, before testing out the outcome measures in patients with a known etiology of low back pain.
- *Urgency of establishing outcome measures* - Dr. Chahade (Brazil) recommended this committee proceed with its recommendations regarding the outcome measures for "non-specific low back pain" studies since time is being lost with current studies being undertaken.
- *Cost effective approach* - Dr. Ehrlich (USA) commented that a cost-effective approach is required for both low back pain of a specific etiology and non-specific low back pain; "non-specific low back pain" has been addressed by this committee first since it is the most common cause of low back pain world wide.

GERMANY-SWITZERLAND-FRANCE - Dr. W. Müller (Germany)

Professor W. Müller, Medical Director of the Hochrhein-Institut für Rehabilitationsforschung, Bad Säckingen(D)/ Rheinfelden(CH), highlighted the operation of his group which is already established as an International Low Back Pain Research Group. The Hochrhein-Institut is undertaking tri-country low back pain epidemiological studies in Germany, France, and Switzerland to determine whether there are any outcome differences due, in particular, to environmental issues, to psychosocial issues, and whether political differences in the health care delivery systems affect patient outcomes. The Hochrhein-Institut has two clinics in each of these countries; each of these three countries have different health care systems. The treatments for low back pain in these three countries is different, these treatments being generalised as follows:-

Germany - "active" physical therapy
Switzerland - "passive" physical therapy
France - combination of both "active" and "passive" physical therapy.

Dr. Müller volunteered to send a copy of the English version of the protocols currently being used to each of the committee members.

SUMMARY:

In summary, Dr. Ehrlich (USA) commented that in many countries there will be difficulties with the translation of the outcome measures where, for example, labourers speak various dialects. Dr. Ehrlich recommended that the committee members continue with pilot studies of 25 patients, with the recommendation that each centre expand to 100-200 persons. In terms of using the various translations of the outcome measures, Dr. Ehrlich commented that the committee members could target different language speaking groups in their countries. For example, Dr. Ehrlich pointed out that the second largest Japanese-speaking population was in Brazil. Dr. Ehrlich emphasised that low back pain studies evaluating the effectiveness of various treatments need to use outcome measures that are valid, applicable cross-culturally, cost-effective, achievable, and are appropriate measures of outcome. He commented that in addition to being used by centres conducting low back pain studies, the outcome measures could be used by drug companies for their research protocols. Dr. Ehrlich re-iterated that a cost-effective approach is required for both low back pain of a specific etiology and non-specific low back pain; "non-specific low back pain" has been addressed by this committee first since it is the most common cause of low back pain world wide. Definition of the terms "non-specific low back pain" and "acute", "sub-acute" and "chronic" need to be clarified for the outcome measures to be used effectively.

5. REVIEW OF WHO-RECOMMENDED CENTRES FOR BACK PAIN RESEARCH

Discussion regarding how to proceed in establishing future WHO-collaborating centres for Low Back Pain Research in various countries ensued. It was generally agreed that these International Collaborating Centres must be "top level" centres, where the research produced is of the highest quality. It was agreed that in order to establish such centres, this Committee will need to develop guidelines on the following:

criteria -- What are the determinants of a "top level" centre?
management -- Who should be managing such centres (i.e. should these centres be managed or supervised by University Bodies)?

It was recommended that one Centre be established first. Dr. Ehrlich (USA), outlined the various procedures that have to be undertaken in order to establish a centre as a "WHO-Collaborating Centre for Low Back Pain". He emphasised that the procedure is long and involved, for example, the Government of the Country has to first demonstrate that Back Pain is a major problem for the country. In terms of proceeding forward with the establishment of the first WHO-Collaborating Centre for Low Back Pain, Dr. Ehrlich (USA) recommended that the Hochrhein-Institut in Germany be considered, since the centre is already an established tri-country research centre, and also has soft tissue rheumatism (e.g. low back pain, fibromyalgia) as one of its areas of emphasis. The

Hochrhein-Institut is well placed to undertake studies comparing the outcome measures of such treatments as spa therapy, physical therapy treatments, cold chamber treatments, drug therapy, to name but a few. Dr. Ehrlich reiterated that it was vital that each country establish that low back pain is a major problem for its people, the huge economic burden caused by low back pain needing to be a priority of the country. Prior to being established as a "WHO-Collaborating Centre for Low Back Pain", a site visit by Dr. Khaltaev (WHO representative) would be required. Subsequently if the Minister of Health of the Country states to WHO that the Low Back Pain Centre is needed for their country, then the establishment of a WHO-Collaborating Centre for studies in Low Back Pain can proceed.

A motion was made to recommend Life College as the Coordinating Centre for the evaluation of Chiropractic treatment world wide, within this initiative. The differences between a WHO-Coordinating Centre and a WHO-Collaborating Centre were again outlined; specifically the first step in most countries should be that a WHO-Coordinating Centre for Low Back Pain be established, with the future goal of developing these centres into WHO-Collaborating Centres for Low Back Pain.

6. DIMENSIONS OF DATA BASE

Low back pain databases need to be collected for each country and translated into DALY's in order that the magnitude of the problem of low back pain can be estimated. In addition, the availability of services for patients with low back pain in each country needs to be identified. This information is vital in order that the "burden of disease" caused by low back pain can be established. Statistical assistance will be required to collate the data. Dr. Arinoviche (Chile) suggested that an ILAR epidemiology fellowship (either one of the existing fellowships or an additional fellowship) could be directed to collating the data for the low back pain chapter of the next edition of the "Burden of Disease". This information was not ready for the April 1995 deadline of the current edition of the "Burden of Disease". The focus of the low back pain chapter should be on "non-specific low back pain", but in future, data on both acute and chronic low back pain patients with and without an identified cause should be included. Planning should begin now in order that a low back pain chapter in the next "Burden of Disease" accurately reflects the enormity of the problem world wide.

7. PSYCHOSOCIAL PARAMETERS

There was discussion of the psychosocial parameters used as outcome measures. It was again emphasized that these measures are important, but there are many difficulties with correct translations into various languages, and cross-cultural problems with various questions. Despite these limitations, it was agreed that psychosocial parameters need to be included in the outcome measures of low back pain studies.

8. DEFINITION AND ASSESSMENT OF BACK PAIN "DISABILITIES"

The definition and assessment of back pain "disabilities" had been discussed during the earlier proceedings of the committee (see above under 4).

9. DATA COLLECTION AND RULES FOR CALCULATIONS (INCLUDING DALY's)

Each country needs to collect the DALY's in order to establish the importance of Low Back Pain as a major economic and social burden for both developed and developing countries. Only Germany and recently the UK have these figures. Calculation of DALY's involves complicated mathematical formulae. The committee recognised that assistance for these calculations will be needed.

10. NEXT MEETING IN ASIA 1996

Dr. Darmawan announced that next meeting of the Committee is scheduled to be in Asia. Previously the plan was for the meeting to be held in Melbourne during the APLAR 1996 conference, but the venue has been changed. Most likely the meeting will be held in Hong Kong, immediately prior to the OMERACT-3 meeting in Cairns, Australia which will take place April 16-19, 1996 and the APLAR meeting in Melbourne, Australia (April 21-26, 1996). Dr. Darmawan was hopeful he would be able to raise some funds for this meeting.
It was the committee's opinion that additional funding from outside WHO needs to be addressed. Substantial costs will arise from the air fares and hotel accommodation for the current participants and an additional two to four people (e.g. a statistician, Dr. McDuffy) i.e. up to a maximum of 15 participants. Dr. Darmawan (Indonesia) is trying to arrange sponsors for the next meeting to cover some of these costs. Dr. Chahade added that a Rheumatology Meeting on Vertebral Disease, with an emphasis on low back pain, is scheduled for September 22-26, 1996 in Brazil at Campo Largo Araucaria (40 km south of Sao Paulo), at which three members of this committee will likely be present.

11. PUBLICATIONS

It was recommended that the clinical outcome measures recommended by this committee be submitted for publication to the *Journal of Rheumatology*, with the authorship of this paper being the members of this committee present at the Amsterdam meeting (plus Dr. Jayson {U.K} who was unable to attend), the authors to be listed in alphabetical order. It was recommended that Dr. Gillies (Canada) prepare this manuscript for publication.

12. FUND RAISING

Official collaboration with other organisations such as ILAR (International League of Associations for Rheumatology) and ISSLS (the International Society for the

Study of the Lumbar Spine) would strength of the initiative of this committee such that funding could be secured for the continuation of this committee's undertakings. A combined WHO-ILAR-ISSLS Back Project would be more likely to secure funding for on-going projects, than if each of these groups operate independently. It was emphasized that funds have to be raised, in order for this committee to continue. Discussion regarding how much money is needed ensued. The allocation of $150,000-200,000/year to support a rheumatologist, with secretary support, to work in Geneva, assisting Dr. Khaltaev was discussed.

13. INTERACTION WITH ILAR

Dr. R. Arinoviche (Chile), as President of ILAR, informed the committee that close co-operation between ILAR and this committee was an important issue. The suggestion, made at the Kuala Lumpur meeting in December 1994, that ILAR might take on the responsibility for being the single fund raiser for the work of the committee is being raised at the ILAR executive meeting (during the concurrent EULAR Congress here in Amsterdam).

14. PLANNING FOR THE FUTURE

The necessity for cross-cultural validation of the questionnaires was discussed in details. The back translation of the questionnaires are being forwarded to Dr. Jayson. Dr. Gillies commented that a trial using the different translations is being planned in Vancouver for various Vancouver ESL (English as a second language) groups. It was decided that the committee should plan to present the results of large scale implementation studies using the outcome measures in various languages, to various ethnic groups world-wide at the next ILAR meeting to be held in Singapore in 1997.

15. LIST OF PARTICIPANTS

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