At the OMERACT III meeting 3 discussion groups were set up to address issues relating to psychosocial measures.
1. What measures can be used to assess an individual’s mental state, mood, emotion, cognition, and coping.
2. What measures are available for assessing pain and fatigue.
3. What measures are available for assessing disability, social functioning, and social support.

Assessment of Mental State, Coping, Mood, Emotion, and Cognition
Group 1 discussed the multiplicity of instruments available to assess these factors. Concern was expressed about the validity of the scales in diseases such as rheumatoid arthritis (RA) and whether indeed such extensive questionnaires were required to assess a particular state. Data were presented to suggest that a simple 3 point scale correlated well with the Hospital Anxiety and Depression Scale (Table 1). The group then reviewed the influence of psychosocial factors such as mood (depressed or improved), coping, social support, health cognitions, cognitive functioning, and fatigue on the RA core set. The group felt that the elements of pain, tender joint count, patient global, physician global, and function were all significantly influenced by psychosocial factors and that it was quite possible that swollen joint count, physician global, erythrocyte sedimentation rate, and radiography might also be influenced in some way by these factors. This suggested that a number of rheumatologists accept that there may be significant links between psychological factors, the immune system, and the disease process. The group felt it important to consider how states such as depression might influence behavior, particularly as regards treatment. It was felt that this might act in both a negative and a positive way. The psychological state of the patient (and the physician) was thought to be most important in the doctor/patient relationship, which was vital to the management process in chronic rheumatic diseases. The group then ranked the psychosocial domains in terms of their influence on the endpoint measures in the core set and felt that, in order of priority, depression, anxiety, and coping were the most important influences followed by social support, health cognitions, positive mood, fatigue, and cognitive functioning.

The various measures available for assessing psychoso-

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<th>Table 2. Examples of Psychosocial Measures.</th>
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| **Depression** | Beck Depression Inventory
| | Hospital Anxiety and Depression Scale
| | Zung
| | CES-D
| | Geriatric Depression Scale
| | Hamilton
| | SCL-90-R
| | SF-36
| | AIMS-2 (mood)
| **Anxiety** | Hospital Anxiety and Depression Scale
| | State Trait Anxiety Inventory (STAI)
| | AIMS-2 (Level of Tension)
| **Health cognition** | Arthritis Helplessness Index
| | Multidimensional Health Locus of Control Scale
| | Arthritis Self-efficacy Scale
| | Mini Mental State
| **Fatigue** | Multidimensional Assessment Fatigue Scale
| | Fatigue Severity Scale
| | Profile of Mood Status
| | Fatigue Assessment Instrument (quantitative and qualitative)
| | Chalder, et al
| | Nottingham Health Profile
| | Piper Fatigue Scale
| | Borg Scale (perceived exertion)
| **Coping skills** | Ways of Coping
| | COPE
| | London Coping with Rheumatoid Arthritis Questionnaire
| | Adaptation of Ways of Coping Scale
| **Social support** | AIMS-2
| | Social Support Questionnaire
| | Interview Schedule for Social Interaction
| **Positive mood** | General Wellbeing Scale
| | Self-Esteem Scale
| | POMS
| **Pain** | VAS
| | Likert scale
| | Dolorimetry
| | Pain diagrams
| | Happy faces
| | Observational
| | Tender point
| | Tolerability
| | Suffering
| | Reduction/relief (VAS)
| | McGill

Table 1. Hospital Anxiety and Depression (HAD) Scale.

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<th>HAD</th>
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<tr>
<td>I am not anxious and/or depressed</td>
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<tr>
<td>I am moderately anxious and/or depressed</td>
</tr>
<tr>
<td>I am severely anxious and/or depressed</td>
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cial factors were then discussed (Table 2). The list is not exhaustive and in most instances more data are required to assess the behavior of the individual measure in a specific rheumatic disease, its sensitivity to change, and the utility of the instrument. It was also felt important to look carefully at currently used measures such as Arthritis Impact Measurement Scale II (AIMS 2) that include some questions that assess domains such as anxiety and depression and consider how they rate against standard psychosocial measures. The group also felt it important to quantify these changes. For example, mild depression or anxiety (subclinical) may have no effect on the course of the disease, but significant anxiety/depression may.

**Measures of Pain and Fatigue**

In terms of important outcome variables, Group 2 rated pain and fatigue (12) as most important followed by depression/depressed mood (10), which was felt to be affected both by disease and number of symptoms (10), satisfaction with health (9), sleep (9), anxiety (8) and well being, self-esteem, loneliness and social factors (3). These were all felt to be important outcome variables. Mediating or moderating variables were considered, such as self-efficacy (10), learned helplessness (6), coping (5), and a range of social support factors (both positive and negative), health locus of control, attributions, and hardiness. Disease related genetic factors were also felt to be important as mediating factors. The group stressed the importance of the doctor/patient interaction in chronic disease.

The group then discussed the measurement of pain and felt there were important issues such as expression, perception, and threshold that were often not taken into account. Other issues that needed to be addressed included duration, frequency, tolerability, provoking factors, and maximum pain. Methodological issues such as the duration of recall were important when comparing pain from one period to another. In RA, pain can be measured in a number of ways, as follows.

**Measures of Pain**

- Visual analog scale (VAS)
- Likert scale
- Dolorimetry
- Pain diagrams
- Happy faces

- **McGill**

Pain in osteoarthritis (OA) was felt to require a different measure, as in the Western Ontario McMaster University Arthritis Index (WOMAC) or Lequesne.

Fatigue was felt to be influenced by many factors — psychological, somatic, and social. Exhaustion was addressed at length and it was considered that this is a difficult concept to explain to patients. It was interesting to note that the Lansbury Index uses the duration of fatigue as a measure of effective therapy and Pinals also includes fatigue as one of the remission criteria for RA. Fatigue can be difficult to measure, and a number of scales have been developed.

**Measures of Fatigue**

- VAS
- Multidimensional Assessment Fatigue Scale
- Profile of Mood Status (fatigue — 7 items, vigor — 5 items, depression — 15 items)

- Fatigue Assessment Instrument (quantitative and qualitative)

- Chalder and Goldenberg
- Nottingham Health Profile
- Rand
- Fatigue Severity Scale
- Piper Fatigue Scale
- Borg Scale (perceived exertion)

In conclusion, the group felt that psychosocial factors, and in particular, pain and fatigue were both important outcome measures and modifying or mediating variables. It was felt these factors were important for stratification of patients, either prior to entry into clinical trials or on analysis. It was also seen that few of these measures had been applied in clinical trials and further studies were necessary. The group identified 2 study groups in pain and fatigue that might work toward developing a research agenda.

**Psychosocial Factors and Disability**

Group 3 discussed the effect of psychosocial factors on measurement of disability and focused on the measurement of social functioning and social support. The group spent some time discussing the complexities of measuring disability and felt that many psychosocial factors would affect outcome. The group focussed on the ICDH classification, with disability referring to problems with acts or behaviors and handicap describing problems with social role performance. Disability and handicap have multifactorial determinants and are the composite outcomes of the full range of physical and psychological disorders experienced by the individual. Different loss of functions and hence different measures would be required depending on the aim of the trial. The disease to be targeted would also influence the measures to be used, as would the effect of age. Most measures such as the WOMAC, AIMS, Health Assessment Questionnaire (HAQ) and Psychosocial Adjustment to Illness Scale (PAIS) were thought to have multiple features.
that particularly raise the issue of composite measures. With instruments such as the SF-36, sensitivity and specificity are limited because they cover a variety of domains such as psychological symptoms, pain, and role functioning.

A number of studies have suggested that there was a relative independence of disability and handicap measures from those of disease activity. This highlights the need to be aware of factors that influence function other than disease activity. Environmental determinants, responsivity, and subscale variation were felt to be important in measurement terms. Discussion took place on how to scale “change” because of an individual’s ability to minimize loss of function through effort. The generalizability of findings from clinical trials is an issue because patients who are unmotivated are more likely to drop out; hence clinical trial outcomes may not predict their treatment response. This is important in assessing both individual and group results. It may be that stratification of samples with psychological matching is important. Placebo effects are important as well.

In terms of the instruments themselves, the length, floor effects, and preference questionnaires such as the MacTar (McMaster Toronto Arthritis Patient Preference Disability Questionnaire) were discussed. It was felt that instruments should be benchmarked with realistic goals for the particular study that was chosen. Strategies developed to assess disability handicap may be important in terms of function in longterm studies and may provide a source of error and require initial reference points. Personalized preferences, cultural issues, and changing technologies may also affect these measurement issues. As a consensus, the group felt it was important to balance samples on psychosocial variables because of the independent importance as determinants of disability. Depression, helplessness, somatization, and anxiety were felt to be important but the specific aims and patient group should determine which are chosen. It was felt that psychosocial variables should be used as covariates in the analysis of outcome variables (e.g., the HAQ) and their effect on the number of patients required in the trials and the strength of the relation needs to be addressed. It was felt that the relative importance of these measures had not yet been appreciated but that multidisciplinary research teams need to be established to explore this further.

Two major areas of research were identified — one would explore the relationship between psychosocial variables and disability measures such as the HAQ and the WOMAC. The second area is that of population based studies of disability and handicap which need to be developed over the long term to provide innovative epidemiological data. It was felt that both these types of studies needed funding and that in many countries support for this sort of research was a relatively low priority.

The issues raised by the 3 groups were debated within the larger group and there was a consensus that psychosocial issues were important to measure in trials and in the disease process generally, but the relative merit of the various instruments and the domains was at yet poorly understood. It was suggested that a working group of OMERACT be established to pursue psychosocial issues along the same lines as has been developed for adverse reactions (Drug Toxicity Working Group). The brief of this group would be to review all psychosocial measures currently available and to obtain data on their use in rheumatic diseases and in particular in intervention studies. The group was also given the task of reviewing psychosocial scales within the current outcome measures such as the AIMS and assessing their validity. The group was also asked to propose the research agenda in this area and to plan a followup meeting. The workshop chairman, Stanton Newman, together with Johannes Rasker, Alexander McFarlane, and Peter Brooks would form the core group and recruit a multidisciplinary group representative of the member Leagues of the International Leagues of Associations for Rheumatology.

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