

QUALITY OF LIFE IN RHEUMATOID ARTHRITIS

D. WHALLEY, S. P. McKENNA,* Z. DE JONG† and D. VAN DER HEIJDE†

Galen Research, Manchester, *Care Outcomes Group, Rheumatology and Rehabilitation Research Unit, School of Medicine, University of Leeds, Leeds and †Department of Rheumatology, University Hospital, Maastricht, The Netherlands

SUMMARY

Patient-completed health status instruments currently available for use with rheumatoid arthritis (RA) patients lack adequate reliability and responsiveness, making them unsuitable for use as outcome measures in clinical trials. A search of the literature failed to identify a quality of life (QoL) instrument specific to RA. The present study was designed to be the first stage in the development of such a measure. Qualitative interviews were held with 50 RA patients, 25 in the UK and 25 in The Netherlands. The interviews indicated that RA has a detrimental effect on many areas of life, including moods and emotions, social life, hobbies, everyday tasks, personal and social relationships, and physical contact. Transcripts of the interviews formed the source of items for the RAQoL, the first RA-specific QoL instrument.

KEY WORDS: Quality of life, Rheumatoid arthritis, RAQoL, Disease-specific, Outcome measurement, Qualitative interviews, Cross-cultural, Needs.

IN recent years, there has been a growing interest in the assessment of quality of life (QoL), particularly in chronic disabling conditions. The importance of the construct was recognized by the UK NHS Review Working Paper on Medical Audit [1] which saw quality of life as an integral part of the audit procedure. Bendtsen and associates [2] conducted a comprehensive review of the literature on QoL assessment in rheumatoid arthritis (RA). This made it clear that there is a lack of consensus about what QoL is and how it should be assessed.

Tennant [3] distinguished instruments intended to assess health status from those developed to measure quality of life. Health status is seen as the presence or absence of disease and its consequences, in largely functional terms. Quality of life goes beyond the impairment, disability and handicap continuum by asking what patients' health status prevents them from doing and also about their emotional response to these restrictions. QoL also reflects the influences of the personal, social and economic resources that an individual has, and the way in which these interact with health status.

There have been two main approaches to the assessment of the effects of RA on patients' lives: quantitative and qualitative.

The quantitative approach employs scores obtained by RA patients using standardized measures of health status. The Health Assessment Questionnaire (HAQ [4]) is the most widely used measure of functional disability in RA. Several instruments, such as the Arthritis Impact Measurement Scale (AIMS [5] and the subsequent AIMS2 [6]), the Nottingham Health Profile (NHP) [7] and the Sickness Impact Profile (SIP) [8], have been designed in an attempt to go beyond the

measurement of physical impairment and disability by addressing more emotional and social aspects of a condition. However, problems have been identified with all three instruments.

None have been found to have adequate reliability [6-9] or to be consistently responsive [10-16]. The NHP and SIP are generic instruments and, as such, were designed to assess health status across a wide range of conditions in population studies rather than in clinical trials. Consequently, they omit many issues that are important to people with RA, making them less able to detect changes in the patient [17, 18]. The AIMS, although designed to be arthritis-specific, still omits important aspects of RA, particularly fatigue [19].

Recently, two other measures have been proposed for use with RA patients: the Short Form Health Survey-36 (SF36 [20]) and the EuroQol [21]. The former is a generic health status measure focusing on function and incorporating some aspects of wellbeing. Like the other generic instruments available, it has limited reliability and responsiveness for use in clinical studies [22, 23]. Furthermore, there is evidence that the measure is not acceptable to elderly respondents [24, 25].

The EuroQol, primarily intended for use in utility analyses, has also been advocated as a generic measure of health-related quality of life that could be applied with RA patients [26]. However, the content of the instrument is rather simplistic and covers function rather than QoL. It has been found to be crude [27], unresponsive [28] and to yield poor response rates [29].

More individual-centred approaches to examining the impact of a condition and its treatment on the patient have been developed, for example, the Schedule for the Evaluation of Individual Quality of Life (SEIQoL) [30]. However, such approaches require a trained interviewer and, hence, have limited applicability in the routine monitoring of patients and in clinical trials.

Using a qualitative approach to the investigation of

Submitted 9 July 1996; revised version accepted 30 January 1997.
Correspondence to: D. Whalley, Enterprise House, Manchester Science Park, Lloyd Street North, Manchester M15 6SE.

the impact of chronic illness on the lives of patients has been a tradition in medical sociology [31–33]. This body of research shows clearly that RA has a major impact on patients. However, the value of the information to QoL research is limited by its emphasis on role functioning.

The need for a valid and reliable patient-completed measure of QoL, specific to RA patients, is clear. Management of RA aims at diminishing active inflammation, preventing irreversible damage and improving the quality of the patient's life. The range of available treatments and the advent of new ones requires an instrument capable of assessing their relative benefits for the patient. The instruments currently available generally assess health status rather than QoL. In addition, none are (and the generic instruments were not designed to be) sufficiently responsive to detect relatively small changes in QoL or health status associated with clinical interventions.

A new approach to the measurement of QoL employs a needs-based model [34]. In this model, QoL is defined as the extent to which individuals are able to meet their needs. Considering QoL in this way has a number of advantages. Rather than ask about functions that are not relevant to all respondents, such as employment and sexual relationships, it is possible to ask about the needs met by such functions. By concentrating on needs, items are more likely to be relevant to all patients, regardless of age, gender, marital status or employment status.

Furthermore, as needs are universal, even though they may be met in different ways in dissimilar cultures, adapting measures for use in other languages and cultures is less problematic. This is particularly advantageous where instruments are required for multinational clinical studies or trials.

The needs model has now formed the basis of a number of disease-specific QoL instruments [34–37]. These instruments have been shown to have greater relevance to, and acceptance by, patients and also to have better psychometric properties than function-based instruments [17].

The present paper reports findings from qualitative interviews in which patients describe the impact of RA on their QoL. The main objective was to explore the impact of the symptoms of RA and its treatment on patients' ability to fulfil their needs. Content analyses of the interview transcripts identified a pool of items that formed the basis of a standardized patient-completed RA-specific QoL instrument. The development work described in this paper was undertaken in both the UK and The Netherlands.

METHODS

The study was approved by ethics committees in both countries and participants gave their informed consent. In-depth qualitative interviews were held with 25 RA patients in each of the UK and The Netherlands.

Patients were included in the study if they reported having received a positive diagnosis of RA. Patients

were excluded from the study if they were confined to bed as a result of their RA or had a significant co-morbidity, such as malignancies or psychiatric disorders. The final instrument is intended for use in clinical trials, which rarely include such patients.

It was important to ensure that a wide range of patients (in terms of age, gender, and disease duration and severity) were included in this initial stage of the development of the instrument. Although patients with mild through to severe forms of the condition were included, severity of condition is not synonymous with level of QoL. The comprehensiveness of the QoL issues covered in the instrument was confirmed through field testing the measure for face and content validity (see de Jong *et al.* [38]).

Potential interviewees in the UK were identified from two sources: the branch organizers of two self-help groups for RA in the North West of England and a consultant rheumatologist in the South East of England. In The Netherlands, patients were recruited from the University Hospital, Maastricht. After having the purpose of the study explained, patients willing to participate were contacted directly by the interviewer.

All interviews in the UK and all but three in The Netherlands were conducted in the patient's home, and lasted between half an hour and 2½ h. With the respondent's permission, the interviews were audio-recorded and the tapes wiped clean after their content had been transcribed. Any information by which the interviewees could be identified was removed from the transcripts.

The interviews were informal and unstructured. Each began with an explanation of its purpose and a reassurance of confidentiality. The role of the interviewer was not to lead the respondents, but rather to encourage them to talk about aspects of their life that they felt were important to them.

RESULTS

No patients asked to participate in the study refused to be interviewed in either country. The interviewees were between 33 and 67 yr of age in the UK, and between 33 and 75 yr in The Netherlands. There were three males and 22 females in the UK, and six males and 19 females in The Netherlands. The duration of illness was between 1 and 26 yr in the UK, and between 7 months and 35 yr in The Netherlands.

As expected, a common consequence of RA was impaired mobility. Limited mobility restricted travel and made respondents dependent on others, leading to feelings of helplessness.

Many interviewees described having problems with dexterity. Some were distressed that they could no longer knit, sew or paint. Many could not write for any length of time or hold a book to read.

Many of the interviewees described feeling angry, frustrated, depressed and irritable. The former two emotions were often linked with the inability to do even simple everyday tasks, whereas irritability tended to be associated with being tired or in pain. Feelings of depression appeared to be more generalized, with no

specific cause. Many spoke of feeling humiliated or embarrassed by having to ask people for help. They would often struggle on and sometimes even hurt themselves rather than ask for help. A strong desire to be rid of pain was commonly expressed. Many respondents spoke of wanting to be 'normal' but, at the same time, they could not remember what it felt like to be free from the disease.

Respondents who had quite severe physical impairment or deformity talked of people staring at them, making them self-conscious. However, not appearing disabled sometimes caused problems for others. Strangers would not help them because they did not look as if they were ill or impaired. Respondents often felt that they could not talk to friends or family about their condition because they looked well. Strangers, and sometimes family, often expected them to carry heavy shopping or reach for things from high shelves. Respondents, especially males, described feeling embarrassed or ashamed when they had to say they were unable to do these tasks.

Problems often resulted from feeling tired or fatigued. This fatigue was of two types: general lethargy, 'it feels like the flu, you're fragile and tired and can't get going' and exhaustion after activity. Respondents had to plan their days so that they had plenty of time to rest. They spoke of having to keep stopping what they were doing because they were exhausted and not being able to go out because they did not have the energy. Interviewees described having to 'pay' for any over-exertion on the following day. Despite becoming tired easily and feeling generally fatigued, many of the respondents had difficulty sleeping at night, mostly because of painful joints.

Some respondents had problems concentrating for any length of time, which most attributed to pain or tiredness. This lack of concentration caused problems with reading, conversation and memory. Some interviewees also found it difficult to maintain interest in anything for more than a short time.

The condition had a major impact on the respondents' social lives and feelings of isolation were common. A number of interviewees had difficulty using a knife and fork, and so felt that eating out was 'a real ordeal'. Holidays and outings were a problem for many respondents because they lacked mobility and were easily fatigued. They had to plan where they were going carefully to ensure that they would not be confronted by flights of stairs or steep hills.

The interviewees felt that the restrictions put on their activities made most days monotonous. Many described becoming bored, frustrated and feeling lazy because they spent so much time resting. The inability to do things also made them feel redundant and a failure.

Relationships with family and friends were often affected, usually because the interviewees were no longer able to participate in all the activities that they had previously. Most problems arose if they had very young children who could not understand why their mother/father did not play with or hold them. This

particular aspect of the problem lessened as the children became older and more aware of the nature of RA. However, even then, the respondents were still distressed at their inability to participate in family activities. Interviewees also reported taking out their emotions on their family and friends, leading to feelings of guilt.

Most of the interviewees reported experiencing some difficulty with physical contact. The problems were in two main areas. The first and most common was with social contact, such as shaking hands and being in crowds. The second was more intimate: hugging and love making. This was not only because the respondent was frightened of being touched, but also because loved ones were afraid of hurting them.

There was a common concern about the long-term effects of the drug treatments for the condition. However, many felt dependent on their medication and could not contemplate being without the drugs.

RA had a dramatic effect on all aspects of the interviewees' lives. Some were angry that they had the condition and many felt as if they were being punished for no reason; 'why me?' was a common question. They were very aware of the progressive nature of the condition. Many feared for the future, the most common concern being a complete loss of independence: 'I worry about who is going to push me around in the future'. However, there was also a great sense of 'taking each day as it comes' and not giving in to the condition that seemed to override concerns about the future.

SELECTION OF ITEMS FOR THE QoL INSTRUMENT

A content analysis of the interview transcripts was conducted to identify potential items for the proposed QoL instrument. Phrases were chosen if they related to needs not being fulfilled or if they described a return in the interviewee's ability to satisfy needs following an improvement in condition. Items concerning symptoms and function were only considered if they were directly related to the fulfilment of a need. It is intended that the QoL instrument will be used in conjunction with measures of disease activity and disability (WHO/ILAR/OMERACT core set for RA).

This analysis provided a large pool of statements (> 500 in each country) appropriate for use in a QoL instrument designed to assess the satisfaction of needs. Items were selected that reflected a single idea, used simple language, were unambiguous, were relevant to all potential respondents and were readily translatable into other European languages.

The patients' own words were used as far as possible, but some items had to be altered to fulfil the above criteria and also so that they were phrased in the first person.

Cross-cultural issues

A major problem in QoL research is that of producing adequate versions of measures in more than one language [39]. Where an instrument is developed

in one country only, it is unlikely that the content will be suitable for other cultures. This problem was addressed by undertaking the development of the measure in the UK and The Netherlands simultaneously. In this way, cross-cultural differences were identified before the measure was produced.

A meeting was held between the UK and Dutch researchers to consider issues raised in the interviews. The item pool from each country was examined to identify items that were conceptually equivalent. Items were included in the measure only if they reflected issues pertinent to patients in both countries. For example, an item concerning anger resulting from inability to do simple tasks that was derived from the UK interviews was rejected, as this emotion had not been expressed by Dutch interviewees.

Following the meeting, a draft 44-item measure was produced that was considered likely to be conceptually equivalent in the two language versions. The instrument was taken forward for psychometric testing (see de Jong *et al.* [38]).

CONCLUSIONS

The interviews in both countries showed that RA has a detrimental effect on many areas of life, including moods and emotions, social life, hobbies, everyday tasks, personal and social relationships and physical contact.

Most of the interviewees had adapted their lives to meet their changing capabilities. It is vital that QoL instruments designed for chronic conditions take this adaptation into account. Many people with RA are severely physically restricted and yet the interviews indicated that mobility limitations are not necessarily distressing in themselves.

Two of the most distressing aspects of the condition are pain and fatigue, both of which contributed to many of the restrictions experienced by respondents. These two areas have been largely neglected by instruments designed to assess the impact of RA on patients, with most emphasis being placed on physical functioning. The needs model utilized here explores the impact of fatigue and pain (in addition to other relevant impairments) on the fulfilment of the individual's needs, and hence assesses their influence on quality of life.

The pool of items derived from the interviews forms the basis for the RAQoL, a QoL instrument designed specifically for use with RA patients. The RAQoL is different from other measures available in that it is built on a clear conceptual model of QoL and its content was derived directly from relevant patients. It was developed using a qualitative approach to produce a quantitative tool suitable for use in clinical trials and in the routine monitoring of individual patients.

The measure is designed to provide valid and reliable information on QoL in RA patients and how this is influenced by interventions. The measure will not allow comparisons between different diseases or lend itself to inclusion in pharmacoeconomic analyses at present. There is growing evidence that health utility and

psychometric health status scales measure different aspects of health outcome [40]. Where the purpose of the clinical trial is to establish the effectiveness of a specific clinical intervention from the patient's perspective, priority should be given to the application of high-quality disease-specific QoL instruments, such as the RAQoL.

The methodology employed in the development of the RAQoL ensures that it will be directly relevant to the patients concerned, and that it will have good face and content validity. As the items contain the words of patients themselves, the instrument will be more immediate and acceptable to respondents. Conducting the interviews and selecting potential items simultaneously in the two countries allows conceptually equivalent versions of the instrument to be developed that are relevant to respondents in both countries. This methodology also makes the instrument more amenable to adaptation when additional language versions are required.

ACKNOWLEDGEMENTS

Acknowledgement is made of the contributions to the project of Dr Adam Young and Joanna Talamo, St Albans City Hospital, and Dr Chris Deighton, Nottingham City Hospital. Special thanks are due to Anne Papageorgiou, Manchester University ARC Unit, and also to the organizers and members of Young Arthritis Care and Arthritis Care in the UK for their participation. The study was partly funded by Pharmacia & Upjohn AB, Uppsala, Sweden.

REFERENCES

1. National Health Service Review. Working paper no 6 medical audit. HMSO: London, 1989.
2. Bendtsen P, Åkerlind I, Hörnquist JO. Assessment of quality of life in rheumatoid arthritis: I Methods and implications. *Pharmacoeconomics* 1994;5:286–98.
3. Tennant A. Quality of life—a measure too far? *Ann Rheum Dis* 1995;54:439–40.
4. Fries JF, Spitz PW, Kraines RG *et al.* Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980;23:137–45.
5. Meenan RF, Gertman PM, Mason JH. Measuring health status in arthritis: the arthritis impact measurement scales. *Arthritis Rheum* 1980;23:146–52.
6. Meenan RF, Mason JH, Anderson JJ. AIMS2: The content and properties of a revised and expanded Arthritis Impact Measurement Scales health status questionnaire. *Arthritis Rheum* 1992;35:1–10.
7. Hunt S, McKenna SP, McEwan J *et al.* The Nottingham Health Profile: subjective health status and medical consultations. *Soc Sci Med* 1981;15A:221–9.
8. Bergner M, Bobbitt RA, Carter WB *et al.* The sickness impact profile: development and final revision of health status measures. *Med Care* 1981;19:787–805.
9. Fitzpatrick R, Ziebland S, Jenkinson C *et al.* A generic health status instrument in the assessment of rheumatoid arthritis. *Br J Rheumatol* 1992;31:87–90.
10. Fitzpatrick R, Ziebland S, Jenkinson C *et al.* A comparison of the sensitivity to change of several health status instruments in rheumatoid arthritis. *J Rheumatol* 1993;20:429–36.

11. Meenan RF, Anderson J, Kazis L *et al.* Outcome assessment in clinical trials: Evidence for the sensitivity of a health status measure. *Arthritis Rheum* 1984;27:1344–52.
12. Anderson J, Firschein H, Meenan R. Sensitivity of a health status measure to short term clinical changes in arthritis. *Arthritis Rheum* 1989;32:844–50.
13. Kazis LE, Callahan LF, Meenan RF. Health status reports in the care of patients with rheumatoid arthritis. *J Clin Epidemiol* 1990;43:1243–53.
14. Fitzpatrick R, Ziebland S, Jenkinson C *et al.* The social dimension of health status measures in rheumatoid arthritis. *Int Disabil Stud* 1991;13:34–7.
15. Liang M, Larson M, Cullen K *et al.* Comparative measurement efficiency and sensitivity of five health status instruments for arthritis research. *Arthritis Rheum* 1985;28:542–7.
16. Liang M, Fossel A, Larson M. Comparisons of five health status instruments for orthopaedic evaluation. *Med Care* 1990;28:632–42.
17. McKenna SP. Quality of life assessment in the conduct of economic evaluations of medicines. *Br J Med Econ* 1995;8:33–8.
18. Guyatt GH, Feeney DH, Patrick DL. Measuring health-related quality of life. *Ann Intern Med* 1993;118:622–9.
19. Papageorgiou AC. Fatigue in rheumatoid arthritis. Thesis, 1994.
20. Hays RD, Shapiro MF. An overview of generic health-related quality of life measures for HIV research. *Qual Life Res* 1992;1:91–7.
21. EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
22. Brazier J, Harper R, Jones N *et al.* Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *Br Med J* 1992;305:160–4.
23. Dixon P, Heaton J, Long A, Warburton, A. Reviewing and applying the SF-36. *Outcomes Briefing* 1994;Issue 4(August):3–25.
24. Hill S, Harries U. Assessing the outcome of health care for older people in community settings: Should we use the SF-36? *Outcomes Briefing* 1994;Issue 4(August):26–7.
25. Tennant A, Hillman M, Chamberlain MA, Fear J. Missing values and the MOS SF36: An over-55 year old sample with arthritis. Annual Scientific Meeting of American College of Rheumatology, October 1995. *Arthritis Rheum* 1995;38 (suppl.):S178.
26. Hurst NP, Jobanputra P, Hunter M, Lambert M, Lochhead A, Brown H. Validity of the EuroQol—a generic health status instrument—in patients with rheumatoid arthritis. *Br J Rheumatol* 1994;33:655–62.
27. Carr-Hill R. A second opinion: Health related quality of life measurement—Euro style. *Health Policy* 1992;20:321–8.
28. Hollingworth W, MacKenzie R, Todd CJ, Dixon AK. Measuring changes in quality of life following magnetic resonance imaging of the knee: SF-36, EuroQol or Rosser index? *Qual Life Res* 1995;4:325–34.
29. Brazier J, Jones N, Kind P. Testing the validity of the Euroqol and comparing it with the SF-36 health survey questionnaire. *Qual Life Res* 1993;2:169–80.
30. McGee HM, O'Boyle CA, Hickey A, O'Malley KM, Joyce CRB. Assessing the quality of life of the individual: the SEIQoL with a healthy and a gastroenterology unit population. *Psychol Med* 1991;21:749–59.
31. Wiener CL. The burden of rheumatoid arthritis. In: Strauss AL, ed. *Chronic illness and quality of life*. St Louis: The CV Mosby Company, 1975:71–80.
32. Locker D. *Disability and disadvantage: The consequences of chronic illness*. New York: Tavistock Publications, 1983.
33. Bury M. Meanings at risk: The experience of arthritis. In: Anderson R, Bury M, eds. *Living with chronic illness: the experience of patients and their families*. London: Unwin Hyman, 1988:89–116.
34. Hunt SM, McKenna SP. The QLDS: A scale for the measurement of quality of life in depression. *Health Policy* 1992;22:307–19.
35. McKenna SP, Hunt SM. A new measure of quality of life in depression: Testing the reliability and construct validity of the QLDS. *Health Policy* 1992;22:321–30.
36. McKenna SP, Doward LC. Quality of life assessment of patients with growth hormone deficiency: Implications for drug therapy. *Pharmacoeconomics* 1994;6:434–41.
37. McKenna SP, Doward LC. Measuring quality of life in recurrent genital herpes. *Eur Rev Appl Psychol* 1995;45:289–95.
38. de Jong Z, van der Heijde D, McKenna SP, Whalley D. The reliability and construct validity of the RAQoL: a rheumatoid arthritis-specific quality of life instrument. *Br J Rheumatol* 1997;36:878–83.
39. Hunt SM, Alonso J, Bucquet D, Niero M, Wiklund I, McKenna SP. Cross-cultural adaptation of health measures. *Health Policy* 1991;19:33–44.
40. Richardson J. Cost utility analysis: What should be measured? *Soc Sci Med* 1994;39:7–21.