Quantitative documentation of benefit/risk of new therapies for rheumatoid arthritis: Patient questionnaires as an optimal measure in standard care

T. Pincus[1], T. Sokka[1,2], A. Kavanaugh[3]

[1]Division of Rheumatology and Immunology, Department of Medicine, Vanderbilt University Medical Center, Nashville, Tennessee, USA; [2]Jyvaskyla Central Hospital, Jyvaskyla, Finland; [3]The Center for Innovative Therapy, Division of Rheumatology, Allergy, and Immunology, University of California San Diego School of Medicine, La Jolla, California, USA.

This study was sponsored in part by Abbott Immunology and Centocor.

Theodore Pincus, MD; Tuulikki Sokka, MD, PhD; Arthur Kavanaugh, MD.

Please address correspondence to: Theodore Pincus, MD, Professor of Medicine, Division of Rheumatology and Immunology, Vanderbilt University School of Medicine, 203 Oxford House, Box 5, Nashville, TN 37232-4500, USA.

Clin Exp Rheumatol 2004; 22 (Suppl. 35): S26-S33.

© Copyright Clinical and Experimental Rheumatology 2004.

Key words: Rheumatoid arthritis, patient questionnaires, assessment, MDHAQ, HAQ.

ABSTRACT

Assessment of benefit/risk of therapies for any disease is best conducted according to quantitative data. In many diseases, such as hypertension or hyperlipidemia, a single quantitative measure serves as a "gold standard" for patient status, but no single measure can serve as a "gold standard' for all individual patients with rheumatoid arthritis (RA). Therefore, indices such as the American College of Rheumatology (ACR) Core Data Set and Disease Activity Score (DAS), are used in clinical trials and other clinical research. These indices include 3 types of measures, which are derived from a health professional [joint counts, global]; a laboratory [erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP)]; or a patient questionnaire [physical function, pain, global]. In most standard clinical care, the majority of clinicians do not collect joint count or patient questionnaire data at most visits. Therefore, assessment and management of most patients with RA is conducted empirically, with the only quantitative data from laboratory tests. Measures on a patient self-report questionnaire of physical function, pain, and global status, are as informative as joint counts, radiographic scores, laboratory tests, or any measure by a health professional to document status, estimate prognosis, and monitor responses to therapies. We suggest that quantitative measurement may be incorporated into standard clinical care most easily and effectively by asking each patient to complete a simple 1-page questionnaire at each visit to a rheumatologist.

Introduction

The benefit/risk of a therapy for any disease is best estimated according to quantitative measures to stratify patients regarding prognosis and appropriate therapy. Documentation in hypertension and diabetes that reversal of quantitative data indicating a poor prognosis leads to prolongation of lifespan has provided important advances (1, 2). It would appear desirable that patients with RA should have similar quantitative assessment as a component of standard care (3-6).

In the quantitative assessment of RA, two important differences are seen compared to most chronic diseases. First, no single measure – whether a joint count, radiograph, laboratory test, or patient questionnaire score – can serve as a "gold standard" for the assessment of clinical status in all individual patients with RA. Therefore, pooled indices of several measures (7) have been developed for quantitative patient assessment. Second, measures obtained from patients have been found to be as informative as measures obtained by health professionals, including joint counts, radiographs and laboratory tests, to document status, develop a prognosis, and monitor responses to therapy (6). Therefore, modern pooled indices to assess patients with RA include quantitative measures provided by patients.

Early pooled indices (Table I) included a "therapeutic scorecard in rheumatoid arthritis" of Steinbrocker and Blazer (8), the Lansbury Index (9), and the Paulus Criteria (10). These indices have largely been supplanted by the ACR Core Data Set (11-13) and the Disease Activity Score (DAS). The ACR Core Data Set includes 3 measures by a health professional assessor [swollen joint count, tender joint count, and global assessment], one laboratory measure [erythrocyte sedimentation rate (ESR) or C-reactive Protein (CRP)], and 3 measures from a patient questionnaire [functional disability, pain, and global assessment] (11-13). Criteria for improvement according to the ACR Core Data Set, notably 20%, 50% and 70%

improvement in swollen and tender joints plus 3 of the 5 additional measures (known as ACR 20, 50 and 70) have been described (14). The DAS includes a swollen joint count, tender joint count, ESR or CRP, and patient assessment of global status (15-17); criteria for improvement according to DAS scores have been described (18, 19). More recently a simplified disease activity index (SDAI) has been described, which includes the 4 measures from the DAS, as well a physician assessment of global status (20). In addition, an index which includes measures only from a patient questionnaire, i.e., physical function, pain and patient assessment of global status, has been developed (21).

Clinical trials are now conducted according to standard quantitative data included in the ACR Core Data Set and DAS. However, standard clinical care of most patients with RA continues a tradition of being conducted without joint counts, patient questionnaires, or any quantitative data other than laboratory tests, and DAS in selected patients who are treated with biological agents in certain settings. For example, at a meeting in Europe in 2003, rheumatologists were asked "Across routine visits of patients with RA under your care (not including clinical trials), what percentage of visits includes a formal tender and swollen joint count?" In response, 13% of rheumatologists indicated "no visit," and only 14% indicated "all visits." Overall, 45% indicated "fewer than 25% of visits," 56% "fewer than 50% of visits," and 70% "fewer than 75% of visits" included a formal joint count. Furthermore, it has been found that fewer than 25% of rheumatologists use patient questionnaires in standard clinical care (22). Therefore, benefit/risk assessment in standard clinical care is based predominantly on empirical, rather than quantitative, assessment with very limited documentation of clinical status and possible improvement (or decline) over time.

In this essay, we suggest that the benefit/risk of any therapeutic intervention in an individual rheumatology patient be approached quantitatively in standard care. Joint count and laboratory measures are certainly valuable, but involve time and expense, particularly relative to patient questionnaires. Ironically, patient questionnaires are the most easily administered and reliable quantitative measures to assess and document status, estimate a prognosis, and monitor responses to therapy in patients with RA. We raise the consideration that patient questionnaire scores should be collected as routine documents in the infrastructure of rheumatology care at each visit of each patient to a rheumatologist (23).

Table I. Indexes of various measures used to characterize patients with rheumatoid arthritis.

Measure	Steinbrocker (8)	Lansbury (9)	Paulus (10)	ACR Core Data Set (11-13)	DAS (16, 17)	SDAI (20)	Pt. only (21)
Joint swelling	+		+	+	+	+	
Joint pain/tenderness	+	+	+	+	+	+	
Joint motion/limited	+						
ESR	+	+	+	+	+	+	
Hemoglobin	+	+					
Functional status	+			+			+
Pain	+	+		+			+
Patient global	+		+	+	+	+	+
Weight	+						
Fever		+					
Muscle weakness		+					
Morning stiffness		+	+				
Fatigue		+					
Assessor global			+	+		+	

Table II. Rationale for completion of patient self-report questionnaires at each visit to a rheumatologist.

1. Patient self-report questionnaires address the primary concerns of patients quantitatively, including pain, physical function, fatigue, and psychological distress.
2. Questionnaire data are as effective or more effective than traditional joint counts, radiographs, and laboratory tests to predict severe outcomes of RA, including functional declines, work disability, and costs, and to predict premature mortality.
3. Questionnaire scores are highly reproducible - higher than seen for 2 assessors performing a joint count or 2 radiologists scoring a radiograph.
4. Questionnaire data are correlated significantly with data from traditional joint counts, radiographs, and laboratory tests, as well as physical measures of functional status.
5. Changes in status in clinical trials may be detected using questionnaires as effectively or more effectively than using the traditional physical, radiographic, or laboratory measures.
6. An index of the 3 measures from the Core Data Set on a self-report questionnaire, functional disability, pain and global status, appears as sensitive as ACR 20 to distinguish active treatment from placebo in a clinical trial.
7. Patient questionnaires which are designed for use in standard clinical care are easily completed by patients.
8. A patient questionnaire can save time for the physician.
9. The patient questionnaire can document clinical status on a given day, which if not collected indicates data forever lost.
10. Self-report questionnaires are effective in all rheumatic diseases, including rheumatoid arthritis, osteoarthritis, fibromyalgia, systemic lupus erythematosus, and scleroderma.
11. Most rheumatologists do not perform quantitative joint counts or collect any other quantitative data at most visits of most patients.

Why should each patient complete a self-report questionnaire at each visit to a rheumatologist in standard clinical care?

A rationale for the use of self-report questionnaires in standard care of patients with rheumatic disease (and possibly any chronic disease) is based on many lines of evidence (Table II). Patient questionnaires address the primary concerns of patients directly and quantitatively, including pain, physical function, fatigue, and psychological dis-

tress. Questionnaires offer measurable insight into the psychosocial problems of patients, which clinicians have always acknowledged to be of great importance but had no simple way to assess (24, 25).

Self-report questionnaire scores are correlated significantly with data from traditional joint counts, radiographs, and laboratory tests, as well as physical measures of functional status (26). Questionnaire data appear the best single representation of clinical status among all available measures (26). Patient questionnaires provide more informative data than joint counts, radiographs, or any known laboratory test to predict and monitor severe long-term outcomes of RA, including functional declines, costs, work disability, death and even joint replacement surgery (6, 25, 27-31). Questionnaire data document that mortality in RA is associated with greater severity of disease, comparable to findings in other chronic diseases such as Hodgkin's disease and coronary artery disease, rather than "unrelated to RA" (32, 33).

Changes in status in clinical trials in RA may be detected using questionnaires as effectively or more effectively than traditional physical or laboratory measures (34-36). This phenomenon results in part from the fact that tender and swollen joint counts are the measures in the Core Data Set which are most likely to improve with placebo treatment, while patient questionnaire measures of physical function and global status show no change with placebo treatment (Table III) (38, 39). The highest relative efficacies in one clinical trial were therefore seen for patient questionnaire measures (Table III).

Patient self-report questionnaire results have been reported most extensively in patients with RA, which is the most prevalent disease managed in rheumatology practices. However, simple self-report questionnaires such as the health assessment questionnaire (HAQ) (40) and its modified (MHAQ) (26) or multidimentional (MDHAQ) (41) versions are effective to describe the status of patients with all rheumatic diseases, including osteoarthritis, fibromyalgia, systemic lupus erythematosus, and scleroderma, as well as RA (41-43). The highest levels of functional disability were seen in patients with RA, while the highest visual analog pain scale scores and highest levels of learned helplessness were seen in patients with fibromyalgia (42, 43). These data were compiled from the distribution of a self-report questionnaire to all patients at all visits in a rheumatology clinical setting.

The patient measures on the ACR Core Data Set (11-13), physical function, pain, and global assessment, have been developed into an index (21), as noted above. This "patient only" index (Table IV) showed a capacity similar to an index of "assessor only" measures (swollen joints, tender joints, assessor global), patient measures plus ESR (the laboratory measure in the Core Data Set), assessor measures plus ESR, as well as a pooled index of all 7 Core Data Set measures, to distinguish active leflunomide or methotrexate treatment from placebo treatment (21). Furthermore, efficacy was similar according to these indices as according to the ACR 20 (14) and DAS (21). These data suggest that collection of patient questionnaire data in standard clinical care may provide data which are as informative as the entire ACR Core Data Set. Even if patient questionnaire data might lose, say, 20% of the information provided by the entire Core Data Set, if a formal count of tender and swollen joints were collected, it might be reasonable to suggest that availability of 80% of optimal data in 100% of patients (at < 20 of the costs) might be preferable to 100% of the optimal in fewer than 10% of the patients who are included in clinical trials.

Table III. Change in ACR Core Data Set measures over 12 months in rheumatoid arthritis clinical trial of leflunomide versus methotrexate versus placebo.

Measure	Leflunomide	Placebo	Methotrexate	Effect size	Relative efficiency
Tender joints	-7.7	-3.0	-6.6	-0.59	1.00
Swollen joints	-5.7	-2.9	-5.4	-0.44	0.56
Physician global status	-2.8	-1.0	-2.4	-0.68	1.33
ESR	-6.3	+2.6	-6.5	-0.41	0.48
HAQ	-0.45	+0.03	-0.26	-0.80	1.84
MHAQ	-0.29	+0.07	-0.15	-0.69	1.37
Pain	-2.2	-0.4	-1.7	-0.65	1.21
Patient global status	-2.1	+0.1	-1.5	-0.81	1.88

ESR: erythrocyte sedimentation rate; HAQ: health assessment questionnaire; MHAQ: modified HAQ.
Sources: Strand V, Cohen S, Schiff M *et al.*: Treatment of active rheumatoid arthritis with leflunomide compared with placebo and methotrexate. *Arch Intern Med* 1999; 159: 2542-50.
Tugwell P, Wells G, Strand V *et al.*: Clinical improvement as reflected in measures of function and health-related quality of life following treatment with leflunomide compared with methotrexate in patients with rheumatoid arthritis: Sensitivity and relative efficiency to detect a treatment effect in a twelve-month, placebo-controlled trial. Leflunomide Rheumatoid Arthritis Investigators Group. *Arthritis Rheum* 2000; 43: 506-14.

Table IV. Improvement with leflunomide, methotrexate or placebo for 3 pooled indices of "patient only", "assessor only" and ACR Core Data Set measures, as well as ACR20 and DAS.

	20% Improvement response			Z scores	
Pooled Index	Leflunomide	Methotrexate	Placebo	Leflunomide vs Placebo	Methotrexate vs Placebo
ACR 20	52%	46%	26%	4.36	3.32
Patient Only	64%	56%	33%	4.85	3.00
Assessor Only	74%	69%	43%	5.12	4.86
All Core Data Set	57%	49%	29%	5.89	5.12
DAS	59%	59%	30%	4.84	4.85

All z scores $p < 0.001$
Source: Pincus T, Strand V, Koch G *et al.*: An index of the three core data set patient questionnaire measures distinguishes efficacy of active treatment from placebo as effectively as the American College of Rheumatology 20% response criteria (ACR20) or the disease activity score (DAS) in a rheumatoid arthritis clinical trial. *Arthritis Rheum* 2003; 48 (3):625-30.

Table V. Some reasons why a patient questionnaire may not be included in standard clinical care.

A. Traditional "biomedical model" paradigm – critical clinical data come from a physician and/or high-technology imaging and laboratory sources, rather than from a patient

B. Most rheumatologists' experience with patient questionnaires is derived from clinical research, in which the collection, scoring and management of patient questionnaire data is seen as a burden, rather than a time-saving asset, in patient care

C. Logistic concerns regarding the HAQ
   1. Cannot be quickly scanned by a clinician to assess patient status
   2. Not easily scored in standard clinical care

D. Specific possible limitations of the HAQ
   1. Score may be increased artifactually by recommending a device, e.g., patient given a cane or jar opener responds "with some difficulty", but now has score of 2 instead of 1
   2. Some activities are correlated at higher levels with activities in other categories than in the same category
   3. 8 of 20 activities determine the overall score – different activities may determine score on different dates
   4. Patient may improve in 1-12 activities, but show no change in HAQ score
   5. Certain activities, such as "shampoo your hair," "chores such as vacuuming or yard work" are not performed by some patients
   6. HAQ does not include scores for psychological distress, fatigue, change in status, or morning stiffness, and other constructs which some clinicians wish to monitor
   7. Floor effects are seen, in that some patients may have normal HAQ scores, but nonetheless have functional limitations.

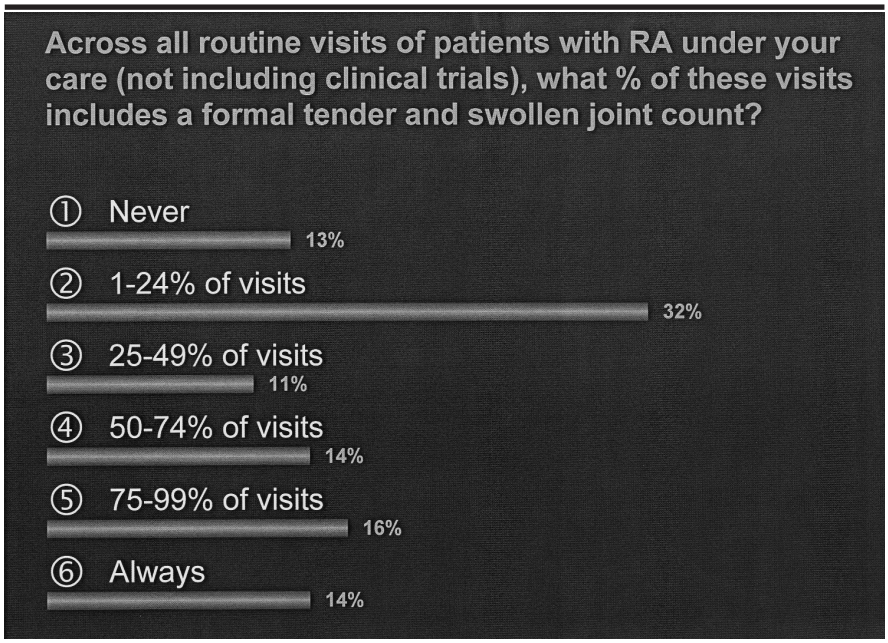

Fig. 1. Responses of about 500 European rheumatologists to a question presented in September 2003 at the European launch of adalimumab: "Across all routine visits of patients with RA under your care (not including clinical trials), what percentage of these visits includes a formal tender and swollen joint count ?" Note that 13% of rheumatologists indicated that no visit included a formal joint count, and only 14% indicated that all visits of patients with RA included formal joint counts. Overall, 45% of rheumatologists indicated that fewer than 25% visits included a formal joint count, 56% indicated that fewer than 50% of visits included a formal joint count, and 70% indicated that fewer than 75% of visits included a formal joint. (By permission of Abbott Immunology)

Why are patient questionnaires not used in standard clinical care?

The HAQ (40) and arthritis impact measurement scales (AIMS) (44) were published in 1980, and evidence that patient questionnaires are better clinical measures to predict morbidity and mortality in RA than laboratory tests or radiographs was published in 1984 (45). Nonetheless most rheumatologists have not incorporated patient questionnaires into standard clinical care. Some of the reasons for this phenomenon (Table V) are discussed below.

First, the traditional "biomedical model" paradigm, the basis for most spectacular advances of 20th-century medicine (46, 47) regards data derived from a physician and/or high-technology imaging and laboratory source as critical. Data from a patient are seen as unimportant, primarily assessed to provide clues to obtain definitive high technology "objective" data.

Second, most rheumatologists have little experience in clinical care with simple questionnaires, and most experience with patient questionnaires involves cumbersome and lengthy questionnaires, designed for clinical research and clinical trials (Table VI). In formal clinical research, extensive questionnaires are appropriate to acquire as complete a database as might be needed to address the study questions. Patients and clinicians recognize and accept the inconveniences of lengthy questionnaires with complex scoring. Indeed, the clinician is not expected to review patient questionnaire data, which are not interpreted at the clinical site, but rather sent to a remote data center for entry into a database (Table VI).

By contrast, a questionnaire designed to be used in standard patient care must be feasible and practical (Table VI), completed by a patient within 5-10 minutes, scanned ("eyeballed") by a health professional in less than 5 seconds, and scored and available in a flowsheet to compare with previous visits in less than 30 seconds. Furthermore, a questionnaire for standard patient care should be clinically applicable to patients with all diagnoses. The questionnaires provide time-saving information to the physician by enhancing a patient's capacity to describe concerns in the limited time allotted for a clinical visit (Table VI).

Use of a patient questionnaire in clinical care may be compared to the development of a kit to assess, say, rheumatoid factor or DNA antibodies in clinical practice. The kit may not provide as precise a measure as might be available through certain research methods. However, the kit allows information to be

Table VI. Features of patient questionnaires in clinical research versus clinical care.

Clinical research	Clinical care
Designed to obtain 100% of the data in 5% of patients	Designed to obtain 80% of the data in 100% of patients
Complete, long – feasibility not an issue	Feasible, practical – patient-friendly, less than 5-10 minutes
Takes time from office routine	Saves time for office routine – facilitates care
Requires > 1 minute to review responses	"Eyeball" responses in < 5 seconds
Scoring requires > 1 minute and/or computer	Scored by a health professional within 15-30 seconds
Results unknown in care	Entered into a flow sheet to compare with previous visits within 60 seconds
Send to data center for computer entry	Review with patient to add to care and documentation
May be specific for disease, eg, osteoarthritis, or construct, e.g., depression	Reflects all primary patient concerns – applicable to patients with all diagnoses
Completed by a few patients	Completed by all patients
Enter into computer	No need for computer

available in a pragmatic fashion in a clinical care setting, which otherwise might not be available at all or be overly expensive for clinical use. As noted above, even if a questionnaire might provide only 80% of the information provided by a complete joint count, ESR and CRP, it appears preferable to have 80% of the information in 100% of patients than 100% of the information in fewer than 10% of patients who are included in clinical trials and other formal research studies.

A number of misconceptions have been mentioned by clinical rheumatologists concerning patient questionnaires, which may be broadly classified into three categories concerning validity, consequences and logistics. Rheumatologists have suggested that patient questionnaires may be unrelated to physical examination, laboratory or radiographic data. However, significant correlations between patient measures and traditional measures are seen if sufficient numbers of patients are included, although the level of correlations indicate that the data are not redundant (26).

The proper use of a questionnaire saves time for the physician, provided that it is easily completed by patients, scanned ("eyeballed") in 5-15 seconds, and scored in 15-30 seconds. The questionnaire does not in any way replace the history and careful joint examination. The purpose of the questionnaire is to reduce the time required to gather factual information and replace it with interpretative time to assess diagnostic issues and to provide patient discussion and counseling. There is no obligation for a rheumatologist to create a computerized database with patient questionnaire data anymore than with laboratory data or radiographic data, although a flowsheet is a very good way to monitor patient status.

Longitudinal databases have been established for post-marketing surveillance of biologic agents. These research databases are necessary to recognize possible problems with safety of the new agents, but cannot provide optimal answers concerning their efficacy and capacity to improve long-term outcomes. Furthermore, these databases usually do not include data concerning patients who are not treated with biological agents, many of whom have favorable outcomes. A more complete picture of the responses of patients to all therapies administered can emerge only from monitoring of consecutive patients at all visits.

How to administer patient questionnaires in standard rheumatology care

A clinician may collect a HAQ, or its modified versions using a very simple system that has been implemented effectively over the last 20 years (Fig. 2) (3,23,48). When the patient registers for the visit, the receptionist asks the patient to complete a questionnaire mounted on a clipboard, along with a soft pencil or felt-tip pen, while waiting to see the physician. The questionnaire should be presented as an important component of medical care, to provide data regarding functional status, pain, global status, fatigue, and psychological status, which cannot be obtained from any source other than the patient herself or himself. A cheerful and enthusiastic manner is important – the patient loses interest if the staff projects a general disdain of questionnaires.

Many clinicians have suggested that it would be desirable to select patients to complete questionnaires on the basis of specific criteria, such as diagnosis, interval since the last questionnaire, or the nature of the encounter (e.g. beginning of new therapy etc.). However, schemes that include only certain patients generally fail in usual clinical practice. It is considerably easier for the office staff to hand a questionnaire to each patient at registration than to attempt to determine which patient should receive a questionnaire, except possibly who is a "new" versus "return" patient. Therefore, in actual clinical practice, the most effective system is to assess every patient at every visit. The only complexity is that there may be a different questionnaire for new patients, such as a 4-sided, 2-page version which may include past history, family history, allergies, surgeries, and illnesses, compared to the 2-sided, 1-page questionnaire for "return" patients. Collection of routine data from consecutive patients at each visit may be supplemented by additional data collection at intervals in certain subsets of patients, if desired.

The questionnaire is completed by the patient before being called into an examining room. Most patients wait at least 5-10 min before seeing a rheumatologist. The questionnaire helps the patient focus on problems and adds to

PT: *XXX* 1st Visit: *11/4/2003* DX ICD9: *714.00* Onset: *01/1996* Education: *8*

VISIT DATE	11/4/03	1/13/04			
PATIENT SELF_REPORT QUESTIONNAIRE DATA					
FUNCTIONAL STATUS **(FN)** [0-10]	2.67	0			
PSYCHOLOGICAL STATUS **(PS)** [0-10]	1.10	0			
PAIN **(PN)** [0-10]	9.6	0.3			
AM STIFFNESS **(AM)** [0-300 min]	60	30			
FATIGUE **(FT)** [0-10]	9.6	0.7			
CHANGE OVER 2 WEEKS **(CH)** [1-5]	M Worse	Same			
GLOBAL STATUS **(GL)** [0-10]	8.9	0.3			
# SYMPTOMS **(SY)** [0-60]	19	4			
VITAL SIGNS					
WEIGHT (lbs)	167	167			
BLOOD PRESSURE (mm/Hg)	114/70	131/81			
JOINT EXAMINATION DATA					
# Tender/pain on motion Joints (#/28)	7	2			
# Swollen Joints (#/28)	14	2			
# Deformed/limited motion Jts (#/28)	11	2			
# Abnormal Joints (#/28)	17	2			
LABORATORY DATA					
ESR (mm/hr) [M:0-20 / F:0-30]	43	8			
CRP (mg/L) [0-10]	30	3			
WBC (thou/uL) [4-11]	6.3	7.9			
HGB (g/dL) [M:14-18/F:12-16]	16.8	17			
HCT (%) [M:42-50/F:37-44]	47.6	49			
PLATELETS (thou/uL) [150-400]	179	207			
ALBUMIN (g/dL) [3.5-5.0]	3.9	4.1			
ALK PHOS (U/L) [40-100]	101	128			
SGOT (U/L) [4-40]	18	17			
CREATININE (mg/dL) [0.7-1.5]	1.1	0.8			
THERAPIES					
Prednisone	N-3 QD	3 QD			
Methotrexate	N-10 QW	C-20 QW			
Folic Acid	N-1 QD	1 QD			
Tylenol with Codeine	O-30 TID	D			

Fig. 2. A practical system for routine completion of patient questionnaires in clinical care.
Abbreviations: N: new therapy; C: change dosage; D: discontinue therapy; O: On – taking at visit; QD: once a day; QW: once a week; TID: 3 times a day.

the encounter with the rheumatologist. Generally, no help from a healthcare professional is needed for a patient to complete the questionnaire. However, approximately 25% of patients do require help from a family member or health professional to complete the questionnaire, which should be willingly provided.

It is necessary that the patient sees that the questionnaire is reviewed by the physician. Patients have commented that they have been unhappy after completing questionnaires in physician's offices if there was no evidence that the information was reviewed by a health professional. The questionnaire may also be reviewed with a nurse or other member of the office staff when the weight or blood pressure are checked, or when the patient is placed in an examination room. This review is not necessary, but may include identification and completion of missing data, medications, patient inquiries, and scoring of the questionnaire scales.

Many options exist for management of questionnaire data, ranging from simply scanning the questionnaire to assess patient status, to formally scoring it, to keeping a flowsheet (Table VII). A flowsheet may be used to facilitate recognition of possible changes in functional capacity, pain, fatigue, or psychological status from previous visits. Flowsheets appear useful in the management of chronic disease in general, and many clinicians record medications, laboratory tests, joint examination find-

ings, and other data on a flowsheet. Our clinic uses a one-page flowsheet, which includes patient questionnaire scores, laboratory data and drugs, which we find very useful in standard clinical care, and is completed at each visit (Table VII).

An example of such a flowsheet is presented in Table VII. This example illustrates a patient who was seen initially on 4 November 2003. He reported one episode of arthritis in 1996, which resolved spontaneously, and he had palindromic episodes between 1996 and 2003. He presented a 2-month history of accelerated generalized arthritis, and was taking acetaminophen (paracetamol) with codeine. He had 7 tender joints, 14 swollen joints, 11 joints with deformity or limited motion, or a total of 17 abnormal joints, an ESR of 43 mm/hr, and CRP of 30 mg/L (upper limit of normal 10). His patient questionnaire scores were (on a scale of 0-10) 2.67 for functional disability (0.8 on a scale of 0-3), 9.6 for pain, 8.9 for global status, 9.6 for fatigue, and he had 1 hour of morning stiffness.

He was given prescriptions for 3 mg/day of prednisone, 10 mg/week of methotrexate, and 1 mg/day of folic acid. When seen 2 months later on 13 January 2004, he had 2 tender joints, 2 swollen joints, 2 joints with deformity or limited motion, ESR of 8 mm/hr and CRP of 3 mg/L. He tolerated methotrexate without any difficulty but continued to have symptoms so his methotrexate was raised to 20 mg/week. He was maintained on 3 mg/day of prednisone. This patient had the type of response that is often seen with 90% improvement in ACR Core Data Set measures, but generally not documented effectively in standard clinical care in most settings.

Clinicians have expressed concerns that questionnaires may interfere with office routine and time management, with consequent increases in costs and time. However, data from a brief questionnaire designed for standard care can provide an important saving of time (after a brief "learning curve," as is required with any new practice).

The senior author has included a patient questionnaire at each patient visit over the last 2 decades, so that robust information concerning functional status, pain, psychological distress, fatigue, global status, review of systems, and medications are known when the patient enters the examination room. This information enables the clinician to focus on matters that require attention at the visit, rather than acquiring basic data from the patient, leading to more efficient and effective clinical care.

Although many specialized questionnaires such as the AIMS (44) and Western Ontario McMaster (WOMAC) (49) osteoarthritis scale are useful in different types of clinical research studies, the HAQ and MDHAQ have proven clinically useful in standard care and research studies for all rheumatic diseases (41, 42). There is no need for a clinician to use an additional questionnaire, other than for specialized research studies or his or her own interests. As noted above, it is unnecessary to use a computer unless one plans to compile data concerning groups of patients into a report.

The standard medical record generally includes little or no quantitative data to document whether patients are better or worse over long periods, and patients often see different physicians over the years. Rheumatologists can monitor consecutive patients in clinical care to recognize long-term outcomes, using patient self-report questionnaires as a standard component of each visit in clinical care (3, 23, 50). The inclusion of patient questionnaire data in the standard care of all patients with rheumatic diseases, in addition to appropriate laboratory tests and imaging data, would add quantitative data to document severity and monitor improvement in all individual patients under the care of any rheumatologist.

Table VII. A practical system for routine completion of patient questionnaires in clinical care.

1. Patient given 2-page questionnaire by receptionist - completed in waiting room
2. Nurse or other staff member may review and/or complete medication data
3. Physician should expect to do as little as possible - should “eyeball” questionnaire
4. Staff member (or physician, but unlikely) may score questionnaire
5. Many options for management of patient questionnaire information:
   a. Simply file in medical record without scoring like a laboratory test report
   b. Questionnaire scored by staff member and filed in medical record
   c. Questionnaire scored, entered into computer flow sheet and filed
   d. Questionnaire scored, entered into computerized flow sheet and filed
   e. Questionnaire scored, entered into computerized flow sheet and flow sheets merged into computer database

References

1. VETERANS ADMINISTRATION COOPERATIVE STUDY ON ANTIHYPERTENSIVE AGENT: Effects of treatment on morbidity in hypertension: II. Results in patients with diastolic blood pressure averaging 90 through 114 mm Hg. *JAMA* 1970; 213: 1143-50.
2. THE DIABETES CONTROL AND COMPLICATIONS TRIAL RESEARCH GROUP: The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993; 329: 977-86.
3. PINCUS T: Documenting quality management in rheumatic disease: Are patient questionnaires the best (and only) method? *Arthritis Care Res* 1996; 9: 339-48.
4. VERHOEVEN AC, VAN DER LINDEN S: Responsiveness of the core set, response criteria, and utilities in early rheumatoid arthritis. *Ann Rheum Dis* 2000; 59: 966-74.
5. FRANSEN J, STUCKI G, VAN RIEL P: The merits of monitoring: Should we follow all our rheumatoid arthritis patients in daily practice? *Rheumatology* 2002; 41: 601-4.
6. PINCUS T, SOKKA T: Quantitative measures for assessing rheumatoid arthritis in clinical trials and clinical care. *Best Pract Res Clin Rheumatol* 2003; 17:753-81.
7. GOLDSMITH CH, SMYTHE HA, HELEWA A: Interpretation and power of pooled index. *J Rheumatol* 1993; 20: 575-8.
8. STEINBROCKER O, BLAZER A: A therapeutic score card for rheumatoid arthritis. *N Engl J Med* 1946; 14: 501-6.
9. LANSBURY J: A method for summation of the systemic indices of rheumatoid activity. *Am J Med Sci* 1956; 232: 300-10.
10. PAULUS HE, EGGER MJ, WARD JR, WILLIAMS HJ, and the COOPERATIVE SYSTEMATIC STUDIES OF RHEUMATIC DISEASES GROUP: Analysis of improvement in individual rheumatoid arthritis patients treated with disease-modifying antirheumatic drugs, based on the findings in patients treated with placebo.

Arthritis Rheum 1990; 33: 477-84.

11. FELSON DT, ANDERSON JJ, BOERS M *et al.*: The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis clinical trials. *Arthritis Rheum* 1993; 36: 729-40.
12. TUGWELL P, BOERS M: OMERACT Committee. Proceedings of the OMERACT Conferences on outcome measures in rheumatoid arthritis clinical trials, Maastrict, Netherlands. *J Rheumatol* 1993; 20: 527-91.
13. VAN RIEL PLCM: Provisional guidelines for measuring disease activity in clinical trials on rheumatoid arthritis (Editorial). *Br J Rheumatol* 1992; 31: 793-4.
14. FELSON DT, ANDERSON JJ, BOERS M *et al.*: American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. *Arthritis Rheum* 1995; 38: 727-35.
15. PREVOO MLL, VAN'T HOF MA, KUPER HH, VAN LEEUWEN MA, VAN DE Putte LBA, VAN RIEL PLCM: Modified disease activity scores that include twenty-eight-joint counts: Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. *Arthritis Rheum* 1995; 38: 44-8.
16. VAN DER HEIJDE DMFM, VAN'T HOF M, VAN RIEL PLCM, VAN DE PUTTE LBA: Development of a disease activity score based on judgment in clinical practice by rheumatologists. *J Rheumatol* 1993; 20:579-81.
17. VAN DER HEIJDE DMFM, VAN'T HOF M, VAN RIEL PLCM *et al.*: Judging disease activity in clinical practice in rheumatoid arthritis: first step in the development of a disease activity score. *Ann Rheum Dis* 1990; 49: 916-20.
18. PREVOO MLL, VAN GESTEL AM, VAN'T HOF MA, VAN RIJSWIJK HM, VAN DE PUTTE LBA, VAN RIEL PLCM: Remission in a prospective study of patients with rheumatoid arthritis. American Rheumatism Association preliminary remission criteria in relation to the disease activity score. *Br J Rheumatol* 1996; 35: 1101-5.
19. VAN GESTEL AM, PREVOO MLL, VAN'T HOF MA, VAN RIJSWIJK MH, VAN DE PUTTE LBA, VAN RIEL PLCM: Development and validation of the European League Against Rheumatism response criteria for rheumatoid arthritis. Comparison with the preliminary American College of Rheumatology and the World Health Organization/International League Against Rheumatism criteria. *Arthritis Rheum* 1996; 39: 34-40.
20. SMOLEN JS, BREEDVELD FC, SCHIFF MH *et al.*: A simplified disease activity index for rheumatoid arthritis for use in clinical practice. *Rheumatology (Oxford)* 2003; 42: 244-57.
21. PINCUS T, STRAND V, KOCH G *et al.*: An index of the three core data set patient questionnaire measures distinguishes efficacy of active treatment from placebo as effectively as the American College of Rheumatology 20% response criteria (ACR20) or the disease activity score (DAS) in a rheumatoid arthritis clinical trial. *Arthritis Rheum* 2003; 48: 625-30.
22. WOLFE F, PINCUS T, THOMPSON AK, DOYLE J: The assessment of rheumatoid arthritis and the acceptability of self-report questionnaires in clinical practice. *Arthritis Care Res* 2003; 49: 59-63.
23. PINCUS T, WOLFE F: An infrastructure of patient questionnaires at each rheumatology visit: Improving efficiency and documenting care. *J Rheumatol* 2000; 27: 2727-30.
24. CALLAHAN LF, BROOKS RH, PINCUS T: Further analysis of learned helplessness in rheumatoid arthritis using a "rheumatology attitudes index". *J Rheumatol* 1988; 15: 418-26.
25. WOLFE F, PINCUS T: Standard self-report questionnaires in routine clinical and research practice - an opportunity for patients and rheumatologists. *J Rheumatol* 1991; 18: 643-6.
26. PINCUS T, CALLAHAN LF, BROOKS RH, FUCHS HA, OLSEN NJ, KAYE JJ: Self-report questionnaire scores in rheumatoid arthritis compared with traditional physical, radiographic, and laboratory measures. *Ann Intern Med* 1989; 110: 259-66.
27. PINCUS T, SUMMEY JA, SORACI SA JR, WALLSTON KA, HUMMON NP: Assessment of patient satisfaction in activities of daily living using a modified Stanford health assessment questionnaire. *Arthritis Rheum* 1983; 26: 1346-53.
28. WOLFE F, PINCUS T: Data collection in the clinic. *Rheum Dis Clin North Am* 1995; 21: 321-58.
29. CALLAHAN LF, BLOCH DA, PINCUS T: Identification of work disability in rheumatoid arthritis: Physical, radiographic and laboratory variables do not add explanatory power to demographic and functional variables. *J Clin Epidemiol* 1992; 45: 127-38.
30. PINCUS T, BROOKS RH, CALLAHAN LF: Prediction of long-term mortality in patients with rheumatoid arthritis according to simple questionnaire and joint count measures. *Ann Intern Med* 1994; 120: 26-34.
31. SOKKA T, HAKKINEN A, KRISHNAN E, HANNONEN P: Similar prediction of mortality by the health assessment questionnaire in patients with rheumatoid arthritis and the general population. *Ann Rheum Dis* 2004; 63: 494-7.
32. PINCUS T, CALLAHAN LF: Early mortality in RA predicted by poor clinical status. *Bull Rheum Dis* 1992; 41: 1-4.
33. PINCUS T, WOLFE F, CALLAHAN LF: Updating a reassessment of traditional paradigms concerning rheumatoid arthritis. *In* WOLFE F and PINCUS T (Eds.): *Rheumatoid Arthritis: Pathogenesis, Assessment, Outcome, and Treatment.* New York, Marcel Dekker, Inc., 1994: 1-74.
34. BOMBARDIER C, WARE J, RUSSELL IJ *et al.*: Auranofin therapy and quality of life in patients with rheumatoid arthritis: results of a multi-center trial. *Am J Med* 1986; 81: 565-78.
35. MEENAN RF, PINCUS T: The status of patient status measures. *J Rheumatol* 1987; 14: 411-4.
36. WOLFE F, MITCHELL DM, SIBLEY JT *et al.*: The mortality of rheumatoid arthritis. *Arthritis Rheum* 1994; 37: 481-94.
37. PINCUS T. CALLAHAN LF: Prognostic markers of activity and damage in rheumatoid arthritis: Why clinical trials and inception cohort studies indicate more favorable outcomes than studies of patients with established disease. *Br J Rheumatol* 1995; 34: 196-9.
38. STRAND V, COHEN S, SCHIFF M *et al.*: Treatment of active rheumatoid arthritis with leflunomide compared with placebo and methotrexate. *Arch Intern Med* 1999; 159: 2542-50.
39. TUGWELL P, WELLS G, STRAND V *et al.*: Clinical improvement as reflected in measures of function and health-related quality of life following treatment with leflunomide compared with methotrexate in patients with rheumatoid arthritis: Sensitivity and relative efficiency to detect a treatment effect in a twelve-month, placebo-controlled trial. Leflunomide rheumatoid arthritis investigators group. *Arthritis Rheum* 2000; 43: 506-14.
40. FRIES JF, SPITZ P, KRAINES RG, HOLMAN HR: Measurement of patient outcome in arthritis. *Arthritis Rheum* 1980; 23: 137-45.
41. PINCUS T, SWEARINGEN C, WOLFE F: Toward a multidimensional health assessment questionnaire (MDHAQ): Assessment of advanced activities of daily living and psychological status in the patient friendly health assessment questionnaire format. *Arthritis Rheum* 1999; 42: 2220-30.
42. CALLAHAN LF, SMITH WJ, PINCUS T: Self-report questionnaires in five rheumatic diseases: Comparisons of health status constructs and associations with formal education level. *Arthritis Care Res* 1989; 2: 122-131.
43. CALLAHAN LF, PINCUS T: The P-VAS/D-ADL ratio: A clue from a self-report questionnaire to distinguish rheumatoid arthritis from noninflammatory diffuse musculoskeletal pain. *Arthritis Rheum* 1990; 33: 1317-22.
44. MEENAN RF, GERTMAN PM, MASON JH: Measuring health status in arthritis: the arthritis impact measurement scales. *Arthritis Rheum* 1980; 23: 146-52.
45. PINCUS T, CALLAHAN LF, SALE WG, BROOKS AL, PAYNE LE, VAUGHN WK: Severe functional declines, work disability, and increased mortality in seventy-five rheumatoid arthritis patients studied over nine years. *Arthritis Rheum* 1984; 27: 864-72.
46. ENGEL GL: The need for a new medical model: A challenge for biomedicine. *Science* 1977; 196: 129-36.
47. CALLAHAN LF, PINCUS T: Education, self-care, and outcomes of rheumatic diseases: Further challenges to the "biomedical model" paradigm. *Arthritis Care Res* 1997; 10: 283-8.
48. PINCUS T: Why should rheumatologists collect patient self-report questionnaires in routine rheumatologic care ? *Rheum Dis Clin North Am* 1995; 21: 271-317.
49. BELLAMY N, BUCHANAN WW, GOLDSMITH CH, CAMPBELL J, STITT LW: Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988; 15: 1833-40.
50. WOLFE F, PINCUS T: Listening to the patient: A practical guide to self-report questionnaires in clinical care. *Arthritis Rheum* 1999; 42:1797-808.