A proposed approach to recognise "near-remission" quantitatively without formal joint counts or laboratory tests: a patient self-report questionnaire routine assessment of patient index data (RAPID) score as a guide to a "continuous quality improvement" strategy

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ABSTRACT

A proposed approach is presented to recognise a status of "near-remission" in a patient with rheumatoid arthritis (RA) on the basis of patient self-report questionnaire data without formal joint counts or laboratory tests. Indices of patient-reported outcome (PRO) measures distinguish active from control treatments in RA clinical trials at levels similar to American College of Rheumatology (ACR) or disease activity score (DAS) 28 improvement levels. PRO measures on a multidimensional health assessment questionnaire (MDHAQ) can be compiled into a routine assessment of patient index data (RAPID) score. RAPID 3 includes the three PRO measures from the ACR Core Data Set — physical function, pain, and global estimate. RAPID 4 adds a self-report joint count from a rheumatoid arthritis disease activity index (RADAI). RAPID 5 adds a physician estimate of global status. RAPID scores may be classified into four preliminary proposed categories, as "near-remission" (0-1), "low severity" (1.01-2), "moderate severity" (2.01-4), and "high severity" (> 4), analogous to the four categories of the DAS28 of "remission" (< 2.6), as well as "low" (2.6-3.19), "moderate" (3.2-5.1), and "high" (> 5.1) disease activity. RAPID scores are correlated significantly with DAS28 (rho = 0.64-0.67, p < 0.001), and about 75% of patients with DAS < 2.6 have RAPID scores < 2, while about 75% of patients with DAS > 5.1 have RAPID scores > 4. RAPID data are available on one side of one page, and are feasible to collect in standard clinical care. RAPID 3 scores may be calculated in about 10 seconds, and RAPID 4 and RAPID 5 scores in 20 to 30 seconds. RAPID scores every 3 months or more on simple flowsheets can be a basis for a "continuous quality improvement" strategy in standard clinical care to recognise a need for aggressive therapy, an inadequate response to a therapy, and "near-remission" status.

Introduction

The subject of remission in rheumatic diseases has aroused great interest over the past decade (1-3). All reported indices for remission in rheumatoid arthritis (RA), including American College of Rheumatology (ACR) criteria (4), disease activity score (DAS) (5, 6) of 1.6 (7-9), DAS28 of 2.6 (9, 10) or 2.4 (11), simplified disease activity index (SDAI) (12), and clinical disease activity index (CDAI) (13), include a formal count of tender and swollen joints. The joint count is the most specific measure of RA status (14), and rheumatologists regard it as the most important measure in patients with RA (15). However, most visits of most patients with RA to rheumatologists do not include a formal quantitative joint count (16), and remission cannot be identified quantitatively in most standard clinical care settings.

A practical quantitative index without formal rheumatologist/assessor joint counts could be of considerable value in a busy clinical setting to provide quantitative guidelines to the rheumatologist concerning patient status, ranging from a need for aggressive therapy to "incomplete response" to "near-remission," as well as responses to therapy. Of course, a rheumatologist can recognise a general range of patient status without quantitative data, just as a clinician can recognise a fever or tachycardia without a quantitative temperature or pulse measurement.

However, quantitative baseline information with follow-up data guide recognition of improvement or worsening with greater precision than qualitative data. Quantitative data have advanced the care of many diseases, including RA. However, in the absence of a single "gold standard" measure (as in hypertension or diabetes) for RA, a pooled index (17) such as the DAS, SDAI, or CDAI is needed.

An index that includes only the three patient-reported outcome (PRO) measures in the Core Data Set—physical function, pain, and global estimate of disease activity—can distinguish active from control treatments at levels similar to ACR or DAS criteria in clinical trials of leflunomide, methotrexate (18; 19), adalimumab (20), and abatacept (21). PRO indices are correlated significantly with the DAS in clinical trials (18-20) and clinical care (22). PRO indices can be calculated in 10 to 25 seconds by a rheumatologist or assistant, using scoring templates on a multidimensional health assessment questionnaire (MDHAQ) (23).

This chapter presents a proposed method to use the MDHAQ to calculate PRO indices as a routine assessment of patient index data (RAPID) score, to identify "near-remission" as well as other levels of patient status in patients with RA without formal joint counts or laboratory tests. RAPID scores may provide a basis for a "continuous quality improvement" strategy to manage patients with RA.

RAPID 3, RAPID 4, and RAPID 5 scores on a multidimensional health assessment questionnaire (MDHAQ)

The MDHAQ (Fig. 1) (23, 24) is a simple two-sided, one-page instrument, derived from the standard HAQ (25), designed for routine clinical care. Like the standard HAQ, the MDHAQ can be completed by most patients in 5 to 10 minutes. Unlike the HAQ, the MDHAQ can be scanned ("eyeballed") by a health professional in 5 seconds, and scored in 15 to 30 seconds. The front side includes 10 activities of daily living, visual analog scales (VAS) for pain, and patient global estimate of status, as well as a self-report joint count from a rheumatoid arthritis disease activity index (RADAI) (26, 27). The reverse side includes a review of systems, recent medical history, fatigue VAS, and demographic data.

The 10 MDHAQ activities are each scored 0 to 3, as with the HAQ, for a possible total of 0 to 30. The 0 to 30 score is converted to 0 to 10 using a template on the right side of the questionnaire to divide the score by 3. The VAS are in a format of 21 circles rather than 10-cm lines, scored 0 to 10 at 0.5 intervals, so that a ruler is not needed for measurement. The RADAI self-report joint count is scored 0 to 48 and converted to 0 to 10 using a scoring template on the right side of the MDHAQ.

A RAPID score can be calculated from these data. RAPID 3 is derived from the three core data set PRO measures, physical function, pain, and global estimate. RAPID 3 can be scored in about 10 seconds using scoring templates available on the current version of the MDHAQ (Fig. 1) (Bergman, Yazici, Pincus, unpublished data). The total score of 0 to 30 can be converted to 0 to 10 using a scoring template at the bottom of the page. RAPID 4 adds the RADAI self-report joint count, and requires about 20 seconds to score. RAPID 5 adds a physician estimate of global status, the ACR Core Data Set measure with the highest relative efficiency to distinguish active from control treatment in most clinical trials (21). RAPID 5 requires about 20 to 25 seconds to score. All three RAPID scores can be converted to a 0 to 10 scale using scoring templates on the bottom of the first page of the MDHAQ (Fig. 1).

RAPID 3, RAPID 4, and RAPID 5 compared to DAS quantitative continuous scales

RAPID scores present a continuous scale with absolute values, similar to DAS28, in contrast to the ACR Core Data Set improvement criteria, which present a change score rather than an absolute score. RAPID scores may be classified into four preliminary proposed categories: > 4 = high severity, 2.01 to 4 = moderate severity, 1.01 to 2 = low severity, ≤ 1 = "near-remission." These scores may be viewed as similar in concept to DAS28 scores: > 5.1 = high disease activity, 3.2 to 5.1 = moderate disease activity, 2.6 to 3.19 = low disease activity, and ≤ 2.6 = remission (7).

RAPID 3 scores were analysed in 236 patients with RA seen in 2005 by three rheumatologists (TP, MB, and YY). Spearman correlations with DAS28 were rho = 0.64 (p = < 0.001) for RAPID 3, 0.64 (p < 0.001) for RAPID 4, and 0.67 (p < 0.001) for RAPID 5. These levels of correlation are similar to correlations of C-reactive protein (CRP) to erythrocyte sedimentation rate (ESR) (28) (or RADAI to physician/assessor joint counts) (27). RAPID 3, RAPID 4, and RAPID 5 appear to give similar clinical information compared to one another and to DAS28, although the indices include only one measure (patient global estimate) in common.

DAS28 and RAPID scores are compared in Table I. Among the 236 patients, 85 (36%) were in DAS28 remission—that is, DAS28 < 2.6, 35 (14.8%) had DAS28 of 2.6 to 3.19, indicating low disease activity; 75 (32%) had DAS28 of 3.2 to 5.1, indicating moderate disease activity; and 41 (17%) had DAS28 > 5.1, indicating high disease activity. Among the 85 patients in DAS28 remission, 71% to 77% had RAPID scores of < 2, indicating "near-remission" or "low severity." Among the 41 patients with DAS > 5.1, indicating high disease activity, 73% to 78% had RAPID scores of > 4, indicating "high" severity.

Therefore, "near-remission," "incomplete response," "high severity," and other states may be recognised in most patients, according to a patient questionnaire. Note the similarity of results according to RAPID 3, RAPID 4, and RAPID 5, suggesting that RAPID 3 may capture almost all relevant quantitative information captured by RAPID 4 and RAPID 5. However, RAPID 4 and RAPID 5 scores may provide greater specificity, and be more acceptable to certain rheumatologists, as discussed below. RAPID scores may provide a pragmatic alternative to DAS28 to identify "near-remission" as a goal of therapy, as well as other levels of patient status, such as inadequate response and high severity.

Table I. DAS28 compared to RAPID 3, RAPID 4, and RAPID 5 scores in 236 patients at three sites.

	RAPID 3 Scores (Routine Assessment of Patients Index Data - RAPID)				
DAS28	0 – 10 = Near remission	1.1 – 2.0 = Low severity	2.1 – 4.0 = Moderate severity	4.1 – 10.0 = High severity	Total
0 - 2.6 = Remission	42 (49.4%)	20 (23.5%)	13 (15.3%)	10 (11.8%)	85 (36.0%)
2.6 - 3.19 = Low disease activity	9 (25.7%)	8 (22.9%)	14 (40%)	4 (11.4%)	35 (14.8%)
3.2 – 5.1 = Moderate disease activity	7 (9.3%)	14 (18.7%)	24 (32.0%)	30 (40.0%)	75 (31.8%)
5.1 + = High disease activity	1 (2.4%)	1 (2.4%)	9 (22.0%)	30 (73.2%)	41 (17.3%)
Total	59 (25.0%)	43 (18.2%)	60 (25.4%)	72 (31.4%)	236
	RAPID 4 Scores				
0 - 2.59 = Remission	40 (47.1%)	22 (25.9%)	17 (20.0%)	6 7.1%)	85 36.0%)
2.6 - 3.19 = Low disease activity	9 (25.8%)	9 (25.8%)	14 (40.0%)	3 (8.6%)	35 (14.8%)
3.2 – 5.1 = Moderate disease activity	7 (9.3%)	14 (18.7%)	30 (40.0%)	24 (32.0%)	75 (31.8%)
≥ 5.1 = High disease activity	0	2 (4.9%)	7 (17.1%)	32 (78.0%)	41 (17.4%)
Total	56 (23.7%)	47 (19.9%)	68 (28.8%)	65 (27.5%)	236
	RAPID 5 Scores				
0 - 2.6 = Remission	42 (49.4%)	24 (28.2%)	14 (15.4%)	5 (5.9%)	85 (36.0%)
2.6 - 3.19 = Low disease activity	9 (25.7%)	8 (22.9%)	14 (40%)	4 (11.4%)	35 (14.8%)
3.2 – 5.1 = Moderate disease activity	6 (8.0%)	18 (24.0%)	32 (42.7%)	19 (25.3%)	75 (31.8%)
5.1 + = High disease activity	0	3 (7.3%)	8 (19.5%)	30 (73.2%)	41 (17.4%)
Total	57 (24.1%)	53 (22.5%)	68 (28.8%)	52 (24.6%)	236

Limitations of the physician/assessor joint count and laboratory tests to assess patients in standard care

It may appear inappropriate not to include a joint count by a physician/-assessor or laboratory tests in an index to assess and possibly classify status of patients with RA, including remission. Rheumatologists regard the joint count as the most important measure to assess patients with RA (15), and the joint count is the most specific measure of clinical status in RA (14). Nonetheless, important limitations are seen to the joint count as a measure of RA status (29).

The time required, thought not great, constitutes an interruption of usual doctor-patient interactions, as the patient expects the rheumatologist to engage in conversation and not necessarily to include formal quantitative measurement. With limited times for visits, matters of interest to the patient could be reviewed, rather than suspension of discussion in order to record joint count information accurately (29). This limitation can be overcome if an assessor is available to perform a formal joint count.

The joint count has poor reliability, which can be improved with training (30). A higher response to placebo is seen with joint counts than with other measures within the ACR Core Data Set (31), accounting for a lower relative efficiency of a tender and swollen joint count than a physician's\ global estimate or most measures to distinguish results of active from control treatment.

A physician's primary role in patient visits is as a data *interpreter* to make decisions concerning therapy, rather than a data *collector*. Undesirable complexities in doctor-patient interactions may emerge when the physician assumes dual roles as both a data collector and data interpreter. Of course, rheumatologists will perform a joint count if required in a clinical trial for compensation, or when a DAS or other index is a prerequisite to use of a therapy such as a biologic agent. However, relatively few rheumatologists have high-quality quantitative joint count data available in their medical records (16).

A formal joint count is required in clinical research studies of remission. However, in clinical practice, it may be far more feasible that the clinician not collect any *formal* data, rather than to suggest that a formal joint count be included in each visit of a patient with RA. That does not mean that joints are not examined qualitatively and carefully. On the contrary, a careful examination is necessary to guide clinical decisions.

It may also be preferable not to include ESR or CRP in an index for standard care. These tests are normal in 40% of patients (32), and do not change in many patients (28). Furthermore, the tests often are not available at the time of visit in many clinical settings, a basis for the clinical disease activity index (CDAI) (13), which does not include laboratory data, in part because it is not available at the time the patient is seen. It is possible to arrange for a patient to have laboratory tests a few days before a visit and to make clinical decisions a few days after the visit, but this type of approach may be cumbersome for doctors or patients or both.

The only physician/assessor measure that is easily collected is the global estimate of clinical status, which ironically has the highest relative efficiency of all physician/assessor measures in clinical trials of leflunomide (31), methotrexate (31), adalimumab (20) and abatacept (33). However, even a global estimate may be superfluous if PRO measures are available.

PRO data appear sufficient to guide formulation of a treatment plan, without the physician performing quantitative measurement. Availability of a patient questionnaire at the time of the visit is analogous to a rheumatologist having results of a bone densitometry test at the time a patient is seen in order to guide a decision regarding possible therapy for osteoporosis, or an

Table II. Continuous quality improvement strategy.

	Principles	Implementation in rheumatology care
Plan	Generate a plan of action on how to address recognised challenges, issues. or opportunities.	Collect patient questionnaire data concerning physical function, pain, and global status at each patient visit, have RAPID 3 score available on flow-sheet that allows comparison with previous visits prior to seeing patient (40).
Do	Execute the plan intended to address the challenges and issues or maximise the opportunities.	Execute this plan in all patients at all visits in standard rheumatology clinical care.
Study	Monitor the outcome of the executed plan.	Monitor whether the plan is reaching a goal of improved outcomes for patients (40); trying to obtain a RAPID score of <1 in all patients with RA, with a possible need to modify according to damage and fibromyalgia.
Act	Respond to the results from the monitoring of the intervention—e.g., undertake more detailed analyses, consider options to address emerging, unforeseen issues.	Respond to the results of monitoring by considering additional strategies and modifications to categories of RAPID scores.

orthopedic physician having available a radiograph to guide clinical decisions.

"Continuous quality improvement" in medical care

An increasingly prominent approach to improving medical care is based on a strategy known as "continuous quality improvement" (34, 35). Long familiar in promoting safety and efficiency in industrial processes, "continuous quality improvement" has evolved over the past five decades into a variety of guises—for example, Quality Improvement, Total Quality Management, and Six Sigma. A "continuous quality improvement" approach maintains a Plan-Do-Study-Act iterative cycle, illustrated according to general principles and as applied to rheumatology clinical care in Table II.

In some senses, development of the DAS may be seen as an early effort to incorporate "continuous quality improvement" through measurement strategies to help guide decisions of rheumatologists regarding therapies. Recent clinical trials, including the Finnish Rheumatoid Arthritis Combination Therapy Trial (FinRACo) (36), TIght COntrol for Rheumatoid Arthritis (TICORA) (37), and BeSt (38), may be viewed as efforts to implement "continuous quality improvement" through frequent assessment of patients with a formal plan of action dictated by observations at these frequent assessments. Development of the MDHAQ also may be viewed as an informal effort to apply principles of "continuous quality improvement" to assessment of patients in standard clinical care (23, 24, 39-41).

The RAPID score for clinical care is regarded as "under development" as part of a "continuous quality improvement" stategy, in response to suggestions of rheumatologists. Scoring of RAPID 3 requires about 10 seconds. Scoring of RAPID 4 adds a further 10 seconds and RAPID 5 another few seconds, for a total of 20 to 25 seconds (Bergman, Yazici, Pincus, unpublished data). The extra 10 to 15 seconds for RAPID 4 or RAPID 5 score, rather than RAPID 3, may be regarded by some rheumatologists as justified, in order to include a joint count and/or physician global score in an index used to monitor patient status. As RAPID 4 and RAPID 5 scores are generally quite similar to those of RAPID 3, other rheumatologists may consider that the pragmatic advantages of saving 10 to 15 seconds would justify RAPID 3, with only physical function, pain, and global scores.

All measurement, particularly in an active clinical setting, presents a compromise between ideal completeness and pragmatic feasibility. Different physicians may view these matters differently, just as some rheumatologists collect ESR and CRP at each visit and others rarely order these tests. Furthermore, all quantitative data must always be interpreted by the clinician and cannot provide guidance without a clinical assessment. Nonetheless, as noted, quantitative data generally provide more informative guidance than might be available without these data.

An example of treating a patient toward a status of "near-remission", using a "continuous quality improvement" strategy based on RAPID scores and frequent visits in standard patient care

Figure 2 presents an MDHAQ that was completed by a patient on 04 Nov 2003. This 61-year-old man had presented on 04 Nov 2003 with severe RA. All his metacarpophalangeal, proximal interphalangeal joints, and wrists were swollen. Figure 3 is a flow sheet documenting his individual measures, as well as RAPID 3, RAPID 4, and RAPID 5 scores, and laboratory tests. He had RAPID 3, RAPID 4 and RAPID 5 scores of 6.6 to 7.2 on a scale of 0-10 (see bottom of MDHAQ). The RAPID score of greater than 4, indicated high severity and that aggressive therapy was indicated. Prednisone 3 mg/day and methotrexate 10 mg/week were prescribed (some rheumatologists may not regard this therapy as "aggressive," but many patients respond to this regimen for many years).

On 13 Jan 2004, a major improvement was seen with RAPID scores of 0.3 on the flowsheet (Fig. 3). On 28 Sept 2004, his scores remained 0.4 to 0.5 seen on the questionnaire (Fig. 4) and the flowsheet (Fig. 3). However, on 28 December 2004, his RAPID scores had increased substantially from 0.4 to 0.5, indicating "near-remission", to 3.4 to 3.9, indicating a high range of "moderate severity" on a 0 to 10 scale (Fig. 5). The flowsheet in Figure 3 illustrates incorporation of MDHAQ data from 28 December 2004 and displays the information available to the rheumatologist at the time of making a decision.

The increase in RAPID scores indicated a strong need to consider additional therapy. The patient was given an injection of methylprednisolone acetate 80

mg and a prescription for adalimumab 40 mg every other week, as illustrated in the subsequent flowsheet in Figure 6. On 08 February 2005, 2 months later (Fig. 6), he returned with RAPID scores of less than 1, mimicking his initial response and indicating "near remission" status. He has been stable through 08 Aug 2006 (Fig. 7). Note that scores on a 0 to 10 scale are quite similar for RAPID 3, RAPID 4, and RAPID 5.

A proposed continuous improvement strategy toward remission for RA based on RAPID scores

Some proposed principles of a "continuous quality improvement" strategy on the basis of RAPID scores in standard care include:

1. Patients are seen and evaluated quantitatively at least every 3 months, or more frequently if doing poorly – perhaps every 6 months after stable for 5 years.
2. A questionnaire such as an MDHAQ is completed by every patient at every visit as part of the infrastructure of standard care (42).
3. Scores for physical function, pain, and global estimate, as well as a RAPID 3, RAPID 4, **and/or** RAPID 5 are calculated by an assistant or the physician in 10 to 25 seconds prior to seeing the patient.
4. Patient status is classified broadly on the basis of RAPID scores prior to seeing the patient into four categories based on a 0 to 10 score:
   a. RAPID scores of ≤ 1 on a 0 to 10 scale indicate "near-remission" the goal of therapy for most patients.
   b. RAPID scores of 1.1 to 2 on a 0 to 10 scale indicate "low sever- ity" and usually do not trigger a change in therapy.
   c. RAPID scores of 2.1 to 4 on a 0 to 10 scale indicate "moderate severity" and suggest consideration of a change in therapy or explanation of why a change is not made.
   d. RAPID scores > 4 on a 0 to 10 scale indicate "high severity" and suggest strong consideration for a change in therapy or an explanation as to why a change was not made.
   e. The RAPID score is analysed by the rheumatologist to determine whether it reflects the RA status of the patient, or some other medical problem—for example, an increase in pain score due to a fracture or acute back pain, just as a change in ESR or CRP must be checked to determine whether it reflects RA status or development of an infection.

Implementation of the "continuous quality improvement" strategy involves the following:

1. Scores of the individual measures and RAPID are entered on a flowsheet to compare with scores at previous visits.
2. The target is "near-remission", i.e. a RAPID score of <1 or low severity, i.e. a score of < 2.
3. A RAPID score > 2 is recognised as a sign to "consider" a change in therapy.
4. A RAPID score > 4 is regarded as a sign to "strongly consider" a change in therapy.
5. An increase of 20% or 2 units of 0 to 10 RAPID score is regarded as requiring consideration of a change in therapy or an explanation.
6. If a decline in RAPID of 20% is seen while receiving current therapy, a change in therapy may not be indicated.
7. These target RAPID levels may often be modified in patients who have extensive joint damage or fibromyalgia, as scores for function, pain, and global status in these patients are unlikely to ever be in the "near-remission" or even "mild severity" range.

The introduction of joint damage and fibromyalgia as possible modifiers of clinical responses may provide a useful clinical guideline. This information may be helpful to explain, for example, why powerful anti-TNF agents results in modest ACR20 responses in only 60% to 70% of patients, while 30% to 40% do not have even this modest response (43). It should be emphasized that implementation of this proposed "continuous quality improvement" strategy requires a careful examination and evaluation of joints by a knowledgeable physician, generally a rheumatologist. The proposed approach is not regarded as a substitute for such an evaluation, but merely a quantitative guide to enhance rational decisions. this is again analogous to monitoring temperature or heart rate to guide clinical decisions, but with a requirement for integration of all sort of other data In the case of a patient with RA, data from a joint count and possibly a radiograph and other imaging procedures, as well as laboratory tests, are often of value.

Conclusions

A patient questionnaire can be collected easily in all clinical practices. The most effective method is for the receptionist to distribute a questionnaire to each patient at each visit, regardless of diagnosis, when the patient registers for the visit (40, 42). RAPID scores on an MDHAQ may serve as guidelines for a "continuous quality improvement" strategy in the care of patients with RA, based on quantitative data in addition to qualitative impressions, without formal joint counts, to classify patient status, including "near-remission" and "inadequate response" in a busy rheumatology clinical setting.

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Fig. 1. (See pages 66-67) A multi-dimensional health assessment questionnaire (MDHAQ), a simple two-sided, one-page instrument, derived from the standard HAQ, designed for routine clinical care. The front side includes 10 activities of daily living, visual analog scales (VAS) for pain and patient global estimate of status, as well as a self-report joint count from a rheumatoid arthritis disease activity index (RADAI). The reverse side includes a review of systems, recent medical history, fatigue VAS, and demographic data. Scoring templates and visual analog scales (VAS) of 21 circles, rather than 10cm lines, are designed to enhance feasibility in standard clinical care. A routine assessment of patient index data (RAPID) score can be calculated. RAPID 3 includes the three core data set patient reported outcome (PRO) measures, physical function, pain, and global estimate, and is scored in about 10 to 15 seconds. RAPID 4 adds the RADAI self-report joint count, and requires 20 to 25 seconds to score. RAPID 5 adds a physician estimate of global status, and requires 25 to 30 seconds to score.

Multi-Dimensional Health Assessment Questionnaire (R771-NP2)

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

FOR OFFICE USE ONLY

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without **ANY** Difficulty	With **SOME** Difficulty	With **MUCH** Difficulty	**UNABLE** To Do
a. Dress yourself, including tying shoelaces and doing buttons?	0	1	2	3
b. Get in and out of bed?	0	1	2	3
c. Lift a full cup or glass to your mouth?	0	1	2	3
d. Walk outdoors on flat ground?	0	1	2	3
e. Wash and dry your entire body?	0	1	2	3
f. Bend down to pick up clothing from the floor?	0	1	2	3
g. Turn regular faucets on and off?	0	1	2	3
h. Get in and out of a car, bus, train, or airplane?	0	1	2	3
i. Walk two miles or three kilometers, if you wish?	0	1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	0	1	2	3
k. Get a good night's sleep?	0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	0	1.1	2.2	3.3

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 PAIN AS BAD AS IT COULD BE

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a.LEFT FINGERS	☐ 0	☐ 1	☐ 2	☐ 3	i.RIGHT FINGERS	☐ 0	☐ 1	☐ 2	☐ 3
b.LEFT WRIST	☐ 0	☐ 1	☐ 2	☐ 3	j.RIGHT WRIST	☐ 0	☐ 1	☐ 2	☐ 3
c.LEFT ELBOW	☐ 0	☐ 1	☐ 2	☐ 3	k.RIGHT ELBOW	☐ 0	☐ 1	☐ 2	☐ 3
d.LEFT SHOULDER	☐ 0	☐ 1	☐ 2	☐ 3	l.RIGHT SHOULDER	☐ 0	☐ 1	☐ 2	☐ 3
e.LEFT HIP	☐ 0	☐ 1	☐ 2	☐ 3	m.RIGHT HIP	☐ 0	☐ 1	☐ 2	☐ 3
f.LEFT KNEE	☐ 0	☐ 1	☐ 2	☐ 3	n.RIGHT KNEE	☐ 0	☐ 1	☐ 2	☐ 3
g.LEFT ANKLE	☐ 0	☐ 1	☐ 2	☐ 3	o.RIGHT ANKLE	☐ 0	☐ 1	☐ 2	☐ 3
h.LEFT TOES	☐ 0	☐ 1	☐ 2	☐ 3	p.RIGHT TOES	☐ 0	☐ 1	☐ 2	☐ 3
q.NECK	☐ 0	☐ 1	☐ 2	☐ 3	r.BACK	☐ 0	☐ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 VERY POORLY

Please turn to the other side

For Office Use Only: RAPID 3 RAPID 3 (0-10)

NR: 1=0.3, 2=0.7, 3=1.0 LS: 4=1.3, 5=1.7, 6=2.0
MS: 7=2.3, 8=2.7, 9=3.0, 10=3.3, 11=3.7, 12=4.0
HS: 13=4.3, 14=4.7, 15=5.0, 16=5.3, 17=5.7,18=6.0, 19=6.3, 20=6.7, 21=7.0, 22=7.3, 23=7.7, 24=8.0, 25=8.3, 26=8.7, 27=9.0, 28=9.3, 29=9.7, 30=10.0

RAPID 4 RAPID 4 (0-10)

NR: 1=0.3, 2=0.5, 3=0.8, 4=1.0 LS: 5=1.3, 6=1.5, 7=1.8, 8=2.0
MS: 9=2.3, 10=2.5, 11=2.8, 12=3.0, 13=3.3, 14=3.5, 15=3.8, 16=4.0
HS: 17=4.3, 18=4.5, 19=4.8, 20=5.0, 21=5.3, 22=5.5, 23=5.8, 24=6.0, 25=6.3, 26=6.5, 27=6.8, 28=7.0, 29=7.3, 30=7.5, 31=7.8, 32=8.0, 33=8.3, 34=8.5, 35=8.7, 36=9.0, 37=9.3, 38=9.5, 39=9.8, 40=10.0

RAPID 5 (0-10)

NR: 1=0.2, 2=0.4, 3=0.6, 4=0.8 5=1.0 LS: 6=1.2, 7=1.4, 8=1.6, 9=1.8, 10=2.0,
MS:11=2.2, 12=2.4, 13=2.6, 14=2.8, 15=3.0, 16=3.2, 17=3.4, 18=3.6, 19=3.8, 20=4.0
HS: 21=4.2, 22=4.4, 23=4.6, 24=4.8, 25=5.0, 26=5.2, 27=5.4, 28=5.6, 29=5.8, 30=6.0, 31=6.2, 32=6.4, 33=6.6, 34=6.8, 35=7.0, 36=7.2, 37=7.4, 38=7.6, 39=7.8, 40=8.0, 41=8.2, 42=8.4, 43=8.6, 44=8.8, 45=9.0, 46=9.2, 47=9.4, 48=9.6, 49=9.8, 50=10.0

1.a-j FN (0-10)

1=0.3 2=0.7 3=1.0 4=1.3 5=1.7 6=2.0 7=2.3 8=2.7 9=3.0 10=3.3 11=3.7 12=4.0 13=4.3 14=4.7 15=5.0 16=5.3 17=5.7 18=6.0 19=6.3 20=6.7 21=7.0 22=7.3 23=7.7 24=8.0 25=8.3 26=8.7 27=9.0 28=9.3 29=9.7 30=10

2.PN (0-10)

4.PTGL (0-10)

RAPID 3 (0-30)

3.a-p JT (0-10)

1=0.2 2=0.4 3=0.6 4=0.8 5=1.0 6=1.3 7=1.5 8=1.7 9=1.9 10=2.1 11=2.3 12=2.5 13=2.7 14=2.9 15=3.1 16=3.3 17=3.5 18=3.8 19=4.0 20=4.2 21=4.4 22=4.6 23=4.8 24=5.0 25=5.2 26=5.4 27=5.6 28=5.8 29=6.0 30=6.3 31=6.4 32=6.7 33=6.9 34=7.1 35=7.3 36=7.5 37=7.7 38=7.9 39=8.1 40=8.3 41=8.5 42=8.8 43=9.0 44=9.2 45=9.4 46=9.6 47=9.8 48=10

RAPID 4 (0-40)

MDGLOBAL(0-10))

RAPID 5 (0-50)

5. Please check (√) if you have experienced any of the following over the last month:

__Fever
__Weight gain (>10 lbs)
__Weight loss (<10 lbs)
__Feeling sickly
__Headaches
__Unusual fatigue
__Swollen glands
__Loss of appetite
__Skin rash or hives
__Unusual bruising or bleeding
__Other skin problems
__Loss of hair
__Dry eyes
__Other eye problems
__Problems with hearing
__Ringing in the ears
__Stuffy nose
__Sores in the mouth
__Dry mouth
__Problems with smell or taste
__Lump in your throat
__Cough
__Shortness of breath
__Wheezing
__Pain in the chest
__Heart pounding (palpitations)
__Trouble swallowing
__Heartburn or stomach gas
__Stomach pain or cramps
__Nausea
__Vomiting
__Constipation
__Diarrhea
__Dark or bloody stools
__Problems with urination
__Gynecological (female) problems
__Dizziness
__Losing your balance
__Muscle pain, aches, or cramps
__Muscle weakness
__Paralysis of arms or legs
__Numbness or tingling of arms or legs
__Fainting spells
__Swelling of hands
__Swelling of ankles
__Swelling in other joints
__Joint pain
__Back pain
__Neck pain
__Use of drugs not sold in stores
__Smoking cigarettes
__More than 2 alcoholic drinks per day
__Depression - feeling blue
__Anxiety - feeling nervous
__Problems with thinking
__Problems with memory
__Problems with sleeping
__Sexual problems
__Burning in sex organs
__Problems with social activities

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5. SX ☐
6. AM ☐
7.CHG ☐
8. EX ☐
9. FT ☐
10.N/Y ☐

6. When you awakened in the morning OVER THE LAST WEEK, did you feel stiff? ☐No ☐Yes
If "No," please go to Item 7. If "**Yes**," **please indicate the number of minutes**_____, **or hours** _____ until you are as limber as you will be for the day.

7. How do you feel TODAY compared to ONE WEEK AGO? Please check (✓) **only one.**
Much **B**etter ☐ (1), **B**etter ☐ (2), the **S**ame ☐ (3), **W**orse ☐ (4), **M**uch **W**orse ☐ (5) than one week ago

8. How often do you exercise aerobically (sweating, increased heart rate, shortness of breath) **for at least one-half hour** (30 minutes)**? Please check** (✓) **only one.**
☐ 3 or more times a week ☐ 1-2 times per month
☐ 1-2 times per week ☐ Do not exercise regularly ☐ Cannot exercise due to disability/ handicap

9. How much of a problem has UNUSUAL fatigue or tiredness been for you OVER THE PAST WEEK?

FATIGUE IS NO PROBLEM O O O O O O O O O O O O O O O O O O O O O O FATIGUE IS A MAJOR PROBLEM
0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

10. Over the last 6 months have you had: [Please check (√)**]**

☐No ☐Yes An operation
☐No ☐Yes Inpatient hospitalization
☐No ☐Yes A new illness, accident or trauma
☐No ☐Yes An important new symptom
☐No ☐Yes Side effect(s) of any drug
☐No ☐Yes Smoke cigarettes regularly
☐No ☐Yes Change(s) of arthritis drugs or other drugs
☐No ☐Yes Change(s) of address
☐No ☐Yes Change(s) of marital status
☐No ☐Yes Change job or work duties, quit work, retired
☐No ☐Yes Change of medical insurance, Medicare, etc.
☐No ☐Yes Change of primary care or other doctor

Please explain any "Yes" answer below, or indicate any other health matter that affects you:

_____

_____

_____

SEX: ☐ Female, ☐ Male **ETHNIC GROUP:** ☐ Asian, ☐ Black, ☐ Hispanic, ☐ White, ☐ Other_____

Your Occupation _____ **Please circle the number of years of school you have completed:**
Work Status: ☐ Full-time, ☐ Part-time, ☐ Disabled
☐ Homemaker, ☐ Self-Employed, ☐Retired,
☐ Seeking work, ☐ Other_____
1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20

Your Name_____ **Date of Birth** _____ **Today's Date** _____

Page 2 of 2 Thank you for completing this questionnaire to help keep track of your medical care. **R771NP2**

Multi-Dimensional Health Assessment Questionnaire (R771-NP2) *04 Nov 03*

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

FOR OFFICE USE ONLY

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without **ANY** Difficulty	With **SOME** Difficulty	With **MUCH** Difficulty	**UNABLE** To Do
a. Dress yourself, including tying shoelaces and doing buttons?	0	1	✓ 2	3
b. Get in and out of bed?	✓ 0	1	2	3
c. Lift a full cup or glass to your mouth?	✓ 0	✓ 1	2	3
d. Walk outdoors on flat ground?	0	✓ 1	2	3
e. Wash and dry your entire body?	0	✓ 1	2	3
f. Bend down to pick up clothing from the floor?	0	✓ 1	2	3
g. Turn regular faucets on and off?	0	✓ 1	2	3
h. Get in and out of a car, bus, train, or airplane?	0	✓ 1	2	3
i. Walk two miles or three kilometers, if you wish?	0	✓ 1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	0	✓ 1	2	3
k. Get a good night's sleep?	0	✓ 1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	✓ 0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	✓ 0	1.1	2.2	3.3

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN ○ ● ○ PAIN AS BAD AS IT COULD BE

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a.LEFT FINGERS	☐ 0	☐ 1	☒ 2	☐ 3	i.RIGHT FINGERS	☐ 0	☐ 1	☐ 2	☒ 3
b.LEFT WRIST	☐ 0	☐ 1	☐ 2	☒ 3	j.RIGHT WRIST	☐ 0	☐ 1	☐ 2	☒ 3
c.LEFT ELBOW	☐ 0	☒ 1	☐ 2	☐ 3	k.RIGHT ELBOW	☐ 0	☒ 1	☐ 2	☐ 3
d.LEFT SHOULDER	☐ 0	☐ 1	☒ 2	☐ 3	l.RIGHT SHOULDER	☐ 0	☐ 1	☐ 2	☒ 3
e.LEFT HIP	☒ 0	☐ 1	☐ 2	☐ 3	m.RIGHT HIP	☒ 0	☐ 1	☐ 2	☐ 3
f.LEFT KNEE	☒ 0	☐ 1	☐ 2	☐ 3	n.RIGHT KNEE	☐ 0	☒ 1	☐ 2	☐ 3
g.LEFT ANKLE	☐ 0	☒ 1	☐ 2	☐ 3	o.RIGHT ANKLE	☐ 0	☐ 1	☒ 2	☐ 3
h.LEFT TOES	☐ 0	☐ 1	☒ 2	☐ 3	p.RIGHT TOES	☐ 0	☐ 1	☒ 2	☐ 3
q.NECK	☐ 0	☒ 1	☐ 2	☐ 3	r.BACK	☐ 0	☒ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL ○ ● ○ ○ VERY POORLY

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

Please turn to the other side

For Office Use Only: RAPID 3

NR: 1=0.3, 2=0.7, 3=1.0 LS: 4=1.3, 5=1.7, 6=2.0
MS: 7=2.3, 8=2.7, 9=3.0, 10=3.3, 11=3.7, 12=4.0
HS: 13=4.3, 14=4.7, 15=5.0, 16=5.3, 17=5.7,18=6.0, 19=6.3, 20=6.7, 21=7.0, 22=7.3, 23=7.7, 24=8.0, 25=8.3, 26=8.7, 27=9.0, 28=9.3, 29=9.7, 30=10.0

RAPID 3 (0-10): **7.2**

RAPID 4

NR: 1=0.3, 2=0.5, 3=0.8, 4=1.0 LS: 5=1.3, 6=1.5, 7=1.8, 8=2.0
MS: 9=2.3, 10=2.5, 11=2.8, 12=3.0, 13=3.3, 14=3.5, 15=3.8, 16=4.0
HS: 17=4.3, 18=4.5, 19=4.8, 20=5.0, 21=5.3, 22=5.5, 23=5.8, 24=6.0, 25=6.3, 26=6.5, 27=6.8, 28=7.0, 29=7.3, 30=7.5, 31=7.8, 32=8.0, 33=8.3, 34=8.5, 35=8.7, 36=9.0, 37=9.3, 38=9.5, 39=9.8, 40=10.0

RAPID 4 (0-10): **6.7**

RAPID 5 (0-10): **6.6**

NR: 1=0.2, 2=0.4, 3=0.6, 4=0.8 5=1.0 LS: 6=1.2, 7=1.4, 8=1.6, 9=1.8, 10=2.0,
MS:11=2.2, 12=2.4, 13=2.6, 14=2.8, 15=3.0, 16=3.2, 17=3.4, 18=3.6, 19=3.8, 20=4.0
HS: 21=4.2, 22=4.4, 23=4.6, 24=4.8, 25=5.0, 26=5.2, 27=5.4, 28=5.6, 29=5.8, 30=6.0, 31=6.2, 32=6.4, 33=6.6, 34=6.8, 35=7.0, 36=7.2, 37=7.4, 38=7.6, 39=7.8, 40=8.0, 41=8.2, 42=8.4, 43=8.6, 44=8.8, 45=9.0, 46=9.2, 47=9.4, 48=9.6, 49=9.8, 50=10.0

1.a-j FN (0-10): **3.0**

1=0.3 16=5.3
2=0.7 17=5.7
3=1.0 18=6.0
4=1.3 19=6.3
5=1.7 20=6.7
6=2.0 21=7.0
7=2.3 22=7.3
8=2.7 23=7.7
9=3.0 24=8.0
10=3.3 25=8.3
11=3.7 26=8.7
12=4.0 27=9.0
13=4.3 28=9.3
14=4.7 29=9.7
15=5.0 30=10

2.PN (0-10): **9.5**

4.PTGL (0-10): **9.0**

RAPID 3 (0-30): **21.5**

3.a-p JT (0-10): **5.4**

1=0.2 25=5.2
2=0.4 26=5.4
3=0.6 27=5.6
4=0.8 28=5.8
5=1.0 29=6.0
6=1.3 30=6.3
7=1.5 31=6.4
8=1.7 32=6.7
9=1.9 33=6.9
10=2.1 34=7.1
11=2.3 35=7.3
12=2.5 36=7.5
13=2.7 37=7.7
14=2.9 38=7.9
15=3.1 39=8.1
16=3.3 40=8.3
17=3.5 41=8.5
18=3.8 42=8.8
19=4.0 43=9.0
20=4.2 44=9.2
21=4.4 45=9.4
22=4.6 46=9.6
23=4.8 47=9.8
24=5.0 48=10

RAPID 4 (0-40): **26.9**

MDGLOBAL(0-10): **6.0**

RAPID 5 (0-50): **32.9**

Fig. 2. MDHAQ completed by a patient with rheumatoid arthritis on 4 November 2003. Note RAPID scores at bottom of page of 6.6 to 7.2, indicating "high severity".

MULTI-DIMENSIONAL HEALTH ASSESSMENT QUESTIONNAIRE (MDHAQ) FLOWSHEET [R764]

PT: Sample Patient	MR# Sample 00-1		DX ICD9: 714.00		DX Onset: 1 Jan 1996			
Address: 203 Oxford House	City, ST Zip: Nashville, TN 37232		Home Ph#: (615) 936-2154					
SSN: SSN-12-9876	DOB: 4 July1942	Sex: M	Marital Status: Married		Race: White			
Work Status: Full-Time	Occupation: Road Contractor		Education: 8		Consent: Yes			
Rheumatologist: Pincus	1st Visit: 4 Nov 2003	Primary MD: Trapper John, M.D.			MD PH#: (615) 936-2151			
Visit Date	4 Nov 2003	13 Jan 2004	28 Sept 2004	28 Dec 2004				
PATIENT SELF-REPORT QUESTIONNAIRE DATA								
1. FN-Functional Status [0-10]	3.0	0	0	0				
2. PN-Pain [0-10]	9.5	0.5	0.5	6.0				
4. PTGL-Global Status [0-10]	9.0	0.5	1.0	5.5				
RAPID 3 [0-30]	21.5	1.0	1.5	11.5				
RAPID 3 [0-10]	7.2	0.3	0.5	3.8				
3. JT CT-Joint Count [0-10]	5.4	0	0.2	1.9				
RAPID 4 [0-40]	26.9	1.0	1.7	13.4				
RAPID 4 [0-10]	6.7	0.3	0.4	3.4				
MDGL-Physician Global [0-10]	6.0	0.5	1.0	6.0				
RAPID 5 [0-50]	32.9	1.5	2.7	19.4				
RAPID 5 [0-10]	6.6	0.3	0.5	3.9				
1a. Psychological Status [0-9.9]	1.10	0	0	0				
5. SX-Symptoms [0-60]	19	4	5	13				
7. AM-Morning Stiffness [0-300]	60	30	0	60				
9. Change in Status [1-5]	M Worse	Same	Same	Same				
10. FT-Fatigue [0-10]	9.5	0.5	0.5	5.0				
11. Interim Events [Yes or No]	Yes	No	No	No				
VITAL STATISTICS								
WEIGHT (lbs)	167	167	159					
BLOOD PRESSURE (mmHg)	114/70	131/81	128/80					
LABORATORY DATA								
ESR (mm/hr) [M:0-20/F:0-30]	43	8	10					
CRP (mg/L) [0.0-10.0]	30	3	7					
WBC (thou/uL) [4-11]	6.3	7.9	8.1					
HGB (g/dL) [M:14-18]/F:12-16]	16.8	17	16.1					
HCT (%) [M:42-50/F:37-44]	47.6	49	48					
PLATELETS (thou/uL) [150-400]	179	207	203					
ALBUMIN (g/dL) [3.5-5.0]	3.9	4.1	4					
GLUCOSE (mg/dL) [70-110]	108	88	79					
ALK PHOS (U/L) [40-100]	101	128	120					
SGOT (U/L) [4-40]	18	17	18					
CREATININE (mg/dL) [0.7-1.5]	1.1	0.8	0.9					
RHEUMATOLOGY DRUGS (C-Change Dose, D-Discontinue, N-New, O-On at visit, P-Parenteral, R-Resume, S-Short-Term, T-Taper, X-Toxicity, W-Renew)								
Tylenol #3	O-30 TID	D						
Naproxen	O-880 Q6H	440 BID	440 BID					
prednisone	N-3 QD	3 QD	3 QD					
methotrexate	N-10 QWK	C-20 QWK	15 QWK					
Folic Acid	N-1 QD	1 QD	1 QD					
Adalimumab								
Depo-Medrol								
NON-RHEUMATIC DRUGS (C-Change Dose, D-Discontinue, N-New, O-On at visit, P-Parenteral, R-Resume, S-Short-Term, T-Taper, X-Toxicity, W-Renew)								
Ranitidine	O-150 BID	150 BID	150 BID					

Fig. 3. Flowsheet documenting individual measures on MDHAQ and RAPID 3, RAPID 4, and RAPID 5 measures, laboratory tests, and therapies prior to 28 December 2004. The flowsheet illustrates the information available to the rheumatologist at the time of the visit of 28 December 2004.

Multi-Dimensional Health Assessment Questionnaire (R771-NP2) *28 Sept 04*

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

FOR OFFICE USE ONLY

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without **ANY** Difficulty	With **SOME** Difficulty	With **MUCH** Difficulty	**UNABLE** To Do
a. Dress yourself, including tying shoelaces and doing buttons?	✓ 0	1	2	3
b. Get in and out of bed?	✓ 0	1	2	3
c. Lift a full cup or glass to your mouth?	✓ 0	1	2	3
d. Walk outdoors on flat ground?	✓ 0	1	2	3
e. Wash and dry your entire body?	✓ 0	1	2	3
f. Bend down to pick up clothing from the floor?	✓ 0	1	2	3
g. Turn regular faucets on and off?	✓ 0	1	2	3
h. Get in and out of a car, bus, train, or airplane?	✓ 0	1	2	3
i. Walk two miles or three kilometers, if you wish?	✓ 0	1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	✓ 0	1	2	3
k. Get a good night's sleep?	✓ 0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	✓ 0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	✓ 0	1.1	2.2	3.3

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN 0 ● 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 PAIN AS BAD AS IT COULD BE

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a.LEFT FINGERS	☐ 0	☒ 1	☐ 2	☐ 3	i.RIGHT FINGERS	☒ 0	☐ 1	☐ 2	☐ 3
b.LEFT WRIST	☒ 0	☐ 1	☐ 2	☐ 3	j.RIGHT WRIST	☒ 0	☐ 1	☐ 2	☐ 3
c.LEFT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3	k.RIGHT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3
d.LEFT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3	l.RIGHT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3
e.LEFT HIP	☒ 0	☐ 1	☐ 2	☐ 3	m.RIGHT HIP	☒ 0	☐ 1	☐ 2	☐ 3
f.LEFT KNEE	☒ 0	☐ 1	☐ 2	☐ 3	n.RIGHT KNEE	☒ 0	☐ 1	☐ 2	☐ 3
g.LEFT ANKLE	☒ 0	☐ 1	☐ 2	☐ 3	o.RIGHT ANKLE	☒ 0	☐ 1	☐ 2	☐ 3
h.LEFT TOES	☒ 0	☐ 1	☐ 2	☐ 3	p.RIGHT TOES	☒ 0	☐ 1	☐ 2	☐ 3
q.NECK	☒ 0	☐ 1	☐ 2	☐ 3	r.BACK	☒ 0	☐ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL 0 ○ 0.5 1.0 ● 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 VERY POORLY

Please turn to the other side

For Office Use Only: RAPID 3

NR: 1=0.3, 2=0.7, 3=1.0 LS: 4=1.3, 5=1.7, 6=2.0
MS: 7=2.3, 8=2.7, 9=3.0, 10=3.3, 11=3.7, 12=4.0
HS: 13=4.3, 14=4.7, 15=5.0, 16=5.3, 17=5.7,18=6.0, 19=6.3, 20=6.7, 21=7.0, 22=7.3, 23=7.7, 24=8.0, 25=8.3, 26=8.7, 27=9.0, 28=9.3, 29=9.7, 30=10.0

RAPID 3 (0-10): 0.5

RAPID 4

NR: 1=0.3, 2=0.5, 3=0.8, 4=1.0 LS: 5=1.3, 6=1.5, 7=1.8, 8=2.0
MS: 9=2.3, 10=2.5, 11=2.8, 12=3.0, 13=3.3, 14=3.5, 15=3.8, 16=4.0
HS: 17=4.3, 18=4.5, 19=4.8, 20=5.0, 21=5.3, 22=5.5, 23=5.8, 24=6.0, 25=6.3, 26=6.5, 27=6.8, 28=7.0, 29=7.3, 30=7.5, 31=7.8, 32=8.0, 33=8.3, 34=8.5, 35=8.7, 36=9.0, 37=9.3, 38=9.5, 39=9.8, 40=10.0

RAPID 4 (0-10): 0.4

RAPID 5 (0-10): 0.5

NR: 1=0.2, 2=0.4, 3=0.6, 4=0.8 5=1.0 LS: 6=1.2, 7=1.4, 8=1.6, 9=1.8, 10=2.0,
MS:11=2.2, 12=2.4, 13=2.6, 14=2.8, 15=3.0, 16=3.2, 17=3.4, 18=3.6, 19=3.8, 20=4.0
HS: 21=4.2, 22=4.4, 23=4.6, 24=4.8, 25=5.0, 26=5.2, 27=5.4, 28=5.6, 29=5.8, 30=6.0, 31=6.2, 32=6.4, 33=6.6, 34=6.8, 35=7.0, 36=7.2, 37=7.4, 38=7.6, 39=7.8, 40=8.0, 41=8.2, 42=8.4, 43=8.6, 44=8.8, 45=9.0, 46=9.2, 47=9.4, 48=9.6, 49=9.8, 50=10.0

1.a-j FN (0-10): 0

1=0.3 2=0.7 3=1.0 4=1.3 5=1.7 6=2.0 7=2.3 8=2.7 9=3.0 10=3.3 11=3.7 12=4.0 13=4.3 14=4.7 15=5.0 16=5.3 17=5.7 18=6.0 19=6.3 20=6.7 21=7.0 22=7.3 23=7.7 24=8.0 25=8.3 26=8.7 27=9.0 28=9.3 29=9.7 30=10

2.PN (0-10): 0.5

4.PTGL (0-10): 1.0

RAPID 3 (0-30): 1.5

3.a-p JT (0-10): 0.2

1=0.2 2=0.4 3=0.6 4=0.8 5=1.0 6=1.3 7=1.5 8=1.7 9=1.9 10=2.1 11=2.3 12=2.5 13=2.7 14=2.9 15=3.1 16=3.3 17=3.5 18=3.8 19=4.0 20=4.2 21=4.4 22=4.6 23=4.8 24=5.0 25=5.2 26=5.4 27=5.6 28=5.8 29=6.0 30=6.3 31=6.4 32=6.7 33=6.9 34=7.1 35=7.3 36=7.5 37=7.7 38=7.9 39=8.1 40=8.3 41=8.5 42=8.8 43=9.0 44=9.2 45=9.4 46=9.6 47=9.8 48=10

RAPID 4 (0-40): 1.7

MDGLOBAL(0-10): 1.0

RAPID 5 (0-50): 2.7

Fig. 4. MDHAQ completed by a patient with rheumatoid arthritis on 28 September 2004. Note RAPID scores at bottom of page of 0.4 to 0.5, indicating "near remission."

Multi-Dimensional Health Assessment Questionnaire (R771-NP2) *28 Dec 04*

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

FOR OFFICE USE ONLY

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without **ANY** Difficulty	With **SOME** Difficulty	With **MUCH** Difficulty	**UNABLE** To Do
a. Dress yourself, including tying shoelaces and doing buttons?	✓ 0	1	2	3
b. Get in and out of bed?	✓ 0	1	2	3
c. Lift a full cup or glass to your mouth?	✓ 0	1	2	3
d. Walk outdoors on flat ground?	✓ 0	1	2	3
e. Wash and dry your entire body?	✓ 0	1	2	3
f. Bend down to pick up clothing from the floor?	✓ 0	1	2	3
g. Turn regular faucets on and off?	✓ 0	1	2	3
h. Get in and out of a car, bus, train, or airplane?	✓ 0	1	2	3
i. Walk two miles or three kilometers, if you wish?	✓ 0	1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	✓ 0	1	2	3
k. Get a good night's sleep?	✓ 0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	✓ 0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	✓ 0	1.1	2.2	3.3

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ● ○ ○ ○ ○ ○ ○ ○ ○ PAIN AS BAD AS IT COULD BE

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a.LEFT FINGERS	☐ 0	☐ 1	☒ 2	☐ 3	i.RIGHT FINGERS	☐ 0	☐ 1	☒ 2	☐ 3
b.LEFT WRIST	☒ 0	☐ 1	☐ 2	☐ 3	j.RIGHT WRIST	☒ 0	☐ 1	☐ 2	☐ 3
c.LEFT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3	k.RIGHT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3
d.LEFT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3	l.RIGHT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3
e.LEFT HIP	☒ 0	☐ 1	☐ 2	☐ 3	m.RIGHT HIP	☒ 0	☐ 1	☐ 2	☐ 3
f.LEFT KNEE	☒ 0	☐ 1	☐ 2	☐ 3	n.RIGHT KNEE	☒ 0	☐ 1	☐ 2	☐ 3
g.LEFT ANKLE	☐ 0	☐ 1	☐ 2	☒ 3	o.RIGHT ANKLE	☐ 0	☐ 1	☒ 2	☐ 3
h.LEFT TOES	☒ 0	☐ 1	☐ 2	☐ 3	p.RIGHT TOES	☒ 0	☐ 1	☐ 2	☐ 3
q.NECK	☒ 0	☐ 1	☐ 2	☐ 3	r.BACK	☒ 0	☐ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ● ○ ○ ○ ○ ○ ○ ○ ○ ○ VERY POORLY

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

Please turn to the other side

For Office Use Only: RAPID 3

NR: 1=0.3, 2=0.7, 3=1.0 LS: 4=1.3, 5=1.7, 6=2.0
MS: 7=2.3, 8=2.7, 9=3.0, 10=3.3, 11=3.7, 12=4.0
HS: 13=4.3, 14=4.7, 15=5.0, 16=5.3, 17=5.7,18=6.0, 19=6.3, 20=6.7, 21=7.0, 22=7.3, 23=7.7, 24=8.0, 25=8.3, 26=8.7, 27=9.0, 28=9.3, 29=9.7, 30=10.0

RAPID 3 (0-10): **3.8**

RAPID 4

NR: 1=0.3, 2=0.5, 3=0.8, 4=1.0 LS: 5=1.3, 6=1.5, 7=1.8, 8=2.0
MS: 9=2.3, 10=2.5, 11=2.8, 12=3.0, 13=3.3, 14=3.5, 15=3.8, 16=4.0
HS: 17=4.3, 18=4.5, 19=4.8, 20=5.0, 21=5.3, 22=5.5, 23=5.8, 24=6.0, 25=6.3, 26=6.5, 27=6.8, 28=7.0, 29=7.3, 30=7.5, 31=7.8, 32=8.0, 33=8.3, 34=8.5, 35=8.7, 36=9.0, 37=9.3, 38=9.5, 39=9.8, 40=10.0

RAPID 4 (0-10): **3.4**

RAPID 5 (0-10): **3.9**

NR: 1=0.2, 2=0.4, 3=0.6, 4=0.8 5=1.0 LS: 6=1.2, 7=1.4, 8=1.6, 9=1.8, 10=2.0,
MS:11=2.2, 12=2.4, 13=2.6, 14=2.8, 15=3.0, 16=3.2, 17=3.4, 18=3.6, 19=3.8, 20=4.0
HS: 21=4.2, 22=4.4, 23=4.6, 24=4.8, 25=5.0, 26=5.2, 27=5.4, 28=5.6, 29=5.8, 30=6.0, 31=6.2, 32=6.4, 33=6.6, 34=6.8, 35=7.0, 36=7.2, 37=7.4, 38=7.6, 39=7.8, 40=8.0, 41=8.2, 42=8.4, 43=8.6, 44=8.8, 45=9.0, 46=9.2, 47=9.4, 48=9.6, 49=9.8, 50=10.0

1.a-j FN (0-10): **0**

1=0.3 2=0.7 3=1.0 4=1.3 5=1.7 6=2.0 7=2.3 8=2.7 9=3.0 10=3.3 11=3.7 12=4.0 13=4.3 14=4.7 15=5.0 16=5.3 17=5.7 18=6.0 19=6.3 20=6.7 21=7.0 22=7.3 23=7.7 24=8.0 25=8.3 26=8.7 27=9.0 28=9.3 29=9.7 30=10

2.PN (0-10): **6.0**

4.PTGL (0-10): **5.5**

RAPID 3 (0-30): **11.5**

3.a-p JT (0-10): **1.9**

1=0.2 2=0.4 3=0.6 4=0.8 5=1.0 6=1.3 7=1.5 8=1.7 9=1.9 10=2.1 11=2.3 12=2.5 13=2.7 14=2.9 15=3.1 16=3.3 17=3.5 18=3.8 19=4.0 20=4.2 21=4.4 22=4.6 23=4.8 24=5.0 25=5.2 26=5.4 27=5.6 28=5.8 29=6.0 30=6.3 31=6.4 32=6.7 33=6.9 34=7.1 35=7.3 36=7.5 37=7.7 38=7.9 39=8.1 40=8.3 41=8.5 42=8.8 43=9.0 44=9.2 45=9.4 46=9.6 47=9.8 48=10

RAPID 4 (0-40): **13.4**

MDGLOBAL(0-10): **6.0**

RAPID 5 (0-50): **19.4**

Fig. 5. MDHAQ completed by a patient with rheumatoid arthritis on 28 December 2004. Note RAPID scores of 3.8 to 3.9, indicating "moderate severity."

MULTI-DIMENSIONAL HEALTH ASSESSMENT QUESTIONNAIRE (MDHAQ) FLOWSHEET [R764]

PT: Sample Patient	MR# Sample 00-1		DX ICD9: 714.00			DX Onset: 1 Jan 1996	
Address: 203 Oxford House	City, ST Zip: Nashville, TN 37232		Home Ph#: (615) 936-2154				
SSN: SSN-12-9876	DOB: 4 July1942	Sex: M	Marital Status: Married			Race: White	
Work Status: Full-Time	Occupation: Road Contractor		Education: 8			Consent: Yes	
Rheumatologist: Pincus	1st Visit: 4 Nov 2003	Primary MD: Trapper John, M.D.				MD PH#: (615) 936-2151	
Visit Date	4 Nov 2003	13 Jan 2004	28 Sept 2004	28 Dec 2004	8 Feb 2005	20 Dec 2005	8 Aug 2006
PATIENT SELF-REPORT QUESTIONNAIRE DATA							
1. FN-Functional Status [0-10]	3.0	0	0	0	0	0	0
2. PN-Pain [0-10]	9.5	0.5	0.5	6.0	0	1.0	1.0
4. PTGL-Global Status [0-10]	9.0	0.5	1.0	5.5	0.5	0	1.0
RAPID 3 [0-30]	21.5	1.0	1.5	11.5	0.5	1.0	2.0
RAPID 3 [0-10]	7.2	0.3	0.5	3.8	0.2	0.3	0.7
3. JT CT-Joint Count [0-10]	5.4	0	0.2	1.9	0	0	0
RAPID 4 [0-40]	26.9	1.0	1.7	13.4	0.5	1.0	2.0
RAPID 4 [0-10]	6.7	0.3	0.4	3.4	0.1	0.3	0.5
MDGL-Physician Global [0-10]	6.0	0.5	1.0	6.0	0.5	0.5	0.5
RAPID 5 [0-50]	32.9	1.5	2.7	19.4	1.0	1.5	2.5
RAPID 5 [0-10]	6.6	0.3	0.5	3.9	0.2	0.3	0.5
1a. Psychological Status [0-9.9]	1.10	0	0	0	0	0	0
5. SX-Symptoms [0-60]	19	4	5	13	3	3	5
7. AM-Morning Stiffness [0-300]	60	30	0	60	0	0	0
9. Change in Status [1-5]	M Worse	Same	Same	Same	Same	Same	Same
10. FT-Fatigue [0-10]	9.5	0.5	0.5	5.0	0	1.0	5.0
11. Interim Events [Yes or No]	Yes	No	No	No	Yes	Yes	No
VITAL STATISTICS							
WEIGHT (lbs)	167	167	159	168	166	164	168
BLOOD PRESSURE (mmHg)	114/70	131/81	128/80	111/71	120/72	122/78	116/76
LABORATORY DATA							
ESR (mm/hr) [M:0-20/F:0-30]	43	8	10	14	14	4	35
CRP (mg/L) [0.0-10.0]	30	3	7	6	8	3.5	31.5
WBC (thou/uL) [4-11]	6.3	7.9	8.1	9.1	9.6	10.5	9.9
HGB (g/dL) [M:14-18]/F:12-16]	16.8	17	16.1	16.6	17	17	17.2
HCT (%) [M:42-50/F:37-44]	47.6	49	48	49	50	49	50
PLATELETS (thou/uL) [150-400]	179	207	203	207	177	226	189
ALBUMIN (g/dL) [3.5-5.0]	3.9	4.1	4	4.4	4.6	4.3	4.3
GLUCOSE (mg/dL) [70-110]	108	88	79	71	81	78	78
ALK PHOS (U/L) [40-100]	101	128	120	135	129	108	145
SGOT (U/L) [4-40]	18	17	18	20	32	28	29
CREATININE (mg/dL) [0.7-1.5]	1.1	0.8	0.9	0.9	1.1	0.9	1
RHEUMATOLOGY DRUGS (C-Change Dose, D-Discontinue, N-New, O-On at visit, P-Parenteral, R-Resume, S-Short-Term, T-Taper, X-Toxicity, W-Renew)							
Tylenol #3	O-30 TID	D					
Naproxen	O-880 Q6H	440 BID	440 BID	440 BID	D-440 BID		
prednisone	N-3 QD	3 QD	3 QD	C-3 BID	2 BID	C-3 QD	C-2 QD
methotrexate	N-10 QWK	C-20 QWK	15 QWK	C-25 QWK	C-15 QWK	C-15 QWK	W-15 QWK
Folic Acid	N-1 QD	1 QD	1 QD	1 QD	1 QD	1 QD	W-1 QD
Adalimumab				N-40 QOW	40 QOW	40 QOW	W-40 QOW
Depo-Medrol				80			
NON-RHEUMATIC DRUGS (C-Change Dose, D-Discontinue, N-New, O-On at visit, P-Parenteral, R-Resume, S-Short-Term, T-Taper, X-Toxicity, W-Renew)							
Ranitidine	O-150 BID	150 BID	150 BID	150 BID	150 BID	75 BID	75 BID

Fig. 6. Flowsheet documenting individual measures on MDHAQ and RAPID 3, RAPID 4, and RAPID5 measures, laboratory tests, and therapies through 08 August 2006. Note that only selected visits are depicted on the flowsheet. Stable RAPID scores of less than 1 indicate "near-remission" status.

Multi-Dimensional Health Assessment Questionnaire (R771-NP2) *08 Aug 06*

This questionnaire includes information not available from blood tests, X-rays, or any source other than you. Please try to answer each question, even if you do not think it is related to you at this time. Try to complete as much as you can yourself, but if you need help, please ask. There are no right or wrong answers. Please answer exactly as you think or feel. Thank you.

FOR OFFICE USE ONLY

1. Please check (√) the ONE best answer for your abilities at this time:

OVER THE LAST WEEK, were you able to:	Without **ANY** Difficulty	With **SOME** Difficulty	With **MUCH** Difficulty	**UNABLE** To Do
a. Dress yourself, including tying shoelaces and doing buttons?	✓ 0	1	2	3
b. Get in and out of bed?	✓ 0	1	2	3
c. Lift a full cup or glass to your mouth?	✓ 0	1	2	3
d. Walk outdoors on flat ground?	✓ 0	1	2	3
e. Wash and dry your entire body?	✓ 0	1	2	3
f. Bend down to pick up clothing from the floor?	✓ 0	1	2	3
g. Turn regular faucets on and off?	✓ 0	1	2	3
h. Get in and out of a car, bus, train, or airplane?	✓ 0	1	2	3
i. Walk two miles or three kilometers, if you wish?	✓ 0	1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	✓ 0	1	2	3
k. Get a good night's sleep?	✓ 0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	✓ 0	1.1	2.2	3.3
m. Deal with feelings of depression or feeling blue?	✓ 0	1.1	2.2	3.3

2. How much pain have you had because of your condition OVER THE PAST WEEK? Please indicate below how severe your pain has been:

NO PAIN ○ ○ ● ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ PAIN AS BAD AS IT COULD BE

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

3. Please place a check (√) in the appropriate spot to indicate the amount of pain you are having today in each of the joint areas listed below:

	None	Mild	Moderate	Severe		None	Mild	Moderate	Severe
a.LEFT FINGERS	☒ 0	☐ 1	☐ 2	☐ 3	i.RIGHT FINGERS	☒ 0	☐ 1	☐ 2	☐ 3
b.LEFT WRIST	☒ 0	☐ 1	☐ 2	☐ 3	j.RIGHT WRIST	☒ 0	☐ 1	☐ 2	☐ 3
c.LEFT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3	k.RIGHT ELBOW	☒ 0	☐ 1	☐ 2	☐ 3
d.LEFT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3	l.RIGHT SHOULDER	☒ 0	☐ 1	☐ 2	☐ 3
e.LEFT HIP	☒ 0	☐ 1	☐ 2	☐ 3	m.RIGHT HIP	☒ 0	☐ 1	☐ 2	☐ 3
f.LEFT KNEE	☒ 0	☐ 1	☐ 2	☐ 3	n.RIGHT KNEE	☒ 0	☐ 1	☐ 2	☐ 3
g.LEFT ANKLE	☒ 0	☐ 1	☐ 2	☐ 3	o.RIGHT ANKLE	☒ 0	☐ 1	☐ 2	☐ 3
h.LEFT TOES	☒ 0	☐ 1	☐ 2	☐ 3	p.RIGHT TOES	☒ 0	☐ 1	☐ 2	☐ 3
q.NECK	☒ 0	☐ 1	☐ 2	☐ 3	r.BACK	☒ 0	☐ 1	☐ 2	☐ 3

4. Considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:

VERY WELL ○ ○ ● ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ VERY POORLY

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

Please turn to the other side

For Office Use Only: RAPID 3

NR: 1=0.3, 2=0.7, 3=1.0 LS: 4=1.3, 5=1.7, 6=2.0
MS: 7=2.3, 8=2.7, 9=3.0, 10=3.3, 11=3.7, 12=4.0
HS: 13=4.3, 14=4.7, 15=5.0, 16=5.3, 17=5.7,18=6.0, 19=6.3, 20=6.7, 21=7.0, 22=7.3, 23=7.7, 24=8.0, 25=8.3, 26=8.7, 27=9.0, 28=9.3, 29=9.7, 30=10.0

RAPID 3 (0-10): **0.7**

RAPID 4

NR: 1=0.3, 2=0.5, 3=0.8, 4=1.0 LS: 5=1.3, 6=1.5, 7=1.8, 8=2.0
MS: 9=2.3, 10=2.5, 11=2.8, 12=3.0, 13=3.3, 14=3.5, 15=3.8, 16=4.0
HS: 17=4.3, 18=4.5, 19=4.8, 20=5.0, 21=5.3, 22=5.5, 23=5.8, 24=6.0, 25=6.3, 26=6.5, 27=6.8, 28=7.0, 29=7.3, 30=7.5, 31=7.8, 32=8.0, 33=8.3, 34=8.5, 35=8.7, 36=9.0, 37=9.3, 38=9.5, 39=9.8, 40=10.0

RAPID 4 (0-10): **0.5**

RAPID 5 (0-10): **0.5**

NR: 1=0.2, 2=0.4, 3=0.6, 4=0.8 5=1.0 LS: 6=1.2, 7=1.4, 8=1.6, 9=1.8, 10=2.0,
MS:11=2.2, 12=2.4, 13=2.6, 14=2.8, 15=3.0, 16=3.2, 17=3.4, 18=3.6, 19=3.8, 20=4.0
HS: 21=4.2, 22=4.4, 23=4.6, 24=4.8, 25=5.0, 26=5.2, 27=5.4, 28=5.6, 29=5.8, 30=6.0, 31=6.2, 32=6.4, 33=6.6, 34=6.8, 35=7.0, 36=7.2, 37=7.4, 38=7.6, 39=7.8, 40=8.0, 41=8.2, 42=8.4, 43=8.6, 44=8.8, 45=9.0, 46=9.2, 47=9.4, 48=9.6, 49=9.8, 50=10.0

1.a-j FN (0-10): **0**

1=0.3 2=0.7 3=1.0 4=1.3 5=1.7 6=2.0 7=2.3 8=2.7 9=3.0 10=3.3 11=3.7 12=4.0 13=4.3 14=4.7 15=5.0 16=5.3 17=5.7 18=6.0 19=6.3 20=6.7 21=7.0 22=7.3 23=7.7 24=8.0 25=8.3 26=8.7 27=9.0 28=9.3 29=9.7 30=10

2.PN (0-10): **1.0**

4.PTGL (0-10): **1.0**

RAPID 3 (0-30): **2.0**

3.a-p JT (0-10): **0**

1=0.2 2=0.4 3=0.6 4=0.8 5=1.0 6=1.3 7=1.5 8=1.7 9=1.9 10=2.1 11=2.3 12=2.5 13=2.7 14=2.9 15=3.1 16=3.3 17=3.5 18=3.8 19=4.0 20=4.2 21=4.4 22=4.6 23=4.8 24=5.0 25=5.2 26=5.4 27=5.6 28=5.8 29=6.0 30=6.3 31=6.4 32=6.7 33=6.9 34=7.1 35=7.3 36=7.5 37=7.7 38=7.9 39=8.1 40=8.3 41=8.5 42=8.8 43=9.0 44=9.2 45=9.4 46=9.6 47=9.8 48=10

RAPID 4 (0-40): **2.0**

MDGLOBAL(0-10): **0.5**

RAPID 5 (0-50): **2.5**

Fig. 7. MDHAQ completed by a patient with rheumatoid arthritis on 08 August 2006. RAPID scores of 0.5 to 0.7 indicate "near remission."

Remission as the treatment goal – the FIN-RACo trial

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ABSTRACT

The Finnish Rheumatoid Arthritis Combination Therapy (FIN-RACo) trial is the first rheumatoid arthritis (RA) clinical trial in which remission served as the primary outcome measure. This chapter reviews the philosophical background, study design, and results of the FIN-RACo trial. The study showed that a third of patients with active early RA may achieve remission with a combination of methotrexate (MTX), sulfasalazine (SSZ), hydroxychloroquine (HCQ), and prednisolone.

Remission as the primary outcome measure

The Finnish Rheumatoid Arthritis Combination Therapy (FIN-RACo) trial was an investigator-initiated multicenter randomised controlled trial in which 18 Finnish rheumatology clinics participated (1). Between 1993 and 1995, 195 patients with early and active rheumatoid arthritis (RA) were enrolled in the study. The patients were randomised to two treatment arms for 2 years: 97 received a combination of methotrexate (MTX), sulfasalazine (SSZ), hydroxychloroquine (HCQ), and prednisolone, while 98 received monotherapy with SSZ (with or without prednisolone), in which MTX was later substituted in 51 patients.

The primary outcome measure of the FIN-RACo study was remission, which was defined as no tender and no swollen joints, morning stiffness ≤ 15 minutes, no pain, and normal erythrocyte sedimentation rate. These remission criteria were those described by the American College of Rheumatology (ACR) (2), but did not include a requirement of no fatigue, as fatigue is regarded as not necessarily reflecting the inflammatory process of RA. However, all 5/5 criteria were required to be met for a patient to be regarded as in "remission," rather than 5/6 in the ACR criteria (2). Therefore, the ACR remission criteria were effectively met by the FIN-RACo criteria.

The FIN-RACo trial was based on a long tradition of treating patients with RA that emphasised early and active care to improve long-term outcomes, as expressed by Luukkainen et al. in 1978: "...In our opinion gold treatment ought to be started in the early stages of RA, before the development of erosions. We are treating not only the actual inflammation of the joints but also the quality of the patient's life for many decades in the future" (3). Clinical rheumatologists who designed the FIN-RACo trial believed that remission could be achieved in a large fraction of patients, although remission had not been used previously as an outcome measure in an RA clinical trial.

Why to aim for remission instead of percentage improvement or low disease activity?

The history of RA is that of a progressive disease with severe long-term outcomes (4) including joint damage, declines in functional capacity, work disability, and early death, which are associated with prior inflammatory activity. Early Finnish studies contributed to evidence that active treatment leads to improved long-term outcomes in many patients with RA. Minimal radiographic progression was observed in individual joints that did not show inflammation in serial clinical examinations (5). Sustained gold treatment was associated with reduced mortality rates in patients with RA (6).

Although it was known that remission was unusual in patients who sought care in rheumatology clinics, it was felt that remission is the optimal treatment goal in RA, analogous to "no evidence of disease" in cancer. Traditionally, RA clinical trials have been designed to identify statistically significant differences between the study treatment and a comparator, reflecting requirements of the United States Food and Drug Administration (FDA) to market a new

therapy. More recently criteria such as ACR 20% or 50% improvement criteria or disease activity score (DAS) have gone beyond mere statistical significance (7). The FIN-RACo trial was the first to incorporate the goal of remission in order to provide the best treatment to the patient whether she/he was randomised to a combination arm or the monotherapy arm.

High remission rates using combination of traditional DMARDs

After two years of treatment, remission was seen in 37% in the combination group and 18% in the monotherapy group ($p = 0.003$) according to the ACR-modified remission criteria (1). Thus, the combination of MTX, SSZ, HCQ, and prednisolone is "remission-inducing" in a third of patients with active early RA. This remission rate in the combination group appears remarkably high with a strict set of remission criteria – remission rates in clinical trials and clinical care are reviewed elsewhere in this Supplement.

It is noteworthy that the time interval from disease onset to institution of therapy was significant in the likelihood of remission in the FIN-RACo monotherapy group. Thirty-five percent of the patients with a short delay of < 4 months were in remission at 2 years in the monotherapy group, while only 11% of those with a long delay of > 4 months met remission criteria at 2 years ($p = 0.021$). In the combination group, the frequency of remission was similar in patients with short (0-4 months) or long delay (> 4 months) of institution of the therapy (8).

Importance of remission as a treatment goal

Several studies show that although measures of inflammatory activity may be stable or somewhat improved over periods of 5 to 10 years, measures of damage may progress (7). Therefore, suppression of inflammation at a level of 20% or 50% appears unlikely to provide optimal long term suppression of disease progression in many patients. In the FIN-RACo study, 22% of patients who had ACR20% or 50% responsesat 6 months and 54% of patients who did not have ACR20% responses, were receiving work disability payments at 5 years (Fig. 1) (9). By contrast, if inflammation was controlled to a level of remission at 6 months, 4.5 years later no patient was receiving work disability payments. Furthermore, loss of productivity was associated with lesser improvement of clinical status (10).

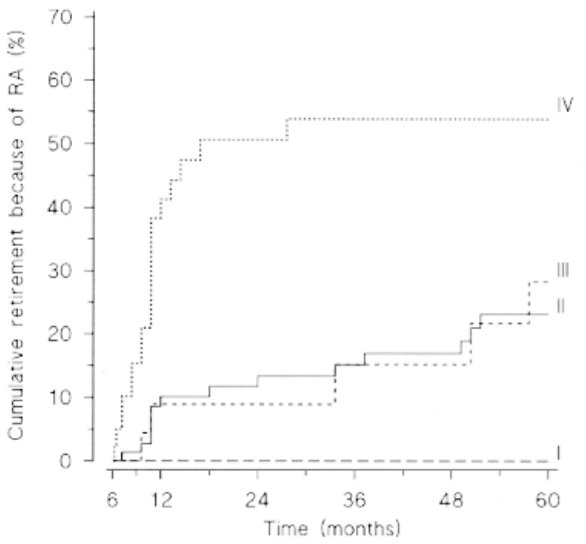

Fig. 1. Rate of permanent work disability over 5 years by 6-month response in the FIN-RACo trial. Rates are adjusted to age, sex, type of job, and level of education. Group I = Remission; II = ACR50% response; III = ACR20% response; IV = less than ACR20% response (Puolakka et al. *Arthritis Rheum* 2005; 52: 36-41, with permission).

Patients who were in sustained remission assessed at 6, 12, and 24 months had practically no progression in radiographic damage in their hands, wrists, and feet, with no increase in mean Larsen score over the 2 years of observation. Patients who were not in sustained remission had an increase in mean Larsen score of 4 of 200 (11).

These observations emphasize the importance of attempting to induce rapid and sustained remission in early RA. The data indicate that improvement rates of ACR20% or 50% are suboptimal goals of therapies for patients with early RA.

A combination of traditional DMARDs is effective in early RA

FIN-RACo patients were randomised to receive combination or monotherapy for 2 years. Subsequently, therapies were at physicians' discretion. The 2-year results favoured early combination treatments, which continued at 5 years in analyses of radiographic progression and work disability. The 5-year median Larsen score was 11 in the initial combination group versus 24 in the monotherapy group ($p < 0.01$) (12). Patients in the initial combination group were more likely to maintain their capacity to continue in paid work over 5 years compared to the monotherapy group (13).

Did glucocorticoids drive remission in the FIN-RACo trial?

In the FIN-RACo trial, the combination therapy included prednisolone 5 mg daily, which could be tapered and discontinued at 9 months if patient remained in remission (1). In the monotherapy arm, prednisolone treatment was at physicians' discretion, and was initiated in 27 (27%) patients at baseline and in another 36 patients at a median of 6 weeks after the onset of the study (14). At the end of the 2-year study, more patients in the monotherapy group than in the combination group were treated with prednisolone (50 vs 43 patients) and the cumulative number of intra-articular glucocorticoid injections was higher in the monotherapy group than in the combination group.

These observations indicate that it appears unlikely that the more favourable results of the combination group in the FIN-RACo trial can be attributable to prednisolone. However, it may be that some individual patients gained considerable benefit from glucocorticoids, and the FIN-RACo trial does not speak against benefits of low-dose glucocorticoids in RA, which have been shown in other early RA