RAPID3—An Index of Physical Function, Pain, and Global Status as "Vital Signs" to Improve Care for People with Chronic Rheumatic Diseases

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Abstract

A guide to RAPID3 (routine assessment of patient index data), an index of three patient self-report measures—physical function, pain, and patient global estimate of status—on a multidimensional health assessment questionnaire (MDAQ) is presented, including development, scoring, use in standard care, and rationale. RAPID3 and its individual components are regarded as "vital signs," which may alert a health professional to unsuspected patient problems, provide a baseline measure to support a change in therapy, and numerically document improvement or worsening over time to complement clinical impressions. MDHAQ-RAPID3 can be incorporated into the infrastructure of standard rheumatology care for completion in the waiting room by every patient with any rheumatic disease at every visit: if there is a reason for a visit, there is a reason for RAPID3 vital signs. RAPID3 is calculated in 5 to 10 seconds, providing similar information to DAS28 (disease activity score) and CDAI (clinical disease activity index), which require a mean of 114 and 106 seconds, respectively. MDHAQ-RAPID3 presents an additional advantage for the patient to optimize the office encounter by completion of the questionnaire in the waiting room. The MDHAQ also includes a review of systems and recent medical history, which can save 2 to 3 minutes per visit for other patient concerns. A physician's clinical decisions ultimately require synthesis and interpretation of all available data, ranging from laboratory tests to patient questionnaire scores. RAPID3 vital signs can contribute to this synthesis toward improved quality, outcomes, and documentation of rheumatology care.

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Rheumatoid arthritis (RA) cannot be assessed in individual patients according to any single "gold standard" measure, such as blood pressure or glucose, and an index is needed.[1] RA indices are based on the Core Data Set[2] of seven measures (Table 1): three assessed by a physician—swollen joint count, tender joint count, and physician global estimate of status; one laboratory test—erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP); and three reported by a patient—physical function, pain, and patient global estimate of status.

The most widely used RA index is the disease activity score 28 (DAS28),[3,4] which includes a 28-tender joint count, 28-swollen joint count, ESR or CRP, and patient global estimate of status (Table 1), with a total score 0-10. Scoring the DAS28 is relatively complex, requiring a calculator or computer for a mathematical formula (Table 1), and a laboratory test, which is often unavailable at the time of the patient visit. These requirements are eliminated in the clinical disease activity index (CDAI),[5] in which the 0-28 tender and swollen joint counts and 0-10 patient- and physician-assessor global estimates are added together for a total of 0-76 (Table 1). While the CDAI is mathematically simpler, a formal quantitative joint count is included that requires 90 to 94 seconds to complete.[6]

RAPID3 (routine assessment of patient index data) is a simple arithmetic composite index of only the three Core Data Set patient self-report measures—physical function (0-3 converted to 0-10), pain (0-10), and patient global estimate (0-10) for a total of 0-30. RAPID3 is based on patient self-report data completed in the waiting room and can be calculated in 5 to 10 seconds.[6,7] This article updates previous reviews[8-15] concerning the development, scoring, clinical strategies, and rationale for the MDHAQ and RAPID3 in usual rheumatology care.

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Table 1 Measures and Ranges of Scores of Indices to Assess Patients with RA

	Indices			
	ACR Core Data Set	DAS28	CDAI	RAPID3
Physician-Assessor Measures				
28-Tender joint count (TJC28)	√	0.56 × sq rt (TJC28)	0-28	—
28-Swollen joint count (SJC28)	√	0.28 × sq rt (SJC28)	0-28	—
Physician global estimate of status	√	—	0-10	—
Laboratory Measures				
Erythrocyte sedimentation rate (ESR) or C-Reactive Protein (CRP)	√	0.70 × ln (ESR)	—	—
Patient Self-Report Measures				
Physical function	√	—	—	0-10
Pain	√	—	—	0-10
Patient global estimate of status (PTGL)	√	0.014 × PTGL	0-10	0-10
Total	—	0-10	0-76	0-30

A. Development of the MDHAQ and RAPID3

The MDHAQ and RAPID3 were developed from the health assessment questionnaire (HAQ)[16] on the basis of experience in usual clinical care, as summarized below:

1. What is the Health Assessment Questionnaire (HAQ)?

The HAQ is a self-report questionnaire published in 1980, with queries concerning 20 activities of daily living (ADL) (Table 2).[16] The patient selects one of four responses to describe capacity to perform each activity: "without any difficulty" (0); "with some difficulty" (1); "with much difficulty" (2); "unable to do" (3). The 20 activities are classified into eight categories of two or three each. Patients also are queried about the use of 13 aids and devices, and help from another person for each of the eight categories.

The HAQ disability score is the mean of the highest of 0-3 scores (among 2 or 3) in each of the eight categories. The score for each category is increased by 1 if a patient uses an aid or device or help from another person. The HAQ generally is completed easily by patients in 5 to 10 minutes. However, complex formal scoring requires 42 seconds,[6] and the 20 activities are on two sides of one page, slowing "eyeball" review by the physician. Some of the activities, such as "shampoo your hair" and "do chores such as vacuuming and yard work" (Table 2) do not apply to some patients.

2. What is the Modified HAQ (MHAQ)?

A modified HAQ (MHAQ), reported in 1983, includes eight activities of daily living, one from each category of the HAQ, in the "patient-friendly" format of the HAQ, with 0-3 scoring (Table 2).[17] The MHAQ was designed for feasibility in usual care, although it performs well in research studies. All eight ADLs are on one side of a page, facilitating rapid "eyeball" review by the rheumatologist. Scoring the MHAQ required less than half the time needed for the HAQ, and scores were correlated significantly with HAQ scores (as would be expected from the same items),[17] as well as with traditional joint counts, radiographs, and laboratory indicators of disease.[18] Additional information regarding psychological distress, fatigue, and change in status was included within a two-page single-sheet format.

3. What is the Multidimensional HAQ (MDHAQ)?

The activities chosen for the MHAQ generally were the simplest among the two or three within each HAQ category (Table 2), as the other activities were not performed by all patients, such as "shampoo your hair" or "take a tub bath." Therefore, MHAQ scores were systematically 0.3-0.4 units lower than HAQ scores.[19] Furthermore, as the status of patients improved in the 1990s, scores of 0 in patients who had recognized functional disability, known as "floor effects," were seen increasingly for both the MHAQ and the HAQ.

In order to address these concerns, a multidimensional HAQ (MDHAQ) (Fig. 1) was developed and reported, in 1999, to include complex activities and psychological status. The MDHAQ reduced the proportion of patients with floor effects for the HAQ and the MHAQ, from 16% and 23%, respectively, to only 5%.[19]

The most recent version of the MDHAQ includes, on page 1 (Fig. 1A), a total of 10 activities (items 1a–j): eight from the MHAQ and two complex activities, "walk 2 miles or 3 kilometers" and "participate in sports and games as you would like" (Table 2).[20] Visual analog scales (VAS) for pain and patient global estimate are in a 21-circle format, so that a ruler is not needed. The three scores for physical function, pain, and global status are scored as RAPID3 (see below). Three psychological items[19] are included in the patient-friendly HAQ format to address sleep, anxiety, and depression (Fig. 1A, items 1k–m).[20] The depression query is correlated significantly with page-long depression questionnaires, such as the Beck Depression Inventory ($r = 0.61$, $p = 0.001$) and the Centers for Epidemiologic Studies Depression Inventory ($r = 0.64$, $p = 0.001$).[19] A self-report joint count, based on the RA disease activity index (RADAI),[21] is also included, but not scored formally.

Page 2 of the MDHAQ, the reverse side, contains queries for a review of systems, change in status, morning stiffness, exercise, recent medical history, and demographic information (Fig. 1B,

Multi-Dimensional Health Assessment Questionnaire (R798-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.

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

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1.PN (0-10):

2.PN (0-10):

4.PTGL (0-10):

RAPID 3 (0-30):

Cat:
HS >12
MS = 6.1-12
LS = 3.1-6
R <3

Please turn to the other side

Figure 1 Multidimensional health assessment questionnaire (MDHAQ). The front page includes 10 activities for function, two visual analog scales (VAS) for pain and patient global estimate of status, and a self-report joint count from a rheumatoid arthritis disease activity index (RADAI). Scoring templates for these measures are available on the right-hand side of the page. An index of the three patient-reported measures, routine assessment of patient index data (RAPID3), can be calculated from an MDHAQ in fewer than 10 seconds.

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. ROS: ☐

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 Better ☐ (1), **Better** ☐ (2), the **Same** ☐ (3), **Worse** ☐ (4), **Much Worse** ☐ (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 (3) ☐ 1-2 times per month (1)
☐ 1-2 times per week (2) ☐ Do not exercise regularly (0) ☐ Cannot exercise due to disability/ handicap (9)

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

FATIGUE IS	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	FATIGUE IS A
NO 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	MAJOR PROBLEM

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

☐No ☐Yes An operation or new illness
☐No ☐Yes A patient visit or stay in a hospital
☐No ☐Yes A fall, broken bone, or other 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 _____
Work Status: ☐ Full-time, ☐ Part-time, ☐ Disabled
☐ Homemaker, ☐ Self-Employed, ☐Retired,
☐ Seeking work, ☐ Other_____

Please circle the number of years of school you have completed:
1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20

Please write your weight: _____ lbs. height: _____ inches

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. **R798NP2**

FOR OFFICE USE ONLY: I have reviewed the questionnaire responses.
Date: _____ Signature_____

Figure 1 The reverse side includes a review of systems, fatigue VAS, recent medical history, and demographic data (not included in scoring, but providing useful data in clinical care).

Table 2 Activities of Daily Living as Included on the HAQ, MHAQ, and MDHAQ

	HAQ	MHAQ	MDHAQ
Dressing and Grooming			
Dress yourself, including tying shoelaces and doing buttons?	+	+	+
Shampoo your hair?	+	–	–
Arising			
Stand up from a straight chair?	+	–	–
Get in and out of bed?	+	+	+
Eating			
Cut your meat?	+	–	–
Lift a full cup or glass to your mouth?	+	+	+
Open a new milk carton?	+	–	–
Walking			
Walk outdoors on flat ground?	+	+	+
Climb up five steps?	+	–	–
Walk 2 miles?	–	–	+
Hygiene			
Wash and dry your entire body?	+	+	+
Take a tub bath?	+	–	–
Get on and off the toilet?	+	–	–
Reach			
Reach and get down a 5-pound object from above your head?	+	–	–
Bend down to pick up clothing from the floor?	+	+	+
Grip			
Open car doors?	+	–	–
Open previously opened jars?	+	–	–
Turn regular faucets on and off?	+	+	+
Other Activities			
Run errands and shop?	+	–	–
Get in and out of a car, bus, train, or airplane?	+	+	+
Do chores such as vacuuming or yard work?	+	–	–
Participate in sports and games as you would like?	–	–	+
Psychological			
Get a good night's sleep?	–	–	+
Deal with feelings of anxiety or being nervous?	–	–	+
Deal with feelings of depression or feeling blue?	–	–	+

Table 3).[20] Both sides can be scanned ("eyeballed") easily for an overview of a patient's situation and include considerable information not assessed by the original HAQ (Table 3).

4. What Are the Components of RAPID3?

RAPID3 is a simple composite index of physical function, pain, and patient global estimate, each scored 0-10, for a total of 30. In clinical trials, RAPID3 is compiled from the HAQ,[16] with 20 activities of daily living (ADLs) to score physical function and two 10-cm line visual analog scales (VAS) for pain and patient estimate of global status.[22] In clinical care, RAPID3 is compiled from an MDHAQ,[19,20] with 10 activities to score physical function and two 21-circle VAS scores for pain and patient global estimate.[23,24]

In development of RAPID3,[22,24] a number of additional "RAPID" scores were analyzed, composed of variables other than those in RAPID3 (function, pain, and global status). RAPID2 is composed of only two variables, physician global and patient global estimates. RAPID4 adds a joint count to RAPID3, which, in clinical trials is a formal 28-swollen and tender joint count by a physician-assessor, and in clinical care is a RADAI[21] self-report joint count. RAPID5 adds to RAPID4 a physician global estimate. RAPID2, 3, 4, and 5 were correlated at similar levels with DAS28 and CDAI, and all distinguished active from control treatments at similar levels to one another, as well as to DAS28 and CDAI in abatacept clinical trials.[22] RAPID4 and RAPID5 were found to require about 20 seconds, rather than 10 seconds, to score.[6] RAPID2 was rejected because of insufficient specificity. The additional time required for calculation of RAPID4 or RAPID5, of which RAPID3 comprises 75% and 60% of the indices, respectively, does not appear justified for incremental information. RAPID3 appears the most time-efficient index to recommend for usual clinical care.

Early reports of RAPID3 included conversion of the raw 0-30 total to 0-10, to provide a range similar to DAS28.[6,14,22,24] However, the raw 0-30 total score, without conversion to 0-10, could be calculated in about 5 rather than 10 seconds.[7] Therefore, it is now suggested that RAPID3 be scored simply as 0-30. In reading the literature, it is rather simple to "undo" the conversion by multiplying a 0-10 score in a published report by 3.

Table 3 Comparison of Health Assessment Questionnaire (HAQ) and Multidimensional Health Assessment Questionnaire (MDHAQ)

	HAQ	MDHAQ
First report	1980	1999
Patient completion	5-10 minutes	5-10 minutes
No. Activities of daily living+	20	10
Pain VAS	10 cm line	21 circles
Patient global VAS	10 cm line	21 circles
Fatigue	Not included	21 circles
Psychological - sleep, anxiety, depression	Not included	3-HAQ format
Review of systems	Not included	60 symptoms
Medical history	Not included	Included
Demographic data	Not included	Included
Social history	Not included	Included
Scoring templates	Not included	Included
MD scan ("eyeball")	15 seconds	5 seconds
Time to score index of three measures	42 seconds	0-30 scale: 5 seconds 0-10 scale: 10 seconds

5. Are the Three Patient-Reported Outcome Measures as Efficient as Formal Joint Counts and Laboratory Data to Distinguish Active from Control Treatment in Clinical Trials?

Relative efficiencies of each of the Core Data Set measures, compared to tender joint count, were similar to distinguish active from control treatment responses in RA clinical trials of leflunomide,[25,26] methotrexate,[25,26] abatacept,[27] and adalimumab.[28] For example, in four adalimumab clinical trials,[28] the three RA Core Data Set[2] patient-reported measures (physical function, pain, and global estimate) had similar relative efficiencies to physician-reported swollen joint count, physician estimate of global status, and CRP, compared to tender joint count (Fig. 2). Varying results in different trials[26-28] support the rationale for a composite index rather than a single measure to assess patients with RA.

A joint examination is required for a diagnosis of RA, and a formal joint count provides the most specific measure to assess activity. However, the sensitivity of joint counts to detect treatment effects generally is no greater, and often less, than patient self-report measures. Similar relative efficiencies of the seven individual RA Core Data Set measures[26-28] are reflected in the similar capacity of RAPID3 to DAS28, CDAI, or ACR20,50,70[29] to distinguish active from control treatments in clinical trials of leflunomide,[25,26] methotrexate,[25,26] adalimumab,[28] and abatacept.[22,27] RAPID3 also distinguishes active from control treatments, similarly to DAS28 and CDAI.[22,25-29]

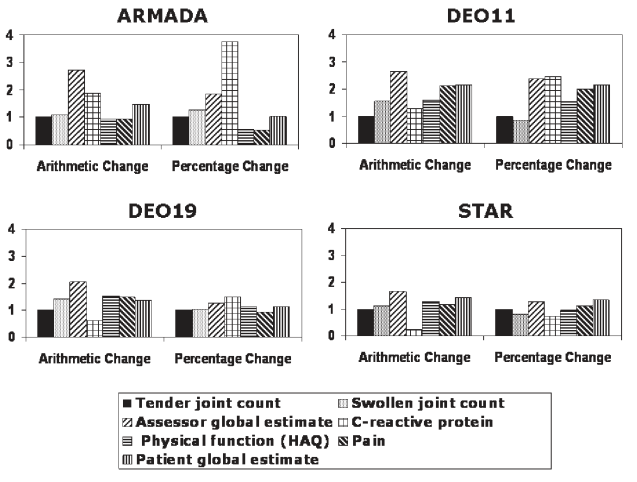

Figure 2 Relative efficiencies of seven Core Data Set measures to distinguish adalimumab from control treatment in four clinical trials, according to arithmetic and percentage changes.

6. Is RAPID3 Correlated Significantly with DAS28 and CDAI in Clinical Trials and Clinical Care?

RAPID3 is correlated significantly with DAS28 and CDAI in clinical trials[22] and clinical care (Fig. 3).[24] The levels of correlation by the Spearman rank order test ($r = 0.65$ to 0.74) are higher than seen for ESR with CRP ($r = 0.50$), although all correlations are statistically significant ($p < 0.001$).

7. Are DAS28 and CDAI Categories for Severe, Moderate, Low Activity, and Remission Associated Significantly with Similar Categories for RAPID3?

Four categories have been established to classify patients as having high, moderate, or low activity or remission, according to the DAS28, CDAI, and RAPID3 (Table 4). Agreement for categories of disease activity according to these quantitative indices is seen in both clinical trials of abatacept[22] and clinical care[24] (Table 5). More than 80% of people with high-moderate DAS28 and CDAI activity (or either alone), which is indicative of an "incomplete response" and a need to consider a change in therapy, have high-moderate RAPID3 activity.

8. Are Results of Clinical Trials for Improvement According to EULAR-DAS28 Criteria Similar to Proposed RAPID3 Criteria?

Response categories for clinical trials have been established by the European League Against Rheumatism[30] (EULAR) on the basis of the DAS28 activity measures:

- Good response: a decrease of more than 1.2 units and a

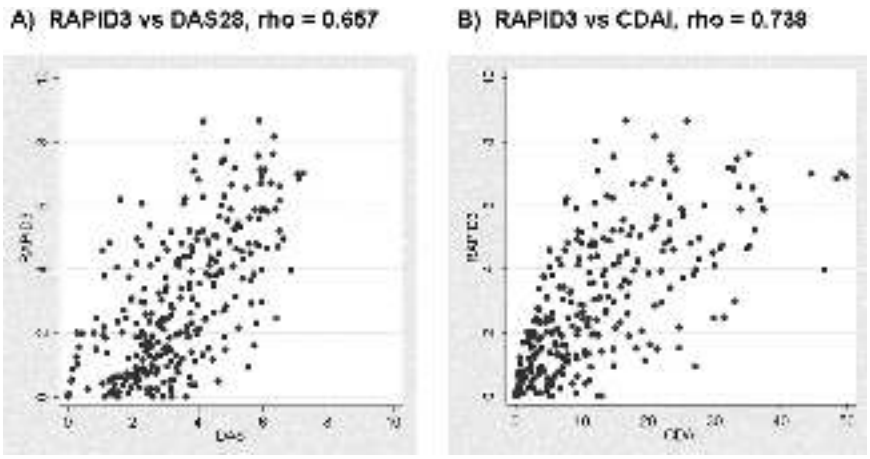

Figure 3 Spearman correlations of RAPID3 versus DAS28 (**A**) (rho = 0.657) and RAPID3 versus CDAI (**B**) (rho = 0.738) in 285 patients with rheumatoid arthritis (RA).[21]

final DAS28 score under 3.2.

- Moderate response: a decrease greater than 1.2 and a final score equal to or greater than 3.2, or a decrease of 0.6-1.2 units and a final score equal to or less than 5.1.
- No response: a decrease less than 0.6, or a decrease of 0.6-1.2 and a final score greater than 5.1.

Proposed RAPID3 response categories are:

- Good response: a decrease of more than 3.6 units and a final score less than 6.
- Moderate response: a decrease greater than 3.6 and a final score equal to or greater than 6, or a decrease of 1.8-3.6 and a final score of equal to or less than 12.
- Poor response: a decrease of less than 1.8, or a decrease of 1.8-3.6 and a final score greater than 12.[31]

Preliminary analyses indicate similar results according to these two types of response criteria in clinical trials of adalimumab,[31] abatacept,[32] and certolizumab pegol.[33]

9. How Much Time is Needed to Score a 28-Joint Count, HAQ, DAS28, CDAI, and RAPID3?

Studies conducted by seven rheumatologists indicate that the mean time to perform a formal tender and swollen joint count, as required for both the CDAI and DAS28, is 90 to 94 seconds (Fig. 4).[6,7] Calculation of an HAQ disability score requires about 42 seconds.[7] Calculation of RAPID3 as a 0-10 score requires 10 seconds and as a 0-30 score, 5 seconds.[7] Calculation of a CDAI requires 106 seconds and a DAS28, 114 seconds.[7] The simpler 0-30 RAPID3 scale requires less than 5% of the time required for DAS28 or CDAI, with similar results.

10. What is Included on Flow Sheets for the MDHAQ-RAPID3?

A flow sheet facilitates longitudinal monitoring of MDHAQ scores for physical function, pain, global estimate, and RAPID3 (Fig. 5). Flow sheets should include medications and laboratory tests for patient management to identify trends and changes. Flow sheets are completed for all patients seen by the authors.

An example of a completed flow sheet (Fig. 5) illustrates a patient who presented with swollen and tender joints characteristic of RA on November 4, 2003. He had an elevated ESR and CRP, and 0-10 scores for physical function of 2.7; pain, 9.5; and global estimate, 9.0. The composite RAPID3 score was 21.2, indicating high severity (Fig. 5). The patient was treated with prednisone 3 mg/day and methotrexate 10 mg/week. Two months later, on January 13, 2004, his joint tenderness and swelling resolved, and his RAPID3 score was 1.0, indicating clear improvement to near remission status. This improvement was maintained over most of 2004. On December 28, 2004, he presented with severe swollen joints, similar to his presentation on November 4, 2003. His RAPID3 score was 11.5 (Fig. 5). He was treated with an intramuscular injection of methylprednisolone and adalimumab. Two months later, on February 8, 2005, his RAPID3 score was 0.5.

A patient's entire course can easily be seen on a one-page flow sheet with questionnaire scores, laboratory tests, and medications, as in Figure 5 which can provide at a glance considerably more information than an electronic medical record (EMR). This flow sheet may be completed using pencil and paper or a simple database, maintained using Access software (Microsoft Corporation, Redmond, Washington). Flow sheets greatly facilitate patient care, with a simple summary of patient status over long periods.

B. Use of MDHAQ-RAPID3 in a Rheumatology Treatment Setting

Collection, scoring, and management of MDHAQ and RAPID3 in clinical care is briefly summarized below, again

Table 4 DAS28, CDAI, and RAPID3 Categories

Activity Level	DAS28 (0-10)	CDAI (0-76)	RAPID3 (0-30)
High activity: change therapy or have a good reason not to	> 5.1	> 22	> 12
Moderate activity: strongly consider change in therapy	3.21-5.1	10.1-22	6.1-12
Low activity: consider change	2.61-3.2	2.9-10	3.1-6
Remission: therapy working	≤ 3.2	≤ 2.8	≤ 3

Table 5 RAPID3 Scores Compared to DAS28 and CDAI in 285 Patients at Three Sites (RAPID3 Scores Revised from 0-10 in Original Publication to 0-30, as Currently Recommended)

	RAPID3 Scores				
DAS28	High Severity 12.1-30	Moderate Severity 6.1-12	Low Severity 3.1-6.0	Near Remission 0-3.0	Total
High activity > 5.1	37 (74%)	11 (22%)	1 (2%)	1 (2%)	50 (17%)
Moderate activity 3.21-5.1	39 (43%)	27 (30%)	16 (18%)	8 (9%)	90 (32%)
Low activity 2.61-3.2	4 (10%)	15 (38%)	10 (25%)	11 (27%)	40 (14%)
Remission 0-2.6	10 (10%)	18 (17%)	24 (23%)	53 (50%)	105 (37%)
Total	90 (31%)	71 (25%)	51 (18%)	73 (26%)	285

Kappa 0.26, Weighted kappa 0.44

	RAPID3 Scores				
CDAI	High Severity 12.1-30	Moderate Severity 6.1-12	Low Severity 3.1-6.0	Near Remission 0-3.0	Total
High activity > 22	39 (78%)	9 (18%)	1 (2%)	1 (2%)	50 (17%)
Moderate activity 10.1-22.0	36 (40%)	33 (36%)	15 (17%)	6 (7%)	90 (32%)
Low activity 2.9-10	15 (16%)	28 (30%)	25 (27%)	25 (27%)	93 (33%)
Remission 0-2.8	0 (0%)	1 (2%)	10 (19%)	41 (79%)	52 (18%)
Total	90 (31%)	71 (25%)	51 (18%)	73 (26%)	285

Kappa 0.32, Weighted kappa 0.51. All percentages are row percentages, except the total in rightmost column (column percentages).

adapted from previous reports.[8-15]

1. How Can the Rheumatologist Orient Office Staff Regarding the Importance of Patient Questionnaires in Patient Care?

Introduction of patient questionnaires into usual clinical care requires a change in office procedure, which may appear initially to add complexity. The staff should be reassured that a patient questionnaire streamlines the flow of information from patient to physician and provides needed quantitative data. The purpose of the questionnaire should be clearly presented to patients as a tool to optimize their care. It should not be presented as tool by which to collect data for research or reimbursement, although it may enhance these activities as well.

The rheumatologist should review and score the questionnaire prior to or while seeing the patient. If both the patients and office staff members recognize the interest and importance to the physician, routine distribution and completion of questionnaires at each visit is easily accomplished. Conversely, if patients and staff sense a lack of interest on the part of the physician, they too will lose interest and resent the apparent extra effort.

2. Why Should the Questionnaire be Included in the Office Infrastructure to be Completed by Every Patient with Any Diagnosis, at Every Visit?

Many rheumatologists suggest that patient questionnaires might be completed only by certain patients, such as those with RA, or at certain intervals, such as every 6 months. This approach generally fails logistically in standard care, as it is virtually impossible for the staff to organize distribution of questionnaires selectively.

Furthermore, if data are collected at periodic intervals, important information may be missed on the day that a new therapy is begun. For example, a RAPID3 score of 5 on a scale of 0-30, indicating low severity, may be collected in January and July. This same patient could have experienced a major flare during the intervening months, with a RAPID3 score of 16 in April, indicating high severity and a need to change therapy. If a change in therapy were made based only on (accurate) clinical impressions without recording a quantitative RAPID3 score, the complementary numerical basis for a change in therapy would not have been made and the patient's improvement not be documented quantitatively. If there is a reason for a visit, there is a reason for the MDHAQ

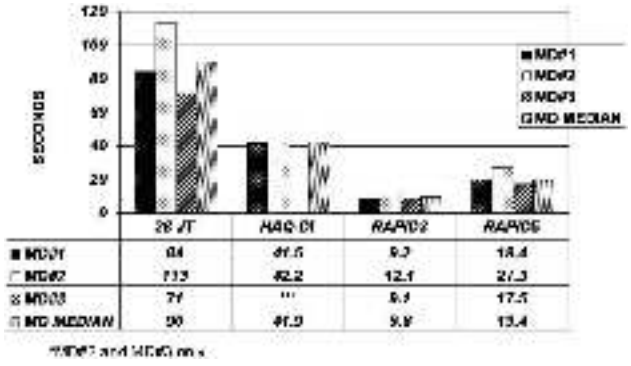

Figure 4 Summary of mean number of seconds to score various rheumatoid arthritis measures, including a 28-joint count, DAS28 (disease activity score), HAQ (health assessment questionnaire), RAPID3 (routine assessment of patient index data), and RAPID5 on a multidimensional HAQ (MDHAQ). Note that RAPID3 requires less than one-eighth the time required for a 28-joint count, and one-fourth the time to score a HAQ.

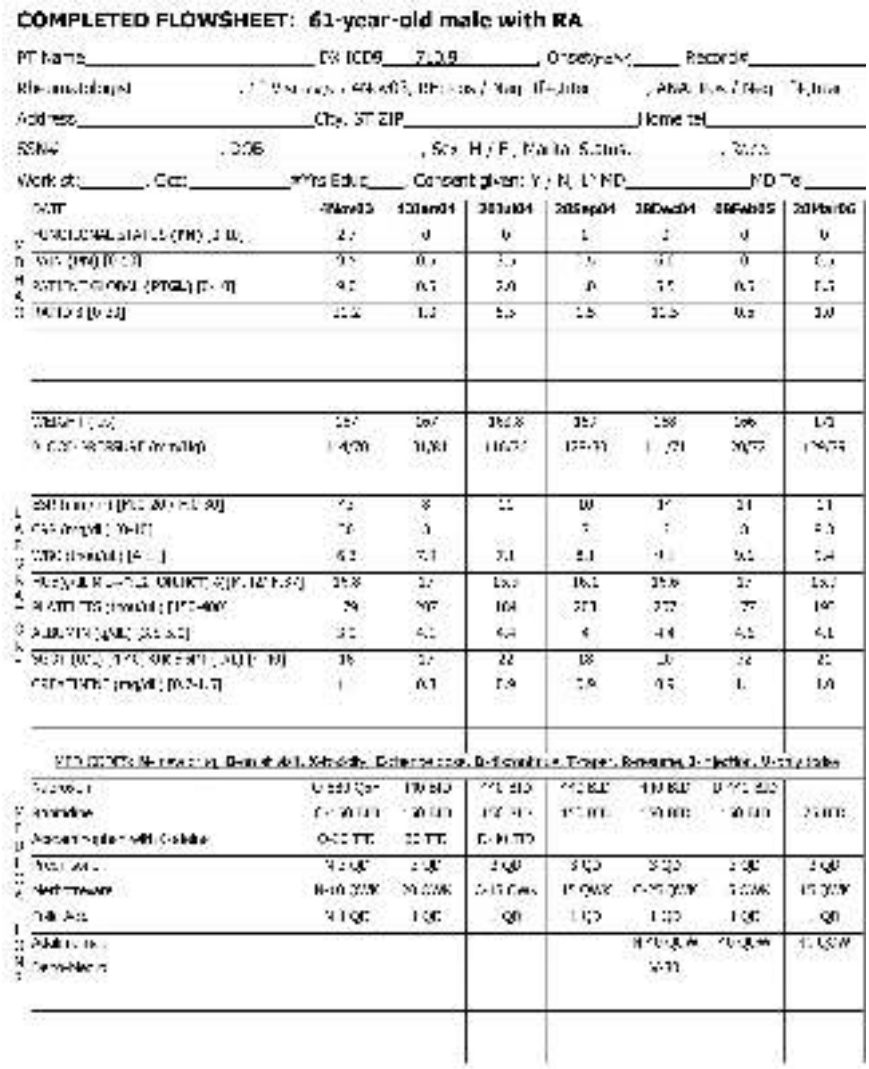

Figure 5 Flow sheet to facilitate longitudinal assessment of a patient in usual rheumatology clinical care. The flow sheet shown is of a male who presented at age 61 with rheumatoid arthritis on November 4, 2003, with scores for physical function of 3.3; pain, 9.5; global status, 9.5; and a RAPID3 score of 22.3 (on a scale of 0-30). He was treated with methotrexate, 10 mg/week, and prednisone, 3 mg/day. Two months later, on January 13, 2004, his RAPID3 score was 1, indicating near remission. He did very well for almost a year, as documented by visits on July 20 and September 28, 2004 (his RAPID3 score was 5.5 on July 20, but this was due to acute back strain and not inflammation, so his therapy was not altered). On December 28, 2004, the patient presented with a severe flare. His joints were once again swollen, and although his physical function score was 0, his pain was 6.0 and global, 5.5. He was offered the possibility of an anti-TNF agent, adalimumab, which he elected to receive. Two months later, on February 5, 2005, all his scores were 0, indicating an excellent response. This status was maintained for more than a year, as indicated by his visit of March 28, 2006.

to be included in the infrastructure of care

3. Why Should the Questionnaire be Completed Before the Visit, Ideally in the Waiting Room, Rather than in the Examination Room or After the Visit?

Most patients spend at least 10 minutes in the waiting room before seeing a rheumatologist, and often much longer. This is the time period in which it is most feasible and desirable for a patient to complete a questionnaire. Completion just before the office encounter helps the patient to focus on concerns and provides information to the physician at the time of care to help guide clinical decisions.

Of course, the questionnaire may be completed in the examination room or after the visit. Some offices send a questionnaire by mail to be completed prior to the visit. This practice loses the advantage of helping the patient to focus on problems immediately before the visit. Furthermore, patients may forget to bring the questionnaire with them, and, if completed a few days prior to the visit, the information may not be current. An office that functions efficiently without a 10-minute wait can schedule patients 10 minutes earlier to include the time for completion of a patient questionnaire.

4. Should the Patient Do the Work Unassisted, If Possible?

Most health professionals feel, at least initially, that data collected by them is more accurate and informative than patient self-report data. Indeed, some data, such as diagnoses, are ascertained more accurately by health professionals than by patients.[34] However, data concerning physical function, pain, fatigue, and global status are ascertained more accurately by patient self-report than by a health professional.[16]

When a patient completes a questionnaire by her or himself, there is only a single observer. When a health professional queries a patient, there are two observers, which reduces, rather than enhances, reproducibility of the data. About 20% of patients need help from office staff or a family member to complete a questionnaire that is provided willingly.[35,36] Nonetheless, the greater the patient's autonomy in recording the data, the more accurate and reproducible it is likely to be, while minimizing staff effort.

5. How Does One Score RADID3 on the MDHAQ?

The 10 activities to assess physical function (FN) on the MDHAQ (Fig. 1A, 1a-j) each are scored 0-3. A total of 0-30 is calculated easily from the number of 1, 2, and 3 scores. The 0-30 total is converted to 0-10, using a scoring template on the MDHAQ, and entered in the FN box.

The two visual analog scales (VAS), to assess pain (PN) and patient global estimate (PTGL), are presented as 21 numbered circles, rather than a traditional 10-centimeter line.[23] The 21-circle VAS presents advantages of not requiring a ruler and avoiding the possible distortion of a 10-centimeter line in photocopying or printing. These scores are entered in the PN and PTGL boxes. RAPID3 is the 0-30 total, scored without a ruler, calculator, computer, or web site, although, in earlier literature, the 0-30 scale was converted to 0-10, as noted above.

6. Why Should the Clinician Review the Questionnaire with the Patient?

A quick "eyeball" review by the physician of the MDHAQ, generally with the patient at the time, can improve the quality and efficiency of a patient visit. The 5 to 10 seconds for such a review gains accurate information quickly, allowing 2 to 3 minutes to focus discussion on the patient's concerns, rather than using 2 to 3 minutes to gather facts about the patient's history.

7. What are the Differences Between Questionnaires Designed for Standard Care and Questionnaires Designed for Research?

Patient questionnaires designed for research may be long and tedious and are not designed for an "eyeball" review by the clinician to obtain relevant information quickly (Table 6).[37-39] Indeed, research questionnaires are sent to a data center for analysis and may add a burden to a clinical care site without adding a benefit to patient care.[37-39] By contrast, simple patient questionnaires designed for usual care are short, can save time for the clinician, and improve the quality of patient visits (Table 6).[37-39] In routine clinical care settings, clinicians should use questionnaires designed for usual clinical care.

8. Why Must the Office Avoid Seeking "Perfection?"

Clinicians often express suggestions to improve the questionnaire content, format, distribution, and electronic automation when they first implement questionnaires in patient care. While development of the MDHAQ reflects many advances, it has been proposed that "80% of the data in 100% of the patients may be preferable to 100% of the data in 5% [or fewer] of the patients" who might be included in clinical research.[39] A less comprehensive measure, which is feasible and applicable in usual clinical care, appears far preferable to no quantitative measure at all. However, a RAPID3 score may provide more than "80%" and indeed may be as informative as a DAS28 or CDAI for patient assessment. RAPID3 may reflect patient and physician goals of treatment as accurately as the number of swollen and tender joints.

C. Rationale for MDHAQ-RAPID3

1. What Are the "Vital Signs" for Rheumatology Care Provided by RAPID3?

Traditional vital signs for inpatient and emergency care, such as temperature and respirations, may alert a health professional to unsuspected patient problems, provide a baseline measure to support a change in therapy, and document improvement or worsening over time numerically to complement clinical impressions. However, traditional vital signs (other than blood pressure) usually are not informative in most outpatient visits of patients with chronic diseases. By contrast, physical function, pain, and patient global estimate and a composite RAPID3—often contribute to the care of chronic diseases and health maintenance.[15] These "vital signs" improve the care of chronic diseases, much as traditional vital signs improve acute care, and serve to enhance the quality and documentation of care.

2. Does Treatment Guided by Quantitative Data Result in Better Patient Status than Usual Non-Quantitative Clinical Care?

Six clinical trials have documented that an approach to treatment informed by quantitative data assessments results in better patient outcomes than usual care without guidance: the Finnish Rheumatoid Arthritis Combination Therapy (FIN-RACo) trial,[40,41] Tight Control for Rheumatoid Arthritis (TICORA) trial,[42] Behandel Strategien (BeSt) or "treatment strategies" trial,[43,44] Computer Assisted Management in Early Rheumatoid Arthritis (CAMERA),[45] Ciclosporine, Methotrexate, Steroid in RA (CIMESTRA),[46-48] and TICORA 2 (a study of step-up versus parallel triple therapy in early active RA).[49]

All six trials used the DAS28 to quantify clinical status. As noted above, RAPID3 is correlated significantly with DAS28,[22,24] but requires only 5 to 10 seconds rather than 114 seconds to calculate.[7] Therefore, RAPID3 could be appropriate for usual clinical care, as used by the authors. However, it would be desirable if prospective controlled studies were performed to evaluate formally whether RAPID3 can be used to guide tight control of RA.

3. What Are Some of the Limitations of Formal Quantitative Joint Counts?

A joint examination is required for a diagnosis of RA and clearly reflects pathogenic mechanisms, in contrast to a patient questionnaire, which is of limited value in diagnosis. Furthermore, a joint count is more specific for changes reflecting RA disease activity than other Core Data Set measures.[50] Nonetheless, a formal quantitative joint count has many limitations, which have received little attention in the rheumatology literature.[11]

Evaluation of joint swelling and tenderness is characterized by a large degree of inter-observer variability,[51-55] although reproducibility can be improved with training.[53] A physical examination may lack sufficient sensitivity to detect inflam-

Table 6 Patient Questionnaire Measures for Clinical Research Versus Clinical Care

Feature	Clinical Research	Clinical Care
Design considerations	Complete, long	Patient friendly, short, completed by patient within 5-10 minutes
Effect on patient visit	Adds time, interferes with flow	Saves time for physician and patient
Type of questionnaire	May be "generic," "disease specific," other research goals	Applicable to patients with all rheumatic diseases
Scoring	Complex, requires computer	Simple, may "eyeball" results; scored in less than 20 seconds
Goal of data	Add to research database	Add to clinical care
Focus of analysis	Groups of patients in clinical trials or observational databases	Individual patients cared for by individual physicians
Data management	Send to data center	Review for patient care; may enter into flow-sheet to compare to previous visits
Major criteria for use	Validity, reliability; assess minimal clinically important significant difference	Document status, medical and medico-legal rationale for aggressive therapies
Disposition of questionnaire	Enter into computer	Enter into flow sheet in medical record

matory activity that is otherwise demonstrable by magnetic resonance imaging (MRI) or ultrasound.[56] The number of tender and swollen joints may decline over 5 to 15 years, yielding an improvement in the joint score, while joint damage and functional declines may progress over that period, leading to frequent work disability and premature death.[57-66] Finally, a formal joint count is time-intensive and interrupts the normal flow of a patient visit.

These reasons may explain why most rheumatologists do not perform a joint count at most visits of RA patients, outside of clinical trials and clinical research.[67] A careful non-quantitative joint examination without formal quantitation may be adequate for usual care, particularly if quantitative RAPID3 vital signs are included. While formal joint counts are needed for clinical trials, RAPID3 provides a more feasible index than a DAS28 or CDAI to assess and monitor patients with RA in usual care.

4. Is Physical Function on a Patient Questionnaire More Significant than Radiographic or Laboratory Data in Prediction of Long-Term Outcomes of RA, Including Work Disability and Mortality?

A review of 53 RA cohorts that described predictors of mortality[68] indicated that significant predictors of mortality in multivariate analyses (Fig. 6) were physical function in 72% of reports in which it was included, comorbidities in 65%, rheumatoid factor in 45%, extra-articular disease in 44%, ESR in 37%, socioeconomic status in 31%, joint count in 22%, and hand radiographs in 11% (Fig. 6). For example, in one cohort of 206 patients (Fig. 7),[69] rheumatoid factor was not a significant predictor of mortality, in contrast to physical function on a modified health assessment questionnaire (MHAQ). All patients with normal function survived 5 years, compared to 65% of patients with scores for functional status of 2 or more on a 0-3 scale.[69] Most reports indicate that a baseline questionnaire measure of physical function is far more significant than a baseline radiograph or laboratory test to predict other severe long-term outcomes of RA,[68] including work disability,[70-72] costs,[73] and joint replacement surgery,[74] in addition to mortality.[12,58,69,75-80]

Nonetheless, the rheumatology and general medical communities, as well as pharmaceutical companies and the general public (supported by rheumatologists), continue to emphasize radiographs and laboratory tests as the most important measures in the prognosis and outcomes of RA. Although radiographs and laboratory tests clearly are related to pathogenic mechanisms, patient questionnaire scores provide the most valuable prognostic data for most long-term outcomes of RA (other than radiographs).

5. Is RAPID3 Useful in All Rheumatic Diseases?

Many valuable indices have been developed over the last two decades for rheumatic diseases other than RA, such as the Western Ontario McMaster osteoarthritis scale (WOMAC),[81] fibromyalgia impact questionnaire,[82] systemic lupus erythematosus disease activity index (SLEDAI),[83] British Isles lupus activity score (BILAG),[84] systemic lupus activities measurement (SLAM),[85] lupus activity index (LAI),[86] European Consensus Lupus Activity Measurement (ECLAM),[87,88] Bath ankylosing spondylitis (AS) functional index (BASFI),[89] Bath ankylosing spondylitis disease activity index (BASDAI),[90] Modified Stoke ankylosing spondylitis spinal score (mSASSS),[91] Bath ankylosing spondylitis metrology index (BASMI),[92] Dougados functional index (DFI)[93] in ankylosing spondylitis, Birmingham vasculitis activity score (BVAS),[94] vasculitis activity index (VAI),[95] and the BVAS-derived Wegener's Granulomatosis Activity Index[96] in vasculitis.

However, as with the DAS or CDAI in RA, these indices are not used at most clinical visits outside of formal research studies. Few patients with OA, fibromyalgia, RA, SLE, AS, or vasculitis receive any benefit of the advances seen in these indices.

The MDHAQ and RAPID3 can be effective in the assessment of patients with all rheumatic diseases,[97] which generally cause problems in physical function, pain, or global status, as quantified by RAPID3 scores, as well as morning stiffness and fatigue, as assessed on the MDHAQ. In osteoarthritis clinical trials, the MDHAQ physical function scale was found to be

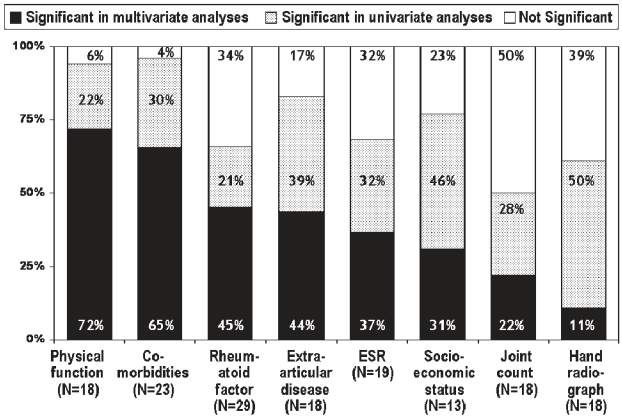

Figure 6 Significance of eight variables as predictors of mortality. In a review of 84 reports concerning mortality in RA, 53 cohorts presented predictors of mortality.[68] For each variable, n equals the number of reports that included the variable, and bars indicate the percentage of those reports in which the variable was a significant predictor of mortality in multivariate analyses (black), in univariate analyses (dotted), or was not significant (white).

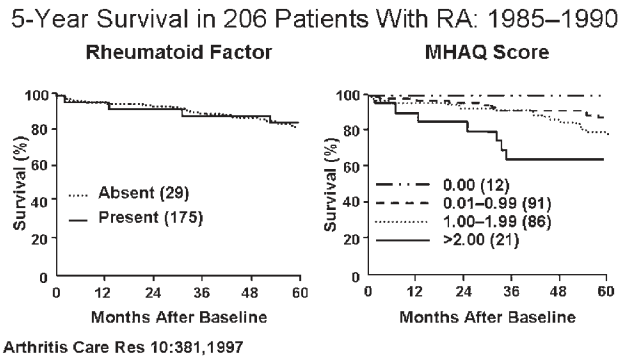

Figure 7 Actual survival of 206 patients with RA over 5 years,[67] according to rheumatoid factor and to physical function assessed on a modified health assessment questionnaire (MHAQ). MHAQ physical function scores assess range from 0 (no difficulty with activities of daily living) to 3 (severe incapacity).

more sensitive to changes in clinical trials than traditional physical measures.[98] A pain VAS is more sensitive than a WOMAC scale to distinguish efficacy of diclofenac-misoprostol or celecoxib from acetaminophen.[99,100] In fibromyalgia, ratios of pain or fatigue to physical function scores, as well as the number of symptoms reported on a review-of-systems symptom checklist on an MDHAQ, distinguish these patients from those with RA as effectively as ESR.[101,102]

Examples of the use of RAPID3 in monitoring patients with SLE, AS, psoriatic arthritis, gout, systemic sclerosis, and other rheumatic diseases are presented in reference 97. These data indicate that an MDHAQ is useful in patients with all rheumatic diseases.[97]

Conclusion

RAPID3 scores, based on self-report patient questionnaire scores, provide informative quantitative data for patient status from one visit to the next. If quantitative data are recorded, an opportunity for documentation and more rational monitoring is gained, along with enhanced efficiency of patient care. If no data are recorded, this opportunity is lost and can never be replaced. It is suggested that all rheumatologists would find it valuable to ask all patients to complete a MDHAQ and to score a RAPID3 at all visits of all patients in usual care.

Disclosure Statement

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